משרד הכלכלה
והתעשייה
השר

כ״ט טבת תשפ״ה
29 ינואר 2025
2025-0170-270

לכבוד
ועדת חריגים

שלום רב,

הנדון: בקשה להוספת תנאי לאסדרה האירופית המאומצת Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety (GPSR)

על פי לפי סעיף 9א2(א)(6) לחוק התקנים, התשי״ג-1953 (להלן: ״חוק התקנים״) ובהתאם להוראות סעיף 2יח לפקודת היבוא והיצוא [נוסח חדש], התשל״ט– 1979 (להלן: ״הפקודה״), בסמכות שר הכלכלה והתעשייה לקבוע בצו תנאי נוסף בתוספת החמישית או לשנות בה תנאי, לפי סעיף זה, בהמלצת ועדת החריגים.

לאור הוראות סעיף 2יח2 לפקודה, פנייה של שר הכלכלה והתעשייה או שר ממונה כהגדרתו בחוק התקנים, להחרגת הוראות מחייבות הקבועות בתוספת החמישית שטרם נכנסו לתוקפן ומועד כניסתן הוא עד ליום 1.3.2025, תיעשה יחד עם שינוי הצו (התוספת החמישית) כך שתבוא לידי ביטוי ההחרגה המבוקשת, וזאת למועד ההחלטה בעניינם בוועדת החריגים.

פניה זו הינה עבור בחינת הוספת תנאי להחלה של האסדרה האירופית המאומצת, Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety (GPSR), המנויה בתוספת החמישית בחוק התקנים וזאת בהתאם למפורט להל

1. אימוץ האסדרה אמור להיכנס לתוקף ביום 01.02.2025.
2. התנאי המבוקש הוא:

״תנאי להחלה: לעניין ריהוט תינוקות וילדים (לולים לתינוקות, מיטות לתינוקות וילדים, שידות החתלה, וכיסא גבוה לתינוק) - חובת עמידה בסף מקסימאלי של שחרור פורמלדהיד, לפי אחת משתי חלופות לדרישה:

א. בהתאם לדרישה הקיימת בתקינה הישראלית הרשמית.

ב. בהתאם לתקנה EU2023/1464 המעדכנת את הוראה מחייבת REACH.״

3. האסדרה GPSR מפנה לאסדרה האירופית המאומצת REACH. אסדרה זו אינה מחייבת היום את העמידה בתנאי של רף מקסימלי לעניין פורמלדהיד, אולם היא צפויה לחייב זאת החל מיום 6.8.2026 (התנאי כבר מופיע באסדרה עם תחילה נדחית בתאריך זה). יצוין, כי חלק מהמדינות באירופה כבר אימצו את האסדרה.
4. לכן, התנאי יהיה מחייב עד ליום כניסת ההגבלות לעניין פורמלדהיד לתוקף בשוק האירופאי. לאחר מועד זה התנאי יתבטל.
5. מטרת התנאי הינה להגן על ציבור התינוקות והילדים מחשיפה לפורמלדהיד המסווג כמסוכן והינו בעל השפעות בריאותיות. כאמור, ההגבלה צפויה להכנס בקרוב גם בשוק האירופי.
6. בהתאם להוראות סעיף 2יח1(ד) לפקודת היבוא והיצוא, לפנייה לוועדת חריגים מצורף חו״ד בעניין ״שיקולי תחרות והפחתת יוקר המחייה״.

בברכה,

חה״כ ניר ברקת
שר הכלכלה והתעשייה

העתקים:
מר מוטי גמיש, מנכ״ל משרד הכלכלה והתעשייה
מר ינון אלרועי, מנהל מערך אסדרה, משרד הכלכלה והתעשייה
עו״ד איילת זלדין, היועצת המשפטית, משרד הכלכלה והתעשייה

משרד הכלכלה והתעשייה
בנין ג׳נרי, רחוב בנק ישראל 5, קריית הממשלה, ת.ד. 3166, ירושלים 9103101
טל. 074-7502888 | פקס. 074-7502198 | sar@economy.gov.il

משרד הכלכלה והתעשייה
מינהל תקינה

23 פברואר, 2025
כ״ה שבט, תשפ״ה

לכבוד
וועדת חריגים
רשות האסדרה

הנדון: <u>הוספת תנאי לאסדרה האירופית המאומצת – פורמלדהיד ברהיטי תינוקות וילדים</u>
סימוכין: דרישת ועדת החריגים להשלמות מיום 12.02.2025

<u>בהמשך למכתבכם שבסימוכין, להלן התייחסות המינהל התקינה לסעיפים 2.א. ו-2.ב. שבמכתב:</u>

א. פורמלדהיד עלול לגרום להשפעות בריאותיות שכן הינו גז המגיב בצורה גבוהה בתנאי טמפרטורה ולחץ אטמוספרי של החדר. חומר זה מסווג על פי רגולציית CLP 1272/2008 כלהלן:

CARCINOGEN CATEGORY 1B
MUTAGEN CATEGORY 2
ACUTE TOXICANT CATEGORY 3
SKIN CORROSIVE CATEGORY 1B
SKIN SENSITISER CATEGORY 1

למידע נוסף אודות החומר ניתן לעיין בכרטיס הזיהוי באתר ECHA – European Chemical Agency משרד הבריאות, המשרד הממונה, יציג את עמדתו בהרחבה.

ב. לעניין הפער שבין התנאי המבוקש לבין האסדרה האירופית המאומצת:

1) אכן קיים פער בין הדרישה לעניין חובת עמידה בסף מקסימלי של שחרור פורמלדהיד בתקינה הישראלית לבין הדרישה בעניין בתקנה EU 2023/1464 המעדכנת את ההוראה המחייבת ה - REACH.

2) להלן טבלה המרכזת את הפער הקיים:

פליטת פורמלדהיד	דרישה בתקנים ישראליים רלוונטיים	אסדרה אירופית – מגבלה החל מאוגוסט 2026 עבור רהיטי עץ
דרישה לחומרי גלם (לפי שיטה EN 717-2)	Release ≤ 3,5 mg/m2h	לא קיימת מגבלה

משרד הכלכלה והתעשייה
בניין ג׳נרי 1, רחוב בנק ישראל 5, ת.ד 3166, ירושלים 9103101
טלפון: 074-7502300 | פקס: 074-7502304
מייל: tkina@economy.gov.il אתר אינטרנט: https://go.gov.il/tkina

דרישה למוצר מוגמר (לפי שיטה EN 717-1)	לא קיימת דרישה*	0,062 mg/m3

* הדרישה לפליטת פורמלדהיד במוצר המוגמר לא אומצה בתקן רשמי בשל היעדר יכולת בדיקה במעבדה בישראל.

הדרישה בתקינה הישראלית הרשמית מבוטאת בערכי מ״ג למטר בשעה והינה עבור חומר גלם – הבדיקה מבוצעת ע״ג פלטה שנחתכת מהמוצר המוגמר.

הדרישה בתקנה האירופאית 2023/1464 מבוטאת בערכי מ״ג למטר מעוקב באוויר – הבדיקה מתבצעת על המוצר המוגמר בתוך תא בדיקה ייעודי Chamber.

מאחר ומדובר בשתי שיטות שונות לא ניתן להשוות בין הדרישות לפליטת פורמלדהיד.

לצורך יישוב ההבדלים בדרישות, מוצע לאפשר דרישת פליטת פורמלדהיד באחת משלוש החלופות הבאות עד למועד ההשמה בשוק האירופאי (06.08.2026):

(א) דרישה עבור חומר הגלם כנהוג היום– Release ≤ 3,5 mg/m2h

(ב) דרישה עבור מוצר מוגמר – Release ≤ 0,124 mg/m3 air

ערך זה הינו לקוח מתוך המלצת Dossier Submitter מטעם ECHA ומובא גם כדרישה מתוך התקן האירופאי EN13986.

(ג) דרישה עבור מוצר מוגמר (אסדרה אירופית חדשה) - 0,062 mg/m3

משכך, ניתן להתייחס לפער שבין חלופה (ב) ו- (ג) לעיל. הערך בחלופה (ב) גדול פי 2 מהערך בחלופה (ג).

משמעות הפער בהיבטיו השונים נבחן עמוקות בטרם החלטת הנציבות האירופאית ומובא במסמך EU 2023/1464. קביעת המגבלה הינה תוצאה של מספר גורמים שנלקחו בחשבון: המלצת ECHA לרף פליטת פורמלדהיד של 0,124 mg/m3 air , המלצה של ועדת הערכת סיכונים (RAC) שקבעה רף נמוך של 0,05 mg/m3 כפועל יוצא מנתוני השפעות כרוניות על בעלי חיים וכן המלצת הועדה לניתוח סוציואקונומי ('SEAC') אשר טענה כי עמידה בדרישה של RAC תוביל להוצאות כספיות כבירות בקרב בעלי הענין. הערך שנקבע עבור פליטת פורמלדהיד במוצרי עץ הינו ערך ביניים 0,062 mg/m3 שהוסכם על ידי הנציבות האירופאית ואשר בא לרצות את הצורך בהגנה על בריאות הצרכנים ובדגש על אוכלוסיות פגיעות ומאידך לא יוביל לנטל כלכלי משמעותי כפי שהיה צפוי בהתאם לרף שהומלץ על ידי RAC (הדו״ח המלא מצורף).

כפי שהוזכר בפנייתנו, היום ועד תום תקופת מעבר לאחר כניסתו לתוקף של העדכון כאמור באסדרה אירופאית מאומצת 2023/1464, אין מגבלה לפליטת פורמלדהיד ברהיטי עץ באסדרת REACH ועל כן בהיעדר קביעת תנאי, ציבור התינוקות והילדים עלול להיות חשוף לחומר מסוכן הגורם להשפעות בריאותיות.

3) בסקירה הנ"ל לא נשקלה אפשרות שהדרישה האירופית המעדכנת לא תיכנס לתוקף, שכן זו נכנסה לתוקפה כבר ביולי 2023. ניתנה תקופת מעבר בשווקים עד ליום 06.08.2026.

<u>להלן התייחסות הממונה על חוקיות היבוא לסעיף 3 שבמכתב:</u>

בקשה של וועדת החריגים	התייחסות הממונה לחוקיות היבוא
פירוט וביסוס הנטען בסיום חוות הדעת הכלכלית: תחת הנחות מסוימות ושיחות עם גורמים משמעותיים בשוק, הבנו כי הבדיקות הנדרשות בתחום הפורמלדהיד עשויות לייקר את חבילת הלידה בכ-300 ₪, שזה בין 2-4%	חבילת לידה מוערכת בהיקף הוצאה של כ-10,000 ₪ ואף יותר. מורכבת ממגוון מוצרים: התקן ריסון לרכב, עריסה, עגלה, חדר לתינוק, שידת החתלה, מוניטור, אביזרים שונים (מוצצים, בקבוקים ונשכנים). בחלק מהמוצרים עבורם נעשית הבדיקה כגון - מיטה לתינוק, כיסא לתינוק (כאשר במוצרים אלו לבידים בו היתכנות לריכוז גבוה מדי של החומר), מגלגלים למחיר המוצר את עלויות הבדיקה במכון התקנים. בממוצע נמסר שחבילת הלידה מתייקרת בכ-300 ש"ח, ומכאן למשל התייקרות של כ-3% בממוצע כתוצאה מהבדיקה (מהדרישה להחרגה).
פירוט לפי איזו חלופה נעשה החישוב – האם לפי התקינה הישראלית הקיימת או לפי התיקון העתידי ל- REACH ; מהו פער העלויות ביניהן?	לפי התקינה הישראלית הקיימת. השחקנים לא יודעים להעריך (בשלב זה) את מרכיב העלות דרך REACH.
פירוט לגבי ההשפעה התחרותית של המוצע	פוגע בהיצע המוצרים, מכיוון שיש יבואנים שהעידו שלפעמים עמידה בהחרגות כאלה מקשה על ביצוע התקשרויות. אך בשל כך שזה המצב הקיים, לא צפויה פגיעה ברמת התחרותיות בשוק.

בברכה,



איגור דוסקלוביץ

הממונה על התקינה

חוות דעת כלכלית – הממונה על חוקיות היבוא

בחינת המשמעות הכלכלית בדרישה לבדיקת סף של שחרור פורמלדהיד במסגרת רפורמת "מה שטוב לאירופה, טוב לישראל"







הקדמה

במסגרת רפורמת "מה שטוב לאירופה, טוב לישראל", אומצה רגולציה שעוסקת ברישום ואיסור כימיקלים (REACH) שנכנסה לתוקף ביום 1.1.2025. לצידה, אומצה רגולציה נוספת (GPSR) שעוסקת במוצרים בפרט, שתיכנס לתוקף ביום 1.2.2025.[1]

רגולציות אלו, עוסקות בין היתר ביבוא לולים לתינוקות, מיטות לתינוקות וילדים, שידות החתלה וכיסא גבוה לתינוק.

כיום, ביבוא סוגי הטובין לעיל, על העוסקים להתייחס להימצאות סף מקסימאלי של שחרור פורמלדהיד על פי התקינה הישראלית בנושא (כולל קסיס).[2]

משיקולי בריאות הציבור, עלה הצורך בהוספת החרגה ברגולציות לעיל ברפורמת "מה שטוב לאירופה, טוב לישראל", וזאת עד ליום 6.8.2026 (אחריו, הרגולציה באיחוד האירופי תתאים לדרישות הרגולטור בישראל). למעשה, ההחרגה בפועל שמבקשים להוסיף היא ש"לעניין ריהוט תינוקות וילדים (לולים לתינוקות, מיטות לתינוקות וילדים, שידות החתלה, וכיסא גבוה לתינוק) חובת עמידה בסף מקסימאלי של שחרור פורמלדהיד, לפי **אחת** משתי חלופות לדרישה: (1) בהתאם לדרישה הקיימת בתקינה הישראלית הרשמית, או –(2) התאם לתקנה EU2023/1464 המעדכנת את הוראה מחייבת REACH."

מכאן, עלה הצורך בהבנת המשמעות הכלכלית על ציבור העוסקים בתהליך היבוא, וההשלכות על רמת התחרות, יוקר המחייה, וכיוצ"ב.

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[1] מקור: סעיף 29 בתוספת החמישית, בחוק החוק התקנים, תשי"ג-1953.

[2] מקור: אתר מכון התקנים | התקן כחלק מהערכה והגבלה של כימיקלים. מקור: "חיפוש מידע על תקנים רשמיים במדינת ישראל".

רקע

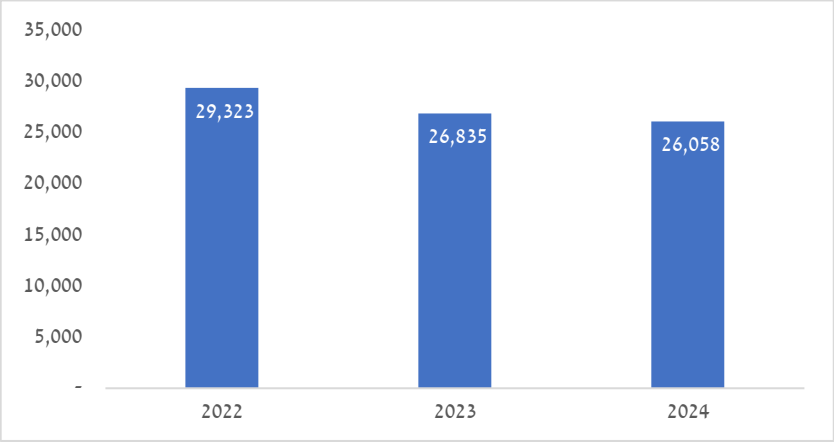
על פי שיחות שקיימנו, בתקנים הרשמיים שעוסקים בסוגי המוצרים לעיל, קיימת הפנייה למספר תקנים, בעניין הכמות המותרת של פורמלדהיד. לשם המחשה – ת"י 37 שעוסק בלבידים.

פרטי מכס מרכזיים

פרט מכס 1 – תחום מוצרי הלולים והמיטות לתינוקות וילדים

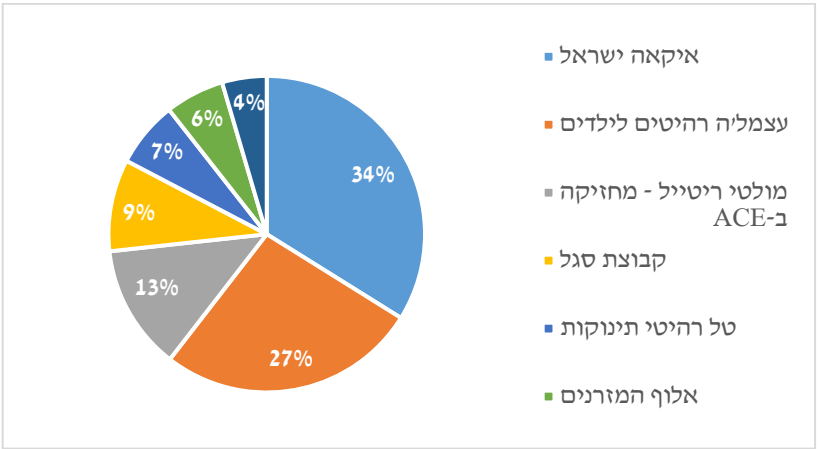
מבדיקה שערכנו, נתוני היבוא כלולים בפרט מכס 9403500000/2 – רהיטים מעץ מהסוג המשמש בחדר שינה, מתוכו בחרנו נתוני יבוא של יבואנים בשוק מוצרי התינוקות והילדים, כאשר חלקם פועלים בשוק מוצרי השינה למבוגרים ובני נוער, ולכן מדובר בהערכה גסה של ערך היבוא.

תרשים 1 – ערך היבוא של רהיטים מעץ מהסוג המשמש בחדר שינה בין השנים 2022-2024, באלפי דולר



על פי שערי החליפין הממוצעים לשנים 2022-2024, ערך היבוא בשנת 2022 הסתכם בכ-98 מיליון ₪, בשנת 2023 בכ-99 מיליון ₪, ובשנת 2024 בכ-96 מיליון ₪, בהתאמה. [3]

תרשים 2 – ערך היבוא של יבואנים מובילים בשנת 2024, ב-% מערך היבוא



[3] על פי נתוני בנק ישראל שער הדולר היציג (ממוצע שנתי) עמד על 3.36 ₪ בשנת 2022, 3.69 ₪ בשנת 2023, ו-3.7 ₪ בשנת 2024.

פרט מכס 2 – תחום כיסאות האוכל הגבוהים לתינוקות

מבדיקה שערכנו, יבוא הטובין לעיל כלול בפרט מכס – "9401000000, מושבים (חוץ מאלה שבפרט 94.02), אם ניתנים להפיכה למיטות או לא, וחלקיהם". כמו כן, מדובר בפרט מכס רחב, שכולל טובין שלא בתחום הבדיקה, ולכן קיים קושי להעריך את היקפי היבוא.

עם זאת, כן ניתן להעריך שחקנים מרכזיים בתחום, ביניהם: "איקאה" ישראל, רשת "שילב" מקבוצת FOX, "במבינו קינג", ו"דוורון יבוא ויצוא".

מכס רחב, הכולל מגוון תתי-פרט, ולכן קיים קושי באיתור נתוני היבוא בתחום.

הכוונה

סקירת שוק ומוצר

המסמך מתמקד בשוק מוצרי התינוקות והילדים, ובפרט ב-2 התחומים המרכזיים הבאים (שההחרגה נוגעת אליהם), כמפורט מטה:

1. תחום הלולים והמיטות לתינוקות וילדים – בתחום פועלים מגוון שחקנים, ביניהם רשתות בפריסה ארצית, כגון "שילב" מקבוצת FOX ורשת "מוצצים", רשתות עולמיות להן נציגות בישראל הפועלות בחנויות ענק כגון – "איקאה", רשתות בוטיק כגון – "עצמל'ה" ו"קבוצת סגל", ויבואנים שונים המוכרים דרך רשתות, או באונליין.
2. תחום כיסאות האוכל הגבוהים לתינוקות – בתחום פועלים שחקנים מובילים בשוק מוצרי התינוקות והילדים, כגון – "שילב", "איקאה" ישראל, יבואנים שונים כגון – במבינו קינג, דוורון יבוא ויצוא, בייבי מישל (סחר), ועוד.

מכר כספי

את המכר הכספי ב-2 התחומים, ניתן להעריך באופן הבא:

- כמות ילודה בישראל לשנת 2022 – 178 אלף תינוקות.
- שיעור הפריון הכולל (מס' הילדים הממוצע לאישה) לשנת 2022 – 2.89.

תחום הלולים והמיטות לתינוקות: תחת ההנחה כי כל משפחה רוכשת מיטה אחת שעוברת בין ילדיה,[4] כמות המיטות השנתית מוערכת באופן גס ב-61 אלף מיטות, ובמונחים כספיים בכ-61-92 מיליוני ₪ בשנה, וזאת תחת ההנחה שמחירן הממוצע של מיטות נע בטווחי מחירים של 1,500-1,000 ₪ למיטה.

באשר לעריסות, משיחות עם יבואנים, עולה כי לא מעט משפחות "מדלגות" על עריסות לטובת מיטות, ולכן שוק העריסות (במונחים כמותיים) קטן יותר, ועומד על כ-12 אלף יחידות בשנה (כ-20% משוק המיטות). במונחים כספיים, מכירות שוק העריסות עומדות על כ-7-5 מיליוני ₪ בשנה וזאת תחת ההנחה שמחיר העריסה הממוצע עומד על 600-400 ₪, נציין כי בשוק עריסות "פרימיום" (בעיקר מפלסטיק ולא מעץ) הנמכרות גם במחירים של עד כ-1,000 ₪.

[4] ישנם כמה דפוסי פעולה בשוק שלהערכתנו מאזנים אחד את השני: מצד אחד, משפחה עשויה לעיתים לשדרג את המיטה הקיימת עקב פגמים, או רכישת שתי מיטות בלידת תאומים (המהווים 5% מכל הלידות בישראל) ומצד שני משפחה עשויה לקנות מיטה או עריסה יד שנייה ואף להשאיל מקרובי משפחה/חברים.

תחום כיסאות האוכל הגבוהים לתינוקות: תחת ההנחה כי כל משפחה קונה כיסא אחד לכל ילדיה[5], כמות הכיסאות השנתית מוערכת באופן גס ב-61 אלף כיסאות, ובמונחים כספיים בכ-18-31 מיליוני ₪ בשנה, וזאת תחת ההנחה שעיקר המכירות הן של כיסאות מודרניים, ובטווחי מחירים של 300-500 ₪ לכיסא.

ממצאים וסיכום

במסגרת תהליך איסוף הממצאים, פנינו ליבואנים שונים, ביניהם יבואנים קטנים, בינוניים, וכן יבואנים הפועלים כרשתות.

להלן תיאור הממצאים ביחס לדפוסי הייבוא:

- <u>הימנעות מטובין הכולל פורמלדהיד</u> – הכוונה להימנעות מיבוא מוצרים המכילים את החומר, <u>בעקבות החששות מאי עמידה בדרישות התקינה בישראל</u>. לצד זה, צוין כי מתקיים למשל יבוא של מוצרים המיוצרים מפוליגל (כלומר, מוצרים מפלסטיק), או לחילופין מעץ מלא בהם החומר לא בשימוש וניתן למצוא ספקים של מוצרים באופן רחב.
- <u>יבוא טובין הכולל פורמלדהיד וספיגת העלויות הנוספות</u> – ישנם שחקנים, ביניהם רשתות גדולות, שספקיהן מייצרים עבורם מגוון מותגים פרטיים. ככל והרשת בישראל, בחרה לייבא מוצרים הכוללים שימוש בחומר, תתקיים פנייה למכון התקנים לצורך וידוא עמידה, שנאמדת בכמה אחוזים בודדים מעלויות היבוא. עלות הבדיקה מוערכת ב- (3000) וההנחה שתתווסף לעלות זו עוד 3000 של עלויות
- <u>ברמה הכללית</u> –יבואנים הופתעו משמירת פערים מאירופה במוצרים אלו וכן ביקשו להיצמד לרגולציה האירופאית.
- <u>פערי מחירים</u>: החרגה יכולה להביא לקושי במימוש מלא של הרפורמה, ובפוטנציאל ההוזלה הטמון בה. מבחינה שערכנו, ישראל יקרה יותר ביחס לאירופה בעשרות אחוזים.

לפי הערכותינו, פוטנציאל החיסכון בתחום מוצרים הנסקרים בנייר, כיסאות גבוהים ומיטות, הוא גבוה כתוצאה מיישום רצף של רפורמות לרבות רפורמת לא עוצרים בנמל. פוטנציאל החיסכון נע סביב 15% ממנו מומש באמצעות הרפורמות הקודמות כ- 8%.[6]

תחת הנחות מסוימות ושיחות עם גורמים משמעותיים בשוק, הבנו כי הבדיקות הנדרשות בתחום הפורמלדהיד עשויות לייקר את חבילת הלידה בכ- 300 ₪ שזה נע בין 2% ל – 4%.

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[5] ישנם כמה דפוסי פעולה בשוק שלהערכתנו מאזנים אחד את השני: מצד אחד, משפחה עשויה לעיתים לרכוש כיסא אוכל חדש (נוסף) עקב אחזקה לקויה של הכיסא הקודם ובעיקר כתוצאה מהפרשים של מס' שנים בין לידות. לחילופין, משפחה יכולה לעשות שימוש בכיסא הקיים לכל ילדיה או להשאיל מקרובי משפחה/חברים. משיחות שערכנו עם יבואנים, נמסר כי אחד ממאפייני הענף הוא רכישת מוצרים חדשים במהלך לידה ראשונה במשפחה.

[6] בהתאם לבדיקות האפקטיביות שבוצעו על ידי הממונה על חוקיות היבוא

משרד הכלכלה
והתעשייה
השר

ט' ניסן תשפ"ה
7 אפריל 2025
2025-0170-430

לכבוד
ועדת חריגים

שלום רב,

הנדון: בקשה להוספת תנאי לאסדרה האירופית המאומצת
עדכון פנייה מיום 29.01.2025
Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety (GPSR)

על פי לפי סעיף 9א2(א)(6) לחוק התקנים, התשי"ג-1953 (להלן: "חוק התקנים") ובהתאם להוראות סעיף 2יח לפקודת היבוא והיצוא [נוסח חדש], התשל"ט– 1979 (להלן: "הפקודה"), בסמכות שר הכלכלה והתעשייה לקבוע בצו תנאי נוסף בתוספת החמישית או לשנות בה תנאי, לפי סעיף זה, בהמלצת ועדת החריגים.

לאור הוראות סעיף 2יח2 לפקודה, פנייה של שר הכלכלה והתעשייה או שר ממונה כהגדרתו בחוק התקנים, להחרגת הוראות מחייבות הקבועות בתוספת החמישית שטרם נכנסו לתוקפן ומועד כניסתן הוא עד ליום 1.3.2025, תיעשה יחד עם שינוי הצו (התוספת החמישית) כך שתבוא לידי ביטוי ההחרגה המבוקשת, וזאת למועד ההחלטה בעניינם בוועדת החריגים.

1. פניה זו, המעדכנת את הפניה שהוגשה לוועדת החריגים ביום 29.01.2025, הינה עבור בחינת הוספת תנאים להחלה של האסדרה האירופית המאומצת, Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety (GPSR), המנויה בתוספת החמישית בחוק התקנים. וזאת בהתאם למפורט להלן

2. אימוץ האסדרה נכנס לתוקף ביום 01.02.2025.

3. התנאי המבוקש עודכן ומאפשר חלופה נוספת המקובלת על ידי משרד הבריאות:

"תנאי להחלה: לעניין ריהוט תינוקות וילדים (לולים לתינוקות, מיטות לתינוקות וילדים, שידות החתלה, וכיסא גבוה לתינוק) - חובת עמידה בסף מקסימאלי של שחרור פורמלדהיד, לפי אחת משלוש חלופות לדרישה:

א. בהתאם לדרישה הקיימת בתקינה הישראלית הרשמית (עבור חומר גלם).

ב. בהתאם לדרישה הקיימת בתקן האירופאי EN13986 (עבור מוצר מוגמר)

ג. בהתאם לתקנה EU2023/1464 המעדכנת את הוראה מחייבת REACH

משרד הכלכלה והתעשייה
בנין ג'נרי, רחוב בנק ישראל 5, קריית הממשלה, ת.ד. 3166, ירושלים 9103101
טל. 074-7582000 | פקס. 074-7582198 | sar@economy.gov.il

משרד הכלכלה
והתעשייה
השר

האסדרה GPSR מפנה לאסדרה האירופית המאומצת REACH. אסדרה זו אינה מחייבת היום את העמידה בתנאי של רף מקסימלי לעניין פורמלדהיד, אולם היא צפויה לחייב זאת החל מיום 6.8.2026 (התנאי כבר מופיע באסדרה עם תחילה נדחית בתאריך זה). יצוין, כי חלק מהמדינות באירופה כבר אימצו את האסדרה.

לכן, התנאי יהיה מחייב עד ליום כניסת ההגבלות לעניין פורמלדהיד לתוקף בשוק האירופאי. לאחר מועד זה התנאי יתבטל.

חלופה ב' נועדה לתת מענה לייבוא מוצרים שעומדים בדרישת הפורמלדהיד עבור מוצר מוגמר בהתאם לתקן האירופאי הקיים.

מטרת התנאי הינה להגן על ציבור התינוקות והילדים מחשיפה לפורמלדהיד המסווג כמסוכן והינו בעל השפעות בריאותיות. כאמור, ההגבלה צפויה להיכנס בקרוב גם בשוק האירופי.

בהתאם להוראות סעיף 2יח1(ד) לפקודת היבוא והיצוא, לפנייה לוועדת חריגים מצורף חו"ד בעניין "שיקולי תחרות והפחתת יוקר המחייה".

בברכה,

חה"כ ניר ברקת
שר הכלכלה והתעשייה

העתקים:
מר מוטי גמיש, מנכ"ל משרד הכלכלה והתעשייה
מר ינון אלרועי, מנהל מערך אסדרה, משרד הכלכלה והתעשייה
עו"ד איילת זלדין, היועצת המשפטית, משרד הכלכלה והתעשייה

משרד הכלכלה והתעשייה
בנין ג'נרי, רחוב בנק ישראל 5, קריית הממשלה, ת.ד. 3166, ירושלים 9103101
טל. 074-7582888 | פקס. 074-7582198 | sar@economy.gov.il

<u>טופס נלווה לפנייה מס׳ 1 ופנייה מס׳ 3 (מסלול רגיל ומסלול הוראת שעה)</u>

<u>פניית שר הכלכלה או שר ממונה בעניינים האמורים בסעיף 9א2(א)(4) עד (6) לחוק</u>

פנייה זו מוגשת על ידי **שר הכלכלה והתעשייה**.

תאריך: **06.04.2025** שם המשרד: **משרד הכלכלה והתעשייה**

שם איש הקשר ותפקידו: **איגור דוסקלוביץ, הממונה על התקינה**; מס׳ טלפון: **050-6240187**

כתובת דוא״ל: **igord@economy.gov.il**

סוג הפנייה והסעיף בחוק:

לקבוע תנאי נוסף בתוספת החמישית או לשנות בה תנאי, למעט שינוי שהוא הקלה (9א2(6) לחוק).

ההוראה המחייבת מושא הבקשה: **רגולציה לבטיחות מוצרי צריכה** –

Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety (GPSR);

מועד תחילתה:

1. ההוראה המחייבת **GPSR – 01.02.2025**

מסמכים מצורפים לפנייה:

- ☐ פירוט הפנייה והנימוקים לה, בחתימת השר הרלבנטי.
- ☐ פרטי ההוראה המחייבת החלה באיחוד האירופי, או העדכון שלה, לפי העניין.
- ☐ עמדת שר הכלכלה או השר הממונה, לפי העניין, בדבר קיומו של חשש לפגיעה בבטיחות הציבור, בבריאות הציבור או באיכות הסביבה, שיקולי תחרות והפחתת יוקר המחייה, קיום תנאי ייחודי במדינת ישראל, אם ישנו.
- ☐ עמדת גורמי המקצוע עמם התייעץ שר הכלכלה או השר הממונה, בדבר השיקולים הנזכרים לעיל.

האם הוגשה פנייה נוספת באותו עניין? לא / כן. אם כן, פרט: **לא.**

האם הפנייה דחופה ומדוע?

מדובר בהשלמה לפנייה שהוגשה ביום ה-29.01.2025. הנושא עוסק בחומר מסוג פורמלדהיד שמהווה סכנה בטיחותית למוצרי תינוקות וילדים ולכן יש דחיפות בפניה.

בפנייה שהוגשה על ידי שר ממונה: האם השר מבקש לצרף כחבר בוועדת החריגים לצורך דיון הוועדה בפנייה את מנכ״ל המשרד או עובד המשרד שימנה המנכ״ל, בהתאם לסעיף 2יח1(ב) בחוק? **לא**

נספח א'

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Formaldehyde and formaldehyde releasers

ECHA/RAC/RES-O-0000006740-76-01/F
ECHA/SEAC/RES-O-0000006931-71-01/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 13 March 2020) and SEAC's opinion (adopted 17 September 2020)

13 March 2020

ECHA/RAC/RES-O-0000006740-76-01/F

17 September 2020

ECHA/SEAC/RES-O-0000006931-71-01/F

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	Formaldehyde and formaldehyde releasers
EC No.:	-
CAS No.:	-

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitter's proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/restrictions-under-consideration on 20 March 2019. Interested parties were invited to submit comments and contributions by 20 September 2019.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Agnes SCHULTE

Co-rapporteur, appointed by RAC: Ruth MOELLER

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on 13 March 2020.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted by consensus.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Luisa CAVALIERI

Co-rapporteur, appointed by SEAC: Klaus URBAN

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on 12 March 2020.

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22919/term on 25 March 2020. Interested parties were invited to submit comments on the draft opinion by 25 May 2020.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on 17 September 2020.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted by consensus.

CONTENTS

OPINION OF RAC AND SEAC.....5

THE OPINION OF RAC.....6

THE OPINION OF SEAC.....7

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC.....8

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK.....8

Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope).....8

Description of the risk(s) addressed by the proposed restriction.....13

Evidence if the risk management measure and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk.....60

Evidence if the existing regulatory risk management instruments are not sufficient76

JUSTIFICATION IF ACTION IS REQUIRED ON A UNION WIDE BASIS.....89

JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE.....90

Scope including derogations.....90

Effectiveness in reducing the identified risks.....118

Socio-economic impact.....123

Practicality, incl. enforceability.....151

Monitorability.....156

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC.....158

REFERENCES.....165

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Formaldehyde EC No 200-001-8 CAS No 50-00-0	1. Articles produced using formaldehyde or formaldehyde releasing substances as such or in a mixture, shall not be placed on the market if the formaldehyde released from them exceeds a concentration of 0.124 mg/m^3 as measured in accordance with the conditions specified in Appendix X. Road vehicles and aircraft produced with the intentional addition of formaldehyde or formaldehyde releasing substances where exposure to consumers can occur in their interior, shall not be placed on the market if the formaldehyde in their interior exceeds a concentration of 0.1 mg/m^3 as measured in accordance with the conditions specified in Appendix X. 2. Paragraph 1 shall apply 12 months from the entry into force of the restriction. 3. By way of derogation, paragraph 1 shall not apply to articles that are only for outdoor use under reasonably foreseeable conditions. 4. By way of derogation, paragraph 1 shall not apply to articles exclusively for industrial and professional use if formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use. 5. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2018/1513. 6. By way of derogation, paragraph 1 shall not apply to the use of formaldehyde and formaldehyde releasers as biocide subject to Regulation (EU) 528/2012. 7. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2017/745. 8. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2016/425. 9. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2011/10. 10. By way of derogation, paragraph 1 shall not apply to articles subject to Directive 2009/48/EC. 11. By way of derogation, paragraph 1 shall not apply to second-hand articles.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on formaldehyde and formaldehyde releasers is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the scope and conditions are modified as proposed by RAC.

The conditions of the restriction proposed by RAC are:

Formaldehyde EC No 200-001-8 CAS No 50-00-0	1. Articles produced using formaldehyde or formaldehyde releasing substances as such or in a mixture, shall not be placed on the market if the formaldehyde released from them exceeds a concentration of 0.05 mg/m^3 as measured in accordance with the conditions specified in Appendix X. Road vehicles produced with the intentional addition of formaldehyde or formaldehyde releasing substances where exposure to consumers can occur in their interior, shall not be placed on the market if the formaldehyde in their interior exceeds a concentration of 0.05 mg/m^3 as measured in accordance with the conditions specified in Appendix X. 2. Paragraph 1 shall apply 24 months from the entry into force of the restriction. 3. By way of derogation, paragraph 1 shall not apply to articles exclusively for industrial and professional use if formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use. 4. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2018/1513. 5. By way of derogation, paragraph 1 shall not apply to the use of formaldehyde and formaldehyde releasers as biocide subject to Regulation (EU) 528/2012. 6. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2017/745. 7. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2016/425. 8. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2011/10. 9. By way of derogation, paragraph 1 shall not apply to articles subject to Directive 2009/48/EC. 10. By way of derogation, paragraph 1 shall not apply to second-hand articles.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction proposed by the Dossier Submitter on formaldehyde and formaldehyde releasers is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope or conditions are modified, as proposed by SEAC, as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are:

Formaldehyde EC No 200-001-8 CAS No 50-00-0	1. Articles produced using formaldehyde or formaldehyde releasing substances as such or in a mixture, shall not be placed on the market if the formaldehyde released from them exceeds a concentration of 0.124 mg/m^3 as measured in accordance with the conditions specified in Appendix X. Road vehicles produced with the intentional addition of formaldehyde or formaldehyde releasing substances where exposure to consumers can occur in their interior, shall not be placed on the market if the formaldehyde in their interior exceeds a concentration of 0.1 mg/m^3 as measured in accordance with the conditions specified in Appendix X. 2. Paragraph 1 shall apply 24 months from the entry into force of the restriction. For trucks and buses paragraph 1 shall apply 36 months from the entry into force of the restriction. 3. By way of derogation, paragraph 1 shall not apply to articles that are only for outdoor use under reasonably foreseeable conditions. 4. By way of derogation, paragraph 1 shall not apply to articles exclusively for industrial and professional use if formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use. 5. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2018/1513 on CMR substances in clothing and footwear. 6. By way of derogation, paragraph 1 shall not apply to the use of formaldehyde and formaldehyde releasers as biocidal products subject to Regulation (EU) 528/2012. 7. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2017/745 on medical devices. 8. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2016/425 on personal protective equipment. 9. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2011/10 on food contact materials. 10. By way of derogation, paragraph 1 shall not apply to articles covered by Appendix C to Annex II to Directive 2009/48/EC on toy safety. 11. By way of derogation, paragraph 1 shall not apply to second-hand articles.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope)

Summary of proposal:

The Dossier Submitter's proposal is to restrict the placing on the market of articles intended for indoor use that release formaldehyde under reasonably foreseeable conditions resulting in consumer exposure. The restriction establishes a maximum emission limit value for articles of 0.124 mg/m^3 in a test chamber (as measured in accordance with the conditions specified in Appendix X to the restriction proposal). Articles that are exclusively used in outdoor environments are not intended to be included within the scope of the proposal. The proposal is intended to cover articles where formaldehyde or formaldehyde releasing substances (also termed formaldehyde releasers) are used in their production (either as such or in mixtures) and where formaldehyde releases occur during use as a result of either the "off-gassing" of residual formaldehyde or from the degradation and chemical reactions of other substances used in the production. The proposal is not intended to cover articles produced without using formaldehyde or formaldehyde releasing substances. In such articles formaldehyde is either not released (because it is not present in the article, e.g. glass articles) or it can be only released by the decomposition of substances naturally present in the materials used to produce the article (e.g. lignin degradation in solid wood) or as a result of combustion.

As well as in the interiors of buildings, the proposal aims also to reduce consumer exposure to formaldehyde in the interiors of vehicles (road, rail, air and water vehicles). In the specific case of road vehicles (e.g. cars, trucks, vans, buses and motor-homes) and aircraft the proposal is intended to restrict the placing on the market of articles where the interior concentration of formaldehyde exceeds 0.1 mg/m^3 under reasonably foreseeable conditions of use. For articles used in rail and water vehicles, the same requirements as for other articles apply as the interior can be reasonably assumed to be similar to living environment in homes and building apartments.

Articles subject to the existing restriction on CMR substances in clothing and footwear (entry 72 of Annex XVII of REACH), articles subject to Regulation (EU) 2017/745 on medical devices, articles subject to Regulation (EU) 2016/425 on personal protective equipment (PPE), articles subject to Regulation 2011/10 on food contact materials, articles subject to Directive 2009/48/EC on toy safety, articles exclusively for industrial and professional use, second-hand articles as well as the use of formaldehyde and formaldehyde releasers as a biocide are intended to be exempted from the proposed restriction.

The restriction proposal considers the risks to human health of exposure to formaldehyde from articles regardless of its original source. Thus, both formaldehyde and formaldehyde releasers are within the scope of the proposal and considered together.

Regarding articles used in construction (e.g. wood-based panels, laminate flooring, wallpapers), the Dossier Submitter notes that, although formaldehyde emissions from these articles affect the general population, they are mostly used by workers and professionals operating in the construction sector. In order to protect consumers from risks related to formaldehyde exposure, the Dossier Submitter considers limiting formaldehyde emissions from these articles at the time when they are placed on the market. For this reason, the restriction proposal is not limited to articles intended for consumer use but relates more broadly to articles through which consumers can become exposed to formaldehyde.

The Dossier Submitter has concluded that formaldehyde release from the consumer use of mixtures for non-biocidal use is adequately controlled and the use of formaldehyde in mixtures for consumer use in concentration ≥ 0.1 % is prohibited according to Commission

Regulation (EU) 2018/675.

RAC conclusion(s):

The proposal aims to restrict the placing on the market of articles that irrespective of the source release formaldehyde in exceedance of 0.124 mg/m³ (1 ppm) in the air of a test chamber used under the conditions prescribed in Appendix X. Further to the derogations mentioned all articles are included that used formaldehyde and/or formaldehyde releasers during production and that release formaldehyde in exceedance of the emission limit. The restriction as proposed by the Dossier Submitter focuses on articles with uses under indoor conditions. It covers also vehicle components used in vehicles of any kind where consumers are exposed in enclosed cabins (road vehicles, vehicles for public transportation, passenger aircraft and ships).

The revised Background Document indicates that road, rail, air or water vehicles are included in the restriction if exposure to consumers to formaldehyde can occur in their interiors. Based on information received in the consultation standard methods are available to measure the concentration of formaldehyde in the interiors of cars and aircraft and that they are commonly applied. For this reason, the Dossier Submitter's revised proposal is to limit concentration in road vehicles and passenger aircraft to 0.1 mg/m³ formaldehyde in the cabin interior. In section 2.2.2.1 of the Background Document, the Dossier Submitter has clarified that in the absence of data on formaldehyde concentrations in rail and water vehicles and in the absence of standard test methods same requirements apply for articles used inside rail and water vehicles as for other articles.

RAC notes that all passengers in road, rail and water vehicles should have the same level of protection, but agrees to leave the decision to the Commission whether rail and water vehicles are to be included in the scope of the restriction, as robust data on exposure are lacking.

The Dossier Submitter informed that the focus of the restriction proposal is on consumer exposure to formaldehyde while worker exposure is outside the scope. The restriction shall not apply to articles exclusively for industrial or professional use if formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use. The Dossier Submitter clarified that the restriction is not limited to articles used by consumers, it relates broadly to articles through which consumers can become exposed to formaldehyde. RAC supports the broad scale of articles covered by the proposed restriction. RAC clarifies that articles used in buildings such as hospitals, schools, kindergartens or other public buildings and buildings with access to the public are covered by the restriction.

While the title of the restriction proposal is on the substance group 'formaldehyde and formaldehyde releasers', the Dossier Submitter has explained that formaldehyde releasing substances include formaldehyde-based substances and those that may release formaldehyde although being produced without the addition of formaldehyde. The scope is on articles produced with the intentional addition of formaldehyde or formaldehyde releasing substances as such or in a mixture. RAC welcomes the clarification of intentional addition to the articles covered and the inclusion of all formaldehyde-releasing substances irrespective of whether their synthesis was based on formaldehyde or not.

RAC generally agrees with the intention of the restriction to protect consumers exposed to formaldehyde against adverse health effects (in particular carcinogenicity). However, RAC does not agree that risks to consumers are sufficiently addressed by the emission limit proposed by the Dossier Submitter for building interior articles and the concentration limit proposed for vehicles, because the Committee considers that consumers are not sufficiently protected from health risks if they are exposed at the WHO guideline value of 0.1 mg/m³ (0.08 ppm) and instead proposes:

- Limiting emissions exceeding concentrations of 0.05 mg/m³ measured in the air of a test chamber under conditions specified in Appendix X for articles, and

- A concentration limit of 0.05 mg/m³ formaldehyde for vehicle cabin interiors (see below).

Articles temporarily contributing to peak levels are not a matter of the scope of this restriction proposal. It is however recommended by RAC that regulatory measures should be considered to limit formaldehyde emissions from ethanol fireplaces.

Key elements underpinning the RAC conclusion(s):

Scope

The broad scope proposed by the Dossier Submitter lists certain groups of articles where formaldehyde or formaldehyde releasing substances are known to be used in the production of articles such as wood-based panels, laminate flooring, wallpaper, furniture, foams, textiles and other articles which are available for use by consumers or to which consumers can be exposed in the indoor environment. The list is non-exhaustive and in principle a wide scale of articles available on the EU market is covered by the scope. RAC recommends providing additional guidance on articles which are potentially covered by restriction, e.g. a publicly available non-exhaustive list of articles/groups of articles which are in the scope of this restriction.

The major source of consumer exposure to formaldehyde or formaldehyde releasing substances was identified in the use of formaldehyde-based resins in wood-based panels used in furniture, construction and other articles. The Background Document clarifies that articles made from materials or mixtures which were used during its production to which formaldehyde or formaldehyde-releasers were intentionally added are within the scope.

The proposal specifies that articles for indoor use are covered as well as outdoor articles that can be used for indoor and outdoor uses. Articles for outdoor use only were proposed to be exempted. As no specification is given, RAC understands the general term ‘articles’ as including those articles that may be used outdoors. The Background Document does not specifically assess the outdoor articles that could also be used indoors (except for wood-based panels that can be used indoor and outdoor), but explains that articles for outdoor use *only* are not within the scope (see paragraph 3 in the text on the proposed Annex XVII entry). From the perspective of enforceability, the Forum in their advice favoured the inclusion of articles for indoor and outdoor uses. RAC can follow this view and finds it likely that outdoor-only articles may be used (including storing) both indoors and outdoors contributing to indoor exposure and making a clear discrimination impossible. RAC agrees with the Forum that an exemption on articles for outdoor use *only* would need further definition (or labelling). RAC concludes that outdoor-only articles should not be exempted from the restriction. In case the Commission decides to derogate outdoor-only articles (as proposed by the Dossier Submitter), RAC proposes to restrict the emissions (in line with the Commission decision on the articles for indoor use) and/or at least to restrict the placing on the market of E2 wood-based panels to avoid placing on the market E2-wood based panels for outdoor use.

Articles that were incorporated in a permanent manner in construction works as defined in the Construction Product Regulation (CPR, EU 305/2011) are included in the scope of the proposed restriction. The CPR requires a CE marking for construction products on the EU market based on a classification as E1 or E2. As the CPR does not set binding limits for placing the product on the EU market, there is no regulatory overlap with the proposed restriction.

The Dossier Submitter also understands that bamboo articles would be included in the scope which covers all articles if formaldehyde and/or formaldehyde releasers are intentionally added in the article during production. RAC recommends including articles made from natural materials containing ingredients/components thereof with intentionally added formaldehyde or formaldehyde-releasers within the scope. Examples of these natural materials are bamboo (including bamboo waste), cork, sisal or any other natural materials used, e.g. in combination with formaldehyde-releasing resins/binders/composite materials. The respective articles may be used as flooring, furniture or other articles (e.g. home decoration).

ECHA Guidance on the requirements for substances in articles (Version 4, June 2017) describes articles either as one-piece (of homogenous composition) or as complex objects made of more than one article. Therefore, the proposal is valid for single parts/components of articles as well as for the articles that are joined together. As a consequence, estimated

emission concentrations of each one of the parts of a complex object (if containing formaldehyde or formaldehyde releasing substances), the whole composite article and the article made as a homogenous single piece (if at least one component releases formaldehyde) should remain below the emission limit (using the testing conditions established in Appendix X of this restriction). This means in effect that testing of complex articles is not needed if none of their components contains formaldehyde or formaldehyde releasing substances or if formaldehyde emissions of (all) individual components are within the limit established by the current proposal (see section 2.2.2.2 of the Background Document).

Formaldehyde released from interior components/construction parts in vehicles are covered by the restriction proposal. Vehicles, defined as any vehicles on roads, on rails, on the water and in the air (cars, buses, trucks, vans, motor-homes, trains, trams, passenger aircraft, water vehicles and any other vehicles for passenger transportation), are covered by the restriction proposal. Respective exposure scenarios were not included in the Background Document as only limited data were available. RAC agrees with the precautionary way forward chosen by the Dossier Submitter to include articles used in vehicles in the scope of the restriction but proposes not to impose a concentration limit for aircraft, based risk-grounds (RCR < 1).

RAC does not agree to apply the emission limit to articles used in rail and water vehicles as proposed by the Dossier Submitter, due to the current lack of standard test methods for such vehicles. Instead, RAC is of the view that a concentration limit should apply to whole cabin interiors of vehicles of any kind (within the scope of the restriction). As vehicle manufacturers operate globally, it is thought that the knowledge on measurements in cabins and other interior spaces as such is available. RAC considers that despite the current lack of a standard test method, these can be developed within reasonable time periods. Despite the fact that robust data on exposure is lacking, RAC notes that all passengers in road, rail and water vehicles should have the same level of protection, but leaves it to the Commission to decide whether rail and water vehicles are to be included in the scope of the restriction.

The restriction does not apply to objects made from solid wood and testing of these articles made from solid wood is not needed provided that formaldehyde/formaldehyde-releaser were not added to the object (or any part thereof) and none of the parts thereof were treated with materials containing formaldehyde or formaldehyde-releasers. The Dossier Submitter explained that testing of construction elements, furniture, flooring or other articles made from solid wood is nevertheless needed (in case formaldehyde or formaldehyde releasers are added to a component or to a mixture used in the production of the article), as formaldehyde may not only be released from wood but can also be released from paints, glues, fillers, foam, coatings/varnish, impregnations and other products used in the production of furniture and to which formaldehyde/formaldehyde releasers were added during production. In addition, furniture can be composed by parts of solid wood and wood-based panels.

Furniture is one group of articles in the scope of the restriction which may contribute significantly to formaldehyde emissions. In addition to glues, coatings, veneers or other binding/coating materials, formaldehyde may be released from wood-based panels or other construction materials (foam, filling for upholstery, etc.) that are commonly used in the production of furniture. Testing of furniture is required if formaldehyde/formaldehyde releaser was intentionally added to either the constructive materials or if formaldehyde/formaldehyde releaser was added to other materials/mixtures or was used as an ingredient in glues, paints, etc. that were used in the production of furniture.

The Dossier Submitter has indicated (in the Background Document) that testing of furniture is not required if all parts used are compliant with the restriction proposal (i.e. have been tested separately or are exempted). Testing of furniture is only required if formaldehyde/formaldehyde releasers are intentionally added (e.g. as part of glues, paints or covers) during the production process of the furniture. This proposal is supported by comments received from the consultation, e.g. No 2060. While textiles used in the coverage of the upholstery in chairs and sofas are covered by Regulation (EU) 2018/1513 requiring not to exceed a concentration limit for formaldehyde of 75 mg/kg, the filling materials (such as foam) used in the production of furniture are not included and the potential release of formaldehyde to the air will be covered by this restriction proposal. Mattresses are included

in the scope.

Clothing and other textiles that come into contact with human skin to an extent similar to clothing subject to the Regulation (EU) 2018/1513 are out of the scope. Textiles not covered by the restriction on CMR, and clothing, related accessories or footwear, or parts thereof, made exclusively of natural leather, fur or hide are exempted from Regulation (EU) 2018/1513. Some guidance on the exemptions is given in the explanatory guide on the restriction on CMRs in textiles[1].

Formaldehyde that may be released from footwear is requested by stakeholders to be exempted from the proposed restriction (see comment No 2742). Formaldehyde and formaldehyde releasers that are classified as CMR or sensitiser will be limited by content either by the CMR restriction or the upcoming restriction on sensitiser in textiles and leather.

Textiles (such as curtains, wall-to-wall carpets and articles made from animal skin/hair) releasing formaldehyde are not covered by other measures and therefore covered by this restriction proposal.

Personal protective equipment (PPE) is regulated under Regulation 2016/425 and is proposed to be exempted from the scope of this restriction. PPE are intended for uses by workers and professionals, their exemption has been requested (consultation comments No 2173, No 2444) as their products have to meet special requirements in terms of safety and functionality. The Forum and the Commission indicated that they are often used by consumers. RAC takes note that according to Regulation 2016/425 materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

RAC supports the view that articles subject to Regulation (EU) 2017/745 on medical devices are also proposed to be exempted from this restriction due to specific functionalities and legal requirements for this group of articles.

According to the Dossier Submitter's proposal formaldehyde emission from toys are not included in the scope if they are subject to Directive 2009/48/EC. Consultation comments proposed toys to be excluded as specific restrictions on toys are in place (e.g. comment No 2002). The European Commission announced on 18 December 2018 to introduce formaldehyde restrictions for specific toys under the Toy Safety Directive 2009/48/EC. The amendment was adopted on 19 November 2019, with proposed date of entry into force in May 2021[2]. The following concentration limits were added to Appendix C to Annex II to Directive 2009/48/EC:

- 1.5 mg/L (migration limit) in polymeric toy material
- 0.1 ml/m³ (emission limit) in resin-bonded wood toy material (0.1 ppm/m³)
- 30 mg/kg (content limit) in textile toy material
- 30 mg/kg (content limit) in leather toy material
- 30 mg/kg (content limit) in paper toy material
- 10 mg/kg (content limit) in water-based toy material.

In accordance with the Forum advice, the Dossier Submitter proposed to exempt food contact material as respective migration limits exist. RAC agrees that migration limits should prevent a significant release to indoor air.

Temporary sources such as cooking, wood burning, candle burning, ethanol fireplaces, cleaning products are not subject to the restriction proposal. They could contribute to high peak concentrations that alone could exceed the concentration limits. Ethanol fireplaces may represent a significant exposure source potentially contributing to long-term consumer risk because measured concentrations exceeded the RAC DNEL and the WHO guideline value by far and their use may be frequent. Formaldehyde in cleaning products should be covered by the biocidal products regulation (Regulation (EU) 528/2012). None of the other temporary

[1] https://ec.europa.eu/docsroom/documents/32006
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L1929&from=EN

sources were identified as having formaldehyde or formaldehyde-releasers intentionally added as formaldehyde occurs as a combustion product. The Dossier Submitter found it difficult to reach a conclusion on the level of a concentration limit and noted that a measure targeting articles would not affect the peak exposure from temporary sources. RAC notes that peak concentration may result from other sources and formaldehyde as a combustion product or from uses in mixtures. Indoor air concentrations of formaldehyde may increase transiently and depending on the use pattern peak concentrations may also be generated repeatedly. RAC understands that the articles identified as temporarily contributing to peak levels are not a matter of the scope of this restriction proposal (either as formaldehyde or formaldehyde releasers were not intentionally added or as the use as biocide in mixtures is exempted). In the view of RAC, the need for regulatory measures should be considered to limit formaldehyde emissions and consumer risk arising from ethanol fireplaces.

Comments received in the consultation recommended to focus on articles exceeding a specific size and to exempt small decorative items (e.g. comment No 2002). The Forum's advice indicates that small items would need a definition. Thus, RAC notes that articles of any size fulfilling the conditions of the restriction are included in the proposal.

The revised wording on the entry proposes to exempt second-hand articles from the proposed restriction in order to promote re-use in the EU. The exemption is based on the assumption that the formaldehyde release has been lowered over time for second-hand articles and off-gassing of residual formaldehyde will be below the emission limit. This follows the advice from the Forum that enforcement may be difficult, as second-hand articles include those produced in the Member States and those imported into the EU. According to stakeholder information the likelihood that wood-based panels and construction material will be re-used as second-hand article was considered as very low, while finding furniture on the second-hand market is more likely. The Dossier Submitter pointed out that no quantitative risk assessment can be performed, as no data on formaldehyde release from second-hand articles are available to RAC.

Recycled board fibres may be used in the production of new boards which as such are not considered as a second-hand article and in the view of RAC are not exempted from this restriction (e.g. consultation comment No 2060).

Description of the risk(s) addressed by the proposed restriction

Information on hazard(s)

Summary of proposal:

Formaldehyde is a highly reactive, acutely toxic substance leading to skin and respiratory tract irritation and corrosion, skin sensitisation, genotoxicity (such as DNA-protein cross links and DNA adducts) and carcinogenicity. Nasal tumours were observed mainly in rats and mice following inhalation exposure of 6 ppm (7.4 mg/m³) formaldehyde and higher.

Even if formaldehyde is a genotoxic carcinogen, SCOEL (2016) considered that a mode-of-action based limit value can be derived. SCOEL considered that tumour induction in the nasal mucosa of rats and mice is the result of chronic proliferative processes caused by the cytotoxic effects of the substance in combination with DNA alterations by endogenous and exogenous formaldehyde.

The most sensitive effect of formaldehyde in humans is sensory irritation. This effect was the basis for the OEL of 0.3 ppm (0.369 mg/m³) for workers proposed by SCOEL (2016) and for the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m³ (WHO, 2010).

It is the Dossier Submitter's opinion that the inhalation cancer risks posed by formaldehyde in the air at the OEL for workers of 0.3 ppm (0.369 mg/m³) as recommended by SCOEL and by the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m³ (0.08 ppm) can be considered to be negligible. Risks associated with consumer exposure to formaldehyde from inhalation are therefore assessed against the WHO guideline value of 0.1 mg/m³.

Other risks from formaldehyde have been considered but the Dossier Submitter has concluded that the risks from the inhalation of formaldehyde are the most significant.

RAC conclusion(s):

RAC takes note of the proposed DNEL which was suggested by the Dossier Submitter by reference to the WHO Guideline for Indoor Air Quality for formaldehyde (WHO, 2010). The WHO considers 0.1 mg/m³ (0.08 ppm) as protective against acute (sensory) and chronic irritation in the airway of the population. As the calculated WHO guideline value of 0.21 mg/m³ (0.17 ppm) for long-term effects was higher than the WHO guideline value for acute effects, the WHO selected the lower acute value of 0.1 mg/m³ formaldehyde as the more appropriate guideline value (see below for further reflections on the assessment factors applied by the WHO in risk assessment).

In its hazard assessment, the Dossier Submitter considers assessments carried out under relevant Community legislation when available in accordance to Point 0.5 of Annex I of REACH. RAC can in principle agree on this approach, if the value is justifiable, up-to-date and in line with the framework on risk characterisation given by REACH. Specifically, RAC should evaluate and demonstrate transparently whether the selected concentration limit (which has been proposed by the Dossier Submitter as the DNEL) is consistent with the REACH framework on DNEL derivation and risk assessment and review whether the selected literature data considered as the most sensitive effect as point of departure (POD) for carcinogenic effects are still appropriate and cover the most recent and appropriate data. To confirm whether the proposed DNEL follows the principles of the REACH framework for risk assessment, RAC conducted a review of: i) whether the chosen point of departure for carcinogenic effects is indeed the most sensitive, ii) whether it is based on sufficiently robust data, and iii) as a consequence, whether it can be considered sufficiently protective for the target population of consumers. RAC compared the robustness of the data underlying the DNEL proposed by the Dossier Submitter - the WHO short-term (30 min) guideline value - with the alternative DNELs derived from the review of all the available data relevant for the effect of concern (carcinogenicity). The Committee applied appropriate assessment factors according to the ECHA Guidance documents.

The following key elements show the outcome considering different options to derive the DNEL. In conclusion of the comparison of calculated DNELs and taking a weight of evidence approach into account, RAC does <u>not</u> agree to base the DNEL on the WHO value of 0.1 mg/m³ formaldehyde as proposed by the Dossier Submitter.

The derivation of the WHO guideline value was mainly based on the study of Lang et al. (2008) who exposed 21 healthy volunteers (11 males and 10 females) to formaldehyde concentrations of 0, 0.19, 0.37 or 0.62 mg/m³ (0, 0.15, 0.3 or 0.5 ppm) acutely for 4 h. The study authors concluded that eye blinking frequency (EBF) was the most sensitive parameter for sensory irritation with a reported NOAEC of 0.62 mg/m³ and a LOAEC of 0.62 mg/m³ with 4 peaks of 1.24 g/m³ (= 1 ppm) formaldehyde. The Dossier Submitter indicates that the most sensitive effect in humans after inhalation of formaldehyde is sensory irritation (eye blinking frequency) and considered this study NOAEC as POD for the DNEL, thus, as surrogate predictive for the long-term carcinogenic effects. RAC acknowledges that data on sensory irritation could be one option to derive a DNEL for formaldehyde assuming that at very low formaldehyde concentrations sensory irritation of the eye and upper respiratory tract is an initial event preceding the cascade of precursors in the tumour development (irritation → inflammation → hyperplasia → metaplasia → tumour). However, depending on the availability and robustness of data and considering duration-related effects, sensory irritation data do not necessarily represent the most sensitive point of departure for DNEL derivation.

It is the view of RAC that due to the small numbers of volunteers (ECHA Guidance R.8: “small” in relation to sample size and setting of AF is specified with 10-30 people) and the very high variability in EBF in the study by Lang et al. (2008) examining acute formaldehyde exposure, the study design and particularly the assessed parameter cannot be considered to be sensitive enough to detect concentration-related effects unless they are considerably marked (i.e. only an exposure concentration of 0.62 mg/m³ (0.5 ppm) with 4 peak exposures to 1.24 mg/m³ (1 ppm) formaldehyde resulted in a significant increase by doubling of EBF rate. Due to the

enormous variability of the measured effect (very large ranges of EBF (~100 fold min-max eye blinking rate at baseline and in exposure groups) resulting in very high standard deviations) and due the low numbers of volunteers (yielding low statistical power), the absence of an effect at lower formaldehyde concentrations is considered uncertain in the study of Lang et al.. Thus, the probability of false negative results at the lower concentrations (below 1.24 mg/m³) cannot be excluded based on the reported study results.

RAC further notes that subjective scores for olfactory symptoms and for eye irritation significantly increased already at ≥ 0.37 mg/m³ (0.3 ppm) formaldehyde in the study of Lang et al. (2008). However, the small number of volunteers and the subjective self-reporting do not allow deriving a robust DNEL. High variability in EBF was also seen in a follow-up study by the same group (Mueller et al., 2013) testing 20 'hyposensitive' and 21 'hypersensitive' male volunteers. This study was not available to WHO in 2010 and did not report evidence for effects on EBF up to 0.87 mg/m³ (0.7 ppm) formaldehyde (4 hours exposure). In this study the comparison of EBF measured during the last 15 minutes of the formaldehyde exposure versus pre-exposure were performed and resulting values revealed a trend towards lower mean differences instead of the expected higher EBF.

RAC notes several weaknesses in both studies among which the low numbers of volunteers lead to uncertainties whether a concentration-related effect is detectable at such high variability of the measured effect. As to the differences in data documentation and study design, the robustness of the results will not increase by adding up the number of the volunteers of both studies.

In addition to this, lower AFs in comparison to the ECHA Guidance recommendations were used by the WHO and the short exposure duration has not been acknowledged (see discussion under 'Key elements' below).

Moreover, there are uncertainties whether the selected parameter (EBF, during acute exposure) is the most appropriate surrogate predictive for the carcinogenic effects after long-term inhalation to formaldehyde. Sensory irritation is generally acknowledged as one of the most sensitive (acute) health effects that have been observed in humans. However, no information is available on other effects preceding (early) tumour response in humans. Reliable sensory irritation data, on the other hand, is not available for animals. RAC notes uncertainties regarding the predictability of EBF after single exposure of 4 h (as done by the WHO) for long-term effects. There are indications from animal studies that prolongation of formaldehyde exposure (up to 24 months) leads to an exacerbation of (non-neoplastic, potentially precursor) nasal effects. The frequency of metaplasia increased with the duration of treatment in rats (Kerns et al, 1983a), and in monkeys the percentage of affected nasal area increased with the duration of exposure (Monticello, 1989).

Although suitable data on sensory irritation are not available for formaldehyde, duration of inhalation exposure to volatile organic compounds has been shown to have an effect on the threshold level for EBF. The eye irritant 2-ethylhexanol at a concentration of 10 ppm increased EBF at the end of 4 h exposure, while it did not affect EBF at the beginning (Kieswetter et al., 2005). This finding underpins that EBF should be monitored continuously during the whole exposure period in order to detect potential inhalation effects, and this was not done in the Lang and Mueller studies.

For the purpose of this restriction, mainly DNELs for long-term inhalation exposure and with regard to local effects are relevant, as carcinogenic effects of formaldehyde were only observed locally in nasal tissue of test animals after long-term inhalation exposure. RAC considers calculations of DNELs for long-term effects identified from precursor events in the development of malignant tumours (Tab. 3) as more appropriate than derivation of acute DNELs.

RAC proposes a lower DNEL of 0.05 mg/m³ (0.04 ppm) based on the weight of evidence taking into account data on various tumour precursor events from several studies on monkeys and rats and applying assessment factors according to the ECHA Guidance to ensure a sufficient margin of safety.

RAC considered separate data sets on the full range of precursor events to the carcinogenic effect (irritation/cytotoxicity, cell proliferation, epithelial dysplasia, metaplasia/hyperplasia, tumour response) and applies assessment factors (AF) according to the ECHA Guidance. Selected studies NOAEC/LOAECs were consistent to those identified and considered robust by RAC (RAC, 2012). RAC proposes a DNEL of 0.05 mg/m³ mainly based on monkey data for relevant precursor effects and taking into account consistent data from rat studies as more robust than the short-term WHO guideline value.

For information, applying an AF of 10 according to the ECHA Guidance for inter-individual differences to the human NOAECs on sensory irritation reported in the studies by Lang et al. and Mueller et al. would result in similarly low DNELs of 0.06 mg/m² (0.05 ppm) and 0.087 mg/m³ (0.07 ppm), respectively.

Key elements underpinning the RAC conclusion(s):

The toxicity of formaldehyde has been extensively reviewed in the recent past, i.e. in the EU by the ECHA report on formaldehyde and formaldehyde releasers (2017) and the RAC Opinion on the harmonised classification and labelling of formaldehyde (2012), including the classification of formaldehyde as mutagen category 2, and carcinogen category 1B (2012). Worldwide formaldehyde has been reviewed as well by the IARC (1995), BfR (2006), the WHO (2010), SCOEL (2016), and ANSES (2016 and 2018).

Toxicity other than mutagenicity/carcinogenicity

Acute toxicity

Formaldehyde is acutely toxic following ingestion, dermal and inhalation exposure and has the following classification: Acute Tox. 3 (H331); Acute Tox. 3 (H311); Acute Tox. 3 (H301). There is one more recently performed guideline conform test (2015) in rats with 4 hours whole-body exposure. As all animals died on study day 1 or 2, the registrant of the REACH dossier self-classified formaldehyde as Acute Tox. 2 (H330, fatal if inhaled).

Irritation/Corrosion

In concentrations between 5 and < 25 %, formaldehyde has irritating properties: Skin Irrit. 2 (H315): 5 % ≤ C < 25 %; Eye Irrit. 2 (H319): 5 % ≤ C < 25 %.

The Dossier Submitter indicates that the most sensitive effect in humans after inhalation of formaldehyde is sensory irritation (eye blinking response): “The studies by Lang et al. (2008) and Mueller et al. (2013) were identified as reliable and provide a NOAEC of 0.5 ppm (0.61 mg/m³) for continuous exposures and of 0.3 ppm (0.37 mg/m³) for continuous exposure with peak exposure (4-times 15 minutes) of 0.6 ppm (0.74 mg/m³). The studies also indicated no sex differences and no differences between hypo-and hyper-sensitive individuals.

The odour threshold of formaldehyde was identified with 0.1 ppm (0.12 mg/m³) with a (range from 0.02 to 0.5 ppm (0.02 to 0.61 mg/m³) (Berglund et al., 2012).”

Formaldehyde is also irritating to the respiratory tract: STOT SE 3 (H335): C ≥ 5 %. Formaldehyde has corrosive properties and has the classification: Skin Corr. 1B (H314) with a concentration limit C ≥ 25 %.

Skin sensitisation

Formaldehyde is a known skin sensitiser which has the classification Skin Sens. 1 (H317). The concentration limit for mixtures for skin sensitisation is 0.2 %. Formaldehyde might also lead to respiratory sensitisation. However, against the background of a widespread use, respiratory sensitisation has been reported only in single cases (DFG, 2010).

Repeated dose toxicity

Regarding repeated dose toxicity, formaldehyde was demonstrated to elicit adverse effects at the site-of-contact (Table 1).

Table 1: Repeated dose toxicity studies

Formaldehyde (mg/m^3)	NOAEC/ LOAEC	Effects	Species, exposure	References
0.25	NOAEC	No metaplasia or hyperplasia	Monkeys, 26 week inhalation exposure	Rusch et al. (1983)
1.24	NOAEC	No histopathological effects in the nose	Rats, 2 year inhalation exposure	Kerns et al. (1983), Swenberg et al. (1980), Woutersen et al. (1989), RAC (2012)
2.5	LOAEC	Rhinitis, epithelial dysplasia, metaplasia, polypoid adenomas		
7.45		Squamous cell carcinoma		
		Cell proliferation increased transiently		Monticello et al. (1996)
12. 4		Cell proliferation increased permanently		

Reproductive toxicity

There is no convincing evidence that formaldehyde would lead to reproductive or developmental effects in humans or in experimental animals at concentrations in the air that do not lead to irritation in the respiratory tract.

Mutagenicity/Carcinogenicity

Formaldehyde has the following harmonised classification: Muta. 2 (H341) and Carc. 1B (H350).

It is well established that formaldehyde is a mutagen and (local) carcinogen, inducing tumours at site-of-contact after inhalation (nasal tissue) but not at distant sites. Tumours were observed mainly in rats and mice following inhalation exposure of 7.45 mg/m^3 formaldehyde and higher. The presence of papilloma (the benign type of squamous cell tumours) and polypoid adenomas at 2.5 mg/m^3 (Kerns, 1983) supported by the presence of dysplastic epithelium (a tumour precursor lesion), alongside rhinitis at that exposure concentration (Kamata, 1997; Swenberg et al., 1980) indicate that 2.5 mg/m^3 is to be considered the LOAEC for the early tumour response in rats. The incidences of squamous cell carcinoma in rats, the dominant tumour type, increased with a steep slope from 6.9 mg/m^3 onwards and reached maximum rates of 38-47 % at formaldehyde concentrations around 18.6 mg/m^3. Spontaneously, nasal tumours in rats are very rare (roughly estimated as below 0.1 % for squamous cell carcinomas according to several sources) and as tumour incidences show concentration-related response, 2.5 mg/m^3 should be considered as the lowest concentration associated with early tumour responses in rats (LOAEC) as concluded by RAC (2012). Based on the available data, no such findings were observed at concentrations up to 1.24 mg/m^3 in rat studies (NOAEC for nasal tumours in rats; RAC 2012). The data base on mice and hamsters is small but provides some evidence for carcinogenic potential in the nasal region (Kerns et al. 1983; Dalbey et al., 1982). Mouse data suggest a lower sensitivity to formaldehyde-induced nasal tumour induction in this species compared to rats, potentially due to differences in minute volume and, thus, inhaled dose. Hamster data, on the other hand, does not allow conclusion on carcinogenicity due to study limitations. In monkeys (almost) continuous exposure to formaldehyde at 0.25, 1.24 or 3.72 mg/m^3 for 26 weeks (a duration which is not adequate to assess the carcinogenic potential), metaplasia and hyperplasia were observed in 1/6 and 6/6 animals of the 1.24 and 3.72 mg groups, respectively. In the monkeys exposed

to concentrations of 0.25 mg/m³, no histopathological changes were found (Rusch et al., 1983). The substance evaluation conclusion derived a LOAEC of 3.7 mg/m³ (NOAEC of 1.24 mg/m³) based on metaplasia/hyperplasia in 6/6 animals at this dose (ECHA, 2019[3]). In contrast the Dossier Submitter and RAC note that the same effect was observed in 1/6 animals at 1.24 mg/m³ and should be interpreted as a dose-response effect and thus 0.25 mg/m³ is the NOAEC. This study previously has not been considered by RAC (2012).

RAC (2012) concluded that the degree of sensitivity to nasal irritation among species is associated with the degree of sensitivity to nasal tumour induction. Localisation of damage to the nasal epithelium also corresponds with tumour site and distribution is attributable to regional dosimetry and/or local tissue susceptibility. “Lesions of similar nature to those seen in rats (and other species) were also induced in monkeys and were considered as relevant for humans. Lesions and increased cell proliferation in the monkey were not confined to the nose and extended to more distal parts of the respiratory tract. Differences in the distribution among species were related to anatomical and airflow differences and can be interpreted as supportive for identifying the nasopharyngeal region as one target area in humans”.

There is no scientific indication of germ cell mutagenicity or systemic availability of formaldehyde leading to tumour formation at distant sites. However, formation of DNA-(mono)adducts, DNA-formaldehyde crosslinks and DNA-protein crosslinks (DPX) at site-of-contact by exogenous formaldehyde inhalation were observed frequently in rats and monkeys at exposure concentrations as low as 0.87 mg/m³ and 2.36 mg/m³, respectively (Lu et al. 2010; Moeller et al. 2011; Yu et al. 2015). While DNA-protein-crosslinking was observed as well in rats exposed to 0.37 mg/m³ formaldehyde after single exposure (6 h) (Casanova et al. 1989), no DNA mono-adducts and DNA–protein crosslinks were detected after 28 days of formaldehyde exposure (6 h/d) of rats at this concentration (Leng et al. 2019). Interestingly, it is noted that while endogenous DPX were demonstrated to be present in all tissues to a high extent, exogenous DPX were only formed in nasal tissue but not at distant sites (Lu et al. 2010). Furthermore, DPX can be eliminated by spontaneous hydrolysis and/or other DNA repair mechanisms and do not accumulate during prolonged exposure to formaldehyde (Casanova et al., 1994). In addition, it was reported that exogenous formaldehyde (even at high doses) does not affect endogenous DNA-adduct levels, whereas adduct formation was generally shown to be formaldehyde concentration dependent (Edrissi et al. 2013). Moreover, it was demonstrated that the amounts of DPX and DNA-adducts formed by endogenous formaldehyde far exceed the amounts of DPX and DNA-adducts formed by exogenous formaldehyde at low concentrations. In the study by Lu et al. (2010), for instance, the exogenous adducts formed following 0.87 mg/m³ formaldehyde exposure were less than 1 % of the endogenous DNA adducts. The authors of the study suggested that a marked increase in cell proliferation induced by exposure to higher concentrations (≥ 7.45 mg/m³) may “play a critical role in converting both endogenous and exogenous labile but pro-mutagenic adducts into mutations”. Similarly, SCOEL (2016) indicated that “mechanistic studies have provided strong evidence that tumour induction in the nasal mucosa of rats and mice is the result of chronic proliferative processes caused by the cytotoxic effects of the substance in combination with DNA alterations by endogenous and exogenous formaldehyde.” RAC agrees with the conclusion that the mode of action of formaldehyde carcinogenicity is probably a combination of DPX formation and increased cell proliferation.

Transient increases in cell proliferation rates were demonstrated at exposure concentrations ≥ 7.45 mg/m³ which become permanent at 12.4 mg/m³ (Monticello et al., 1996; Casanova et al., 1994; Meng et al., 2010). Likewise, IARC (2006) concluded that “genotoxicity is greatly amplified by cell proliferation, resulting in a marked increase of malignant lesions in the nasal passages” at formaldehyde concentrations above 7.45 mg/m³. It is, however, noted that non-significant dose-related increases in cell proliferative activity could already be demonstrated at 2.5 mg/m³ (Monticello et al., 1996; Meng et al., 2010). Although not statistically significant, a roughly 2-fold increase in cell proliferation was observed at 2.5 mg/m³ in the study by Meng et al. (2010), a value which could serve as LOAEC for increased cell replication. A study by Speit et al. (2011) similarly found small but significantly increased cell proliferation at 0.62, 1.24 and 2.5 mg/m³. However, RAC concluded that “the most sensitive sub-sites of

[3] https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e6413

the nasal turbinates (lateral meatus, nasoturbinate, nasopharynx) showed non-identical proliferation rates at different concentrations". A rather monotonic dose-response for each single region was observed at and above 2.5 mg/m³. Thus, 2.5 mg/m³ may be considered the LOAEC for cell proliferation after inhalation of formaldehyde, as concluded by RAC (2012) and by ECHA (2019) in the substance evaluation procedure. Accordingly, Andersen et al. (2010) examined the concentration and exposure duration transitions in formaldehyde mode of action (MOA) with pharmacokinetic (PK) modelling and with histopathology and gene expression in nasal epithelium from rats exposed to 0, 0.87, 2.5, 7.45, 12.4, or 18.61 mg/m³ formaldehyde (6 h/day) for 1, 4, or 13 weeks. Patterns of gene expression varied with concentration and duration. At 2.5 mg/m³, sensitive response genes (SRGs) associated with cellular stress, thiol transport/reduction, inflammation, and cell proliferation were upregulated at all exposure durations. The LOAEC for cell proliferation is, thus, considered 2.5 mg/m³, while 1.24 mg/m³ could be considered the NOAEC. Data further suggests that formaldehyde induced cell proliferation does not increase with increased exposure duration (Casanova et al., 1994; Monticello et al., 1996; Meng et al., 2010; Speit et al., 2011).

Generally it is concluded, in accordance with SCOEL (2016), that "the dose-response relationships for all parameters investigated, such as damage to the nasal epithelium, cell proliferation, tumour incidence, the formation of DPX and DNA-adducts, is very flat for low level exposures and becomes much steeper at higher concentrations."

Nevertheless, SCOEL (2016) also concluded that "the background incidence of nasal tumours in rodents and of nasopharyngeal tumours in humans is very low in spite of the appreciable amount of endogenous DNA adducts. One of the reasons may be the low physiological proliferation rate of the respiratory epithelium, and as long as this is not increased (which requires exposure to concentrations of more than 2.5 mg/m³), the probability of tumour formation also is low." It is agreed that significantly increased cell proliferation rates were observed at ≥ 7.45 mg/m³. However, (non-significant) dose-related increases in cell proliferative activity were detected at 2.5 mg/m³, and DPX formation due to exogenous formaldehyde could already be seen at 0.37 mg/m³ in formaldehyde exposed rats. In addition, the presence of papilloma and polypoid adenomas in rat nasal tissue at 2.5 mg/m³ formaldehyde (Kerns, 1983b) and the presence of dysplastic epithelium at that exposure concentration (Kamata, 1997; Swenberg et al., 1980, Kerns, 1983a) indicate that 2.5 mg/m³ should rather be seen as LOAEC for the early tumour response in rats instead of a NOAEC as concluded by RAC (2012). Based on the available data, the NOAEC for nasal tumours in rats could be considered 1.24 mg/m³.

The Background Document noted that Wilmer et al. (1989) concluded that exposure duration plays a minor role compared to exposure concentration with respect to histopathological changes, as well as cell turnover in the rat nasal respiratory epithelium. However, the data of the study do not allow a firm conclusion, as effects in rats were seen only after intermittent exposure to formaldehyde concentrations of 4.9 mg/m³. The highest continuously tested concentration was 2.5 mg/m³. At this concentration – which was also tested intermittently – no effects were seen independent of the exposure regimen. Kerns (1983a) found increased frequencies of squamous metaplasia in rat nose at level I at 2.5 mg/m³ and 6.9 mg/m³ and comparing animals after 6, 12, 18 and 24 months of exposure (additional group plus 3 months without treatment (27 months)). The same duration-related effect was true for rats exposed to 17.7 mg/m³ formaldehyde for the levels III to V, while 100 % were affected at levels I and II at all treatment durations assessed.

Figure 1 and Figure 2: Frequencies of squamous metaplasia in rat nasal cavity, Kerns 1983a

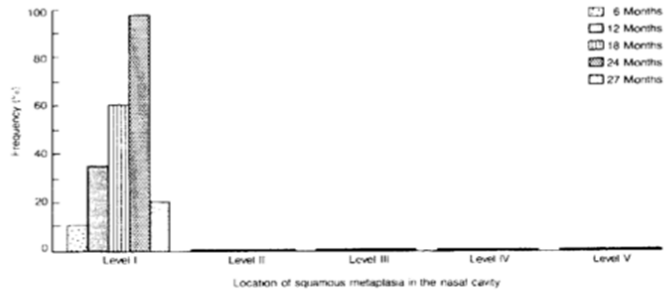


Figure 5 Frequency of squamous metaplasia in the nasal cavity (level I) of Fischer 344 rats exposed to 2 ppm formaldehyde vapor.

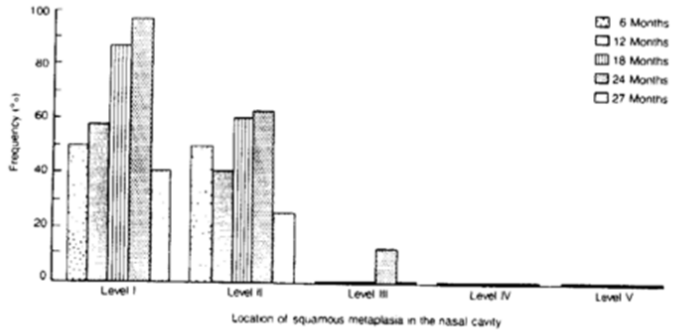


Figure 8 Frequency of squamous metaplasia in the nasal cavity of Fischer 344 rats exposed to 5.6 ppm formaldehyde vapor.

Monticello (1989) found minimal progression of histologic changes between 1 and 6 weeks in monkeys exposed to 7.4 mg/m³. However, after 6 weeks the percent of affected nasal area was significantly increased indicating that the duration has an effect on the extension of the lesion. Monkeys after 26 weeks (Rusch et al., 1983) exposed to doses of 1.24 mg/m³ or higher showed metaplasia and hyperplasia supporting the hypothesis that prolongation of treatment lowers the LOAEC. RAC confirms that formaldehyde shows dose-response related effects, however a certain effect of the treatment duration on the frequency or extension of nasal effects is also obvious and an AF for duration of the exposure should be considered in parallel.

It is agreed in accordance with the RAC conclusion on formaldehyde carcinogenicity (2012) that experimental results and mechanistic data support “the existence of a threshold type dose-response for induction of nasal tumours, with regenerative cell proliferation being the predominant feature in the carcinogenic process. The genotoxicity of formaldehyde is also expected to play a role above this threshold.” However RAC further reflected the uncertainties that “the data does not allow a firm conclusion on a threshold-mode of action or the identification of a threshold”, while SCOEL (2016) considered that “the apparent NOAEC of 1 ppm [1.24 mg/m³] can be considered a mode-of-action based NOAEC for carcinogenic effects at the portal-of-entry” (SCOEL 2016). In line with the Dossier Submitter, RAC concludes that formaldehyde is a locally acting genotoxic carcinogen for which a mode-of-action based limit value for its carcinogenic effect in the nose is very likely. Whether the WHO threshold value of 0.1 mg/m³ can be considered sufficiently conservative for formaldehyde risk assessment is discussed in the next section.

Related to dermal exposure and carcinogenesis, formaldehyde is poorly absorbed through intact skin; rapid metabolism makes systemic effects unlikely following dermal exposure. In dermal initiation/promotion studies, formaldehyde did not initiate or promote skin tumorigenesis in mice. From a mouse skin painting study, no skin tumours were observed in 16 male and 16 female mice with topical application of 200 µg formaldehyde twice a week at the end of the study after 60 weeks (Iversen, 1986).

Derivation of DNELs

Dossier Submitter proposal on DNEL

RAC notes the Dossier Submitter's indication that the most sensitive effect of formaldehyde in humans is (acute) sensory irritation (NOAEC of 0.6 mg/m³ for eye blinking response) and further indicates that the threshold value of 0.1 mg/m³ is considered appropriate and sufficiently conservative to protect the general population including children from local formaldehyde-related effects including cancer effects.

This value was selected by the Dossier Submitter in agreement with the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m³ (WHO, 2010). This WHO guideline value was based on the NOAEC of 0.6 mg/m³ for eye blinking response and was adjusted by using an assessment factor of 5 derived from the modelled standard deviation of a threshold for another effect, i.e. nasal pungency (sensory irritation), identified by testing volatile organic substances other than formaldehyde (Hau et al. 2000), leading to a value of 0.12 mg/m³, which then has been rounded down to 0.1 mg/m³.

The WHO guideline value is intended to be a short-term (30-minutes) value. The WHO (2010) stated that the use of the short-term (30-minute) guideline value of 0.1 mg/m³ will also prevent long-term health effects, including nasopharyngeal cancer. Nielsen et al. (2017) re-evaluated the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m³ and concluded that "overall, the credibility of the WHO guideline [of 0.1 mg/m³] has not been challenged by new studies".

This threshold value is, according to the Dossier Submitter, in line with the DNEL for the general population derived by the registrant of the REACH dossier, who reported a DNEL of 0.1 mg/m³ for long-term inhalation exposure, local effects (BASF, 2017), and with the values recommended by other international organisations.

The DNEL as proposed by the Dossier Submitter is in agreement with a recommendation from the German BfR (2006) that considered 0.124 mg/m³ formaldehyde as "safe level". The German Umweltbundesamt (UBA) in 2016 has confirmed the WHO value of 0.1 mg/m³ formaldehyde as indoor air guideline value. In 2018, the French ANSES (2018) re-evaluated the reference values for formaldehyde and concluded on an indoor air value of 0.1 mg/m³ which is in line with the WHO guideline value. This value is higher than the previously by AFFSET derived short-term exposure level of 0.05 mg/m³ (2 hours) and their long-term exposure level of 0.01 mg/m³ proposed for indoor air guidelines (AFSSET, 2007).

JRC (2005) performed a "Critical Appraisal of the Setting and Implementation of Indoor Exposure Limits in the EU". With respect to formaldehyde, JRC concluded that "Due to being ubiquitous pollutant in indoor environments and to the increasing evidence indicating that children may be more sensitive to formaldehyde respiratory toxicity than adults it is considered a chemical of concern at levels exceeding 1 µg/m³, a concentration more or less corresponding with the background level in rural areas." The value proposed by JRC of 0.001 mg/m³ is based on studies investigating respiratory symptoms and pulmonary function in children and adults, e.g. Krzyzanowski et al. (1990). Effects were reported at formaldehyde concentrations as low as 0.037 mg/m³.

However, UBA (2016) performed a review of epidemiological studies investigating the association between formaldehyde exposure and the induction or exacerbation of asthma in children. On the basis of the available data, UBA concluded that there is no clear association between formaldehyde exposure in the indoor environment and asthma in children. It was stated that the above mentioned epidemiological studies (e.g. Krzyzanowski et al., 1990) suffer from small sample sizes (which was much larger than in the studies by Lang et al. (2008) and Mueller et al. (2013)), from implausible formaldehyde concentrations, and the fact that other substances or factors initiating asthma and asthma-like complaints were not adequately considered. Results derived from controlled human exposure studies as well as animal experiments support their opinion.

RAC analysis on DNEL

In the following tables a detailed overview on the derivation of DNELs based on different PODs is shown (acute effects in Table 2 versus long-term effects in Table 3), including the WHO-based DNEL proposed by the Dossier Submitter and the various DNELs based on relevant cancer precursor events. It provides the basis for the selection of the most appropriate DNEL in order to assess the health risks from long-term exposure to formaldehyde:

Table 2: DNELs calculated from acute effects (WHO guideline value either as published by WHO (2010), or RAC derived using REACH AF) and short-term DNA adduct formation (both without correction to long term effects)

Endpoint for selection of point of departure for DNEL derivation (and reference)	NOAEC (LOAEC) [mg/m³] (exposure duration)	Assessment Factors (AF)	Overall AF	Resulting DNEL [mg/m³]*
Dossier Submitter proposal based on WHO (2010)				
Nasal irritation in humans *(used by Dossier Submitter for DNEL derivation)* (Lang et al., 2008; Mueller et al., 2013)	0.6 (NOAEC) (to derive short-term (30 min) guideline value)	5 - derived by WHO from modelled standard deviation of the nasal pungency threshold from other irritants than formaldehyde	5	0.1
Alternative calculation by RAC according to ECHA Guidance				
Nasal irritation in humans (*used by Dossier Submitter for DNEL derivation)* n = 10 adult males, 11 adult females (Lang et al., 2008)	0.6 (NOAEC) (short-term: 4 h)	REACH-AFs (GD R8, R.8.1.2.8): 1 – allometric scaling/ remaining interspecies differences 10 – intraspecies differences (large variation, small sample sizes)**	10	0.06
Nasal irritation in humans n = 41 adult males (Mueller et al., 2013)	0.87 (NOAEC) (short-term: 4 h)	REACH-AFs (GD R8, R.8.1.2.8): 1 – allometric scaling/ remaining interspecies differences 10 – intraspecies differences (large variation, small sample sizes)**	10	0.087
Formation of DNA-(mono)adducts, DNA-formaldehyde crosslinks and/or DNA-protein crosslinks (DPX) at site-of-contact (Casanova et al., 1989; Lu et al., 2010; Moeller et al., 2011; Edrissi et al. 2013)	0.37 (LOEC) (short-term: 6 h)	REACH-AFs (GD R8, R.8.1.2.8): 2.5 – remaining interspecies differences# 3.16 – intraspecies differences## 3 – LOAEC → NOAEC	23.7	0.01
DNA adduct formation Monkey 2 d, 6 h/d (2, 6 ppm) (Yu et al. 2015)	2.4 (LOAEC) (short-term: 2 d, 6 h/d)	REACH-AFs (GD R8, R.8.1.2.8): 2.5 – remaining interspecies differences# 3.16-intra-species	23.7	0.1

		differences[##] 3 – LOAEC → NOAEC		

* Without correction for chronic exposure

** AF 10 justified by high inter-individual variability of the effect and small number of individuals tested

Interspecies AF 2.5 for remaining interspecies differences for local, respiratory effects (default factor according to guidance R8)

Intraspecies AF 3.16. Although ECHA Guidance foresees default factor of 10, the AF was reduced to 3.16 to address local effects only.

Table 2 illustrates the resulting DNELs using either assessment factors according to the WHO and ECHA Guidance, respectively, based on acute toxicity data. The table is starting with the Dossier Submitter proposal as a baseline proposal: The WHO (2010) Guideline for Indoor Air Quality for formaldehyde sets a threshold value for formaldehyde inhalation of 0.1 mg/m³ (intended as a short-term (30 min) guideline value; WHO, 2010). This guideline value is based on a NOAEC of 0.6 mg/m³ for eye blinking response after a single acute (4 h) exposure (based on a study by Lang et al., 2008) and is adjusted by using assessment factor 5 derived from the modelled standard deviation of nasal pungency (sensory irritation) threshold, leading to a value of 0.12 mg/m³ which has been rounded down to 0.1 mg/m³.

RAC notes that the use of such a low AF was not justified and differs significantly from the default AF of 10 in the ECHA Guidance. A standard deviation of approximately 100 % of mean EBF observed by Lang et al. (2008) does to RAC's view not justify a reduction of the AF for intraspecies differences to 5. Moreover, the use of modelled standard deviation of a different effect (i.e. nasal pungency) resulting from other irritants than formaldehyde (Hau et al. 2000) may not be predictive for the variability observed in the eye blinking response to formaldehyde. Hau et al. (2000) used data on the nasal pungency threshold of various VOC (but not formaldehyde) in groups of 3 or 4 anosmics which were tested between 1990 and 1994 using a subjective scoring technique, and originally published by Cometto Muniz and Cain (1990, 1991, 1993 and 1994). It is likely that the variability of a threshold concentration against nasal pungency shows lower variability as EBF for which the range of EBF/minutes in controls was extremely large (3-120 in Lang et al., 2000). RAC considers that the AF of 5 does neither reflect the variability of EBF nor the uncertainties of the database.

Using the same point of departure but applying assessment factors according to ECHA Guidance, a DNEL of 0.06 mg/m³ is derived (Table 2). The assessment factor of 10 was employed to address intraspecies variability in the target population and the uncertainties (regarding false negative responses) due to the small number of volunteers. According to ECHA Guidance R8 (Annex R.8-15: Guidance on Derivation of DNEL/DMEL from Human Data) an assessment factor of 10 shall be applied "*when the human study is small and the sample in the study is homogenous and therefore no significant part of human variability could be regarded as covered*." The guidance further specifies that "*when substance specific information is obtained from studies where the sample size (number of people) is small (10-30), it is not justified to set a low AF, since the effects of human variability cannot be fully observed in a study with a relatively small sample size. […] Use of AFs lower than the standard assessment factors is appropriate when it can be shown that some of the factors that cause the intraspecies variation in the target population, such as gender, age, nutritional status, health, susceptibility and genetic polymorphism have been covered in the study population*".

The studies by Lang et al. 2008 and Mueller et al. 2013 (the latter was a follow-up study of the Lang study and was not considered by the WHO) are comparably designed; however, the number of participants is rather low (Lang et al., 2008; Mueller et al.; 2013) and only adults were tested.

The variability in eye blinking frequency (EBF) in the volunteers was reported to be high at baseline and in the exposure groups (mean ± standard deviation, median (range): control: 28.2 ± 30.2, 20 (3-120); 0.6 mg/m³ (NOAEC): 29.2 ± 29.7, 18 (2-128); 0.6 mg/m³ + 4 peak exposures at 1.24 mg/m³ : 46.3 ± 45.6, 37 (2-200) (Lang et al. 2008)). The LOAEC for EBF in the study by Lang et al. (2008) was 0.62 mg/m³ with 4 peak exposures at 1.24 mg/m³ which gained significance due to a doubling of the mean EBF. A range of factors (age, gender, mental state, environmental factors, habituation) may have influence on EBF resulting in physiological variability of this parameter, thus explaining the high range of EBF even

observed in volunteers exposed to air only (Doty et al., 2004). Subjective scores for olfactory symptoms and for eye irritation significantly increased ≥ 0.3 ppm (0.37 mg/m³) of the Lang et al. study but were not taken into consideration for LOAEC setting by WHO.

Similarly, a high variability in mean (and median) differences in EBF at the end of exposure compared to pre-exposure was seen in control and exposed groups in the study by Mueller et al. (2013, additional Table online Resource 6), who only exposed male volunteers. The resulting data (no raw data but means ± standard deviations and medians reported) is indicative of being non-parametrically distributed and for such data the use of repeated-measures ANOVA, which was chosen by the study authors for statistical analysis, is not recommended. RAC notes that Mueller and colleagues did not find evidence for increased EBF at any tested formaldehyde concentration up to the highest tested concentration of 0.87 mg/m³ formaldehyde (4 h) (NOAEC) using this approach. Mueller and his group examined so-called “hyposensitive” and “hypersensitive” persons, whose self-rating of pain after 2 seconds of exposure to carbon dioxide gas were used to classify the individual into one of two groups (above/below the median sum value). RAC considers it uncertain whether this method is representative of the inter-individual differences in the general population.

The NOAEC of 0.62 mg/m³ (without peak exposures) obtained by Lang and colleagues (2008) might be considered as consistent with the lack of observations at test concentrations up to 0.87 mg/m³ (4 h) in the study by Mueller et al. (2013). However, exposed volunteers showed a tendency towards reduced mean differences (comparing EBF at the end of the exposure to pre-exposure values) instead of an expected higher EBF (inconsistent type of response). Nevertheless, in the view of RAC, such small numbers of volunteers and such a high variability of EBF in both studies do not allow a dose-related effect to be detected (unless the effect is sufficiently strong). Under these conditions (small size of samples, males only, very high variability of the test parameter, lack of data on continuous EBF monitoring during exposure) the lack of observed effects cannot be considered as evidence for the absence of dose-related effects.

In addition to the uncertainties reported above, the variability of the results obtained might not reflect the variability of the general population, particularly of children, as indicated in a review by the JRC (2005). It is also noted that the respective exposure treatments in the studies by Lang et al. and Müller et al. were rather short (4 h) single exposure events (Lang et al., 2008). It is not known whether the threshold value for EBF would be different (i.e. lower) for formaldehyde, if exposure duration and/or frequency were expanded.

Further weaknesses were identified in the Lang study: Data from male and female volunteers were pooled, although increased eye redness in females indicated a gender-specific difference. Furthermore, EBF data were only reported for one time point (195 min after start of exposure). EBF counts within 90 seconds out of a 6 min video record are not representative for time-course effects. Counts could be biased due to manual counting, although alternative methods using continuous recording with portable electrodes were available at the time of study. In addition, exposure conditions with peak levels of formaldehyde are less relevant for consumers.

In conclusion on the study of Lang et al. (2008) and Mueller et al. (2013), RAC considers that the absence of a sensory irritation effect at formaldehyde concentrations below 1.24 mg/m³ (1 ppm) is uncertain. Due to high variability of the measured effect (large ranges, high standard deviations), the low numbers of volunteers (yielding low statistical power) and the additional uncertainties identified, false negative results at 0.62 mg/m³ (0.5 ppm) or lower cannot be excluded. The studies of Lang et al. (2008) and Mueller et al. (2013), thus, cannot be used to derive a DNEL, because the uncertainties are too high. In case a DNEL would be calculated anyway, the uncertainties would deserve much higher assessment factors than those chosen by WHO (2010).

Hence, RAC does not consider the results of the short-term studies to be reliable, nor does it consider that they are the most appropriate measure to address the long-term concerns of formaldehyde exposure. It is noted that even if considered reliable, then the application of an AF of at least 10 for the uncertainties on inter-individual variations would be needed, as the high range of variability and the additional uncertainties need to be taken into account, when

deriving a DNEL[4]. Applying an AF of 10 according to the ECHA Guidance would have resulted in DNEL values of 0.06 and 0.087 mg/m³, respectively, i.e. lower than the threshold value derived by the WHO (0.1 mg/m³).

Short-term data on DNA adduct formation and DPX formation may be considered to derive a DNEL for acute effects (Table 22) and lead to a value of 0.01 mg/m³. This is based on a LOEC determined by Casanova et al. (1989) who reported DPX formation at formaldehyde levels as low as 0.37 mg/m³ (single 6 h exposure; lowest tested concentration). It is noted that there is one recent study indicating that there might be a threshold for DPX formation, as Leng et al. (2019) could not find evidence for formation of DNA mono-adducts and DPX after 28 days of formaldehyde exposure (6 h/d) of rats at 0.37 mg/m³ (Leng et al. 2019). The data showing DPX formation in rat nasal tissue at 0.37 mg/m³ after 6 h are inconsistent to those demonstrating the lack of DPX formation after 28 days (6 h/d) of exposure, because DPX can be eliminated by spontaneous hydrolysis and/or other DNA repair mechanisms and, thus, the likelihood of tumour development is assumed to be low. Studies further provide evidence that DPX formation at concentrations as low as 0.77 and 2.5 mg/m³ will not accumulate during prolonged exposure to formaldehyde (Casanova et al., 1994). Accordingly, as discussed in the mutagenicity section, results indicate that at low doses the incremental DNA damage may be repaired due to cell proliferation not being elevated. Therefore, the genotoxic potential of formaldehyde is not expected to give rise to mutagenicity at low doses and the effects of DPX formation cannot be regarded as adverse per se. Consequently, a DNEL derived based solely on genotoxicity results is considered inappropriate.

For long-term DNEL derivation, in the following a variety of precursor events in the tumour development and observed in studies with prolonged exposure were considered. The following table presents the basis for the selection of the most appropriate DNEL to assess the health risks from long-term exposure to formaldehyde (Table 3).

Table 3: DNEL derivation developed by RAC for different points of departure (in mg/m³) considering precursor events to malignant tumour responses (and documenting for comparison the DNELs from malignant tumour responses) using AFs (for local effects) following ECHA Guidance

Precursor event Species and dosing scheme	NOAEC (mg/m³, and time-corrected POD)	Assessment Factors (AF)	Overall AF	Resultant DNEL (mg/m³)
DNA adduct formation Rat 28 d, 6 h/d, Interim sacrifices 7, 14, 21, 28 d (Yu et al. 2015) (DNEL for information only)	2.48 (LOAEC) Time-corr [§] LOAEC 0.62	2.5 - inter-s*,# 3.16 - intra-s*,## 3 – LOAEC → NOAEC (3 subacute-subchron)	23.7 (71.1)	0.03 (0.01)
Cell proliferation Rat 6 h/d, 5 d/wk, 13 wks (cell proliferation roughly 2-fold higher than in controls at next higher concentration of 2.5 mg/m³) (Anderson et al., 2010; Meng et al., 2010; Speit et al., 2011)	1.24 Time-corr NOAEC 0.22	2.5 - inter-s* 3.16 - intra-s* 2 - subchron-chron	15.8	0.01
Metaplasia hyperplasia Monkey 22 h/d, 7 d/wk, 26 wks (Rusch et al., 1983)	0.25 (NOAEC) 1.25	2.5 - inter-s* 3.16 - intra-s* 2.5 - inter-s* 3.16 - intra-s*	7.9	0.03

[4] ECHA Guidance R.8, Annex R.8-15: Guidance on Derivation of DNEL/DMEL from Human Data

	(LOAEC)	3 - LOAEC → NOAEC	23.7	0.05
Cytotoxicity inflammation metaplasia hyperplasia benign tumours Rat 6 h/d, 5 d/wk, 13 wks Increased rates of benign nasal tumours (papillomas, polyploid adenomas), as well as inflammation and regenerative cell proliferation (nasal epithelial meta-/ hyperplasia/dysplasia) in the nasal cavity of rats, indicative of early tumour response. (Swenberg et al. 1980; Kerns, 1983a, Kerns 1983b; Woutersen et al., 1989; Kamata, 1997)	1.24 Time-corr NOAEC 0.22	2.5 - inter-s* 3.16 - intra-s* 2 - subchron-chron	15.8	0.01
Malignant tumours Rat 6 h/d, 5 d/wk, 24 m (Kerns, 1983a, Kerns 1983b; Monticello et al. 1996) (DNEL for information only)	2.5 Time-corr NOAEC 0.45	2.5 - inter-s* 3.16 - intra-s* 10 - severity of effect	79	0.006

§ NOAEC/LOAEC from repeated dose studies corrected for chronic exposure and 24 h/d, 7 d/w (DNA adduct formation corrected for subchronic exposure)
s* species (AF for interspecies or intraspecies differences of sensitivity),
Interspecies AF 2.5 for remaining interspecies differences for local, respiratory effects (default factor according to guidance R8)
Intraspecies AF 3.16 Although ECHA Guidance foresees the default factor of 10 also for local effects the AF was reduced to 3.16 to address differences in toxicodynamics only. In comparison to the EBF data, inter-individual variability is assumed to be lower.

As illustrated in Table 3 above, a cascade of precursor events has been identified to occur in the development of malignant tumours in studies with prolonged exposure duration in rats (and other species). Similar effects were also reported in studies on monkey although no malignant tumours have been observed in this species (as no carcinogenicity studies are available).

Interspecies differences with humans are thought to be minor for monkeys and thus RAC gives preference to the monkey data in comparison to the rat data, even if from an older study. To allow transparency and to show consistency (or differences related to DNELs) among species, data on rats and monkey relevant for DNEL derivation are summarised in Table 3.

DNA adduct formation in rats exposed to 2.48 mg/m³ formaldehyde at intervals of 7, 14, 21 and 28 days (6 h/d) showed a tendency to continuously increase towards a steady state level and revealed a DNEL of 0.03 mg/m³ (0.01 mg/m³ if corrected for subchronic duration) (Yu et al. 2015). Genotoxicity will not be considered as stand-alone effect for the DNEL derivation, but relevant studies are considered to indicate the size of the DNEL for information/comparison purposes.

As the interplay between cell proliferation and genotoxic effects is considered crucial for tumour formation in the nasal tissue, a DNEL was calculated based on the NOAEC of 1.24 mg/m³ for increased cell proliferation in rat nasal mucosa. The derived mode-of-action-based DNEL is 0.01 mg/m³.

A DNEL of 0.01 mg/m³ can also be calculated based on the NOAEC of 1.24 mg/m³ for the of early tumour response in rats (taking events such as cytotoxicity, hyperplasia/metaplasia/dysplasia and benign tumour tumours and assessment factors according to REACH into account) as indicated in several studies (Kerns, 1983a, Kerns 1983b; Monticello et al. 1996).

A DNEL of 0.03 mg/m³ was derived based on a study in monkeys showing metaplasia and/or hyperplasia in nasal turbinates. Monkeys were continuously exposed (22 h/d, 7 d/wk, 26 wks) to 0, 0.25, 1.25 or 3.7 mg/m³ formaldehyde without any exposure free time in between for repair of lesions and without subsequent analysis of reversibility of effects (Rusch et al., 1983). Out of six males per group, 0/6 (control), 0/6 (2nd control group) 0/6 (0.25 mg/m³), 1/6 (1.25 mg/m³) and 6/6 (3.7 mg/m³) showed meta/hyperplasia. Monkeys in the high dose group showed an increased incidence of hoarseness (frequency of 32 out of 156 clinical observations), congestion (36), and nasal discharge (62). While generally observed throughout the study, these signs tended to be more numerous during the last 13 weeks of exposure. In the low- and mid-level groups, observations were noted sporadically (but at a dose-related higher frequency than in controls) throughout the study and were reported as of minimal grade. Total incidences of nasal discharge were 9, 5, 30, 42, and 62 in these groups (same order of groups as above). In contrast to the study author, who concluded that only the effects at the high dose were related to the formaldehyde exposure, RAC concludes that 1.25 mg/m³ should be considered as LOAEC and lesions at this concentration not as incidental based on the dose-related steep increase in the incidences of metaplasia/hyperplasia and clinical signs.

22 h of exposure may be seen as representative for the consumer exposure assuming that residents stay 24 h in their home. Uncertainties remain as data on severity/extension of the nasal lesions were not given and because 26 weeks of exposure is too short to forecast the long-term consequences of metaplasia/hyperplasia that persisted at least to the end of study after 6 months. This treatment duration is not sufficient to assess the carcinogenic potential, it is, however, considered long enough to detect precursor lesions. Whether a squamous metaplasia/hyperplasia, which persisted until week 26, is readily reversible is questionable. An additional AF to adapt for lifetime effects and the longer lifetime expectance for monkeys in comparison, may optionally be considered, but has not been applied here. Taking the NOAEC as POD for DNEL derivation, the resulting DNEL is 0.03 mg/m³, while starting from the LOAEC of 1.25 mg/m³ the derived DNEL is 0.05 mg/m³.

For comparison, considering only the malignant tumour response (in rats), assuming a threshold mode of action and applying the same assessment factors for interspecies and intraspecies differences and an additional AF of 10 for severity of effects according to the ECHA Guidance, the derived DNEL would be 0.006 mg/m³.

Although the rat DNELs on DNA adduct formation and cancer precursor effects were lower and may therefore be considered to be taken forward, RAC decided to take preference of a long-term DNEL and proposes a DNEL of 0.05 mg/m³ based on the LOAEC of the study on monkeys (Rusch et al., 1983) and taking into account all additional DNELs derived based on studies on precursor events observed in rats, which were in a similar range. The focus on monkey data is mainly due to larger interspecies differences assumed for effects in the rat than in the monkey. Starting from the LOAEC instead of the NOAEC as POD was considered more robust by RAC as it takes also remaining uncertainties due to the dose spacing into account.

Table 4: DNELs based on different points of departure considered as precursor events to malignant tumour responses in comparison to the malignant tumour response

Precursor events	DNA adduct formation	Cell proliferation in rats	Metaplasia/ hyperplasia in monkeys	Cytotoxicity, metaplasia/ hyperplasia and benign tumours in rats	Malignant tumours in rats for comparison
DNELs (mg/m³)	0.03 (0.01#)	0.01	0.03* 0.05**	0.01	0.006

if corrected for sub-chronic exposure duration
* POD NOAEC
** POD LOAEC

In this opinion document, the above mentioned NOAEC for cell proliferation (1.24 mg/m³), the NOAEC for cytotoxicity/inflammation/hyper-/metaplasia (1.24 mg/m³) and NOAEC for malignant tumours (2.5 mg/m³) are consistent to those identified by WHO (2010) for long-term effects.

WHO derivation of a long-term guideline value (for comparison)

In addition to the short-term (30 min) guideline value of 0.1 mg/m³ the WHO compared the short term value for formaldehyde with the long-term threshold and concluded that the short-term value also prevents from long-term effects, as it was the lower of the two values. To understand this conclusion, a view on the calculations by WHO is needed: For long-term effects, including cancer, WHO calculated a guideline value for workers of 0.21 mg/m³, starting from the NOAEC for cell proliferation of 1.24 mg/m³ in rats. The WHO applied an AF for interspecies differences of 3 (2.5 acc. to REACH for local effects) and an AF of 2 for differences in human inter-individual sensitivity (noting that there is a lack of information for the precursor cancer effects in humans, REACH recommends a default AF of 3.15 for local effects if not otherwise justified). Starting with a NOAEC of 1.25 mg/m³ as POD, applying an AF of 3 for interspecies differences and AF of 2 for intra-species differences the resulting WHO long-term guideline value of 0.21 mg/m³ was above the WHO value derived for acute sensory irritation (0.1 mg/m³). Justification for using an AF of 2 for intra-species differences was that for the carcinogenic effects the WHO (p. 122, WHO, 2010) found the assessment factors given by Nielson et al. (2008) for setting of workplace limit values (OELs) appropriate (for the general population (which is not supported by ECHA Guidance as AF for consumers). The WHO stated that no evidence on accumulation of effects were given for sensory irritation (without showing data supporting this statement) and, thus, did not consider time extrapolation factors.

The WHO also calculated an alternative approach using “biologically motivated computational modelling methods”, “predicting that the 80-year lifetime additional risk is ≤ 10^{-6} at 0.2 ppm (0.246 mg/m³) for non-smokers” (Nielsen et al. 2017[5]; Conolly et al. 2004[6]). Their assessment led to a predicted additional risk of 2.7 × 10^{-8} for continuous lifetime exposure to 0.125 mg/m³ and a predicted additional risk of 10^{-6} or less for non-smokers continuously exposed to 0.25 mg/m³. The WHO concluded that the use of the short-term (30-minute) guideline value of 0.1 mg/m³ will, hence, also prevent long-term health effects, including nasopharyngeal cancer.

The WHO did not take into account the inhalation study on monkeys (Rusch et al. 1983) to which however RAC puts more weight as compared to the studies in rats.

RAC proposal on DNEL

All in all, from an analysis of all the available hazard data and a comparison of the derived DNELs for the identified precursor events in different studies and species, the animal data comes across as coherent (consistent across species) and well supported (numerous studies with different durations), while the data on sensory irritation in humans are not considered as sufficiently reliable due to the weaknesses observed in the available studies, which are described in detail above. Taking into account the uncertainties due to small numbers of volunteers and whether a 4 hour exposure reflects 24 h daily living conditions of consumers, the various weaknesses of the study performance, the high variability of EBF responses and applying AF according to REACH Guidance (which does not justify a lower AF than default AF of 10), the DNEL for sensory irritation in humans would be lower than the WHO guideline value based on identical study data (0.06 and 0.09 mg/m³, respectively, versus 0.1 mg/m³).

When comparing the “human DNELs” with the DNELs derived based on NOAECs/LOAECs from animal studies, it becomes obvious that the value of 0.06 mg/m³ is close to the “animal DNELs” in the range of 0.01-0.05 mg/m³. Whether the results from animal studies depict better starting points for DNEL calculation than results of human studies is debatable. In general, “*human data are in principle the most relevant source of information on human*

[5] https://www.ncbi.nlm.nih.gov/pubmed/27209488
[6] https://www.ncbi.nlm.nih.gov/pubmed/15254341

toxicity" (ECHA Guidance R.8, section R. 8.1.2.8). However, both ECHA Guidance (e.g. Chapter R.4 and R.8) and SCOEL (2017) stress the need to integrate all available evidence when drawing overall conclusions for each endpoint. The ECHA Guidance R.8 further notes: "*Since there may be limitations in reliability of human studies (e.g. problems in study design, analysis and reporting as well as limited coverage of the different target organs), they are normally considered together with animal and other data*" using an integrated approach. In the current case, it needs to be kept in mind that the human studies in question assess an acute effect due to the rather short exposure time. A long-term extrapolation based on this surrogate effect, which has previously thought to be the most sensitive effect after formaldehyde inhalation, would create high uncertainty. Moreover, the study populations were considerable small (in total 21 and 41 volunteers, respectively) and variability was very high which hampers observation of effects unless very marked. This means false negative outcomes based on the studies of Lang et al. (2008) and Mueller et al. (2013) cannot be excluded.

For this restriction proposal a long-term DNEL should be in focus, bearing in mind that the impact of the duration of the exposure should not be ignored for the risks from long-term exposure of the general population to formaldehyde. Thus, the lower threshold values derived based on the animal studies, which in fact investigated precursor events in the development of tumours (which cannot be estimated in humans), is considered more reliable/robust than the value derived based on the available human data.

RAC proposes to take a DNEL of 0.05 mg/m³ based on the weight of evidence of the observations in monkeys supported by similar or even lower DNELs from rat studies, forward for the consumer risks to be addressed within the restriction proposal.

As a follow-up of discussions at RAC meetings ECHA organised on 5 February 2020 an open RAC dialogue with stakeholders in order to discuss the evidence from the studies of Lang et al. (2008) and Mueller et al. (2013). Reviews from two experts (Christoph van Thriel, Pamela Dalton) assessed the validity of Lang et al. (2008) and Mueller et al. (2013) studies on behalf of industry. In general, their conclusions on the strengths and weaknesses were in line with the criticisms described above by RAC. Industry concluded that the Mueller study is inappropriate for DNEL derivation and suggested to take the results from Lang et al. (providing some indication for a NOAEC for sensory irritation in humans) in combination with the uncertainties resulting from a background incidence of eye irritation in the general population which – in their view – does not allow to discriminate sensory irritation from indoor air in comparison to low formaldehyde concentrations. They presented evidence from a review by Paustenbach et al. (1995) who considered available studies from 1977-1993 (all except one based on subjective self-reporting). In their view, the review demonstrated a mean incidence of 20 % of the general population showing increased sensory irritation ("primarily eyes") without exposure to formaldehyde. The 20 % incidence with increased irritation, however, resulted from a limited number of studies out of which those with increased sensory irritation rates were on asthmatics (two studies, see Table 3 of the respective publication) and one study that was not correctly cited by Paustenbach (Bender et al., 1983 who measured the response time to formaldehyde concentrations up to 1 ppm, no effects seen for clean air). Thus, the observation that increased sensory (eye) irritation is a common finding in the general population cannot be supported in review of the Paustenbach publication. Industry proposed to use a NOAEC of 0.37-0.62 mg/m³ (0.3-0.5 ppm) (based on the Lang et al. 2008) study) and to apply an AF of 3-5 for inter-individual differences in the general population. The use of such low AF was considered justified by industry, as the WHO (2010) stated that no hypersensitive groups like elderly people, asthmatics and children could be identified. The observation that inter-individual differences in sensory irritation exists is generally acknowledged (sensitive subgroups are e.g. young adults and children, females, individuals with dry eye symptoms). However, reliable studies with objective data on EBF are lacking on subgroups (e.g. children, asthmatics) in order to be able to identify whether they respond to lower threshold concentrations of formaldehyde than other population groups (for review on sensory irritation see Bruening et al., 2014). Thus, the absence of suitable data does not support deviation from the default by lowering the AF.

Information on emissions and exposures

Summary of proposal:

Formaldehyde is a high-production volume chemical predominantly used as a chemical intermediate for the synthesis of formaldehyde-based resins and other chemicals. Formaldehyde-based resins are widely used in the production of articles which, as a result, may release formaldehyde during use. The primary use of formaldehyde-based resins is in the manufacturing of wood-based panels, where they act as a bonding agent for wood particles. Such resins are also used in the production of other wood-based products (e.g. furniture and flooring) and for wallpapers, foams, parts for vehicles and aeroplanes, textile and leather products etc.

The Dossier Submitter considers formaldehyde released from articles into indoor air as the primary route for consumer exposure. The exposure assessment therefore focuses on inhalation exposure from articles and consists of three elements:

1. Based on a literature review, relevant formaldehyde emission sources in indoor air have been identified, including solid wood, wood-based panels, furniture, wallcoverings, paints, mineral wool, foams, and textiles (curtains and carpets). The Dossier Submitter concludes that wood-based panels (or rather urea formaldehyde resins used in these panels) and other wood-based articles made from such panels (e.g. furniture) are the main (permanent) formaldehyde emission sources in indoor air. Temporary emission sources, including various combustion sources (e.g. wood burning, smoking, candle burning, cooking, ethanol fireplaces), have also been identified as having the potential to lead to high formaldehyde concentrations in indoor environments. Temporary combustion sources are however outside the scope of the proposed restriction.

2. On the basis of a review of the literature on measured formaldehyde concentrations in indoor air in the EU, the Dossier Submitter concludes that formaldehyde levels do not exceed the WHO Guideline for Indoor Air for formaldehyde in the majority of cases.

3. Formaldehyde concentrations have been estimated for an exposure scenario (consisting of three sub-scenarios) that assumes the conservative case of newly built homes where wood-based panels are used as construction material and where other typical formaldehyde emitting sources, such as furniture made from wood-based material or textiles, are present. The assumption of newly built homes means that estimations are based on data derived from newly produced materials. Formaldehyde release is higher when materials are new and declines over time as formaldehyde is off-gassed. No decrease in formaldehyde emissions due to ageing of materials has been assumed by the Dossier Submitter in its estimations. Based on the results of the estimations, the Dossier Submitter concludes that the WHO guideline value could be exceeded under specific circumstances, such as the use of high emitting materials in large quantities.

Other exposure routes and sources, in particular dermal exposure and inhalation exposure from mixtures, have also been addressed but these were not further considered as the Dossier Submitter concluded that risks from inhalation of formaldehyde released from articles are the most significant.

RAC conclusion(s):

RAC shares the view of the Dossier Submitter that the inhalation route is the relevant route to consider for this proposal. The exposure assessment is plausible, but uncertainties exist in both (higher and lower) directions. The measured emissions from the reviewed literature reflects mostly average housing situations in newly built or refurbished homes but some aspects of typical reasonable worst case situations are not covered, e.g. (very) small sleeping chambers with a full wall-unit for furniture, tighter building envelopes for renovated houses meeting higher energy efficiency standards, etc. Such living situations are nevertheless likely to be representative e.g. for metropolitan areas where rental or buying prices are particularly

high. The same holds true for the parameters chosen for the modelling of indoor concentrations of formaldehyde in the reference room.

The reference room is intended to cover a reasonable standard scenario but not realistic worst-case situations like very small and less ventilated rooms as mentioned above. No exposure assessment has been performed for vehicle cabin interiors, including road, rail and water vehicles, and aircraft cabins. Some literature references and information from the consultation reporting formaldehyde concentrations in cars and aircrafts were considered by RAC.

RAC notes that worker exposure is out of the scope of the restriction.

Key elements underpinning the RAC conclusion(s):

The Dossier Submitter assessed a building interior scenario based on measurement data and estimated formaldehyde concentrations under a residential exposure scenario that reflects the situation of a newly built private home that uses wood-based panels as construction material and feature a number of other formaldehyde emitting articles.

No dedicated exposure scenario for vehicle (road, rail, aircraft, boats and ships) interior was assessed by the Dossier Submitter.

Building interior scenario

The Dossier Submitter carried out a literature review on measured formaldehyde concentrations in indoor air in the EU. In the majority of the studies, the focus was on relatively newly fabricated houses, as new and newly renovated houses usually tend to have higher indoor formaldehyde concentrations. An overview of the measured indoor air formaldehyde concentrations in the EU as found in literature is provided in Table 6 of the Background Document. In nine of the included studies the indoor air concentrations were measured in conventional houses in Austria, Denmark, Finland, France, Germany, Italy, Lithuania, Spain, and Sweden. Three further studies were carried out in Austria, France, and Sweden in passive and low energy houses. As far as the studies addressed different emission sources, MDF and chipboard panels were found to be the strongest formaldehyde sources next to smoking, in case this was also taken into account. Based on previous literature reviews and the reported formaldehyde concentrations in the Background Document, the Dossier Submitter concluded that formaldehyde levels do not exceed the WHO Guideline value in most cases.

This exposure assessment is plausible for average housing situations as most of the literature covers typical buildings and homes. However, it is not entirely clear if/how the measurement data are representative for realistic worst case situations like very small and/or highly furnished rooms, e.g. small sleeping chambers with a full wall unit, or tighter building envelopes for renovated houses meeting higher energy efficiency standards, or use of high formaldehyde-emitting materials, etc.

Taking into account the DNEL agreed by RAC of 0.05 mg/m^3, the P50/GM values are below the DNEL in 8/9 studies presented in the Background Document, the P95/max values however exceed the DNEL in 7/9 studies in Table 6 of the Background Document on conventional houses, this includes the following studies:

- German prefabricated houses (empty, built with low-emitting (30 %-E1) panels): P50/GM 38 µg/m^3, P75 = 50.8 µg/m^3 and max = 118 µg/m^3, with 22/60 (36 %) houses exceeding DNEL in the range of 50-118 µg/m^3 (Salthammer and Gunschera, 2017),

- Swedish conventional houses and housing stock: Max < 55 µg/m^3 and < 95 µg/m^3, no details available on the number of buildings exceeding DNEL (Langer et al., 2015). In Langer and Bekö (2013) GM concentrations were 22 µg/m^3 in 157 single family houses and 11.5 µg/m^3 in 138 apartments in Sweden. Significantly higher values were found in dwellings built between 1955 and 1980 than in older or newer buildings.

Concentrations were higher in houses at the countryside or without mechanical ventilation,

- Austrian conventional houses: P50 = 40 and 31 µg/m³ and P95 = 67 and 59 µg/m³, for first and second measurement, no details available on number of houses exceeding DNEL (Wallner et al., 2015),

- Danish houses: Max = 110 µg/m³, 4/19 (21 %) houses in the range of 40-60 µg/m³ close to the DNEL, 5/19 (26 %) houses in the range of 60-110 µg/m³ exceeding DNEL (Kolarik 2012), houses erected within 6 years prior to measurements, with wooden floors and some (but not extensive use of) additional surfaces covered by wood-based panels,

- French houses: P50 = 20 µg/m³ and max = 86 µg/m³, no details available on the number of buildings exceeding DNEL (Langer et al., 2016),

- Lithuanian houses: Max = 52.3 µg/m³, 1/11 buildings exceeding the DNEL, these houses were built from concrete and low-energy buildings with technical ventilation running at 0.5 h^{-1} (Kaunelienė et al., 2016),

- Spanish houses: Median = 56 µg/m³ and max = 91 µg/m³, > 50 % of buildings exceeding the DNEL (Villanueva et al., 2015); smoking shown as having a negative impact on formaldehyde concentrations was interpreted as related to the opening of the window,

- Italian houses: Median = 16 (± 8) µg/m³ and max = 42.4 µg/m³ for a total of 59 houses (in 31 non-smoker homes median = 15.1 (± 6.8) µg/m³ and Max = 31.4 µg/m³) (Lovregilo et al., 2016),

- Finnish houses: Median = 19-26 µg/m³ and max = 26-37 µg/m³. The study is not representative for conventional houses, as these were built with low emitting materials only (Jarnstrom et al., 2006).

As clarified by the Dossier Submitter, the measurement data do not reflect specific worst case living scenarios which are, in the view of RAC, nevertheless highly likely to be representative (e.g. for metropolitan areas where rental or buying prices are particularly high and people tend to live in small flats and apartments).

In the Jarnstrom et al. study (2006) the observed low GM and maximum values (≤ 37 µg/m³) were reached. This may be due to the use of only low-emitting materials according to the "Finnish Classification of Building Materials" (material class M1 limit: 0.05 mg/(m²h) (corresponding to 40 % E1) in all the buildings (constructed with on-site built concrete cast or manufactured cored concrete slab) with mechanical exhaust only in 5 buildings or combined mechanical/exhaust ventilation system operating in 3 other buildings), but also related to a higher ventilation rate (mean ventilation rate 0.95 h^{-1}, measured simultaneously with air concentration measurements). Indoor air samples were taken in a closed room (bedroom), inhabitants were asked to avoid cleaning, smoking, and the use of fragrances in the morning prior to the measurements, and additional ventilation 24 h before measurement was discouraged. The first measurement was performed before the occupants had moved in, with ventilation system running for 1-8 weeks. Formaldehyde concentrations at this level remained low after 6 months, with tendency to increase after 12 months.

Regarding the study on 60 new German prefabricated houses (Salthammer and Gunschera, 2017), these measurements were performed under conditions with windows and doors closed for several hours (not specified in the reference, no data on simultaneously measured air exchange rate) before the beginning of the sampling procedure. RAC considers closed windows and doors is a realistic daily situation, e.g. during night-time in winter. Furthermore, it has been also raised by one Member State that these data from the Association of German Prefabricated Construction (Bundesverband Deutscher Fertigbau e.V., BDF) cover solely empty houses build according to the strict standards of the Qualitätsgemeinschaft Deutscher Fertigbau and only wood-based materials emitting at maximum 0.03 ppm (30 % of class E1)

in the test chamber according to EN 717-1 have been used. Thus, the formaldehyde concentrations originate from low emitting construction materials. Potentially additional sources, especially furniture (which will inevitable contribute additionally under normal living conditions), are not accounted for in this German study[7].

Generally, it is difficult to directly compare the measurement values reported in different studies. The Dossier Submitter in the Background Document has not analysed different study designs and exposure influencing parameters and measurement conditions. This is an uncertainty RAC has to accept. 367 measurements in newly prefabricated houses between 1996 and 2006 revealed similar GM of 0.04 ppm (0.05 mg/m³), 14 % exceeded 0.1 ppm formaldehyde (Salthammer et al., 2010). As in the same period air exchange rates were reduced, the authors concluded the emission rates have fallen (without giving more details on differences with regards to other parameters (such as standards of the panels, furniture, air exchange, age of the building). This type of housing is commonly made with wood-based materials such as particle board and OSB.

RAC took note of further studies. In a project reported by the German Federal Environmental Agency (UBA, 2008), data from German VOC-indoor-air measurements of the past five years delivered by 19 institutes of the Association of Ecological Research Institutes (AGÖF) were entered into a database. Single measurements from the years 2002 to 2006 have been collected on various kinds of building types and different uses including residential houses, offices, kindergartens, etc. The measurements were conducted purpose-/occasion-driven, thus may have higher percentages with higher values. These data included 30 datasets on formaldehyde with 414 measurements. The authors report a median of 32 µg/m³, a P90 of 83 µg/m³ and a P95 of >100 µg/m³. It was further observed that there was no significant decrease in concentration during months and up to 5 years after renovation (UBA 2008).

UBA published the environmental surveys on indoor air in Germany performed by passive sampling since 1985. In the first survey (1985/86, 327 data), P50 and P90 were 55 µg/m³ and 106 µg/m³; in the more recent survey from 2003 to 2006 (555 residences) reduced P50 and P95 values of 23 µg/m³ and 47.7 µg/m³ were reported.

In agreement with air formaldehyde concentrations in homes published in more recent studies (2006-2016, Table 6 of Background Document) a literature research on earlier studies published in 1990-2008 revealed mean formaldehyde concentrations in homes/dwellings in several European countries/cities below the proposed DNEL of 50 µg/m³ (46.1 µg/m³ highest mean value) (Sarigiannis et al., 2011). This literature review reported several maximum values higher than 50 µg/m³ (76 µg/m³ (UK), 115 µg/m³ (Austria), 83-93 µg/m³ (FR), and 171 µg/m³ (UK)). Other reviews on studies published before 2000 cited concentrations of up to 270 µg/m³ (as mean or single values) in EU homes (Kotzias et al., 2005). Indoor concentrations in 252 German residences measured from 1985 to 1993 on request of individuals who complained about irritations revealed 31 % above 125 µg/m³, the annual mean concentrations ranged from 80 to 136 µg/m³ (Salthammer et al., 1995). There are indications on lower P50 and P90 values which were reported by Salthammer et al. (2010) comparing surveys conducted in the 1990ies with survey after 2000. No information is available on the percentage of measurements exceeding 50 µg/m³ in both, the studies of Salthammer et al. (2010) and Salthammer (2019).

The range of formaldehyde air concentrations in buildings from studies (which outline the maximum values and have been conducted in EU Member States) published in the year 2000 or thereafter (see Table 4 in Kolarik et al., 2012) exceeded maximum concentration of 100 µg/m³ in three studies and of 50 µg/m³ in seven studies of a total of eight studies (cited

[7] According to the BDF, the use of low-formaldehyde materials has been a fixed requirement for BDF companies for years. These companies have been forming the Quality Community of German Prefabricated Buildings (QDF) since 1989. According to the QDF constitution, since 2003 QDF companies have only used wood-based materials whose formaldehyde content does not exceed 0.03 ppm (according to EN 717-1), i.e. 70 % below the current German legal requirements (between 1989 and 2003, 0.05 ppm was the limit value). To facilitate this standard a QDF positive list is compiled by BDF based on analysis results submitted by wood-based panel manufacturers. Semi-annual publication is based on short test intervals. In addition, QDF companies test the wood-based panels they use and indoor air quality is analysed annually. The study referred to by RAC was conducted 2014-2016. See constitution of the QDF, chapter 6.8, p. 18ff: https://www.fertigbau.de/bdf/wer-wir-sind/qualitaetsgemeinschaft/index.html https://www.fertigbau.de/bdf/was-wir-tun/technik-normung.html

in the Background Document). Kolarik (2012) concluded that CE marking for construction products does not exclude the possibility of exceeding the WHO guideline value (related to the CE marking).

In one of the latter seven studies reporting exceedance of 50 µg/m³ (Marchand et al., 2008), a formaldehyde concentration range of 7-83 µg/m³ and a mean of 32.2 µg/m³ was measured in 162 dwellings. Formaldehyde concentrations of > 50-60 µg/m³ were found in 6-7 % of these homes.

Marquart (2013) reviewed studies on older homes of varying ages and new (prefabricated) houses. The 13 reviewed studies on older homes cover 2500 measurements (studies are partly discussed above and include also two non-European studies). Almost all study maximum values were below 0.1 mg/m³, a reasonable worst-case estimate (3-4th highest maximum value) was proposed as 0.085 mg/m³, while the average/central tendency for these older homes was considered as 0.025 mg/m³. Also, for other studies, e.g. Sarigannis (2011) and Salthammer (2010) average concentrations in homes of various ages were shown to be below the RAC DNEL of 0.05 mg/m³. For rather newly built or prefabricated houses, studies showed slightly elevated levels.

For the studies made available in the Background Document, in 7 out of 9 studies the P95 or max values exceeded the DNEL. Max values which are reported by the Dossier Submitter were in the range of 52-118 µg/m³.

Salthammer (2019) reviewed GM/P50 estimates for representative studies (partly overlapping with the Background Document and Marquart, 2013) and under “normal living conditions” in the range of 11-42 µg/m³, typically below 30 µg/m³. This range covers 13 individual studies. For only two of these studies a P95 estimate was provided (German UBA study: 47.7 µg/m³ and the study by Raw et al.: 61.2 µg/m³). The study selection should cover “real life exposure”, however, selection respectively exclusion criteria of Salthammer (2019) are not clear for RAC (a range of studies discussed by RAC above, studies which are considered relevant, is not considered in this review). It is common practice in the risk assessment to consider max values in case P90/P95 estimates are not available. A reasonable worst-case estimate from Salthammer (2019) cannot be derived by RAC. Generally, an exact P90 estimate for all the above discussed exposure studies cannot be derived by RAC. However, the estimate of 0.085 mg/m³ proposed by Marquart is well within the range of the reported P90/P95/max values.

RAC noted that the overall database on formaldehyde concentrations in homes/dwellings showed that concentrations in conventional houses (furnished or assumed to be furnished) exceed the RAC DNEL by percentages of 6-7 %, 21 % or 50 % depending on the study considered. This is interpreted as an average housing situation. Modern prefabricated houses, measured without furniture, although produced using low emitting wood-based panels (with emission levels in the rage of 0.3 ppm), revealed in 36 % of tested buildings formaldehyde levels higher than the RAC DNEL. The derived P90/P95/max values taken from individual studies in the majority of the cases exceeded the RAC DNEL to a certain extent (see Table 5) and in some studies exceeded also the WHO guideline value.

Table 5: Modified Table 6 of the Background Document to illustrate exceedance of air concentration above the DNEL

	Study (Year, Member State)	No of buildings, building characteristics	P50/GM	P95/max	Exceeding WHO Guideline	Exceeding DNEL 50 µg/m³
Conventional houses	2014-2016, DE	60, new prefabricated houses, empty Low emitting materials 30 % E1	38	/118	2 %	Max > DNEL 36 % > DNEL
	2012-2014, SE	21, newly built I: conventional houses II stocking house	I: 16 II: 17	I: < 55 II: < 95	I: 0 % II: 0 %	Max > DNEL #

	2011, ES	22, all ages	56	/91	0 %	Max > DNEL > 50 % > DNEL
	I: 2010-2012 II: 2011-2013, AU	61, I: 3 months, II: one year	I: 40 II: 31	I: 67 II: 59	I: 1 % II: 0 %	P95 > DNEL #
	2008, IT	59	/16 (± 8)	42.4	0 %	Max < DNEL
	2007, DK	19, New buildings	40/45	/110	11 %	Max > DNEL 21 % 40-60 µg/m³ 26 % 60-110 µg/m³ (> DNEL)
	2003-2005, FR	567	20/20	/86	0 %	Max > DNEL
	1999-2001, FI	≥ 4, I: 0 months, II: 6 months III: 12 months, Low emitting materials (M1: ~40 % E1) ACH 0.79 -1.45 h^{-1} (means 0.91-0.98 h^{-1})	I: 19 II: 21 III: 26	I: / 26 II: / 28 III: / 37	0 %	Max < DNEL
	2014, LI	11, new	31	/ 52.3	0 %	Max > DNEL 1/11 > DNEL
Passive/ low energy houses	20, 2012-2014, SE	20, newly built	11	< 20	0 %	Max < DNEL
	I: 2010-2012, II: 2011-2013, AU	62, I: 3 months II: one year	I: 27 II: 22	I: 53 II: 46	I: 2 % II: 0 %	Max > DNEL
	2009-2010, FR	7, newly built	/ 23			No further data

#percentage of houses/dwellings > DNEL not derivable

The presence and contribution of individual emission sources to the measured formaldehyde indoor concentrations often remain unknown in the reviewed literature on conventional and passive houses. Table B.8 (Annex to Background Document) and the review of Salthammer (2019) provide an overview on steady state concentrations and emission rates for various products used in buildings, furniture and construction, mainly measured in a test chamber according to EN 717-1.

In Table B.8 emission rates/concentrations (max values) are reported for wood-based products including plywood (0.18-2.65 mg/(m²h), particle board (0.04-2.52 mg/(m²h), OSB (0.042 mg/m³), MDF (0.2-3.6 mg/(m²h), different kind of laminate flooring (0.028-0.35 mg/(m²h), and multi-layer solid wood flooring (0.008-0.125 mg/m³). Salthammer (2019) reports mean area specific emission rates of 58.5 µg/(m²h) for particle boards based on European inter-laboratory comparison data from Yriex et al. (2010). Steady state air concentrations (28 days of testing) related to laminate flooring reported in Salthammer (2019) range from 0.005 ppm for HDF up to 0.03 ppm for HDF, MDF and particle board (23 °C, RH 45 %, ACH 1 h^{-1}, L 1 m^2/m^3) for the data coming from Marutzky (1997) and for own unpublished measurement results obtained later than 2012 with a range from < 3.8 to 28.3 µg/m³ (23 °C, 50 % RH, ACH 0.5 h^{-1}, L 0.4 m^2/m^3).

Other emission sources evaluated in Salthammer (2019) included mineral wool, paints and wall coverings. For mineral wool, an inter laboratory comparison experiment (11 laboratories) on formaldehyde emitted from mineral wool board using small test chambers (Wiglusz et al., 2000) yielded a range between 44 µg/(m²h) and 210 µg/(m²h) with a P50 value of 57 µg/(m²h). Unpublished WKI data from eight different samples of mineral wool (four glass wool, four stone wool) report for 96 h concentrations between 10 µg/m³ and 66 µg/m³ (GM 31.0 µg/m³, T 23 °C, RH 50 %, ACH 1 h^{-1}, L =1 m^2/m^3). The range of 10-66 µg/m³ also mentioned for mineral wool (without any further details) by a consultation comment (No 2569).

From the available chamber experiment data, RAC concludes that wood-based panels are the

most important sources of formaldehyde indoor emissions, followed by furniture (see below) and others. Data on textile are limited (see below) indicating rather low emissions; older data may not be representative for todays' fabrics.

To better understand the exposure in addition to the measurement data available in the literature the Dossier Submitter also estimated formaldehyde concentrations in indoor air by modelling an exposure scenario that is intended to reflect the situation in newly built homes. The exposure estimations are based on Monte Carlo simulations for the European Reference Room (V = 30 m^3 / temp = 23 °C / RH = 50 %, see Background Document Table 7 or EN 16516), following an approach taken from Salthammer and Gunschera (2017). First, Monte Carlo simulations of emissions rates were carried out for different emission sources (according to Table B.10) using log-normal distributions. These simulated emission rates were then used to derive reference room concentrations from the respective sources assuming steady-state conditions at 0.5 air exchanges h^{-1}. Finally, the simulated reference room concentrations for the different sources were added, taking into account the outdoor air, indoor chemistry, and the sink effect. Three sub-scenarios equipped all with formaldehyde releasing articles (doors, textile, flooring, ceiling, walls, furniture, window) but differing in the loading factors for particle board used for walls and ceiling (see Table 8 of the Background Document), the central scenario B assuming particle board for ceiling and two walls. For the three sub-scenarios the simulated concentrations for sub-scenario A, B and C were in 10.9 %, 20.9 %, and 34.3 %, respectively, above the WHO value, with a P95 concentration of 0.129 mg/m^3, 0.149 mg/m^3 and 0.164 mg/m^3, respectively. Even the P50 estimate for the sub-scenario A (ceiling but no wall covered with particle board) did exceed with 0.056 mg/m^3 the long-term DNEL of 0.05 mg/m^3.

Indoor chemistry is considered to reflect chemical reactions (i.e. surface and gas phase ozone reactions) in the indoor environment leading to formaldehyde release. A 25 % reduction in formaldehyde concentrations is assumed due to adsorption and absorption processes taken into account as the sink effect. Salthammer and Gunschera (2017) pointed out that in the case of formaldehyde simple addition of emission rates leads to unrealistically high results and the reference room modelling therefore greatly overestimates formaldehyde concentrations in comparison with the provided measurement data. It is therefore plausible to assume that in case of formaldehyde the emissions do not add up linearly. RAC acknowledges that this contributes to an overestimation of aggregated air concentrations, however points out that the sink concept presents an important refinement of an otherwise screening level assessment (here only the removal of substance from the room air by ventilation would be considered) (Delmaar, 2010). The sink effect is a concept that is normally not applied/applicable for risk assessment purposes. In its recommendations to the Dossier Submitter, RAC raised the attempt to consider adding more information on the concept of sink effects (what kind of reactions and dynamics lead to a decrease of formaldehyde concentrations; e.g. reactions with water and other compounds like amino functionalities that lead to decreases etc.). The Dossier Submitter, however, did not provide further information. The exposure scenario in the report is based refined higher tier modelling with ConsExpo. Although the results may be still conservative in comparison with measurement data, the exposure scenario is not a "classic" worst case approach for several reasons:

- Realistic worst case Tier 1 modelling / screening level assessment as usually applied under REACH would be based on a more conservative (deterministic) model, e.g. in this case a well-mixed room model based on high percentiles (P95 or maximum values) of the emission factors taken into account rather than the distributions thereof and without certain refinements (such as the sink effect). It could then be assumed that the concentration in the reference room with a loading factor of 1 m^2/m^3 is twice as high as in the test chamber as the air exchange rate is half. While it is not a worst-case approach taking mean emission rate estimates for a start, RAC considers a probabilistic approach based on emission rate distributions and a higher tier assessment an acceptable approach as chosen by the Dossier Submitter. It is further noted that the 75 % reduction in emission rates applied to the uncovered material stems from one publication which reported a rather wide range of emission reduction of 70-98 % (Salthammer and Gunschera, 2017). The Dossier Submitter considers this value as conservative as it is "towards the lower end of the 70-98 % range of emission reductions" that the authors observed for different types of coverings. No confirmatory data are available to RAC at

the time of preparing the opinion.

- The room dimensions and loading factors of the European Reference Room might reflect a realistic scenario, but do not really cover reasonable worst case situations (e.g. tiny houses/apartments, a (very) small sleeping chamber, small rooms with lots of furniture, e.g. wooden book cases and books, etc.). In the consultation this has also been raised by one Member State strongly suggesting running the simulations with a room size of 20 m^3 instead of 30 m^3 to reflect realistic situations such as small children bedrooms. Another comment informed that the loading factor for furniture creating high emissions was 1 m^2/m^3 and thus exceeds the assumption by the Dossier Submitter (consultation comment No 2006).

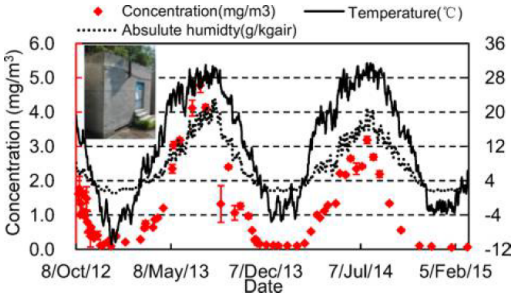
- In the simulation no variations in relative humidity (RH) and temperature were considered. Air formaldehyde concentrations, however, are strongly dependent on climatic conditions (temperature and humidity). Especially humidity is significantly influencing formaldehyde release; this has been presented by Jarnstrom et al., 2006 and Fraunhofer WKI (Meyer et al., 2014) and Liang et al. (2015). Recently Wilke et al. (2019) showed that changing from 23 °C/45 % (which are the actual parameters according to EN 717-1) to 28 °C/60 % doubled the formaldehyde concentrations in the chamber. In chamber experiments (EN 717-1) it was shown that variation of relative humidity in the range of 15 to 80 % delivered formaldehyde concentrations of about 0.05 ppm to 0.25 ppm. Liang demonstrated maximum concentration 30-50 times the minimum concentrations within one year under realistic room climatic conditions (see below under “aging”). The modelling approach employed by the Dossier Submitter, according to Salthammer, relies on a linear model with loading and air exchange rate as variable parameter without the parameters that would cover climatic conditions. It is however acknowledged that no validated model exists to estimate formaldehyde concentrations for the residential setting considering the influence of these climatic parameters (humidity, temperature). The by WKI developed exponential mathematic model takes better account for humidity but has been developed for estimating steady state concentrations in test chambers. The Dossier Submitter correctly acknowledges the uncertainties related to climatic conditions in the Background Document (section 3.1).

- In the simulation, a fixed air exchange rate (ACH) of 0.5 h^{-1} has been used which does not cover lower ACHs that would be more realistic for several situations, e.g. energy-efficient renovated houses. This issue has also been raised in the consultation by one Member State. RAC agrees that 0.5 h^{-1} is the desired minimum value for hygienic reasons and the standard to be expected for newly build houses where a technical ventilation system manages the air exchanges, it is however not reflecting real life in many situations where renovated buildings are airtight and ventilation is relying on manual ventilation by occupants. In the view of RAC, a rate of 0.2 h^{-1} is a more realistic value for such living conditions. Such low ventilation rate is also very likely during night times when windows are closed when sleeping for several hours, e.g. due to noisy surroundings or at low temperatures. This is considered particularly relevant in typically small sleeping chambers. Salthammer (2016) presents measured median ACH values from different studies for residential houses and dwellings. For European buildings, the median values ranged from 0.43 to 0.68 h^{-1} typically around 0.5 h^{-1}, showing that in 50 % of houses/dwellings ACH is indeed below 0.5 h^{-1}. In a study by the German BAM (mentioned in the consultation comments, Wilke et al., 2019), reduction of the air exchange rate of 1 h^{-1} to 0.5 h^{-1} in a chamber test according to EN 717-1 lead to increase in formaldehyde concentrations by a factor of 1.6. RAC therefore recommended the Dossier Submitter to consider also lower air exchange rates. Additional calculations have been provided in the updated Background Document, Annex E.2, taking into account a distribution of air exchange rates instead of a fixed value to cover a wider range of cases by assuming a log-normal distribution with a geometric mean of 0.52 h^{-1} and a geometric standard deviation of 1.49 h^{-1}. RAC acknowledges the efforts of the Dossier Submitter, to adapt the Monte Carlo simulations, using a log-normal distribution for the air exchange rate, which also cover situations with lower air exchange rates (e.g. a closed bedroom during heating periods etc.) and therefore cover more realistic situations. The Dossier Submitter has concluded (section 3.1 of the Background

Document) that for the higher percentiles (P75, P90 and P95) the formaldehyde concentrations are higher than in a situation with a fixed ACH. For the three sub-scenarios the simulated concentrations for sub-scenario A, B and C were then in 15.2 %, 28.1 %, and 38.6 %, respectively above the WHO value, with a P95 concentration of 0.153 mg/m^3, 0.184 mg/m^3 and 0.207 mg/m^3, respectively. Still, the P50 estimate for the sub-scenario A (ceiling but no wall covered with particle board) did exceed with 56 µg/m^3 the long-term DNEL of 0.05 mg/m^3.

- On the other hand, no aging (i.e. decrease of formaldehyde emissions over time as a result of off-gassing) was considered by the Dossier Submitter initially, which may overestimate formaldehyde concentrations. In the updated Background Document Annex E.2, the Dossier Submitter adopted the approach by Salthammer (2019) who, based on data from various test studies, applied a normally distributed weighting factor with a mean of 0.4 and a standard deviation of 0.1 to walls (Wall 1), ceiling (Ceiling 1) and furniture to consider ageing effects of wood-based materials. In the view of RAC however, formaldehyde concentrations are strongly seasonal and no robust (long-term measurement) data is available that allow derivation of an ageing factor. According to Salthammer (2019) most available data on aging refer to test chamber results of freshly produced materials measured after 28 days. (Liang et al., 2015) studied long-term emissions from MDF in a full-scale experimental room. Lower formaldehyde concentrations by 20–65 % in the corresponding months of the second year were reported. Under the assumption that the lifetime of wood-based materials in housing is ten years or more, Salthammer estimated a weighting factor of 0.4. RAC doubts the robustness and relevance of the derived aging factor based on this study, for different reasons: it cannot be regarded as sufficiently representative and may overestimate an effect of aging and off-gassing. The study covered less than three years (Oct 2012-Feb 2015), only two summer seasons. During summer the formaldehyde emissions repeatedly increased, and these increases strongly correlated with the room temperature and humidity. The authors calculated the decrease of 20-65 % comparing mean values of one season during two or three years. The emissions during the seasons within a year were not regarded. The maximum value in the second summer is still high (3.19 vs. 4.78 mg/m³ in the first summer, 0.38 and 0.12 mg/m³ maximum in the first and second winter). No data is available on long-term decrease after years and depending on percentages and behaviour of formaldehyde in the resins, formaldehyde emission may be stable (with variations depending on temperature and humidity) during years. Only one type of material, MDF, was investigated. No data was made available to RAC on aging behaviour under realistic conditions for various, diverse, articles and materials in the scope of the restriction, including wood-based furniture, covered versus uncovered particle board, textile, etc. What concerns realistic conditions, the most prominent influencing factor in this study was absolute humidity (with a correlation coefficient of 0.89) and temperature, demonstrating that climatic conditions are of outmost importance in emission behaviour of formaldehyde. According to Liang, the levels and ranges differed in different seasons, with summer > spring > autumn > winter, and the maximum concentration was 30-50 times the minimum, exhibiting significant differences in the same year. The mean concentration in summer was 20 times that in winter. Therefore, indoor formaldehyde concentrations and trends were strongly seasonal.

Figure 3 and Table 6: Indoor formaldehyde concentration and emission and humidity and temperature profiles for the experimental room (Liang et al. 2015)



time period	season	concentration (mg/m³)			emission rate (mg/m²·h)		
		mean	min	max	mean	min	max
9/10/2012–30/11/2012	autumn[a]	1.00	0.33	1.77	0.57	0.18	1.02
1/12/2012–28/2/2013	winter	0.19	0.09	0.38	0.10	0.04	0.23
1/3/2013–31/5/2013	spring	1.38	0.28	3.18	0.80	0.16	1.84
1/6/2013–31/8/2013	summer	3.59	1.32	4.78	2.07	0.76	2.76
1/9/2013–30/11/2013	autumn	0.79	0.15	2.4	0.45	0.08	1.38
1/12/2013–28/2/2014	winter	0.11	0.1	0.12	0.06	0.05	0.06
1/3/2014–31/5/2014	spring	1.07	0.17	2.21	0.61	0.09	1.28
1/6/2014–31/8/2014	summer	2.52	2.17	3.19	1.46	1.25	1.84
1/9/2014–30/11/2014	autumn	0.66	0.1	1.33	0.38	0.05	0.77
1/12/2014–28/2/2015	winter	0.07	0.05	0.08	0.03	0.02	0.04

The data indicate that a trend to lower max values ('aging') occurs in the first 2-3 years when comparing formaldehyde concentrations for the same season over time. However, in fact, the maximum concentration occurred in summer rather than at initial introduction of the material. RAC considers seasonal effects having a much stronger impact than ageing. Thus, it is considerably uncertain and not justified to derive a general ageing factor for risk assessment for formaldehyde release from a diversity of articles and use conditions in the scope of this restriction. The formaldehyde decrease from one summer to the other (2013/2014) was about 30 %, while mean concentrations in the first summer 2013 were 3.6-fold compared to the initial measurements in autumn 2012. Still in summer 2014 concentrations exceed the initial measurements by a factor of 2.5.

Based on another study (Pei et al., 2016), where within three months, formaldehyde concentrations in dormitories decreased by 50 %, RAC came to a similar conclusion as before based on the Liang study. Also, in the Pei study no long-term investigation was performed, only three months have been analysed. Within this time from summer to autumn in Tianjin, humidity and temperature decreased (variation 15-30 °C outdoor, 5 °C change indoor, relative humidity fluctuation 55-75 %) thus in line with Liang et al. study, formaldehyde concentrations are expected to have decreased due to seasonal variations. Furthermore, the natural ventilation was ACH 5-10^{-1}, which cannot be accepted as a representative or a worst case "normal living" condition for European buildings. Temperatures of 30 °C and more and RH of 60-70 % for a period of several weeks is not a representative condition. It is plausible that with constant dry condition (RH 50 %) formaldehyde emission rates will decrease. However, it is equally plausible that warm and humid conditions will cause dynamics repeatedly leading to material processes that result in increased emission rate. This fact must be acknowledged when deriving ageing factors. The Dossier Submitter considered an aging factor of 0.4 in its sensitivity analysis: For the three sub-scenarios considering a log-normal distribution of air exchange rates (as described above) and the effect of aging, the simulated concentrations for sub-scenario A, B and C were then in 2.6 %, 4.5 %, and 6.5 %, respectively above the WHO value, with a P95 concentration of 84 µg/m³, 97 µg/m³ and 107 µg/m³, respectively. Even so, only, the P50 estimates for all the three sub-scenario (36 µg/m³, 43 µg/m³, 48 µg/m³ for scenario A, B, C, respectively) were below the RAC DNEL of 0.05 mg/m³, the P75 of 59 µg/m³ for the central scenario exceeded the DNEL.

Considering seasonal differences in formaldehyde concentrations of 30-50 times within one year, the study raises further uncertainties as regards to the published measurement data as presented by the Dossier Submitter. Seasonal and climatic conditions during the conduct of the various studies and the influence on formaldehyde concentrations have not been evaluated by the Dossier Submitter. It is also noted that emission chamber experiments are carried out at a constant temperature of 23 °C and relative humidity of 50 % (EN 16516), while realistic conditions are variable with higher temperatures and humidity in a range of European countries suggested to trigger higher emissions.

RAC is of the opinion that the applied modelling approach can be considered conservative. However, it needs to be acknowledged that the modelling approach has its uncertainties. The presented model does not fully address the variety of parameters and living situations such as different construction standards, seasonal variations, public buildings, tiny houses/mobile homes, very small chambers with potentially high loading which would be required for a worst-case exposure

scenario. On the other hand, the chosen approach leads to an overestimation of the formaldehyde concentration in indoor environments as the contributions from a variety of emission sources are simply added up. Such concentrations aim to reflect the situation in newly built houses where no decrease of formaldehyde concentrations due to off-gassing is considered.

- *Contribution of furniture in the building construction scenario*

Furniture may contribute to formaldehyde indoor concentrations and may release formaldehyde from multiple components used in its production: formaldehyde releasing wood-based panels, formaldehyde releasing glues bonding wood-based panels or wood panels or/and painted/coated surfaces releasing formaldehyde. Veneers and lacquer commonly used in furniture contribute to long-term emissions (Jensen et al., 2001). Formaldehyde used as fumigant or preservative in fabrics and foams are additional sources (Anderson et al., 2016). The Dossier Submitter highlighted that the voluntary emission level (E1) adopted by the manufactures of wood-based panels is supported by the European furniture industry. As this voluntary measure refers only to the panels produced in the EU and is not binding, furniture without compliance to the voluntary emission can be expected on the EU market and may significantly contribute to formaldehyde in the indoor air. In total 16.4 % of the market share for consumed furniture products are imported into the EU (28 MS) (CSIL, 2017[8]).

Measurement data demonstrated that furniture is a major source of formaldehyde and contributes significantly to the indoor concentrations. The indoor formaldehyde concentration increased up to 69 µg/m³ (measurements documented for 10 days) after the installation of carpet flooring, carpet adhesives and a sideboard made of lacquered particle board into a 48 m³ test house ("EURIMA-WKI test house study") built of low emitting material producing a (background) concentration of 22 µg/m³ (increase of 68 %) (Salthammer et al., 2010).

Blondel et al. (2011) identified furniture as a major source of formaldehyde emission in 24 students rooms (average sizes 11 m², ACH 0.52-1.36 h^{-1}, mean T 18.6-23.3°C, RH 40-50 %, houses > 10 y, furniture > 5 y) that contributed to a mean indoor concentration to 21.3 µg/m³. Based on measured indoor concentrations, surface emissions rates and air flux inputs the contributions of indoor sources were calculated in a mass balance model with furniture and building materials representing the highest contributions of 45 % and 43 %, respectively. In a case study on newly built timber houses, Plaisance et al. (2017) identified furniture as a main source of indoor concentration (70 % based on a chemical mass balance) in a newly built timber frame (passive) house with ACH 0.1 h^{-1} in France.

Anderson et al. (2016) found formaldehyde air concentrations of above 0.1 mg/m³ in three of twenty pieces of furniture containing wood-based panels and surfaces preferably treated with acid-curing lacquer when tested according to EN 717-1 conditions with a loading of 1 m²/m³ for these three samples. Other pieces of furniture emitted low formaldehyde levels if calculated on m²/m³ basis. The authors developed three typical scenarios of sets of furniture, which, if added in sum (and ignoring remaining uncertainties as real testing of a set of standard furniture has not been done in a test chamber), all exceeded the 0.1 mg/m³ level. Based on the authors' proposal for three typical furnishing scenarios loading factors of 0.72 m²/m³, 0.75 m²/m³ and 0.88 m²/m³ were calculated by the Dossier Submitter and a loading factor of 0.75 m²/m³ has been chosen for the exposure scenarios in the modelling approach.

Formaldehyde emissions were detected in 21 of 29 tested furniture products following ISO 16000-9 at highly variable emission rates of 11.5 to SER 381.3 µg/(unit²h) (mean 67.4) (Leroux et al., 2016).

In order to establish a mandatory labelling of volatile emissions from furniture in France by 2020, emission rates from 26 complete furniture units were tested in large-scale test chambers and compared to the sum of emission rates of each component separately tested in smaller chambers (Roux et al., 2016). For children furniture products to be used as household furniture, formaldehyde emissions were generally higher for the whole furniture

[8] https://www.worldfurnitureonline.com/research-market/european-furniture-outlook-0065941.html

products than for the sum of its components, while for furniture products intended for used in day nursery/nursery school (with only 1-2 components, low emissive products) emission rates from the sum of components were largely comparable to the whole product (see also consultation comment No 2071). Comparative testing of a representative child bedroom (chest of drawers, bed with slatted base and mattress, desk) yielded about 2 times higher steady state concentrations (83 µg/m³) in a large-scale test chamber (32 m³, ACH 0.5 h^{-1}, T 23 ± 2 °C, RH 50 ± 5 %) than in a realistic test house (43 µg/m³) (RH < 40 % first ten days, then ~50 %) after 28 days. The higher concentration in the test chamber may be related to lower temperature and lower RH in the test house or differences in adsorption to other surfaces. The authors concluded that estimates in a test chamber can be considered as a conservative approach. The emission rates of the 11 furniture pieces (tested 'unit') tested in this study (Mean/Min/Max: 254/8/863 µg/(unit*h) were comparable to those of the 21 products of the Anderson (2016) study (Mean/Min/Max: 240/10/850 µg/(unit*h).

The emission rates used by Salthammer for furniture (Table B.8 in the Annex to the Background Document) for the input parameters for the Monte Carlo simulation carried out by the Dossier Submitter and RAC with an emission rate GM = 17.8 ± 2.54 µg/(m²h) (Table B.10 in the Annex to the Background Document) indicate a prominent role for formaldehyde emissions from furniture (see simulations in Table 10 of the Background Document: P95 sub-scenario C: 124 µg/m³ attributed to furniture). According to the simulations, furniture is the most important emission source. However, the following drawbacks need to be understood. The GM and Geometric Standard Deviation (GM = 17.8 ± 2.54 µg/(m²h)) according to Salthammer were derived based on a limited set of data. The representativeness of the few input measured emission rates (acc. to EN 717-1, Anderson 2016) to be used for conducting Monte Carlo simulation deriving GM emission rate estimates to be used as an input for the Monte Carlo simulation is questionable in the view of RAC. This is manifested in a high standard deviation of 2.54. Considering that in the modelling, in contrast to particle board ceiling and walls, no further coverage (-75 % emission reduction) is taken into account, and a furniture loading factor of 0.75 is used (which is higher than PB loading in sub-scenario A and B) this inevitably leads to such high room concentrations attributable to furniture (and its broad distribution of emission rates). In the view of RAC, these results therefore need to be taken with caution (see also section on uncertainties).

RAC notes that furniture products significantly contribute to the indoor formaldehyde concentrations. Furniture alone can, under certain conditions, contribute up to 50 % of the overall formaldehyde concentration in a room.

- *Contribution of textiles in the building construction scenario*

Textiles such as carpets, rugs, curtains and upholstery fabric are not covered by Regulation (EU) 2018/1513. Thus, they are included in this restriction proposal.

Recent experiments indicate rather low emissions for curtains up to 5 µg/(m²h) (Salthammer et al. 2019). These results concur with data reported in earlier studies, in which formaldehyde emission from drapery fabric made of different materials (100 % cotton, 100 % polyester, 100 % polyacrylic, 100 % viscose or a blend of 77 % rayon and 23 % cotton) was reported to be on average below 5 µg/(m²h) (Aldag et al., 2017; Pickrell et al., 1983). Only one curtain was reported to emit higher formaldehyde levels (14.6 µg/(m²h) (Pickrell et al., 1983).

For carpets, area specific emission rates were quite variable: a formaldehyde emission rate of up to 57.2 µg/(m²h) was measured for one carpet after 24 h, while the same sample emitted only 18.2 µg/(m²h) after 168 h (Hodgson et al. 1993). In other studies, formaldehyde emission rates for carpets and carpet tiles were below 28.2 µg/(m²h), with higher off-gassing rates for foam-backed carpets (Pickrell et al., 1983; Yu et al., 1997; Katsoyiannis et al., 2008). Steady state concentrations (72 h) of 2.8-14 µg/m³ were reported for test chambers of different sizes ranging from 30-0.28 m³ (ACH 0.5 h^{-1}, T 23 °C, RH 45±5 %, L = 0.4 m²/m³) (Katsoyiannis et al., 2008). Contrary to the results of Hodgson et al. (1983), Katsoyiannis et al. (2008) could not find clear evidence for a reduction of formaldehyde emission rates over time.

Only one study was found reporting formaldehyde emission rates for upholstery fabric which

were referred to as rather low (< 1 µg/(m²h); Pickrell et al., 1983).

RAC notes that data on textiles are limited and indicate rather low emissions for these types of articles; older data may not be representative for today's fabrics.

Exposure scenario: Vehicle interior – articles used as car and vehicle cabin components

In the Background Document, the Dossier Submitter presented formaldehyde use data for Europe. 60 % of the formaldehyde amount available in the EU is used for manufacture of UF (41 %), PF (9 %), MF (7 %) for a variety of consumer articles, mainly wood-based building/construction parts. Next to the construction/building sector, important amounts of PF are used in automobile applications; MF resins are also used in minor amounts (< 5 % of the MF) in the automotive sector. MDI and PMO with 8 % and 7 %, respectively of the EU formaldehyde, are used in relevant amounts in the automotive industry. Furthermore, other substances manufactured from formaldehyde are used amongst others in the automotive sector, such other substances amount to 17 % of the EU formaldehyde (Penta, BDO, HTMA).

Thus, the use of formaldehyde releasing materials in the automotive industry sector is considered significant and the scope of the restriction as proposed by the Dossier Submitter covers formaldehyde emissions from articles used not only in buildings but also in other indoor environments, i.e. interior of vehicles such as cars and public transport.

RAC assessed the exposure scenario for vehicle cabin/cars based on information available in the public domain and based on information provided in the consultation.

In the update of the Background Document, limited data on estimates of formaldehyde emissions into vehicles interior from Chinese cars were presented showing that the Chinese standard of 100 µg/m³ was exceeded at temperatures of ≥ 29 °C (Chien, 2007). No measurement data on formaldehyde cabin concentrations of cars on the European market were documented by the Dossier Submitter. Studies confirmed that increases in temperatures correlate to higher formaldehyde concentrations in the cabin inside, e.g. maximum measured formaldehyde concentration of 1.27 mg/m³ observed in static testing scenarios (cars > 5 y old, parking mode) with Δ T of +(5-25) °C in the cabin in comparison to the outdoor temperature (30 °C) (Noordin et al., 2018). Although brand models may be similar in Malaysia (where the study of Noordin has been conducted) to cars on the EU market, there are uncertainties (due to possible inter-brand differences) on the formaldehyde concentrations in cars on the EU market. Geiss et al. (2009) reported median cabin formaldehyde concentrations of 19.6 µg/m³ at summertime and 4.7 µg/m³ during winter in 23 parking cars (22 non-smoker cars) driving on Italian roads. The maximum values were much lower in comparison to the data from Noordin (43.6 µg/m³/summer and 14.7 µg/m³/winter). Off-gassing from materials used in the production of the vehicle is assumed as a major source of formaldehyde, as the formaldehyde cabin concentrations were markedly higher than outdoor concentrations with a higher indoor/outdoor ratio during summer.

Higher peak values of 250-350 µg/m³ were measured in three cars (24-158 d after first approval, exposed to sun) at 60°C in a study from Global 2000 (2005), while lower levels of 40 and 92.4 µg/m³ were recorded at 65°C in two other studies cited by the Danish report (Danish EPA, 2017). For a short stay in a hot car (scenario 1) Danish EPA calculated a Risk Characterisation Ratio (RCR) of 2.5-3.5 based on 100 µg/m³ considered as a tolerable level. Average formaldehyde concentrations of 3.6 µg/m³ (86.8 µg/m³ at 24°C/24 h) revealed an RCR of 0.04 (scenario 2) for daily commuting (daily 2 x 1 h).

Bauhof and Wensing (2009) reported mean concentrations of 40, 52 and 43 µg/m³ in the interior of six cars tested in a test stand with daily 8 h heated up to 65 °C as new vehicle or after 20 and 40 days of ageing. Interestingly the measurement in a vehicle test station after some hours in a parking mode without ventilation and being exposed to the sun revealed high formaldehyde concentration of about 170 µg/m³. However, the dataset is limited as only one new car was tested, no details (e.g. on temperatures) were reported by the authors from Volkswagen.

A study funded by the Japanese Government on 101 different types of Japanese domestically produced cars (< 3 y) found formaldehyde in the cabin in 100 % of cars (measured at parking mode, personal belongings removed a day before, no smoking status reported) at a median concentration of 19 µg/m³ (range 7.5-61) (Yoshida et al., 2006a). Mean formaldehyde levels of these types of cars at one month after delivery (at 32 °C, interior humidity 45 %) were 31 µg/m³ (range 17-67 µg/m³, with smoking lead to significantly higher mean) (Yoshida et al., 2006b).

Formaldehyde concentrations in the driving mode with the ventilation system in use are expected to be lower than in parking mode. Meininghaus et al. (2007) measured a mean concentration of 4.7 µg/m³ while driving on the motorway and in two German cities (measured with manual ventilation system in the cabin and at the air inlet). Marchand et al. (2006) (also cited by Sarigiannis et al., 2011) reported mean values of 13.9 and 16.6 µg/m³ for cars at indoor parking and driving at fluid traffic, mean GM of 26.8 µg/m³ were measured while driving at heavy traffic. The authors considered cabin air quality as depending on driving conditions, traffic density, ventilation modes and type of roadway. Measured data were limited to two cars (less than two years old) measured at in a parking garage (2 samples) and one 8-year old car measured during driving (2 samples each in fluid and dense traffic, assumed to be measured in the same car) in the Strasbourg area. No details on temperature, ventilation and humidity are available.

Cabin concentrations in 90 taxis in Teheran (Iran) of non-smoking drivers (sampling 30 min before and after refuelling, during driving at 30 ± 5 km/h with windows closed and air conditioners off) revealed mean concentrations of 0.8-1.1 ppm (1-1.3 mg/m³) in four taxi models (Bakhtiarie et al., 2018). Levels were higher after refuelling than before, and higher in taxi cabins of taxis > 1 y than < 1 y. Whether these high levels are representative for taxis in Europe, remains uncertain due to lack of data.

Off-gassing of VOC including formaldehyde from vehicle trim components (PVC, polyurethane, foam, carpets, adhesives etc.) affect vehicle interior air quality. Emissions from materials used to equip vehicle interior depends on several factors, including air temperature and relative humidity inside vehicle, the air exchange rate, type of material and the age of vehicle. Typically, a car is an assembly of a multiplicity of different materials, in small enclosed space, resulting in complex chemical composition of air. Extreme exposure situations due to sun irradiation on cars during parking may occur under realistic conditions.

The Dossier Submitter contacted the European Automotive Industry Association (ACEA) in the course of preparing the restriction proposal. ACEA indicates that for more than 15 years formaldehyde release to the vehicle interior has been monitored by manufacturers. In the consultation, a study has been mentioned by ACEA where in 2014, more than one hundred passenger cars were analysed and where the formaldehyde concentration values measured were in line with the automotive voluntary target value of 100 µg/m³ in the “ambient mode” of ISO 12219-1 (similar to UNECE the 2017). Later in the consultation, actual figures (µg/m³) have been provided by ACEA from recent measurements according to ISO 12219-1 in ambient mode on cars from 10 companies (Table 7):

Table 7: Recent measurements (µg/m³) provided by ACEA on cars from 10 companies

Company	Min	Max	Average
A	6	75	31
B	6	91	18
C	6	65	24
D	6	91	29
E	28	52	40
F	4	47	19
G	8	15	11
H	11	58	24
I	16	45	31
J	12	62	31

The number of cars, the year of measurements, and the concentration percentiles are unknown to RAC. The high variance of results according to ACEA is attributable to the whole range of categories of vehicles and different companies (different vehicle size, differences in design, different materials used in the cars, level of finish the vehicles, interior trim). This appears plausible to RAC and it may be not be appropriate to derive average estimates.

The ECE-TRANS-WP29-1143 method and the ISO 12219-1 define three different modes of condition for the use of the vehicle: “ambient mode”, “parking mode” and “driving mode”. The current regulations and the automotive industry voluntary approach are based on the “ambient mode” test, which is considered a worst-case scenario (static measurement at 23 °C, no renewal of air). It is considered that under real driving conditions the formaldehyde concentrations will be lower due to a much higher air exchange rate in vehicle compartments. The parking mode at high temperatures cannot be considered worst case under real exposure, as it cannot be assumed that passengers will stay for long time in the stationary vehicle with air conditioning set off and windows closed. RAC agrees with this rationale.

Another study referred to (“Statistics of Vehicle test regarding VIAQ requirements in Russia”) was carried out on 157 vehicles with air recirculation off and ventilation on showed that in driving conditions vehicle users are exposed to very low formaldehyde concentration, in idling mode less than 10 µg/m³ for 96 % of the cases, and between 10 to 40 µg/m³ for 4 % of the cases. Furthermore, formaldehyde values below 10 µg/m³ were reported in 99.9 % of the cases, if the vehicle is moving at a constant speed. With reference to Meininghaus et al. a significant reduction of interior emissions in general in real driving interior emission tests compared with emission test on a test stand, measured at 65 °C indoor air temperature (~170 µg/m³ test stand conditions), was observed – test details and number of measurements however are unknown to RAC.

ACEA provided furthermore information on exposure determinants. Based on “Sociological survey of HVAC operating modes Ford-Nami”, 95 % of vehicle´s user spent two hours per day at maximum in a vehicle (60 % 1-2 hours, 5 % more than 2 hour). With reference to an ANSES expertise report, the ACH in a vehicle may range between 1.0 and 3.0 h^{-1} with an average about 1.75 h^{-1}.

RAC concludes that the ambient mode (static measurement at 23 °C, no renewal of air) of the testing standard is appropriate for analysing formaldehyde concentrations. Generally, RAC agrees with the ACEA that interior emissions should be measured in full vehicle interior cabin and that chamber testing of individual components is not appropriate. In the ambient mode, the RAC DNEL was frequently exceeded. The maximum concentration in the above-mentioned studies was 91 µg/m³. For 7 out of 10 car manufacturers the maximum figures exceeded the DNEL, only three companies stayed with their measurement range below the DNEL.

Exposure scenario: Aircraft interior

The following exposure information on formaldehyde in aircraft is available in the public domain:

The 2018 SAE Aerospace Information Report (Aerospace Information Report, 2018) presents data generated for a study periods of up to 20 years and in a range of environments including aircraft bleed air, aircraft cabins, homes, and offices. For cabin interior three studies (EASA Preliminary measurement campaign, B787 study, Rosenberger 2015, ACER) are summarised with data on different airlines and aircraft types reporting formaldehyde values with mean estimates in the range of a few microgram below 20 µg/m³. The maximum estimates, if presented, were up to 44 µg/m³ (Rosenberger et al., n = 143 samples A320, n = 200 samples A380), thus below the RAC DNEL.

In the EASA research project on preliminary cabin air quality measurement campaign (EASA, 2014) conducted on bleed air supplied as well as no-bleed air supplied air crafts, two studies are reported (EASA.2014.C15 and the B787 study) on 69 measurement flights performed between July 2015 and June 2016 on eight types of aircraft/engine configurations and defined flight phases. Low amounts of formaldehyde with ranges of 0.03-48 µg/m³ (EASA study) and

0.02-17 µg/m³ (B787 study) are reported.

In the National Academy of Sciences Report (2002) on Airliner Cabin environment and the health of passengers and crew, the Committee on Air Quality in Passenger Cabins of Commercial Aircraft reports estimations of formaldehyde concentrations produced by pyrolysis and ozone-reactions (69 ppb), but also actual measurement data with maximal concentrations of formaldehyde were 2.1-3.1 µg/m³ in bleed air and 6.4-13.0 µg/m³ in cabin air, thus low, however based on 10 flights only (based on the publication from Nagda et al., 2001).

The US Federal Aviation Administration Centres of Excellence (ACER, 2012) Report presents data from passenger cabins of 83 commercial flights with six aircraft models (2 Airbus, 4 Boeing). For two airlines sampled, formaldehyde was detected in 49 % of the samples (N = 70), range 0-12 µg/m³.

The aircraft cabin is somewhat distinct than other interior environments. The cabin is pressurized with a considerably low relative humidity, a complex mixture of gas-phase and surface chemical reactions, periodically high ozone levels prompting “reactive chemistry” hypothesis (e.g. formaldehyde as an oxidation product in ozonolysis of limonene). Ventilation rates are high, potentially contributing to low formaldehyde concentrations measured during flight operation. Formaldehyde concentrations have been measured in the range of < 0.005 to 0.044 mg/m³ in different studies (Wolkoff et al., 2016), thus lower as compared to residential buildings and below the DNEL of 0.05 mg/m³. It should also be noted that sources of VOC in the cabin air are multiple: service and humans, chemical reactions, fuels, materials, combustion, non-fuel oil, cosmetics and perfumes, and cleaning agents and disinfectants. Therefore, contribution of formaldehyde-emitting articles to the overall formaldehyde concentration in aircrafts cabins may be only minor (Wang et al., 2014). RAC considers a relevant contribution of formaldehyde-emitting articles to consumer exposure during aircraft flights considerably uncertain. It is also assumed that consumers normally will not be exposed frequently and only shortly (with exemption of frequent long-distance passengers and cabin crew).

RAC concludes that based on available test reports, formaldehyde cabin interior measurements in aircrafts were below the RAC DNEL including the maximum concentrations presented. The sources of formaldehyde emissions in aircrafts may be several including ozone reaction products, oil and fluids and their degradation/pyrolysis products, cleaning products/disinfectants, passengers themselves. RAC cannot identify a risk due to articles used in aircraft construction and interior design to long-term health risk of passengers.

Uncertainties in the exposure assessment

- *Representativeness of indoor measurement data versus modelling estimations*

While overall availability and reliability of measurement data is considered rather well by RAC, they may not cover realistic worst-case situations. There is an obvious discrepancy of the measurement data and the higher tier modelling results, the measured concentrations being considerably lower than the estimated concentrations, even so in most situations the 95th percentile or maximum concentrations were above the by RAC agreed DNEL. High measured indoor concentrations of formaldehyde are an ongoing cause for complaints of tenants, e.g. in Germany where German courts have ruled that surpassing the threshold of 0.1 mg/m³ in the room air of rental apartments, confirmed by an expert report, leads to a reduction of the tenants' rent (LG Lübeck, 2019).

This raises the question whether the measurement data are representative, or the modelling data are too conservative, which is probably the case. Regarding the Monto Carlo simulations, according to the Dossier Submitter, this may be explained by limitations inherent to the approach chosen. Monte Carlo simulations of formaldehyde emission rates were conducted for the various emission sources, and for each source these simulated emission rates were then translated into formaldehyde concentrations in the European Reference Room and added up. According to Salthammer and Gunschera (2017), the Reference Room concept greatly

overestimates the formaldehyde concentrations in indoor areas when diverse sources are simply added together and that overestimations remain even when taking into account ageing and sink effects. Then the Dossier Submitter suggests that conservative assumptions were made in the exposure scenario, not necessarily representative of the situation in EU homes, in particular: the assumed presence of a considerable amount of formaldehyde emitting materials; a 75 % emission reduction from covering wood-based panels with a primer and dispersion paint being conservative; furthermore, the Dossier Submitter did not assume a reduction of formaldehyde emissions due to ageing of materials, which would result in lower predicted concentrations. Regarding the latter point, RAC notes that the majority of representative studies measured formaldehyde in newly built houses, and even in empty houses (German study). Furthermore, formaldehyde emissions may increase after the initial installation due to seasonal variation (see below on ageing). RAC cannot fully agree with the Dossier Submitter position that the simulations actually reflect a very conservative approach, but agrees that overestimation may exist, in particular due to the variety of emissions simply added up and an off-gassing with time, and takes furthermore note of another important uncertain element: in the modelling data next to particleboard, furniture is the most prominent emission source and these furniture estimates contribute to the discrepancy between the available measurement data and modelling estimates. The modelling assumptions overall lead to formaldehyde concentrations in the European Reference Room in the higher percentiles (P90 and P95 of 94 µg/m^3 and 138 µg/m^3, respectively, for sub-scenario C considering ACH distribution) mostly driven by furniture, which is not supported by the actual measurement data, because they exceed the maximum values in the measurement data produced on fully equipped homes. The few concentration estimates for furniture summarised above (43 µg/m^3, single estimate new material, Roux et al.; 21.3 µg/m^3 mean estimate aged material, Blondell et al.; 47 µg/m^3 single estimate including carpet and carpet adhesives, Salthammer, 2010) do also not support such modelling result.

Moreover, it is obvious that formaldehyde emission from treated articles is a complex process. Indoor concentrations are a result of a variety of parameters including material type and its inherent emission behaviour (diffusion resistance), room volume and loading, air exchanges, humidity, temperature, indoor air chemistry, etc. Thus, only an approximation is possible since no direct relationship between chamber experiment results and realistic exposure concentrations exist. RAC notes the following uncertainties regarding the presented measurement data:

- *National construction standards and materials emission class:*

The sources of formaldehyde emissions and loading in analysed buildings are not known. For most studies it is unclear which formaldehyde emission class (sub-E1, E1, E2) of wood-based panels was used in these homes for construction. For the German study only 30 %-class E1 materials were used and measurements were performed in empty houses, thus without additional formaldehyde sources such as furniture (according to comments provided in the consultation).

According to Table 6 of the Background Document, measurement data available cover studies on conventional houses from Germany, Sweden, Spain, Austria, Italy, Denmark, France, Finland and Lithuania. Studies on passive and low energy houses were performed in Sweden, Austria and France. Of these countries, Austria, Denmark, Germany, Italy, and Lithuania have adopted national legislation to limit formaldehyde emissions from wood-based panels. The national limits correspond to the E1 emission class. For Spain, Finland and France, Table C.2 of Annex to Background Document on the share of E1 and E2 panels in the EU production of wood-based panels, 2017, was 0 % for Plywood and Particle board class E2 for Spain and Finland, and 1 % for France, respectively. Countries with a considerable share of these E2 class panels, such as Portugal, Romania, Slovakia, Ireland, Estonia, Bulgaria, are not covered by the measurement data. Actual amounts of E1 and E2 emission class wood-based panels placed on the market and used for construction in the different EU countries, however, are unknown to RAC. The fact that measurement data come mainly from countries with national legislation limiting formaldehyde emissions by E1 emission limit or from countries that have no or negligible EU production of E2 panels raises the question whether there could be bias in the measurement data. Thus, there is uncertainty whether the data can be considered representative for the different situations in the countries regarding production and the shares

of the use of E1 versus E2 class panels. Whether measurement data may in particular reflect the E1 class (and even sub-class E1) panel emission situation is uncertain and may underestimate formaldehyde concentrations in certain living situations. Although measurement data on Finnish houses built with low emitting panels (0.05 mg/m^3) showed low indoor concentration, the reviewed data do not allow to correlate emission classes with a general trend to lower or higher formaldehyde concentrations.

- *Recent and future EU construction standards*

The building exposure scenario was assessed by the Dossier Submitter with measurement data on conventional houses and passive/low energy houses, as well as Monte Carlo simulations. The data may not cover existing buildings renovated to improve energy-efficiency and it has been reported in literature that formaldehyde concentrations increased after energy renovation of buildings (Földvary et al., 2017). The 2010 Energy Performance of Buildings Directive and the 2012 Energy Efficiency Directive are the EU's main legislative instruments promoting the improvement of the energy performance of buildings within the EU. The new Directive 2018/844/EU, Energy Performance of Buildings Directive (EPBD), introduces targeted amendments to Directive 2010/31/EU, aimed at accelerating the cost-effective renovation of existing buildings. EU countries will have to establish stronger long-term renovation strategies, aiming at decarbonising the national building stocks by 2050. All new buildings must be nearly zero-energy buildings by 31 December 2020 (public buildings by 31 December 2018).

In the building exposure scenario, the Dossier Submitter looked specifically on newly build homes, while in the modelling approach a fixed air exchange rate reflecting a well-ventilated room was considered. RAC did not identify in the Background Document specific measurement data on renovated buildings with improved isolation/energy efficiency. Improving energy efficiency results in airtight buildings due to increased isolation, but no legal requirement for occupant-independent ventilation, i.e. technical ventilation system, does exist. For new buildings, in particular zero-energy buildings and passive houses, technical ventilation may reasonably be assumed to be indispensable in order to meet the energy-standard in such houses, and a European Reference Room air exchange rate of 0.5 h^{-1} considered by the Dossier Submitter in the Monte Carlo simulations is an average performance of such a ventilation system. The study by Wallner et al. (2015) comparing conventional houses relying on window opening with energy-efficient houses equipped with mechanical ventilation shows that indoor air quality in energy-efficient new houses was higher (including lower formaldehyde concentrations) than in conventional new.

Studies from Italy (Lovregio, 2015) and Spain (Villanueva, 2015) may have covered such renovated buildings and flats. However, it is unclear whether renovations covered the building envelope and energy-efficiency.

The assumptions in the view of RAC are therefore valid for newly built energy efficient houses, but not for energy-renovated building stock. Studies have shown that indoor air quality and room climate parameters showed significantly better results in mechanically ventilated homes compared to those relying on ventilation from open windows and/or doors. For renovated buildings aiming for more energy efficiency, however, the situation is uncertain. For instance, for technical reasons only a decentralised ventilation system may be feasible (which may reasonably be assumed to be less effective compared to a technical system, i.e. ACH << 0.5), while practically nowadays in many such renovation projects no technical system is installed with reliance on manual ventilation by window opening. Studies have shown that such renovation measures lead to reduced air exchange rates in case no technical ventilation system is installed, and this leads to an increase in formaldehyde indoor concentrations. Földvary et al. (2017) investigated the indoor air quality in 20 apartments of a single residential building before and after its renovation. Formaldehyde concentrations increased after renovation and were positively correlated with CO_2 and relative humidity. Therefore, in the view of RAC there are uncertainties whether the measurement data cover realistic worst-case situations including renovations to increase energy-efficiency. Notably, these dwelling situations will unavoidable become more frequent in the future and a standard situation for existing buildings. A worst-case ventilation rate may be well below 0.5 h^{-1}.

RAC recommended to the Dossier Submitter to specifically attempt risk characterisation of renovated existing buildings. The reasonable worst case of indoor air concentrations measured in different studies (Figure 5, Background Document) for conventional and energy-efficient and passive houses was estimated as 0.085 mg/m³ (Marquart et al., 2013), i.e. already above the DNEL of 0.05 mg/m³, suggesting that significantly lower ventilation rates in energy-renovated existing buildings may lead to reasonable worst case indoor concentrations significantly exceeding the DNEL and even the WHO reference value. The Dossier Submitter considered in the updated Background Document a log-normal distribution of ACH in the modelling approach as a sensitivity analysis. RAC modelled a fixed low ACH 0.2 h^{-1} to assess the impact of the parameter. Results confirm a significant influence on the indoor formaldehyde concentrations (section below).

- *Other building interior scenarios - public buildings*

The Dossier Submitter assessed a standard resident scenario. No dedicated exposure scenario is included to assess formaldehyde emissions in non-resident private office buildings, public buildings, in particular in schools. For a school class room scenario key parameters are different as compared to the European Reference Room, such as bigger room size and volume, wall area, occupancy, ventilation rate, high loading factors / surface areas of major product categories and unit quantities of pupil desks and seating in the school classroom, visual aid boards, etc. Based on a high occupancy of classrooms (e.g. 30 students) a higher ventilation rate is needed as compared to resident situations. The California Standard Method for the testing and evaluation of VOC emissions from indoor sources using environmental chambers[9] provides reference classroom parameters. An effective ventilation rate of 0.82 h^{-1} on average is recommended. In practice, however, often furniture is placed close to the windows and heating elements and manual ventilation by window opening is insufficiently performed. A research study on energy-efficiency in German schools showed that for 96 energetic renovated schools, only 60 % considered a ventilation concept, 40 % technical ventilation and 20 % a ventilation plan[10].

The EU-JRC AIRMEX study[11] on VOC measurements in public buildings and schools/kindergartens in eleven European cities in total analysed about 1 000 samples from 182 working environments (offices, class rooms, waiting halls) in public buildings, schools and kindergartens, from 103 private (home) places and from adult volunteers (148 samples) for VOCs and CARBs. Overall, the AIRMEX study did not indicate higher formaldehyde exposure in public buildings as compared to private buildings, rather tend to be lower (Kotzias, et al. 2009). Formaldehyde concentrations varied from 1.5-49.7 µg/m³ (mean 16.7 µg/m³, P95: 31.5 µg/m³) in public buildings/schools at eleven European cities measured during 2003-2008 (Geiss et al., 2011). High maximum concentrations of 100 and 210 µg/m³ were reported in earlier studies on indoor air quality in schools (Sarigiannis et al., 2011). Indoor air quality data from a study on 41 classrooms in 20 container schools and container kindergartens installed between 1970 to 2010 at 15 sites in Germany were submitted (Ministerium für Soziales, Arbeit und Gesundheit des Landes Schleswig-Holstein, 2011) during the consultation (comment No 2275) revealing P50 values of 52.3 µg/m³ (P90 120 µg/m³, max 173 µg/m³, median T 20°C, RH 49 %) formaldehyde concentrations. Another consultation comment (No 2214) informing on concentrations ranging from 0.0068 to 0.036 ppm reported for traditional and portable classrooms in the United States of America were noted.

RAC considers specific exposure assessment for classrooms and kindergarten justified. For Germany, cases of increased formaldehyde concentrations in classrooms and kindergarten are reported by the EGGBI (Europäische Gesellschaft für Gesundes Bauen und Innenraumhygiene (Geiss et al., 2011)). It was therefore further recommended to the Dossier Submitter to compare calculated building concentrations based on emission factors measured by chamber experiment for a standard room and a standard classroom with reference class room parameters. In response, the Dossier Submitter compared the European Reference Room dimensions, ACH, and loading factors considered in its assessment with the standard

[9] https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/EHLB/IAQ/CDPH%20Document%20Library/CDPH-IAQ_StandardMethod_V1_2_2017_ADA.pdf

[10] https://www.eneff-schule.de/index.php/Veroffentlichungen/Veroffentlichungen-Allgemein/veroeffentlichungen-allgemein.html

[11] https://data.europa.eu/euodp/en/data/dataset/jrc-airmex-campaigns-data

class room parameters according to the California Standard Method for the testing and evaluation of VOC emissions from indoor sources using environmental chambers, concluding that the central scenario B of the Background Document covers such a school class room equipped with 27 desks and chairs and visual aid board. RAC acknowledges this comparison. Considering also available measurement data, remaining uncertainties appear fairly low and agrees that the assessment is sufficiently conservative as regards to loading factors to also cover classrooms.

- *Other building interior scenarios – recent trends small homes construction*

RAC takes note of the tiny-house movement, an architectural and social movement advocating a simply living style in down-sized homes, and other living situations in mobile homes, caravans, holiday houses. The Dossier Submitter did not prepare a dedicated exposure scenario on formaldehyde emissions in such small-sized homes built with conventional materials, including wood and wood-based panels, and considers such situations are covered by its assessment based on the European Reference Room.

Regarding construction design, although recent trends in the construction of mobile homes more and more replaces wood materials for walls, roof and flooring, still for indoor walls and interior equipment wood-based panels and textiles such as carpets are used. Big-sized caravans can achieve a size of 2.5 m × 8 m, normal travelling caravans less with up to about 2.3 m × 4.5 m. Tiny houses are small housings composed of conventional materials such as aluminium, wood, glass, which may include also resin-coated plywood, with a small room size, typically between 15-45 m^2. Tiny houses are less insulated for reasons of weight-saving, thus not as tight as conventional houses, have small room volumes making ventilation important, either window opening or mechanical such as simple solar-ventilators. Comparing to the European Reference Room parameters, small mobile and tiny homes have similar dimensions and features (such as one door and window) although may be even smaller, and likely characterised by less air exchanges ($<< 0.5\ h^{-1}$). For caravans high loading factors for potentially formaldehyde emitting materials used for interior walls and equipment is likely. Some older data were reviewed in Salthammer (2010) confirming that relatively high formaldehyde concentrations can be measured in mobile homes. For instance, Dingle et al. (2000) report on 192 Australian caravans with a mean of 29 ppb (range 10-855 ppb) for occupied caravans (n = 60) and 100 ppb (range 8-175) for 132 unoccupied caravans, respectively, pointing also out that concentrations in mobile homes result from higher loading rates with wood-based materials of approximately 1.4 m^2/m^3 and lower air exchange rates compared to conventional buildings. Tiny houses are usually constructed in a sustainable ecologically way, with solid wooden walls without surface treatment because it is part of the definition of a tiny home that it is constructed with environmentally conscious and renewable materials. However, there are discounters offering tiny houses constructed less expensive using wood-based panels, although it may not be the standard.

It is uncertain whether such unconventional and more trendy living forms contribute to consumer risk. Overall uncertainties seem fairly low considering that the restriction will also apply to the interior of such small homes, which are occupied by a very minor share of the population. Based on the above considerations at least for sustainable constructed tiny homes, the use of and formaldehyde emission from wood-based panels and other construction parts appears less relevant. RAC therefore considers it acceptable to not assess a specific exposure scenario for mobile and tiny houses for the following reasons: 1) lack of specific information on the use of formaldehyde in the construction of such mobile homes and tiny houses nowadays, respectively the environmentally conscious design of tiny houses, 2) lack of data on interior formaldehyde emissions in such housings, 3) lack of information on the practical relevance and use of such specific homes as permanent residence. Estimation of formaldehyde concentrations for a smaller room volume of 20 m^3 instead of 30 m^3 as suggested by one Member State is however a better approximation for such an interior living situation. RAC has modelled a smaller room with a higher loading of 1.4 m^2/m^3 to assess the impact of reduced room size which suggested a rather moderate impact (see next section).

- *Monte Carlo-Simulation: choice of model, assumptions and parameters*

The exposure estimations are based on Monte Carlo simulations for the European reference

room. The Dossier Submitter estimated formaldehyde concentrations under an exposure scenario that reflects the situation of a newly built home that uses wood-based panels as construction material and feature a number of other formaldehyde-emitting articles. In this scenario, no aging is considered, and formaldehyde concentrations will be higher in newly built homes, and therefore this reflects a conservative approach. RAC however identified uncertainties in the choice of the modelling approach, parameters and assumptions:

– Higher tier probabilistic modelling based on emission rate distributions was applied, which covers all ranges including the lower percentiles, while a deterministic well-mixed room modelling based on default high percentile point estimates (P95 or max) would provide only a worst-case conservative estimation. While it is not a classic worst-case approach taking mean estimates for a start, RAC considers it is acceptable in a probabilistic approach for a realistic higher tier estimation of possible variations.

– Sink effect: a concept that is usually not applied/applicable in risk assessment and therefore deserves a robust justification.

– An evolution of formaldehyde with time has not been considered in the modelling approach. A factor of a mean decay ('ageing' factor) of 0.4 (± 0.1) has been reflected in the sensitivity analysis by the Dossier Submitter to account for a decreasing release during the life-time of wood-based panels based on the study by Liang et al. (2015) and adopting the approach by Salthammer (2019). However, this approach is not robust due to the strong seasonal variations of formaldehyde concentrations (with temperature and humidity) that were not reflected when adopting this approach.

– A 75 % reduction in emission rates applied to the uncovered material stems from one publication, in which a rather wide range of emission reduction of 70-98 % was reported.

- A fixed air exchange rate of 0.5 h^{-1} used, which does not cover lower ACHs that would be more realistic for several situations. Under real living situations ventilation rates may be higher but also much lower, which may lead to underestimation of exposure. This has been reflected by the Dossier Submitter in an update of the Background Document.

- No simulation for a wider range of temperature and humidity, parameters which significantly influence formaldehyde emissions, was conducted. This is considered an important uncertainty.

The chosen parameters for the European Reference Room seem to be not particularly conservative when considering small rooms (e.g. small sleeping chambers). This applies obviously to the room dimensions, but also to the loading factor(s) and air exchange rates. In the course of the consultation also much higher measured formaldehyde concentrations (1.3-1.4 mg/m^3) were reported after refurbishment of a small bedroom with cabinets made of MDF in an old building (e.g. consultation comment No 2006). Removal of the furniture reduced air concentration to 0.1 mg/m^3. A room volume of < 20 m^3 is considered a better approximation of such situations.

Monte Carlo simulations were based on published emission rates from test chamber results for formaldehyde releasing products (Table B.8, Annex to Background Document) and for each emission source the Geometric Mean and Geometric Standard Deviation (Table B.10, Annex to Background Document) were taken as input parameter. While it is not a worst-case approach taking mean estimates for a start, RAC considers it is acceptable in a probabilistic approach for a realistic higher tier assessment. It is also acknowledged that it has been experimentally shown that formaldehyde emission in test house conditions may show lower emission rates than in chamber experiments (Roux et al.; 2016). Furthermore, in the approach a variety of emission sources are considered and simply added up. RAC agrees that this may lead to overestimation of exposures. One further uncertainty is related to the limited availability of chamber derived emission rates for a variety of the sources considered in the Reference Room concept. For wood-based particleboards, the data base is comprehensive (see Table B.8 of the Annex to the Background Document), however for furniture, paints, laminate, etc. the emission data are rather rare. Emission rates used in the model (see Table B.10) show quite high Geometric Standard Deviations (close to or exceeding 2) for furniture,

laminates, doors, and outdoor air. This results in high exposure estimates in the high percentiles, which evidently exceed the range from actual measurement data by far.

In order for RAC to tackle some of these uncertainties and suggestions from the consultation, as a sensitivity analysis on exposure influencing parameters, the Monte Carlo simulations carried out by the Dossier Submitter have been verified and repeated considering some variations. Results are presented with reference to the RAC DNEL and WHO guideline value. As in the Background Document the simulation of sub-scenarios A-C of the Dossier Submitter was applied.

For RAC modified scenarios, following modifications were considered:

- Two different room dimensions to assess the effect of small room dimensions and high loading (Dimensions of a child's room according to Danish Environmental Protection Agency, 2018)
    - European Reference Room as considered by the Dossier Submitter, 30 m^3
    - Smaller room reflecting small chambers, mobile homes, etc., respectively higher loading of ceiling and walls with particle board, 17.5 m^3.
- Different air exchange rates to assess the effect of less and occupant dependent ventilation, e.g. as typically during night-time in small sleeping chambers:
    - Desired for hygienic reasons and achievable by technical ventilation and considered by the Dossier Submitter, ACH 0.5 h^{-1}
    - Reduced rate for manual occupant dependent ventilation and tighter building envelope, ACH 0.2 h^{-1}. (Fehlmann and Wanner, 1993; Strøm-Tejsen et al., 2014; Batog and Badura, 2013).
    - Log-normal distribution of air exchange rates with ACH 0.52 ± 1.49 h^{-1}.
- To assess the overestimation introduced by the emission rate distribution, RAC repeated a simulation setting furniture emissions to zero by introducing L = 0 for furniture.

Table 8: Small and less ventilated room parameters and European Reference Room parameters

PARAMETER NAME	RAC PARAMETER VALUE	RAC LOADING FACTOR (L)	DOSSIER SUBMITTER PARAMETER VALUE	DOSSIER SUBMITTER LOADING FACTOR (L)
Temperature	23 °C		23 °C	
Relative humidity	50 %		50 %	
Air exchange rate (ACH)	0.2 h^{-1} 0.52 ± 1.49 h^{-1}		0.5 h^{-1} 0.52 ± 1.49 h^{-1}	
Room volume	17.5 m^3		30 m^3	
Room dimensions	3.5 × 2 × 2.5 m (1 door, 1 window)		4 × 3 × 2.5 m (1 door, 1 window)	
Surface floor	7 m^2	0.4 m^2/m^3	12 m^2	0.4 m^2/m^3
Surface ceiling	7 m^2	0.4 m^2/m^3	12 m^2	0.4 m^2/m^3
Surface walls	23.9 m^2	1.4 m^2/m^3 (rounded)	31.4 m^2	1 m^2/m^3 (rounded)
Surface door	1.6 m^2	0.05 m^2/m^3 (rounded)	1.6 m^2	0.05 m^2/m^3 (rounded)
Surface window	2 m^2	0.05 m^2/m^3 (rounded)	2 m^2	0.05 m^2/m^3 (rounded)
Sealing	0.2 m^2	0.007 m^2/m^3	0.2 m^2	0.007 m^2/m^3

Table 9: Exposure scenario and sub-scenarios

SCENARIO / SOURCE	A: PB CEILING	B: PB CEILING + PB IN TWO WALLS	C: PB CEILING + PB IN ALL WALLS
Wall 1	PB, L = 0 (non-formaldehyde emitting material used)	RAC: PB, L = 0.7 (small room), or Dossier Submitter: PB, L = 0.6 (ERR) Covering: -75 %	RAC: PB, L = 1.4 (small room), or Dossier Submitter: PB, L = 1.0 (ERR) Covering: -75 %
Ceiling 1	PB, L = 0.4, Covering: -75 %		
Wall 2	Paint, L = 1.4		
Ceiling 2	Paint, L = 0.4		
Flooring	Laminate, L = 0.4		
Furniture	Dossier Submitter: L = 0.75, RAC: L = 0		
Textiles	L = 0.3		
Door	L = 0.05		
Window	L = 0.05		
Outdoor air			
Indoor chem.			
Sink	-25 %		

Results Dossier Submitter scenario

European Reference Room, well ventilated: 30 m^3, ACH = 0.5 h^{-1}, furniture L = 0.75. Total loading factors are 3.35, 3.95 and 4.35 for sub-scenarios A, B, and C, respectively.

Table 10: Summary of simulated formaldehyde concentration in 100 000 rooms – Dossier Submitter scenario

Scenario / Measure	A: PB ceiling	B: PB ceiling + PB in two walls	C: PB ceiling + PB in all walls
P50 [µg/m^3]	56	76	88
P75 [µg/m^3]	74	95	109
P90 [µg/m^3]	103	124	138
P95 [µg/m^3]	129	149	164
Above WHO Guideline	*10.9 % of rooms*	*20.9 % of rooms*	*34.3 % of rooms*
Above RAC DNEL	*63.2 % of rooms*	*94.1 % of rooms*	*98.8 % of rooms*

Results RAC scenario 1

European Reference Room, less ventilated: 30 m^3, ACH = 0.2 h^{-1}, furniture L = 0.75. Total loading factors are 3.35, 3.95 and 4.35 for sub-scenarios A, B, and C, respectively.

Table 11: Summary of simulated formaldehyde concentration in 100 000 rooms – RAC scenario 1

Scenario / Measure	A: PB ceiling	B: PB ceiling + PB in two walls	C: PB ceiling + PB in all walls
P50 [µg/m³]	131	180	212
P75 [µg/m³]	176	228	264
P90 [µg/m³]	248	300	337
P95 [µg/m³]	313	364	400
Above WHO Guideline	*79.4 % of rooms*	*98.7 % of rooms*	*99.9 % of rooms*
Above RAC DNEL	*100 % of rooms*	*100 % of rooms*	*100 % of rooms*

Results RAC scenario 2

Small room, well ventilated: 17.5 m^3, ACH = 0.5 h^{-1}, furniture L = 0.75. Total loading factors are 3.25, 4.05 and 4.65 for sub-scenarios A, B, and C, respectively.

Table 12: Summary of simulated formaldehyde concentration in 100 000 rooms – RAC scenario 2

Scenario / Measure	A: PB ceiling	B: PB ceiling + PB in two walls	C: PB ceiling + PB in all walls
P50 [µg/m³]	58	80	103
P75 [µg/m³]	76	100	126
P90 [µg/m³]	105	129	155
P95 [µg/m³]	130	154	180
Above WHO Guideline	*11.3 % of rooms*	*25.2 % of rooms*	*53.9 % of rooms*
Above RAC DNEL	*66.9 % of rooms*	*96.8 % of rooms*	*99.9 % of rooms*

Results RAC scenario 3

Small and less ventilated room: 17.5 m^3, ACH = 0.2 h^{-1}, furniture L = 0.75. Total loading factors are 3.75, 4.55 and 5.15 for sub-scenarios A, B, and C, respectively.

Table 13: Summary of simulated formaldehyde concentration in 100 000 rooms – RAC scenario 3

Scenario / Measure	A: PB ceiling	B: PB ceiling + PB in two walls	C: PB ceiling + PB in all walls
P50 [µg/m³]	135	192	248
P75 [µg/m³]	180	241	305
P90 [µg/m³]	252	313	379
P95 [µg/m³]	317	376	422
Above WHO Guideline	*82.7 % of rooms*	*99.5 % of rooms*	*100 % of rooms*
Above RAC DNEL	*100 % of rooms*	*100 % of rooms*	*100 % of rooms*

The above simulations (Dossier Submitter scenario) show that in the scenarios A-C (identical to those considered by the Dossier Submitter in the Background Document), in 63-99 % of rooms formaldehyde concentrations exceed the RAC DNEL. These fractions are markedly higher than those estimated by the Dossier Submitter in comparison to the WHO level.

Lowering room dimensions, respectively higher loading of 1.4 m^2/m^3 for walls and ceiling as characteristic for small children sleeping chambers or mobile homes (RAC scenario 2), has a somewhat limited impact. Sub-scenario C with ceiling and all walls covered with particle board and equipped with further articles may thus be considered to cover also situations with different room dimensions.

The most prominent effect can be attributed to lowering the air exchange rate as assessed with ACH 0.2 h^{-1} resulting in formaldehyde concentrations exceeding the RAC DNEL in 100 % of rooms in all sub-scenarios and concentrations increasing by 2- to 3-fold. The scenario of the Dossier Submitter employing a log-normal distribution of air exchange rate (Background Document Annex v.2) for considering the European Reference Room dimensions was assessed against the RAC DNEL. As a result, the P50 concentrations for all sub-scenarios were above the RAC DNEL with 59-89 % of simulated rooms exceeding the DNEL:

Results Dossier Submitter scenario

European Reference Room: 30 m^3, ventilation distribution ACH = 0.52 ± 1.49 h^{-1}, furniture L = 0.75. Total loading factors are 3.35, 3.95 and 4.35 for sub-scenarios A, B, and C, respectively.

Table 14: Summary of simulated formaldehyde concentration in 100 000 rooms – Dossier Submitter scenario

Scenario / Measure	A: PB ceiling	B: PB ceiling + PB in two walls	C: PB ceiling + PB in all walls
P50 [µg/m^3]	56	74	87
P75 [µg/m^3]	81	105	121
P90 [µg/m^3]	118	147	167
P95 [µg/m^3]	153	184	207
Above WHO Guideline	*15.2 % of rooms*	*28.1 % of rooms*	*38.6 % of rooms*
Above RAC DNEL	*58.5 % of rooms*	*80.5 % of rooms*	*88.7 % of rooms*

The overestimation introduced by furniture emissions is illustrated in the following scenario:

Results RAC scenario 4

European Reference Room: 30 m^3, ventilation distribution ACH = 0.52 ± 1.49 h^{-1}, furniture L = 0. Total loading factors are 2.6, 3.2 and 3.6 for sub-scenarios A, B, and C, respectively.

Table 15: Summary of simulated formaldehyde concentration in 100 000 rooms – RAC scenario 4

Scenario / Measure	A: PB ceiling	B: PB ceiling + PB in two walls	C: PB ceiling + PB in all walls
P50 [µg/m³]	33	51	62
P75 [µg/m³]	44	67	83
P90 [µg/m³]	56	87	109
P95 [µg/m³]	65	103	128
Above WHO Guideline	*0.4 % of rooms*	*5.6 % of rooms*	*13.7 % of rooms*
Above RAC DNEL	*15.4 % of rooms*	*51.4 % of rooms*	*69.7 % of rooms*

This simulation result shows the contribution of furniture in the modelled indoor concentrations. Compared to the above Dossier Submitter scenario air concentrations are significantly reduced and appear now in a realistic range when comparing with measurement data. Still, only for the light-loading scenario A and the P50 estimates, the air concentrations are below or close to the DNEL. In terms of magnitude, the DNEL is exceeded up to 2.5-fold (sub-scenario C – P95).

Overall, the Monte Carlo simulations results suggest that the DNEL is likely exceeded under real exposure situation under certain conditions. Acknowledging the uncertainties, exceedance of the DNEL in the range of 2-3-fold appears to be a reasonable estimate. The modelling approach has its uncertainties. While it does not fully address the variety of parameters, lacks important exposure determinants (climatic conditions) and also considers refinements (such as sink effect), the chosen approach leads to overestimation to some extent that needs to be acknowledged (as discussed above). Although the model is an approximation only, the results are useful because they highlight general uncertainties in the risk assessment of formaldehyde emissions from articles and also strongly suggest exceedance of the DNEL in realistic exposure situations.

- *Temporary emission sources and peak exposure*

Emissions from temporary sources are of relevance for the overall formaldehyde concentration in indoor air. The Dossier Submitter excluded temporary emission sources from the scope of the restriction and includes only articles where formaldehyde or formaldehyde releasers have been intentionally added (or were used) in the production process. Temporary emission sources include, but are not limited to, burning candles and incenses, cooking and related activities, ethanol fireplaces, wood combustion, smoking, and formaldehyde containing mixtures.

Mixtures are, among the temporary sources, those with intentionally added formaldehyde. The Dossier Submitter assessed exposure from the use of mixtures including all-purpose and floor cleaning, furniture polishing, brush and roller paint, bottled glue and two-component glue. Exposure estimates for these mixtures with formaldehyde concentrations of 0.09 % just below the SCL were in the range of 0.014-0.059 mg/m³, thus for all scenarios below the WHO guideline value. The Dossier Submitter therefore concluded the risk from mixtures is adequately controlled.

The upper range estimate of 0.059 mg/m³ for application of furniture polishing liquid exceeds the RAC long-term DNEL. However, the scenario presents an infrequent and short-term scenario which does not raise a long-term concern. Furthermore it is specified in the Annex of the Background Document (B.4.1) that the exposure has been estimated for a worst case scenario assuming formaldehyde concentrations of 0.09 % w/w just below the GCL of 0.1 % and assuming default ConsExpo conditions (the parameter values according to ConsExpo

cleaning products factsheet are chosen to generate a conservative or reasonable worst-case exposure estimate, i.e. in the order of the magnitude of a P99 of the population distribution[12]).

In its recommendations to the Dossier Submitter, RAC raised the attempt to consider a worst-case exposure scenario with peak exposure due to temporary emission sources. In the view of the Dossier Submitter, emissions from temporary sources have limited duration and, except for the case of cleaning, or formaldehyde released into the environment is a by-product of combustion. These sources only contribute to peak exposure (which has limited duration) and their contribution to indoor air formaldehyde concentrations varies widely and depends on the type of source and the number of sources that are active simultaneously. According to the Background Document inclusion of a number of temporary sources (based on reasonable case assumptions) would generate formaldehyde concentrations in the reference room above the WHO guideline value solely as a result of formaldehyde released from these sources. Such a situation would make it difficult to reach any conclusion on the need to limit emissions from articles as peak exposure from temporary sources would be mostly unaffected by a measure targeting articles.

RAC acknowledges that mixtures, even cleaning products releasing formaldehyde, may not be used daily, they are used normally only for a short time (minutes up to very few hours) and exposure would last only very transiently for the use duration. Therefore, RAC considers it acceptable to not consider peak exposure arising from discontinuous use of mixtures in the exposure scenario for building interiors. Difficulties in reaching any conclusions on the need to limit emissions from articles are acknowledged because the restriction option would not affect high short-term peak exposure in such scenario. RAC may, however, recommend that the risk from temporary sources should elsewhere be considered.

Formaldehyde or formaldehyde-releasers are not intentionally added to, or used in the production of, other temporary emission sources than mixtures. However, Formaldehyde emitted from different combustion processes may have a high short-term impact on indoor quality. RAC notes that formaldehyde emissions arising as by-product from combustion of incenses and ethanol fireplaces lead to considerably high indoor concentrations exceeding both the long-term DNEL of 0.05 mg/m^3 and the WHO guideline value of 0.1 mg/m^3. Burning incenses in chamber tests showed chamber concentrations that were widely spread and ranged from approximately 0.02 mg/m^3 to 0.3 mg/m^3. In contrast, personal and indoor measurements of formaldehyde in homes of a Swedish town where wood burning was used for daily heating were not increased in comparison to non-wood burning homes (Gustafson et al., 2007).

Decorative fireplaces operated with liquid ethanol emit gases from combustion; VOCs and particulate matter are released into the room. In emission test chamber under typical living room environmental conditions maximum values of formaldehyde measured were between 0.4 mg/m^3 and 0.9 mg/m^3 in the exhaust gas of four decorative ethanol fireplaces, thus exceeding even the WHO guideline value by far. In a study on alcohol-powered flueless fireplace combustion and its effects on indoor air quality (EC, 2015[13]), it has been concluded that formaldehyde, the most harmful species among those detected in the study, is emitted at a rate from 2 up to 120 mg/kg of fuel. These emission factors largely exceeded most of other domestic sources. The volume of the room, where these appliances are used, is very important in determining the actual exposure of the users to potentially toxic species. A frequent and continuous usage of such appliances in a poorly ventilated room may have a detrimental effect on the human health. From the experimental tests performed, in the case of a gel appliance, up to 5 mg/m^3 of formaldehyde was measured, in average below 1 mg/m^3. Salthammer (2019) reported measured lower maximum concentrations using ethanol 94 % or gel type up to 0.45 ppm (0.54 mg/m^3) from four fireplaces. A range of recommendations were made concerning technical standards, user recommendations on the label, maximum tank capacity, product performance evaluation, etc.

The Dossier Submitter clarified that REACH does either not apply for certain combustion

[12] Cleaning Products Fact Sheet. Default parameters for estimating consumer exposure. Updated version 2018. https://rivm.openrepository.com/bitstream/handle/10029/621291/2016-0179.pdf?sequence=4&isAllowed=y
[13] http://publications.europa.eu/resource/cellar/63cf6e63-1931-46b5-baf7-f230f9e4a5c8.0001.01/DOC_1

sources (such as cooking) or other regulatory measures (e.g. imposing closed burning chamber and local exhaust system for ethanol fireplaces under building code) which could be more effective and proportionate than a restriction under REACH. In the view of RAC, regulatory measures should be considered to limit formaldehyde emissions and consumer risk arising from ethanol fireplaces. Measured concentrations exceeded the RAC DNEL and the WHO guideline value by far, and if ethanol fireplaces do present an emission sources that may be used in high frequency (e.g. daily) and for several hours, it may represent a significant exposure source in a house-hold potentially contributing to long-term consumer risk.

- *Exposure scenario public transport and rail cabin interior – articles used as train or public road transport cabin components*

Road public transport

According to ACEA, road passenger vehicles are tested according to ISO 12219-1 and UNECE (2017) mutual resolution. RAC notes that buses for public transport, motor caravans, and trucks only used for transport of goods, in accordance with the descriptions given in ISO 3833, are excluded from ISO 12219-1, and the UNECE resolution includes passenger cars and light duty trucks used as passenger cars only. RAC has no information on formaldehyde emissions, cabin interior concentrations, and applicable standards for these specific road vehicles and no information has been provided in the consultation. RAC therefore considers that it is not possible to attempt risk characterisation and considers a relevant contribution of formaldehyde-emitting articles to consumer risk during commuting considerably uncertain but notes that public transport/bus commuting is a relevant means of daily transportation of consumers.

Rail vehicle cabin interior

Rail vehicle are in the scope of the restriction proposed by the Dossier Submitter, but no specific exposure scenarios for these interior environments have been assessed. The indoor air quality of railroad passenger cabin may also be compromised by chemical pollution. The sources of chemicals in the passenger cabin are the passengers with their belongings, the inflowing outdoor air, and the interior materials like floorings, seats, paints, and adhesive. No information on use volumes used by the railway industry is available to RAC but use of potentially formaldehyde-emitting articles is assumed. In absence of specific information on formaldehyde emissions and associated sources, respectively the impact of formaldehyde-emitting articles, RAC considers a relevant contribution of formaldehyde-emitting articles to consumer risk during railway commuting (aboveground train and metro) considerably uncertain, but notes that railway commuting, as for road vehicles, is a relevant means of daily transportation of consumers. RAC therefore recommended the Dossier Submitter to attempt the assessment of a rail cabin passenger exposure scenario. According to the Dossier Submitter, no information is available on type and emission potential of articles and materials used in rail cabins and specific ambient conditions (i.e. ACH, temperature, humidity, volume and number of occupants) vary considerably from case to case. The European Union Agency for Railways (ERA) has been contacted by the Dossier Submitter but no relevant information came up and no relevant information has been submitted in the consultation. Based on these uncertainties, RAC considers it not possible to attempt risk characterisation.

Characterisation of risk(s)

Summary of proposal:

The conclusion of the Dossier Submitter's risk assessment is that human health risks from formaldehyde release from consumer articles are not adequately controlled in all scenarios. Even though a review of the literature on measured formaldehyde concentrations in indoor air in the EU shows that formaldehyde levels do not exceed the WHO Guideline for Indoor Air for formaldehyde in the majority of cases, estimations by the Dossier Submitter suggest this guideline can be exceeded under certain circumstances (new homes, use of high emitting materials in large quantities).

With regard to formaldehyde release from mixtures for consumer use, the Dossier Submitter

concludes that risks to human health seem adequately controlled. This conclusion is based on available literature information and the outcome of an exposure estimation using ConsExpo.

RAC conclusion(s):

Building exposure scenario:

RAC concludes that human health risks from formaldehyde release from interior consumer articles are not adequately controlled. Based on the identified literature on measurement data from different EU countries on conventional and passive/energy-efficient houses presented in the Background Document, in the majority of studies P90/95/max measured formaldehyde concentrations exceeded the long-term DNEL of 0.05 mg/m^3, and in some studies even the WHO guideline value. The approximate reasonable worst-case value proposed by Marquart (2013) based on various literature studies was estimated as 0.085 mg/m^3. This estimate is well in the range of the available P90/95/max estimates from individual studies summarised above by RAC and presented by the Dossier Submitter in the Background Document. An exactly calculated P90 estimate cannot be derived from the various studies covering a multitude of study designs, measurement conditions, (unknown) exposure determinants (such as equipment and age of houses or climatic conditions). RAC concludes that the RCR is > 1. The summarised exposure obtained from different studies leads to an RCR = 1.7 when using the reasonable worst-case estimate of 0.085 mg/m^3 reported by Marquart (2013) is used. The housing situations reported by the Dossier Submitter reflect rather average living conditions and not realistic worst-case situations; some reported P95 and maximum concentrations[14] exceed 0.1 mg/m^3 with resulting RCR > 2).

European market road vehicle/car interior:

Measurements in ambient mode available from ten car manufacturers (number of cars analysed unknown) showed concentrations below 0.1 mg/m^3, range 4-91 µg/m^3. The DNEL was exceeded by the maximum values from the measurement range provided by 7/10 companies, thus RAC concludes that 1 < RCR < 2 (measured in ambient mode in accordance to the standard ISO 12219-1). Consumers may stay typically up to 2 hours per day in car, the remaining time in their homes. While a task-related RCR for car cabin interiors would be accordingly lower, combined exposures from homes/buildings and car cabin interiors may still exceed the DNEL under average exposure conditions (RCR > 1).

Aircraft interiors:

Based on the available data on aircraft cabin interior, RAC concludes that RCR < 1 (flight operation mode). The range of formaldehyde concentrations including the maximum estimates were below the RAC DNEL. Passengers may stay only a few hours in an aircraft on average. Long-distance (one-or several stops) flights might indeed take almost one day, however this is not considered a long-term exposure scenario. Task-related RCR would therefore be accordingly lower (RCR << 1). Sources of formaldehyde are multiple in aircraft. The measured concentrations may be related to other sources not in the scope of the restriction.

As to the data available and comments received no relevant data are available to assess the exposure conditions in trains and road vehicles other than cars (public transport by bus). Conclusively, no estimate of the risks attributed to these exposure scenarios can be given. In principle, acceptable risk levels are identical to homes and cars with cabin concentrations sufficiently low to show RCR < 1 in relation to the RAC DNEL.

Key elements underpinning the RAC conclusion(s):

In residential buildings, the exceedance of the DNEL is typically observed for the measured P95/max values presented in the Background Document. Only for few studies it was possible for RAC to estimate the percentage of houses with exceedance of the DNEL: 36 % in the

[14] Maximum concentration considered for those studies where no P95 is available to RAC (i.e. DE study on 60 pre-fabricated houses and DK study on 19 new buildings, see Table 5)

study on German prefabricated houses (Salthammer and Gunschera, 2017), > 26 % in Danish houses (Kolarik, 2012), > 50 % in Spanish houses (Villanueva et al., 2015), and 9 % in Lithuanian houses (Kaunelienė et al., 2016).

While average/P50 concentrations are typically reported below the DNEL, e.g. central tendency of all data of 0.025 mg/m³ as published in the review of Marquart (2013) and average estimates reported by Salthammer (2019) of up to ~0.04 mg/m³ (RCR = 0.5-0.8), these housing situations likely reflect average living situations. In a study with low emitting sub-class E1 standard (30 %-class E1) in 36 % of the assessed German prefabricated new unequipped houses the long-term DNEL was exceeded (2 % exceeded the WHO guideline value). RAC notes that such prefabricated houses are based on a wood and panel construction and are a frequent and rising construction choice. This construction design therefore is associated with high panel loading and may explain high formaldehyde concentrations even if using materials emitting only 0.03 ppm (30 %-class E1), apart from steady-state measurement design (closed doors and windows).

Realistic worst-case situations including tight building envelopes with limited air exchanges or small high furniture chambers very likely may exhibit even higher formaldehyde concentrations exceeding the WHO guideline value of 0.1 mg/m³ (RCR > 2).

The Dossier Submitter's Monte Carlo simulations for the three differently loaded sub-scenarios resulted in median concentrations of 0.056-0.088 mg/m³ and a P95 of 0.129-0.164 mg/m³ with 10.9-34.3 % exceedance of the WHO value. In the comparison with the long-term DNEL, these P50 and P95 values result in RCR = 1.12-1.8 (P50) and RCR = 2.58-3.28 (P95), respectively. Available literature and the ConsExpo modelling show the sensitivity of the formaldehyde concentrations depending on room volume and actual room loading, air ventilation, and climatic conditions. RAC simulated air concentrations situations considering the log-normal distribution of ACH 0.52 ± 1.49 h^{-1} used by the Dossier Submitter and a smaller room volume of 17.5 m³. The P50 and P95 estimates for the sub-scenarios were 0.056-0.087 mg/m³ and 0.153-0.207 mg/m³, with 59-89 % simulated rooms exceeding the RAC DNEL. RCR of 1.12-1.74 (P50) and 3.06-4.14 (P95) are calculated. These simulated estimates very likely overestimate realistic formaldehyde concentrations, e.g. due to the unrealistic high contribution of furniture emissions in the modelling approach, and the observation that chamber emission rates might be actually higher compared to real (test) house conditions, or due to the simple addition of the various emission sources.

Overall, in the view of RAC it is reasonable to assume that the RCR is in the range of 2-3 (which may be considered as realistic worst case) considering underestimation by measurement data and overestimation by modelling.

Concerning road vehicle/car interior risk characterisation, RAC shares the following considerations:

According to the comments provided by ACEA, for European vehicles formaldehyde concentrations should not exceed the voluntary limit value 0.1 mg/m³ measured in whole vehicle interior in the "ambient mode" according to the applicable specific standard ISO12219-1 or UNECE (2017). For whole vehicle interior measurements, the emissions and resulting air concentrations are directly to be compared with the respective DNEL. Air concentrations of 0.1 mg/m³ in the ambient mode compared with the DNEL of 0.05 mg/m³ would therefore directly convert to an RCR = 2, and could result even in RCR of > 2 under climatic conditions and parking mode with temperatures that would further rise formaldehyde concentrations.

Some actual data have been made available by ACEA upon request during the consultation. Measurement data from ten car manufacturers in ambient mode (number of cars analysed unknown) showed concentrations below 0.1 mg/m³, range 4-91 µg/m³. The DNEL was exceeded by the maximum values from the measurement range provided by 7 out of 10 companies; thus, RAC concludes an RCR > 1 < 2 (ambient mode, 24 hours exposure/day). No percentiles can be derived from these data. For three companies, the measurement range stayed below the DNEL. Exposures in driving mode (with ventilation) may be much lower (RCR < 1), while exposures during parking mode in elevated temperature (without ventilation) may be much higher (RCR > 2). It is, however, considered that it is unlikely that

consumers stay for long times at high temperatures (up to 65°C) without ventilation during parking. Thus, this scenario is a short-term peak exposure scenario, which is not further considered by RAC.

Consumers stay in a car for only few hours per day at maximum, a reasonable worst-case exposure of 2 hours/day may be assumed based on the survey data provided by ACEA (95 % of users have exposure between 1-2 hours/day). The resulting task-related RCR would be below 1, i.e. RCR < 0.17 (task-related 2 hours/day, ambient mode).

For risk characterisation it is assumed that consumers stay up to 24 hours/day in their homes and at maximum two hours/day in the car. For vehicle users, the remainder of the time they may be exposed in the interior of their homes. Thus, risks from the building construction scenario and the vehicle scenario are considered in a sum. For vehicle users (2 hours/day) daily formaldehyde combined exposures from homes/buildings and car cabin interior may exceed the DNEL under average exposure conditions (RCR > 1). Considering that P95/max measurement estimates for buildings in some studies exceeded the WHO guideline value, a combined RCR > 2 is also realistic.

Aircraft interiors: Available measurement data from different airlines, aircraft models, and flight operation phases show formaldehyde concentration ranges below the DNEL: <0.005 to 0.048 mg/m^3. Therefore RCR (24 h/day) is < 1. Passengers may stay only a certain amount of time in an aircraft on average, ~ 1 hour at minimum for short-distance and up to several hours for longer distances. Inter-continent long-distance flights (one or several stops) might indeed take overall one day, however this is not considered a long-term (repeated) exposure scenario. Task-related RCR would therefore be accordingly lower (RCR << 1). RAC further considers that sources of VOC in the cabin air are multiple: service and humans, chemical reactions, fuels, materials, combustion, non-fuel oil, cosmetics and perfumes, and cleaning agents and disinfectants. The available data do not allow RAC to identify a consumer risk from articles used air in craft cabin interior construction and design.

Uncertainties in the risk characterisation

Emission of formaldehyde from various treated articles made from different materials is dependent on a variety of parameters, including inherent material characteristics (material type, formaldehyde amounts incorporated and bound to matrix, and diffusion resistance) and external factor including room volume and material loading (m^2/m^3), air ventilation, humidity, temperature, ageing of material, further contributing factors (indoor chemistry, sink effect, coverage of material). Emission rates are therefore only indirectly related to indoor air concentrations via the exposure scenario.

A variety of uncertainties in the exposure assessment have been identified by RAC (see previous section). These concern both, the availability, robustness and representativeness of the available measurement data, as well as the evident limitations and uncertainties in modelling formaldehyde indoor air concentrations by taking into account only some variables in a linear well-mixed room model. Acknowledging these uncertainties, RCR are estimated by RAC as an approximation as close as possible.

Evidence if the risk management measure and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

European manufacturers of wood-based panels adopted a voluntary industry agreement in 2007 to produce only panels complying with the formaldehyde emission class E1 as defined in the harmonised European Standard EN 13986 and to no longer place higher formaldehyde emitting class E2 panels on the EU market. The E1 emission class sets a limit on the release of formaldehyde from wood-based panels at a concentration of 0.124 mg/m^3 in the air of a test chamber used under the conditions prescribed in the European Standard EN 717-1. Wood-based panels with formaldehyde releases above 0.124 mg/m^3 fall into emission class

E2. Voluntary agreements or commitments with respect to limiting formaldehyde emissions exist also in the European furniture and automotive industries.

Articles that are not compliant with the voluntary agreements can however still be placed on the EU market, due to non-compliant EU producers and/or extra-EU imports. For wood-based panels, the Dossier Submitter estimates that higher formaldehyde emitting class E2 panels account for about 6.5 % of all wood-based panels consumed in the EU in 2016. Such high formaldehyde emitting articles could potentially contribute to indoor air formaldehyde concentrations that exceed the WHO guideline value under specific circumstances.

RAC conclusion(s):

RAC concludes that risk management measures and operational conditions implemented and recommended by the manufactures and/or importers of building and road vehicle interior articles are not sufficient to control the risk.

Key elements underpinning the RAC conclusion(s):

Voluntary agreements or commitments with respect to limiting formaldehyde emissions exist in the European wood-based panel industry, furniture and automotive industries. These voluntary measures aim in limiting formaldehyde releases to 0.124 mg/m^3 in a test chamber according to EN 717-1 in case of wood-based panels and 0.1 mg/m^3 for car interior according to sector-specific standards. Even so, articles not compliant with these voluntary measures may be placed on the market.

Building interior scenario:

Air concentrations in a test chamber are to be set in relation to a health-based reference value via the exposure scenario with air concentrations depending on the materials emissions in the chamber test, the room volume, the air exchange rate, and the actual loading of the room:

$$C = \frac{E_a \cdot A}{n \cdot V}$$

Equation 1: C = indoor air concentration, E_a = area-specific emission rate [(µg/(m^{2}h)], air change rate n [h^{-1}], ratio of product surface area A [m^2] to the room volume V [m^3] (AgBB, 2018)

Under real use conditions, respectively considering a realistic indoor exposure scenario, acknowledging:

- the actual loading of the room with the article/material in question, and the combination of the various articles and multitude of materials used interior and potentially emitting formaldehyde,
- an actual realistic air exchange rate of < 1 h^{-1} (even < 0.5 h^{-1}),
- the actual room volume which may be well below 30 m^3,
- relative humidity and temperatures under real use conditions (significantly influencing formaldehyde release),

RAC concludes that employed materials, which are compliant with the E1 class emission limit of 0.124 mg/m^3 according to EN 717-1 chamber test, may lead to significantly high formaldehyde air concentrations in indoor environments that may exceed the long-term DNEL and also the WHO guideline value.

The conclusion by RAC is based on:

1) the available measurement data demonstrating the mean or median concentrations

up to the RAC DNEL and frequent exceedance of the DNEL (in most studies the P95/max figures exceeded the DNEL, while the measurement data are understood as "average" exposure situation), this despite the fact that a voluntary E1 limit has been implemented by EU wood-based panel industry and several Member States having adopted this as a mandatory emission limit,

2) While an E1-compliant article, such as wood-based panels, may not lead to exceedance of room concentrations at the level of the DNEL, it is strongly suggested that the multitude of articles and materials used simultaneously in construction and equipment of buildings may do so in combination,

3) The available studies show exceedance of the DNEL for high loading situations with sub-E1 class material. High loading situations are for instance prefabricated wood-panel based houses, for which a German study conducted 2014-2016 (by the Association of German Prefabricated Construction, BDF) has shown that even when using only 30 %-E1-class materials the DNEL was exceeded. For such houses the use of E1 materials would lead to exceedance of the WHO value by far,

4) As per simple equation (see above, this equation is used in chamber experiments including EN 717-1 and EN 16516 for calculation of emission rates based on measured chamber air concentrations) and based on the Dossier Submitter's refined calculation for wood-based panels using the above equation with consideration of sink effect (-25 %), emission reduction by coverage (-75 %), and assuming background exposure from other sources of 43 µg/m^3, showing that the E1 emission level (0.124 µg/(m^{2}h)) for wood-based panels in all sub-scenarios (L = 0.4, L = 1.0, L = 1.4) lead to an exceedance of the RAC DNEL. The L = 1.4 loading scenario leads to an exceedance just above the WHO guideline value of 100 µg/m^3 (see Figure 10 in section 2.5.1 of the Background Document),

5) The available Monte Carlo simulations carried out by the Dossier Submitter and RAC for the European Reference Room featuring a number of emission sources and based on GeoMean emission rates derived from actual chamber experiments indicating exceedance of the RAC DNEL, this is in particular also to be considered in situations with insufficient ventilation. While the simulations are overestimating actual exposures, they still suggest exceedance of the DNEL under certain conditions,

6) Climatic parameters not reflected in the chamber experimental conditions but relevant in reality, i.e. high relative humidity and temperature, may cause dynamics that result in an increase of emissions after installation of the materials in buildings. This has been shown in experiments with test houses over a period of several months up to 3 years (Liang et al., Pei et al.),

7) Based on RAC's own simulations in order to approximate an emission limit, as follows:

RAC adopted the calculation approach of the Dossier Submitter (Background Document, section 2.5.1) with modifications:

<u>The equation used by the Dossier Submitter</u>:

The following equation has been used by the Dossier Submitter to assess the proposed emission limit in relation to resulting room concentrations (which should not exceed the WHO guideline value of 0.1 mg/m^3). In this approach, the emission limit (SER) has been applied to wood-based panels. Other emission sources have been accounted for by the background exposure.

Equation 2: Room concentration C = SER * 0.75 * 0.25 * L / ACH + 0.043 mg/m^3, where:

SER = Area-specific emission rate (mg/(m^{2}h)), 0.75 = sink effect; 0.25 = emission reduction by coverage, L = Loading of 0.4, 1.0, 1.4 m^2/m^3, ACH = 0.5 h^{-1}, Background concentration = 0.043 mg/m^3 for other emission sources than wood-based panels.

Regarding its limitations: The equation presents a well-mixed room model with a constant emission rate and is a simplification as it assumes that mixing occurs rapidly, conditions (e.g., ACH, emission factor) are not continuously changing over time. The model represents steady state formaldehyde concentrations estimated from emission rate data; it cannot estimate time dependent levels. Compared to equation 1, formaldehyde is assumed to be lost due to absorption or transformation (by introducing a sink of -25 %) and emissions of panels are reduced due to material coverage (by introducing -75 %), this to avoid overestimation of the indoor exposure situation. Other sources than wood-based panels are considered in the background exposure derived by the Dossier Submitter based on summing up median chamber emission rates for remaining sources.

Modifications introduced by RAC:

In order to derive a SER aiming to result in a room concentration not exceeding the DNEL:

C (DNEL) = SER * 0.75 * 0.25 * L / ACH + 0.025 mg/m^3, where:

DNEL = 0.05 mg/m^3, SER = Area-specific emission rate (mg/(m^2h)), 0.75 = sink effect; 0.25 = emission reduction by coverage, L = Loading of 1.4 m^2/m^3, ACH = 0.5 h^{-1}, Background concentration = 0.025 mg/m^3 for other emission sources than wood-based panels.

Justification of parameters:

The room concentration should not exceed the health-based reference value, i.e. DNEL of 0.05 mg/m^3 derived by RAC in order to ensure RCR < 1. RAC proposes to acknowledge the discrepancy between measurement and modelling data (and the conservative nature of the modelling approach), then the parameters are defined such as to reflect a realistic average scenario:

- Desired ACH of 0.5 h^{-1} for hygienic reasons (for illustration, ACH = 0.5 and 0.2 h^{-1} are presented)

- Coverage of wood-based panels by other materials (e.g. gypsum, primer, paint) reducing emissions,

- The sink effect as proposed by the Dossier Submitter, reducing formaldehyde concentrations due to adsorption/desorption processes,

- High particle board loading = 1.4. Best case loading situation (L < 1.0, sub-scenario A) and medium loading = 1.0 (sub-scenario B) may not cover loading situations of e.g. prefabricated houses which are frequently built (for illustration L = 1.0, 1.4, 2.0 is presented).

  Background exposure concentrations originating from other emission sources in the room including furniture and other sources (e.g. doors, windows, indoor chemistry, etc.) were 0.025 mg/m^3. In line with the Dossier Submitter's own judgement the background concentration estimate of 0.043 mg/m^3 is a very conservative estimate for remaining emission sources excluding wood-based panels, because it is at the upper range of median/mean indoor concentrations measured for fully equipped houses. RAC points out that the employed equation has its origin and application domain solely to convert steady state chamber air concentrations to constant emission rates. The SER is indirectly related to resulting room concentrations via the exposure scenario and its influencing parameters and uncertainties. Translating this equation to real room situations these parameters and uncertainties have to be acknowledged. Considering a background concentration of 0.043 mg/m^3, a SER of close to 0.010 mg/(m^2h), i.e. SER = 0.013 mg/(m^2h), is calculated, which would represent a reduction of the E1 limit by a factor of ~10. The summed-up background concentration is an overestimation for the average exposure situation. A resulting SER of 0.013 mg/(m^2h) may not be supported by actual measurement data (RCR > 1, realistic worst case estimate = 0.085 mg/m^3 proposed by Marquart (2013), range of P95/max = 52-118 µg/m^3 in studies presented by the Dossier Submitter) and the Monte Carlo simulation results. In weight of evidence consideration based on measurement data

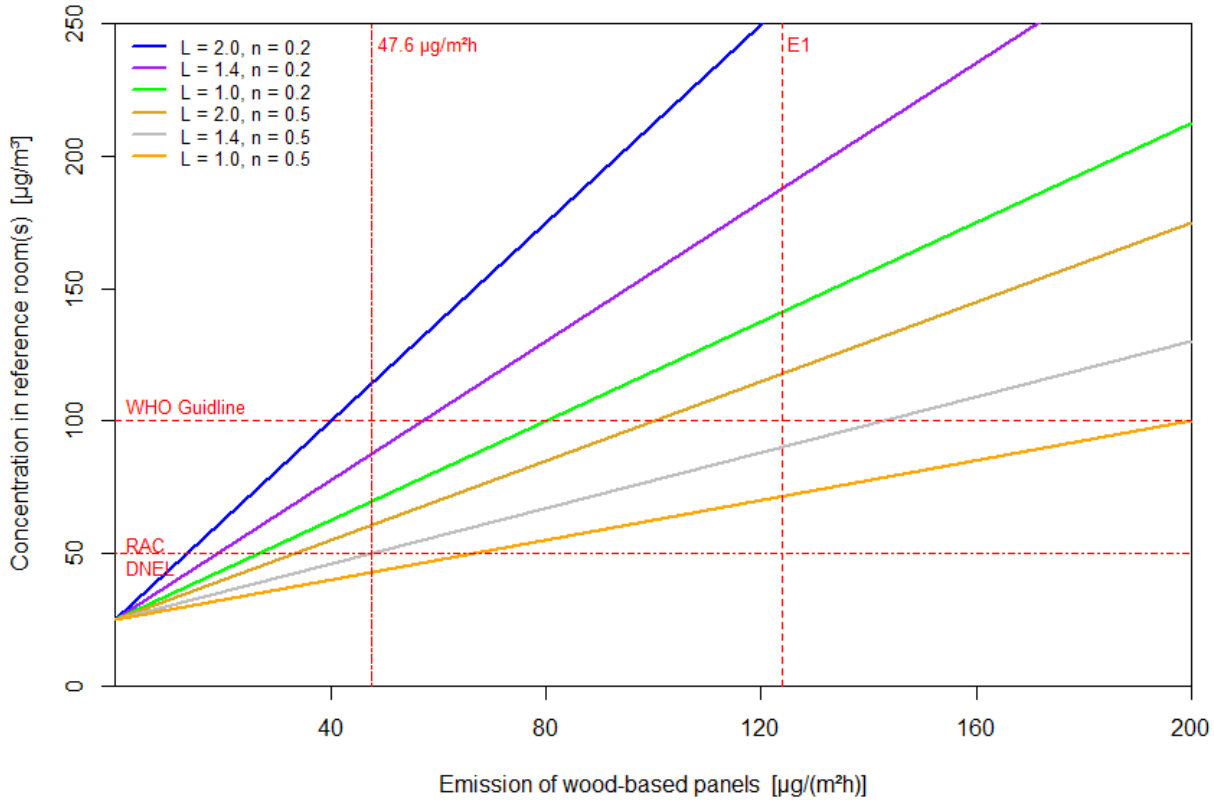
and modelling data the RCR is assumed to be in the range up ~2-3 (RWC). Considering instead average room concentrations of 0.025 mg/m³ (central tendency estimate proposed by Marquart (2013), range under "normal living" conditions of 11-42 µg/m³ proposed by Salthammer (2019)), 0.025 mg/m³ is considered an appropriate background exposure estimate for the remaining emission sources. This is also supported by the available source-specific data. Wood-based panels and furniture have been shown to be the two main emission sources and both may contribute with up to 40-45 % each. Considering the upper median/mean range for indoor concentrations of equipped houses or rooms close to the DNEL of 0.05 mg/m³, then 0.025 mg/m³ is a good estimate for the remaining emission sources dominated by furniture and excluding wood-based panels.

The resulting SER is:

Equation 3: 0.05 mg/m³ = SER * 0.75 * 0.25 * 1.4 (m²/m³) / 0.5 (h⁻¹) + 0.025 (mg/m³)

SER = 0.048 mg/(m²h), according to the equation this SER assumes chamber experiment measurements under the conditions of L = 1 and ACH = 1 h⁻¹, such as under the conditions of EN 717-1.

Figure 4: graphical presentation of SER (RAC scenario = grey)



Measurements under different conditions such as EN 16516 would translate into a different SER, e.g. with L = 1 and ACH = 0.5 h⁻¹ as per equation: SER = 0.095 mg/(m²h)[15]. A simple translation as per equation serves illustration purpose only and actual emissions may be dependent on testing conditions and type of article. Testing SER under different conditions requires robust correlation of the testing methodologies and parameters.

The resulting SER (rounded to 0.05 mg/(m²h), is thus ~40 % of E1.

The available measurement data do support this limit. The SER is an approximation. The following uncertainties are noted:

↑↓ Formaldehyde emission process is complex and different articles and materials may

[15] (0.05 mg/m³ = SER * 0.75 * 0.25 * 1.4 (m²/m³) / 1 (h⁻¹) + 0.025 (mg/m³)

exhibit different inherent emission characteristics (diffusion resistance),

- ↓ Studies have shown that up-scaled chamber conditions (to test houses) may lead to relatively lower formaldehyde air concentrations,

- ↓ Ageing effect due to off-gassing of formaldehyde with time is not considered,

- ↓ The relationship between ACH and resulting air concentrations may not be linear (the above equation overestimating),

- ↓ Reduction of emissions from wood-based panels will secondarily reduce emissions from furniture build from wood-based panels, thus lowering the background exposure considered (the above equation overestimating),

- ↑ In case of insufficiently ventilated rooms (ACH < 0.5 h^{-1}) levels may exceed the DNEL as per equation,

- ↑ If testing of SER is performed at T = 23 °C / RH = 45 %, actual climatic conditions may lead to significantly higher emissions.

RAC points out that due to the complexity of the emission process with the multitude of exposure determinants and articles used interior, an emission limit can only be derived by approximation. The available measurement data do not allow a correlation of emission rates with indoor concentrations. The above calculations therefore can be employed to establish an appropriate limit value, which however need to be further reflected in light of 1) higher tier modelling helpful to understand exposure reduction by lowering the emission limit compared to the voluntary limit E1 in an uncertainty analysis, 2) the available actual measurement data and derived RCR, 3) review of already existing limits implemented in the various countries (see next section).

1. Emission limit: Monte Carlo simulations

As regards to 1) RAC assesses the impact of different (fix level) emission limits in the Monte Carlo simulations as an uncertainty analysis:

The following scenarios based on the European Reference Room are simulated:

- Loading factors: sub-scenario A, B, C with particle board (PB) total loading of L = 0.4, 1.0, 1.4 m^2/m^3 (wall L = 0, 0.6, 1.0 respectively, and L = 0.4 for ceiling), emission reduction by 75 % due to coverage.

- Air ventilation distribution: ACH = 0.52 h^{-1} ± 1.49 σ

- Emission rates: SER for wood-based panels using fixed limit emission rate:

  – SER = 0.124 mg/(m^2h) (Dossier Submitter proposal emission limit, E1, with reference to WHO guideline value)

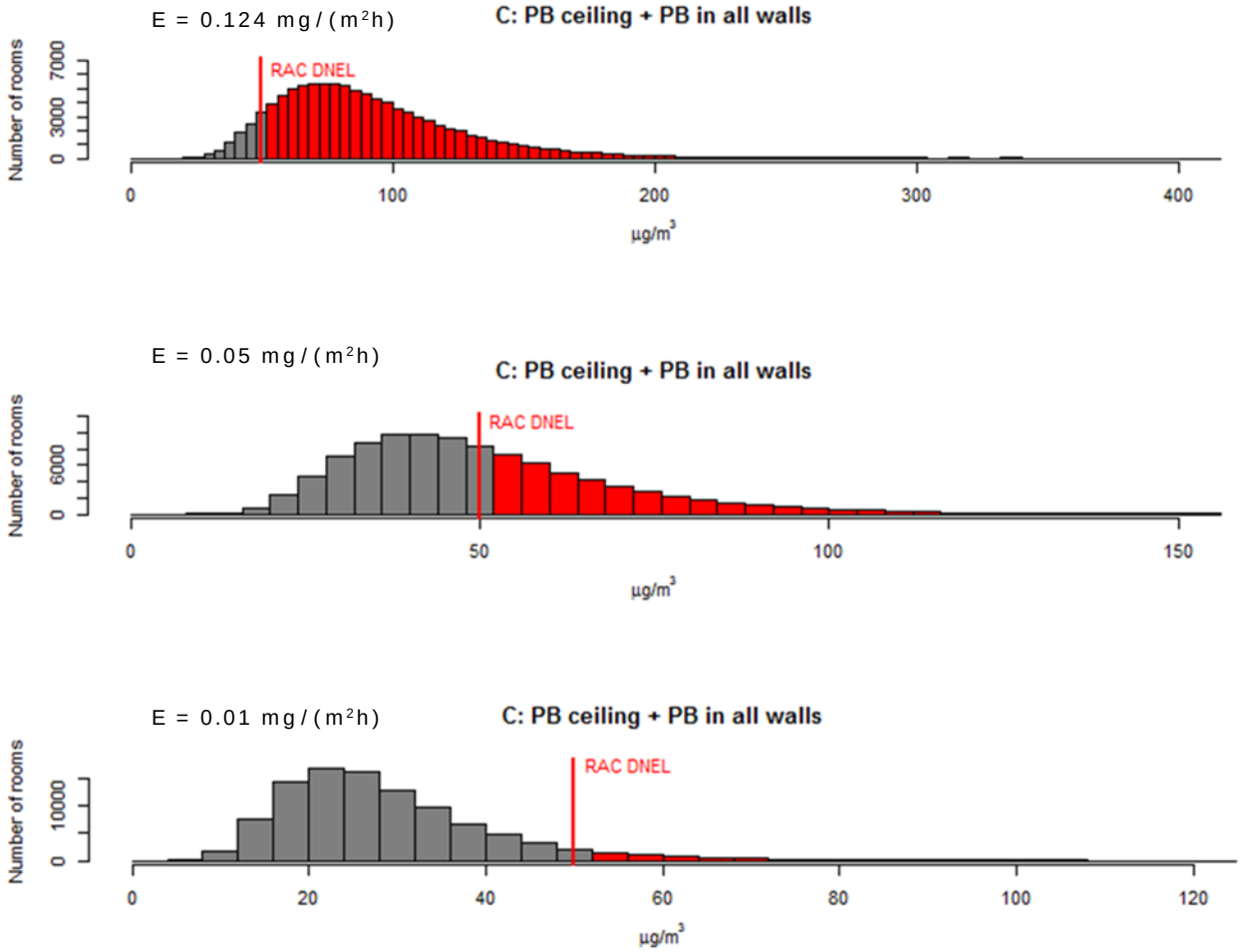
  – SER = 0.05 mg/(m^2h) (RAC proposal emission limit, 40 %-E1, with reference to RAC DNEL)

  – SER = 0.01 mg/(m^2h) (Alternative conservative scenario, (high source loading / insufficient ventilation), with reference to RAC DNEL)

SER (GM ± GSD derived from chamber experiments) for other emission sources are identical to those considered by the Dossier Submitter's Monte Carlo simulations in the Background Document, with the exception of furniture. In order to overcome some of the conservatism of the Monte Carlo simulations, the emissions from furniture have been set to zero, because evidently they are significantly overestimated (see section uncertainties in exposure), which will introduce bias in this analysis. In addition, it is difficult to reflect that secondarily emissions from furniture made from wood-based panels would decrease. Although in absolute

terms the results are difficult to interpret due the limitations of the simulation approach, some conclusion may be derived from the results:

Figure 5: Histograms of Monte Carlo simulation considering different fix emission limits for wood-based panels of 0.124, 0.05, 0.01 mg/(m²h) (sub-scenario C, L = 1.4 for particle board)



From the histograms it is indicated that limiting the emissions by an upper permissive emission rate of 0.05 mg/(m²h) or less compared to the E1 level has the potential to prevent those exposure situations with the highest formaldehyde concentrations.

In reality the emission sources (wood-based panels or other articles) compliant to the restriction will show a distribution of the emission rate up to the emission limit. In the above simulation, the assumption of a fixed upper limit emission rate may therefore be an overestimation compared to a scenario based on a distribution below the limit. This uncertainty may provide some margin of safety. As an example: Monte Carlo simulation for the fix E1 limit for wood-based panels of 0.124 mg/(m²h) results in air concentrations of 197 µg/m³ (P90), while the P90 result for the emission distribution of GM 79 ± 1.37 µg/(m²h) results in 167 µg/m³.

Table 16 below provides the percentile concentrations. When comparing the P90 estimates for the three emission limit scenarios it is indicated that a further reduction of an emission limit down to 0.01 mg/(m²h) may achieve further exposure reduction and significantly increases the likelihood for situations with RCR < 1 (P90 = 0.44 mg/m³). However, the exposure reduction capacity per emission rate unit is being reduced in the lower range because the combination of several low level emitting materials (sub-E1 class panels, door, window, paints, flooring, etc.) and other formaldehyde sources which will not be affected by the proposed emission limit (such as outdoor air and indoor chemistry reactions) still will add up to the room concentrations. Under the chosen model assumptions, 45 % is achieved by reducing the limit by 60 % (E = 0.05 mg/(m²h)), while lowering the limit further down to 0.01 mg/(m²h), i.e. an additional factor of 5, is less effective with overall 68 % reduction with

reference to the E1 level. An interpretation of the results in absolute terms considering percent of rooms below the DNEL is hampered due to the inherent model uncertainties. However, remembering the mean/median estimates of measurement data usually below the DNEL, it can be concluded that a significant share of indoor exposure situations may benefit from a reduced emission limit, however a risk reduction effect is difficult to forecast based on the below modelling (92.0 %/43.2 %/5.7 % below the DNEL) and likely an overestimation.

Table 16: Monte Carlo simulation results considering different emission limits for wood-based panels: percentiles (sub-scenario C, PB L = 1.4)

	Emission limit wood-based panels			Exposure reduction achieved by emission limits compared to the Dossier Submitter proposal E1
Room concentration (mg/m^3)	0.124 ($mg/(m^2h)$) (E1)	0.05 ($mg/(m^2h)$) (40 % of E1)	0.01 ($mg/(m^2h)$) (8 % of E1)	
P50	0.084	0.047	0.026	RAC proposal: Limit reduction by 60 % compared to E1 shows exposure reduction by ~45 % (P90 above the DNEL), Further reduction of the limit down to 8 %-E1 shows overall exposure reduction by ~68 % compared to E1 (P90 below the DNEL) (66 % of the exposure reduction achieved with a low Emission limit of 0.01 $mg/(m^2h)$ can be achieved with E = 0.05 ($mg/(m^2h)$).
P90	0.138	0.076	0.044	
% rooms above DNEL	92.0	43.2	5.7	RAC proposal: 43 % of rooms are simulated to have air concentration exceeding the DNEL. Further reduction of the limit (8 %-E1) achieves ~ 95 % of rooms below the DNEL.

Regarding the relevance of a significantly lower limit of 0.01 $mg/(m^2h)$, RAC takes note of the results of a study using the multizone CONTAM airflow and contaminant transport analysis software developed by U.S NIST to calculate indoor air flows and pollutant concentrations. The model was applied by Järnström et al. (2011) to calculate source strength to achieve indoor concentrations of no more than 0.03 mg/m^3 formaldehyde in a typical Finnish one family house having six rooms. The formaldehyde target concentrations have been identified by Finnish VTT based on its indoor air database as an “optimal” value for residential buildings, i.e. related to non-complaint residential buildings. Considering a mechanical ventilation in the simulation operating at 0.92 h^{-1} between 7-9 am and 5-7 pm and 0.48 h^{-1} for the remaining time, an SER value of less than 0.01 $mg/(m^2h)$ for surfaces was calculated based on the bed room with the highest simulated concentration. The house was simulated as unfurnished with building material as the only contaminant source. The model requires detailed information in particular to model airflow and air leakage pathways, and the results obtained for Finnish single-family houses may not be representative for the different residential indoor situations relevant to this restriction. Nevertheless, comparing the results to the RAC analysis for the European Reference Room with Monte Carlo simulation, the two model exercises turn out to be quite consistent and supportive in their results: An SER of 0.01 $mg/(m^2h)$ for wood-based panels (remaining sources see Annex to the Background Document, Table B.10: broadly below 0.01 $mg/(m^2h)$, except door (L= 0.05 m^2/m^3, unfurnished (L = 0)) lead to P50 and P90 air concentrations of 0.026 mg/m^3 and 0.044 mg/m^3, respectively, for the high loading scenario C. Noted, that ACH is considered as distribution (0.52 h^{-1} ± 1.49 σ) the high percentile concentrations reflect the lower end ventilation rates of the distribution, i.e. below the fixed ACH considered in the Finnish study.

The above results were derived for the high PB loading situation of walls and ceiling (sub-scenario C, L = 1.4). When looking at the medium loading scenario B (or even situations where walls are not covered with PB, scenario A, see Table 17), room concentrations and

percent of rooms exceeding the DNEL are further reduced. The P50 concentrations are below the DNEL for all sub-scenarios. Equally it needs to be concluded that in particular insufficient air exchange rates (< 0.5 h^{-1}) accounted for in the higher percentiles are associated with significantly higher room concentrations. Similar, climatic conditions introducing emission dynamics would lead to higher emissions, while ageing due to off-gassing eventually would lead to time-dependent reduction. It is acknowledged, that an emission limit may not prevent all the exposure situations exceeding the DNEL. In the hierarchy of risk management, however, limiting the emission source has priority.

Table 17: Monte Carlo results: Percentile estimates for sub-scenario A, B, C in comparison for RAC proposed emission limit 0.05 mg/(m^2h)

Percentiles (mg/m^3)	sub-scenario C (PB L = 1.4)	sub-scenario B (PB L = 1.0)	sub-scenario A (PB L = 0.6)
P50	0.047	0.040	0.029
P75	0.060	0.051	0.037
P90	0.076	0.065	0.047
P95	0.088	0.075	0.055
% rooms above DNEL	43.2	26.8	7.8

Regarding the relevance of a higher emission limit, RAC compared the proposed limit with the 50 %-E1 (0.062 mg/(m^2h)), which is in use by some of the voluntary labelling schemes (see next sections). Compared to the proposed 0.05 mg/(m^2h) (40 %-E1), the P50 room concentration for scenario C is estimated to exceed the DNEL when using the higher limit. The simulated P90 and P95 concentrations exceed the DNEL in all sub-scenarios, the P75 exceed the DNEL in the medium and high loading scenarios B and C. For sub-scenario C, the P90 is 0.086 mg/m^3, which is broadly corresponding to the proposed realistic worst case exposure estimate for residential houses based on measurement data as suggested by Marquart (2013), i.e. 0.085 mg/m^3. The P95 matches the WHO guideline value, i.e. a corresponding RCR = 2 is estimated. It is therefore concluded that higher limits including the 50 %-E1 are not sufficient to prevent exposures exceeding the DNEL.

Table 18: Monte Carlo results: Percentile estimates for sub-scenario A, B, C in comparison for an alternative emission limit 0.06 mg/(m^2h) (50 %-E1)

Percentiles (mg/m^3)	sub-scenario C (PB L = 1.4)	sub-scenario B (PB L = 1.0)	sub-scenario A (PB L = 0.6)
P50	0.053	0.044	0.030
P75	0.068	0.057	0.039
P90	0.086	0.072	0.050
P95	0.100	0.083	0.058
% rooms above DNEL	56.3	36.6	10.2

RAC concludes that an emission limit of 0.05 mg/(m^2h) (conditions Appendix X) may be effective in reducing formaldehyde concentrations significantly. In many living situations it can be expected that the air concentrations will be reduced in a way that RCR <

1, but there may still be situations where the RAC DNEL is exceeded. Lower limits may bring additional exposure reduction with air concentrations below the RAC DNEL, for the exposure reduction effect by further lowering the limit, it is concluded that the limit would need a significant further reduction down to ~0.01 mg/(m²h) to achieve RCR < 1 for realistic worst case situations. For higher emission limits than the by RAC proposed (> 0.05 mg/(m²h), i.e. 50 %-E1), the contrary apply. Higher emission limits are not supported by the analysis as the likelihood for exposure situations may increase where RCR > 1.

2. Emission limit: Measurement data and RCR

RAC established an RCR for the building interior scenario average exposure situation of > 1, with P95/max estimates from available studies exceeding RCR of 2. Even if exposure may be underestimated for certain situations, the available modelling results, which likely overestimate exposure, suggest that RCR may be in the range of 2-3 for realistic worst-case situations not covered in the measurement data available and assessed by RAC above.

It is further considered that a considerable share of wood-based panels on the EU market may reflect the E1 level.

A variety of sources contribute to indoor concentrations, amongst sources that will not be affected by an emission limit, either because they are not in the scope of the restriction (temporary sources, contribution from outdoor air, indoor chemistry reactions), or because emissions are already low. These sources will inevitably still contribute to indoor air concentrations. A restriction limiting high emissions in the range of the RAC proposed limit or the E1 applicable to permanent sources therefore cannot prevent all exposure situations that may be of concern. A lower emission limit therefore aims in avoiding high level chronic exposure situations which are of most concern. It cannot guarantee that under certain situations the DNEL may still be exceeded.

Based on the risk assessment, considering an RCR > 2 (for the high percentiles for the "average exposure situation"), an emission limit lowered by at least a factor of 2 starting from the established E1 limit is considered justified by RAC.

3. Emission limit: Concentration limits and standards in place

RAC assessed which limits exist in different countries, European and non-European, in particular considering also voluntary initiatives, certification and labelling schemes. Table 19 is a summary of this analysis, which is described in detail in the next section, it should demonstrate which levels are in place under different contexts indicating what is already in use and more and more common.

Table 19: Overview of mandatory and voluntary formaldehyde concentration limits and labelling schemes for wood-based construction materials, furniture and other products.

Wood-based construction materials/panels used indoors - Obligatory formaldehyde concentration limits and labelling schemes (EU and international) (selection)			
Country/Countries	Specifics/Applicability	Formaldehyde concentration limit / Labelling schemes	Test method
Sweden, Denmark, Austria, Netherlands, Italy, Lithuania, Greece	Wood-based construction products/panels used indoors	0.124 mg/m³ (E1)	EN 717-1
Belgium	Products used as flooring, or as support, or for installation of floors	0.1 mg/m³	EN 16516
German DIBt and AgBB	Construction products used in habitable and recreation	0.1 mg/m³	EN 16516

	rooms		
France	Construction products installed indoors, including wood-based panels for room partitioning and suspended ceilings, doors and windows, floor and wall coverings, paints and lacquers	*Four classes for mandatory labelling:* 0.01 mg/m³ (A+) 0.06 mg/m³ (A) 0.12 mg/m³ (B) > 0.12 mg/m³ (C)	EN 717-1
Russia	Wood-based construction products/panels	0.124 mg/m³ (E1)	EN 717-1
China	Particle boards, plywood, bamboo flooring used indoor	≤ 1.5 mg/L (similar to E1) ≤ 5.0 mg/L (similar to E2), can be used indoor, if surface treated beforehand	Desiccator method
	MDF, HDF and OSB used indoor	≤ 9 mg/100 g (similar to E1) ≤ 30 mg/100 g (similar to E2) can be used indoor, if surface treated beforehand	Perforator method
Australia, New Zealand	Wood-based construction products/panels used indoors, particle board, plywood	*Three classes for mandatory labelling:* E0: ≤ 0.5 mg/L E1: ≤ 1.5 mg/L E2: ≤ 4.5 mg/L	Desiccator AS/NZS 4266.16
	MDF used indoors	*Three classes for mandatory labelling:* E0: ≤ 0.5 mg/L E1: ≤ 1.0 mg/L E2: ≤ 4.5 mg/L	Desiccator AS/NZS 4266.16
Norway, South Africa, Switzerland, Mauritius	Wood-based construction products/panels used indoors	≤ 0.124 mg/m³ (E1)	EN 717-1
Japan	Plywood, flooring, structural panels, (structural) glued laminated timber and (structural) laminated veneer lumber used indoor	*With limitations*: 1.5 mg/L (F**; similar to E1) 0.5 mg/L (F***; ≈ 0.054 mg/m³ acc.to EN 717-1) *Without limitations*: 0.3 mg/L (F****; ≈ 0.034 mg/m³ acc.to EN 717-1)	Desiccator method
USA (CARB)	Particle board	0.112 mg/m³ (≈ 0.087 mg/m³ acc.to EN 717-1)	ASTM E 1333
	MDF	0.137 mg/m³ (≈ 0.15 mg/m³ acc.to EN 717-1)	
	Thin MDF (thickness < 8 mm)	0.161 mg/m³	
	Hardwood plywood / laminated products (from 20124 onwards)	0.062 mg/m³	
Canada	Currently: proposal submitted (effective probably in 2020) – see values for USA		

Wood-based construction materials/panels used indoors - Voluntary formaldehyde concentration limits and labelling schemes (selection)			
Name	Specifics/Applicability	Formaldehyde concentration limit [mg/m³]	Test method
EU-Ecolabel	Wood-, cork- and bamboo-based floor coverings	< 50 % of E1: for all floor coverings and non-MDF/non-HDF core boards and < 65 % of E1: for untreated MDF/HDF core boards or formaldehyde emissions lower than CARB or F***/F****	NA
European Panel Federation (EPF)	Wood composite materials/panels for indoor use	0.124 mg/m³ (E1) Proposed voluntary market class of ½E1 (0.062 mg/m³)	EN 717-1
German Wood-Based Panel Federation (VHI)	Wood composite materials/panels for indoor use	0.124 mg/m³ (E1) Proposed voluntary market class of ½E1 (0.062 mg/m³)	EN 717-1
Main Association of the German Wood Industry (HDH)	Wood composite materials/panels for indoor use	0.124 mg/m³ (E1) Proposed mandatory market class of ½E1 (0.062 mg/m³)	EN 717-1
French furniture manufacturers association (l'Ameublement français)	Wood composite materials/panels for indoor use	0.124 mg/m³ (E1) Proposed voluntary market class of ½E1 (0.062 mg/m³) for materials resulting in automatic compliance of (complex) articles with E1 standard	EN 717-1
Belgian Superior Health Council	Wood composite materials/panels for indoor use	0.03 mg/m³ (≈ ¼E1)	EN 717-1
Flemish Indoor Environment Decree (IED)	Wood composite materials/panels for indoor use	0.01 mg/m³ guidance value 0.1 mg/m³ “intervention value”	EN 717-1
French High Council for Public Health (HCSP), ANSES and FR MSCA	Wood composite materials/panels for indoor use	0.01 mg/m³ Recently proposed as limit value corresponding to the A+ class of the French labelling system.	EN 717-1
Italian Green Public Procurement (GPP)	Construction works and construction products employed in public sustainable building projects	0.06 mg/m³ (according to the A class of the French labelling system; ~ ½E1)	EN 717-1
Finish MN1 labelling system	Building materials, fixture and furniture without padding or textile coverings used in ordinary workspaces and residences	*Three voluntary labelling classes:* M1: < 0.01 mg/m³ M2: 0.01-0.025 mg/m³ M3: >0.025 mg/m³	EN 717-1
Swedish Byggvarubedömningen (BVB)	Construction products for interior use, including wallboard, floor covering, sealing, paint, wallpaper,	*Two labelling classes:* Recommended: < 0.05 mg/m³	EN 717-1

	caulking, adhesive and putty	*Still acceptable:* 0.05-0.124 mg/m³	
German Association of German prefabricated construction (QDF)	Wood composite materials for e.g. ceilings, walls or roofs of prefabricated houses	0.037 mg/m³	EN 717-1
	Interior constructions (e.g. panels, parquet flooring, laminate flooring)	0.037 mg/m³ or E1 for raw materials 0.062 mg/m³ for finished products	EN 717-1
Blue Angel RAL-UZ 76	Panel-shaped materials used for interior construction and furnishing	0.037 mg/m³	EN 717-1
Blue Angel RAL-UZ 176	Ready-to-use interior floor coverings as well as to panels and interior door elements, if those products consist predominantly (> 60 % by volume) of wood and/or wood- based materials (chipboards, core boards, fibreboards, veneer-faced boards, each non-coated or coated), including parquets, laminates, linoleum, cork and other materials on wood-based substrates	0.037 mg/m³ or E1 for raw materials 0.062 mg/m³ for finished products	BAM test method based on EN 16000-9
German TÜV PROFiCERT	Wooden and wood-based construction products used indoors and interior superstructures	*Two labelling classes:* Standard: 0.06 mg/m³ Premium: 0.01 mg/m³	EN 16516
German Qualitätsgemeinschaft Holzwerkstoffe e.V.	Wooden and wood-based construction products	*Two labelling classes:* Top: 0.124 mg/m³ Premium: 0.062 mg/m³	EN 717-1
Austrian Ecolabel	Wooden and wood-based construction products and floorings made of wood	0.062 mg/m³ (0.037 mg/m² for surface-treated wood-based materials)	EN 717-1
Eco-institute-label	Wooden and wood-based floorings, laminate and panels	0.036 mg/m³	EN 717-1
Natureplus	Plywood boards, porous and hard/medium wood-fibre bards, chip and particle boards, OSB for construction purposes, laminated wood-based boards, as well as MDF boards; interior doors made from wood, wood-based materials and adhesive-bonded wood products for construction purposes	0.036 mg/m³	TM-01 (DIN EN ISO 16000 series expanded by the natureplus implementation rules)
	Wood and wood-based flooring	*Two labelling classes:* Solid un-glued products: 0.036 mg/m³ Glue-laminated products: 0.048 mg/m³	
Indoor Air Comfort by Eurofins	Glues, sealing compounds and paints, textile and elastic flooring, but also for wood-based flooring and plasterboards	*Two labelling classes:* Indoor Air Comfort: 0.06 mg/m³	EN 16516

		Indoor Air Comfort Gold: 0.01 mg/m³	
UL GREENGUARD Gold	Hardwood plywood (HWPW), particle board (PB), and medium density fibreboard (MDF)	CARB standard (for details see above) Finished products: 0.009 mg/m³	ASTM E 1333 UL 2821 GREENGUARD Test Method for Building Materials, Finishes and Furnishings
Furniture - Mandatory formaldehyde concentration limits (selection)			
Country	Specifics/Applicability	Formaldehyde concentration limit [mg/m³]	Test method
Denmark	Wood-based materials used in the manufacture of furniture and related parts	0.124 mg/m³	EN 717-1
	Sales of fixed and movable objects, which also includes furniture and kitchen elements	0.134 mg/m³	
France	Wood-based furniture products	*Four classes for mandatory labelling:* 0.003 mg/m³ (A+) 0.005 mg/m³ (A) 0.0.1 mg/m³ (B) > 0.01 mg/m³ (C) Proposed in 2017, thought to be implemented in 2020	EN 16000-9
Russia (TP TC 025/2012)	Wood-based furniture products	0.012 mg/m³	EN 717-1?
Furniture - Voluntary formaldehyde concentration limits (selection)			
Name	Specifics/Applicability	Formaldehyde concentration limit [mg/m³]	Test method
EU-ecolabel	Furniture, if the content of wood-based panels in the final furniture product (excluding packaging) exceeds 5 % w/w	< 50 % of E1: for all supplied wood-based panels, in the form that they are used in the furniture product (in other words, unfaced, coated, overlaid, veneered), and which were manufactured using formaldehyde-based resins and < 65 % of E1: for untreated MDF boards or formaldehyde emissions lower than CARB or F***/F****	NA
European Furniture Industries Confederation (EFIC)	Wood-based panels and furnishing products made from them	0.124 mg/m³ (E1) Proposed mandatory market class of ½E1 (0.062 mg/m³)	EN 717-1
Blue Angel RAL-UZ 38	Ready-to-use indoor furniture and slatted frames made predominantly	0.037 mg/m³ or E1 for raw materials	BAM test method based on EN 16000-9

	(> 50 % by volume) of wood and/or wood-based materials (chipboards, core boards, fibreboards, veneer-faced boards, each non-coated or coated	0.062 mg/m³ for finished products	
Blue Angel RAL-UZ 117	Upholstered furniture	0.06 mg/m³ or	BAM test method based on EN 16000-9
Austrian Ecolabel	Materials used for (textile covered) furniture	0.062 mg/m³	EN 717-1
	Specific case of textile covered armchairs	0.062 mg/m³ for finished product	EN 16516
	Toys made of glued wood	0.037 mg/m³	EN 717-1
The Golden M (“Das Goldene M”)	Furniture	0.06 mg/m³	EN 717-1
Nordic Swan Ecolabel	Furniture	MDF: 0.124 mg/m³ (E1) All other panels: 0.07 mg/m³	EN 717-1
Indoor Air Comfort	Furniture (Testing of furniture includes the testing of a whole (complex) article; and incorporating the number of furniture pieces that would be located in a room of the size of the European Reference Room)	*Two labelling classes:* Indoor Air Comfort: 0.06 mg/m³ Indoor Air Comfort Gold: 0.01 mg/m³	EN 717-1
UL GREENGUARD	Furnishing products	*Two labelling classes:* Standard: 0.061 mg/m³ Gold: 0.009 mg/m³	ASTM E 1333 or ASTM D 6007 or UL 2821 GREENGUARD Test Method for Building Materials, Finishes and Furnishings
Ökotex	Upholstery	0.1 mg/m³	ISO 16000-9 or ISO 16000-11, plus ISO 16000-3 for formaldehyde determination by HPLC/UV
CertiPUR (EuroPur)	Furniture	0.01 mg/m³	ISO 16000-9 or ISO 16000-11, plus ISO 16000-3 for formaldehyde determination by HPLC/UV
Carpets, toys and others - Voluntary formaldehyde concentration limits			
Name	Specifics/Applicability	Formaldehyde concentration limit [mg/m³]	Test method
EU-ecolabel	Textile floor coverings	0.01 mg/m³	ENV 13419-1 (with EN ISO 16000-3 or VDI 3484-1 for air sampling and analysis)
Blue Angel RAL-UZ 120	Elastic floorings	0.06 mg/m³	EN 16000-9

Blue Angel RAL-UZ 128	Textile floorings	0.025 mg/m³	DIN ISO 16000-28/ VDI 4302 combi
German TÜV PROFiCERT	Textile floorings	Premium: 0.004 mg/m³	EN 16516
Indoor Air Comfort	Textile floorings	Gold standard: 0.004 mg/m³	EN 16516
Association of Environmentally Friendly Carpets e.V. (Gemeinschaft umweltfreundlicher Teppichboden; GUT)	Textile floorings, incl. carpets	0.004 mg/m³ No formaldehyde allowed to be used in production process	EN 717-1?
Matrasses and others - Voluntary formaldehyde concentration limits			
Name	Specifics/Applicability	Formaldehyde concentration limit [mg/m³]	Test method
The Golden M (“Das Goldene M”)	Matrasses	Class A: 0.06 mg/m³	EN 717-1
Blue Angel RAL-UZ 119	Matrasses	0.02 mg/m³	BAM test method based on EN 16000-9
Ökotex	Matrasses	0.1 mg/m³	ISO 16000-9 or ISO 16000-11, plus ISO 16000-3 for formaldehyde determination by HPLC/UV
UL GREENGUARD	Office seating	0.0045 mg/m³	ASTM E 1333 or ASTM D 6007 or UL 2821 GREENGUARD Test Method for Building Materials, Finishes and Furnishings
Nordic Swan Ecolabel	Toys	MDF: 0.09 mg/m³ All other panels/boards: 0.07 mg/m³	EN 120 or similar methods approved by Nordic Ecolabelling

In conclusion, RAC notes that several EU countries already apply a mandatory formaldehyde emission limit for certain types of wood-based panels that is slightly lower than the E1 standard. Moreover, the low amount of panels with a higher emission rate as the E1 standard produces and used in the EU region, as well as the diverse range of voluntary certification labels and marks are indicative of consumers caring more and more about improving indoor air quality at home. The numerous types of voluntary certification labels and marks further indicate that the production and use of wood-based panels with formaldehyde emission significantly lower than E1 (i.e. ½E1, ⅛E1 or even lower) is in fact already possible and common. With respect to furniture and other articles, such as matrasses or toys, considerably lower limit values are already in place on a mandatory and voluntary basis, respectively.

Overall, RAC concludes that a lower emission limit than the existing E1 standard is already in use and mandatory in some countries, and therefore appear feasible and is becoming more and more common based on a voluntary basis. The emission limit E1 proposed by the Dossier Submitter is not expected to introduce significant risk reduction for those Member States that haven even slightly lower limits already in place.

Taking the above calculations and reflections (emission limit, points 1.–3.) into consideration, RAC proposes limiting emissions equal to or exceeding a concentration of 0.05 mg/m³ measured in a test chamber according to the prescriptions in Appendix X, which will achieve a significant risk reduction for the building interior situation (aiming in RCR < 1 with reference to the long-term DNEL of 0.05 mg/m³).

Vehicle cabin interior:

In the automotive industry, test methods and a voluntary approach in reducing the amount of formaldehyde released from vehicle interiors have been implemented in order to work towards harmonisation of standards and implementation of voluntary limit values for formaldehyde in vehicle indoor emissions. A range of methods have been developed by ISO/TC 146/SC 6 for sampling of VOC and SVOCs from vehicle interiors and the materials used. A voluntary emission limit of 0.1 mg/m³ for European cars is applicable in automotive industry according to ACEA. For the vehicle interior measurements are directly carried out within the cabin, therefore concentrations are directly compared to the respective DNEL. Finally, RAC does not consider the voluntary limit of 0.1 mg/m³ measured in whole car interior ambient mode as safe, because it allows exposure exceeding the DNEL by a factor of 2 yielding RCR = 2. Measurement data provided by ACEA show exceedance of the DNEL for 7/10 companies, max value 91 µg/m³. RAC has no information on the manufacturers' compliance vis-a-vis the voluntary limit value, and whether in particular cars produced by non-EU manufacturers for the EU market and cars produced by manufacturers for other markets than the EU but finally placed on the EU market are complying with this standard. In addition, cars not compliant with this measure may be placed on the EU market, as compliance is voluntary. Moreover, other road vehicles that may be used by consumers, such as minibuses or mobile homes/caravans, are not in the scope of this voluntary limit.

For interior environments of other road vehicles (buses, vans, mobile homes, trucks and heavy-duty road vehicles), rail vehicles and ships for passenger transport, no assessment of risks is possible due to lack of robust exposure data.

RAC is of the opinion that in principle the same level of protection should apply to consumers exposed in all kind of vehicles. Therefore, an exposure limit for vehicle cabin interior should prevent RCR > 1, thus RAC proposes a concentration limit of 0.05 mg/m³ applicable to cabin interior of all vehicles in the scope of the restriction.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

The Dossier Submitter identified a number of regulatory measures – both at the European and the national level – that aim at limiting formaldehyde emissions from articles in indoor environments:

- The Construction Products Regulation (EU) No 305/2011 (CPR) sets out harmonised rules for the marketing of construction products in the EU. The CPR requires a CE marking for construction products before they are placed on the internal market. Construction products for which a harmonised European standard exists must comply with the relevant standard to obtain the required CE marking. While the harmonised standard for wood-based panels (EN 13986) defines two formaldehyde emission classes – E1 and E2 – it does not restrict the placing on the market of higher formaldehyde emitting class E2 wood-based panels.

- Currently, eight Member States have adopted national legislation to limit formaldehyde emissions from wood-based panels. These legally binding emission limits generally correspond to the E1 emission class. However, despite these initiatives, to date no EU-wide harmonised regulation of formaldehyde emissions from articles exist. According to the Dossier Submitter, this results in different levels of risk reduction across the EU and the potential for consumer exposure to formaldehyde levels above the WHO guideline value persists in indoor environments under certain circumstances.

The Dossier Submitter also examined other possible Union-wide risk management options but concluded that these measures were assessed as inappropriate to address all of the sectors and products contributing to risk.

RAC conclusion(s):

RAC agrees that existing measures are inappropriate. This conclusion is based on the Dossier Submitter assessment and based on RAC's own analysis on which relevant formaldehyde limits do exist. RAC identified a wide range of measures, mandatory and voluntary. The analysis was extended also to non-European context in order to assist RAC in develop an appropriate limit value (see previous section). In the following a comprehensive overview on existing limit values is provided. For the sake of completeness, this section includes also non-European countries and voluntary measures (industry standards and labelling/certification schemes) for different types of products/materials in the scope of the restriction, and thus provides the complete picture (summary table is presented in the previous section):

Construction materials and indoor air quality of buildings

National limit values within the EU

Since 1985, the emission class E1 became mandatory for wood-based panels in Austria, Denmark, Germany and Sweden. The EU-wide Construction Products Directive, however, was only enacted in 1988, enforcing that construction products placed on the EU market need to "meet an essential requirement for "Hygiene, Health and the Environment" , (Ruffing et al., 2011) which also addressed indoor air quality and specifically formaldehyde emissions indoor. In 2004, the EN 13986 standard was published, distinguishing the E1 (≤ 0.124 mg/m³) and E2 (0.124-0.373 mg/m³) class in Europe based on formaldehyde release rates of wooden particle boards, fibreboards and panels. The Construction Products Regulation (EU) 305/2011 (CPR) accordingly introduced the requirement of a CE marking in 2013 for construction products before they can be placed on the EU market. This harmonised European standard includes the mandatory classification of wood-based panels into either E1 or E2 (Oppl, 2014), which both, however, are considered not sufficient by RAC. Nevertheless, several EU countries set more strict rules in their national regulations.

The Belgian regulation on VOC emissions from construction products was published in 2014 and applies amongst others to all products used as flooring, or as support, or for installation of floors[16]. Emission limit for formaldehyde from wood composites is set to 0.1 mg/m³ (according to CEN/TS 16516). The Swedish regulation on VOC emissions from construction products' limit value for formaldehyde emission, on the other hand, is in line with the existing E1 standard: the regulation proposes a limit value for formaldehyde emission of 0.124 mg/m³ (acc. to EN 717-1)[17]. Contrary to the Belgian regulation, the Swedish regulation also covers all interior floors, but also walls and ceilings. Similarly, the current German, Danish, Austrian, Dutch[18], Italian, Lithuanian and Greek[19] VOC regulations on construction products foresee a formaldehyde emission limit for wood-based products, that is in agreement with E1 (0.124 mg/m³ according to EN 717-1). The German Institute for Construction Technology (Deutsches Institut für Bautechnik; DIBt), moreover, published a guideline specifying that construction products used in habitable and recreation rooms within German buildings must emit lower formaldehyde concentrations than 0.1 mg/m³ according to the EN 16516 standard[20]. This value is in accordance with the NIK-value published by the German "Ausschuss zur gesundheitlichen Bewertung von Bauprodukten" (AgBB)[21].

The French regulation on VOC emissions from construction products, on the other hand,

[16] https://cdnmedia.eurofins.com/corporate-eurofins/media/2291/kb_vloerbekleding_ar_revetements_sols.pdf
[17] https://www.kemi.se/en/global/rapporter/2015/rapport-8-15-halsoskadliga-kemiska-amnen-i-byggprodukter.pdf
[18] National legislation in the Netherlands only refers to particleboard and the emission limit is somewhat higher than the one corresponding to the E1 emission class (see Background Document).
[19] Some EU Member States have restrictions on producing class E2 panels (see Section 1.5.1 in the Background Document), with the exception of Greece, because it is not clear whether the legislation is respected.
[20] https://www.dibt.de/fileadmin/dibt-website/Dokumente/Referat/P5/Bauregellisten/MVV_TB_2017-1_inkl_Druckfehlerkorrektur.pdf
[21] https://www.umweltbundesamt.de/sites/default/files/medien/360/dokumente/agbb-bewertungsschema_2018.pdf

includes a mandatory labelling of construction products installed indoors, including wood-based panels for room partitioning and suspended ceilings, doors and windows, floor and wall coverings, paints and lacquers into one of four emission classes based on emission testing according to EN 717-1: A+, A, B and C (Décret n° 2011-321). The limit values for the four emission classes with regard to formaldehyde are as follows: < 0.01 mg/m³ (A+), < 0.06 mg/m³ (A), < 0.12 mg/m³ (B) and > 0.12 mg/m³ (C). Since 2012, all respective products must be labelled according to their emission class in addition to the obligatory CE marking.

National limit values outside of the EU

Russia applies a formaldehyde emission limit of 0.124 mg/m³ for (coated) chip and particle boards, as well as plywood, in accordance with the current E1 standard[22]. However, as indicated in Table C.3 of the Background Document, E2 panels are still available on the market.

Measured according to the national compulsory standard GB18580-2001 ("Limit of formaldehyde Emission of Wood-based Panels and Finishing Products" (Zhang et al., 2018) and converted to the European EN 717-1, China applies a formaldehyde emission limit of 0.12 mg/m³ for particle boards, plywood, MDF, HDF and OSB (minimum of (Chinese) E1 standard; ≤ 1.5 mg/L according to the desiccator method (plywood); ≤ 9 mg/100 g according to the perforation method (MDF particle board)) already since 2002. In addition, and until 2018, however, the Chinese authorities allowed E2 wood-based panels for indoor use, if these are surface treated beforehand[23]. Since then, the E1 standard is mandatory for wood-based panels used for interior decoration; E2 can only be used if the surface is treated. Moreover, due to the increasing demand, many manufacturers are trying to adopt the E0 standard in production.

In Australia and New Zealand, MDF and particle boards can be assigned to either of the following formaldehyde emission classes: E0 (≤ 0.5 mg/L, desiccator method AZ/NZS 4266.16), E1 (≤ 1.5 mg/L for particle board acc. to desiccator method; ≤ 1.0 mg/L for MDF acc. to desiccator method) or E2 (≤ 4.5 mg/L desiccator method AZ/NZS 4266.16)[24,25,26]. Lower voluntary limit values are available e.g. with the "Good Environmental Choice Australia" ecolabelling standards[27].

A minimum emission limit of E1 for wood-based panels is similarly constituted in Norway, South Africa, Switzerland and Mauritius (see Background Document). In Norway, moreover, the guideline value for formaldehyde in indoor air was set to 0.06 mg/m³ (Salthammer et al., 2010).

The four emission classes F*/F*s, F**, F*** and F**** are distinguished in Japan[28]. For plywood, flooring, structural panels, (structural) glued laminated timber and (structural) laminated veneer lumber the following average limit values were set by the Japanese Ministry of Agriculture, Forestry and Fishery (MAFF Japan) as part of the Japanese Agricultural Standard (JAS) using the glass desiccator method: 5.0 mg/L (F*/F*s), 1.5 mg/L (F**; similar to E1 class), 0.5 mg/L (F***; 0.054 mg/m³ acc. to EN 717-1) and 0.3 mg/L (F****; 0.034 mg/m³ acc. to EN 717-1) (Zeleniuc, 2016). For fibre and particle boards, as well as adhesives identical limit values are used; however, no F*/F*s category exists for those products. All plywood, fibreboard, wooden boards and other wooden products must be labelled with their formaldehyde emission grades. Wooden products with different formaldehyde emission grades are foreseen for different uses: e.g. F**** plywood can be used interior without limitations, while F*** and F** plywood can be used interior with some limitations,

[22] https://ivth.org/content/download/taho2014/Vortrag_Schwab.pdf
[23] https://ivth.org/content/download/taho2014/Vortrag_Schwab.pdf
[24] https://www.ntl-chemicals.com/wp-content/uploads/2019/02/MDF_Yearbook_2017_2018_Article_NTL_Chemical_Print-1.pdf
[25] http://timberveneer.asn.au/wp-content/uploads/2018/12/formaldehyde-in-veneered-products-3-1.pdf
[26] https://www.chimarhellas.com/mlS8RYRg7/images/publications/files/formaldehyde_2008.pdf
[27] https://www.geca.eco/wp-content/uploads/2017/08/Panel-Boards-GECA-04-2011-v2i.pdf
[28] https://ivth.org/content/download/taho2014/Vortrag_Schwab.pdf; https://www.chimarhellas.com/mlS8RYRg7/images/publications/files/formaldehyde_2008.pdf

while F* plywood is not allowed to be used indoor at all.

The US EPA recently issued new regulations with regard to formaldehyde emission in composite wood products, which are consistent with the limits that were previously only in effect in California under the California Air Resource Board's Airborne Toxic Control Measure (CARB ATCM or CARB). The new regulations became effective nationally in 2017. Since then composite wood products need to be CARB-approved by independent and authorized certifiers to comply with the formaldehyde emission limits and to get a respective certification mark. Relevant composite wood products include panels and component parts made of hardwood plywood, MDF, thin MDF and particle board, but also finished goods made from these materials, such as furniture, cabinetry, flooring and other building materials[29]. Moreover, prefabricated and manufactured homes, such as mobile homes and trailers/campers are no exception from this rule. Formaldehyde emission limits are dependent on the type of composite wood panel. Particle boards must not exceed a formaldehyde emission limit of 0.09 ppm (0.112 mg/m³), while MDF and thin MDF (maximum thickness of 8 mm) shall not exceed 0.11 ppm (0.137 mg/m³) and 0.13 ppm (0.161 mg/m³), respectively. Hardwood plywood must not exceed a formaldehyde emission limit of 0.05 ppm (0.062 mg/m³), even if particle board or MDF is used in the core. Laminated products are defined as products, in which a wood veneer is affixed to a particle board platform, a MDF platform or a veneer-core platform and that is a component part used in the construction or assembly of a finished good and that are produced by the manufacturer or fabricator of the finished good in which the product is incorporated. Such products are treated as "finished goods" until 22 March 2024. Afterwards they will be treated as hardwood plywood, except for laminated products that are made using phenol formaldehyde or no-added formaldehyde adhesives. The emission limit values are reflecting a chamber concentration measured according to the ASTM E 1333 test method. Comparative values in the chamber test according to EN 717-1 are as follows: particle boards: 0.07 ppm (0.087 mg/m³); MDF > 8 mm: 0.12 ppm (0.15 mg/m³))[30]. Approved certifications are valid for 2 years, however manufacturers are obliged to conduct regular quality control testing and quarterly inspections by authorized certifiers are mandatory. If only NAF (no-added formaldehyde) and/or ULEF (ultra-low emitting formaldehyde) resins are used in construction, manufacturers may apply for an exemption from the third-party certification requirements[31].

In 2019, Canada published its draft regulation on formaldehyde emissions from composite wood for indoor use[32], which will become effective 180 days after its publication in the Canada Gazette (Part II) under the authority of the Canadian Environmental Protection Act, 1999 (CEPA). Publication is targeted for 2020. The proposed formaldehyde emission standards are identical to those used in the US CARB (hardwood plywood and laminated products: 0.05 ppm; particle board: 0.09 ppm; MDF: 0.11 ppm; thin MDF: 0.13 ppm; measurements according to ASTM E1333 or ASTM D6007).

Voluntary limit values

In addition to the rules laid down in the different national regulations, several voluntary national and EU-wide recommendations and certification programs exist for materials used in construction, of which several are described below.

The EU-ecolabel, for example, established criteria for wood-, cork- and bamboo-based floor coverings.

The EU-Ecolabel specifies, that floor coverings manufactured by using formaldehyde-based core boards, adhesives, resins or finishing agents that are used or manufactured by using formaldehyde-based adhesives or resins have to fulfil either of the following points to get certified[33]:

[29] https://legacy-uploads.ul.com/wp-content/uploads/sites/2/2017/01/10435-EPA-FA-White-Paper_FINAL-2.pdf
[30] https://www.ihd-dresden.de/fileadmin/user_upload/pdf/IHD/Service/Projektberichte/2011/ 09_Formaldehyd-Online_Messung.pdf
[31] https://www.chimarhellas.com/mlS8RYRg7/images/publications/files/formaldehyde_2008.pdf
[32] http://gazette.gc.ca/rp-pr/p1/2019/2019-06-29/html/reg3-eng.html
[33] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017D0176&from=EN

- Formaldehyde emissions that are lower than 50 % of the threshold value allowing them to be classified as E1 as defined in Annex B to EN 13986+A1 (applying to all floor coverings and non-MDF/non-HDF core boards);

- Formaldehyde emissions that are lower than 65 % of the E1 as defined in Annex B to EN 13986+A1 threshold limit applying to untreated MDF/HDF core boards;

- Formaldehyde emissions that are lower than the limits set out in the California Air Resources Board (CARB) Phase II or the Japanese F-3 star or F-4 star standards.

With regard to wooden panels in general, the European Panel Federation (EPF) – an industry association – proposed a European-wide harmonisation of E1 as the minimum allowable standard for wood composite materials. In general, the EPF seeks to ensure that no panels circulate within Europe with an emission level above the E1 standard (i.e. E2). Accordingly, EPF members have committed to manufacture only in line with E1 (or lower) already since 2007. Moreover, in 2018 the EPF suggested introducing a new voluntary "market class", the ½E1 (or E0.5) standard, with an emission limit set at half the value of E1 when tested according to EN 717-1[34]. In the consultation (comment No 2627), the EPF commented that a lower emission level (i.e. "80 % below E1"), on the other hand, is considered to be disproportionate, even "industry threating and society harming". RAC notes that the proposed emission limit is not 80 % below E1, but rather 50-60 % below E1, a limit value within the range of ½E1, which was recently supported by the EPF.

With regard to national recommendations, the introduction of a voluntary ½E1 (E0.5) standard is also supported by the German Wood-Based Panel Federation (Verband der Deutschen Holzwerkstoffindustrie e.V.; VHI)[35].

Similarly, the Main Association of the German Wood Industry (HDH; Hauptverband der Deutschen Holzindustrie) favours such a low limit value for formaldehyde emission with regard to wood-based panels (i.e. ½E1), but rather advocates a mandatory EU-wide obligation to conform with this limit[36].

The Deutsche Bauchemie, a German association for manufacturers of construction-chemical products, likewise advocates a maximum formaldehyde emission limit of 0.124 mg/m³ under the conditions of the intended use during service life. In the consultation comments from the Deutsche Bauchemie, it was indicated that the possible formaldehyde emissions from construction chemical products are significantly lower than the E1 standard. Thus, they proposed in the consultation that the reference test method should only be used by the national enforcement bodies if, in cases of doubt, they want to check whether a product meets the requirements.

The French furniture manufacturers association (Union nationale des industries de l'Ameublement français) approves the currently proposed formaldehyde emission limit value of 0.124 mg/m³ (evaluated according to the EN 717-1) for wood-based panels (E1)[37]. In the consultation comments (No 2615), the French furniture manufacturers association further indicated that a lower limit value of 0.062 mg/m³ (=½E1 (E0.5); according to EN 717-1) is supported, particularly for specific articles and furniture elements containing wood-based panels (raw material, without coatings/coverings or laminated surfaces/edges). In the consultation comments, such a complementary requirement was suggested to replace measuring the emissions of complex/bulky items such as assembled furniture which is considered technically or economically not feasible (and which is incidentally an environmental aberration in terms of transport and waste production). The compliance of the raw materials used for a specific product with the ½E1 standard was proposed to allow an automatically guaranteed compliance with the formaldehyde emission limit value of 0.124 mg/m³ of the whole end product. This approach, however, would need further evidence showing

[34] https://europanels.org/wp-content/uploads/2019/05/CI024-18_Press-release-EPF-supports-the-Single-Market.pdf
[35] https://europanels.org/wp-content/uploads/2019/07/EUWID-Special-June-2019-EPF-plans-to-introduce-voluntary-emission-class-for-formaldehyde.pdf
[36] http://www.tischler-news.de/detail.asp?ID=1947
[37] https://www.hcsp.fr/Explore.cgi/avisrapportsdomaine?clefr=732

applicability of the method before its implementation. RAC further considers testing of construction elements, furniture, flooring or other articles made from E1 panels and carrying the (voluntary) CE label as needed, because formaldehyde may not only be released from the E1 panel but can also be released from paints, glues, fillers, foam, coatings/varnish, impregnations and other products to which formaldehyde/formaldehyde releasers were added and which were used in the production of the articles.

The Belgian Superior Health Council proposes a rather strict maximum formaldehyde emission value of 0.03 mg/m³ (¼E1 or E0.25) for wood composite materials, while the Flemish Indoor Environment Decree (IED) even recommends a guidance value of only 0.01 mg/m³ with an "intervention value" of 0.1 mg/m³ (measured after 28 days in accordance with EN 717-1)[38]. Respective members are obliged to implement these standards.

The French High Council for Public Health (HCSP) has just published an opinion on the guideline for the management of indoor air quality concerning formaldehyde (13 September 2019), highlighting the need to respect a 0.03 mg/m³ threshold indoors for chronic exposure to formaldehyde in order to protect the general population, especially considering the multiplicity of formaldehyde indoor sources[39]. Similarly, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) proposes to introduce an emission class corresponding to the A+ class (0.01 mg/m³) of the French labelling system. The French authorities proposed in the consultation (comment No 2733) to consider, in the restriction proposal, the labelling of articles placed on the market based on their formaldehyde emissions, as it is already mandatory in France for wood-based construction materials. Besides the mandatory labelling of construction products, AFFSET published a guideline on the limitations of VOC emission by construction products into indoor air (AFFSET, 2009[40]). Based on testing following ISO 16000 protocols, limit values after 28 days for formaldehyde are ≤ 0.01 mg/m³. For public buildings France has set long-term standards at 0.03 mg/m³ from 1 January 2015 with further reduction to 0.01 mg/m³ from 2023 (Décret no. 2011-1727[41]).

In 2016, the Italian Green Public Procurement (GPP) of construction works defines minimum criteria for construction works, with focus on energy consumption and other sustainability issues[42]. This regulation is strictly voluntary for construction works and construction products employed in public sustainable building projects. It contains minimum requirements on VOC emissions from wooden and wood-based materials that correspond to the E1 standard. In Italy, a stricter limit value, which corresponds to the French VOC class A (< 0.06 mg/m³, according to CEN/TS 16516 or ISO 16000-9 or equivalent standards) was established.

In Finland, the voluntary M1, M2 and M3 labelling system is available for building materials, fixture and furniture without padding or textile coverings used in ordinary workspaces and residences. Materials that have not been tested shall not be granted a classification label[43]. The aim of the classification is to enhance the development and use of low-emitting building materials. M2 refers to a formaldehyde emission limit of 0.01 to < 0.025 mg/m³, while products with M1 certification need to emit lower formaldehyde levels (< 0.01 mg/m³ at the age of 4 weeks, according to EN 717-1)[44]. M3 materials exceed the M2 criteria. The Finnish Association of Building Owners and Construction Clients (RAKLI), the Finnish Association of Architects (SAFA) and the Finnish Association of Consulting Firms (SKOL) all recommend their members the use of this classification system and especially the use of low emitting (M1) materials in order to achieve high-quality construction.

The Byggvarubedömningen (BVB) is a business association consisting of Sweden's major property owners and building contractors. Members of this association commit to a common standard, specifically with respect to environmental and health aspects. The certification

[38] https://cdnmedia.eurofins.com/corporate-eurofins/media/2290/kb_emissies_faq_v1_2_en.pdf
[39] https://www.hcsp.fr/Explore.cgi/avisrapportsdomaine?clefr=732
[40] https://www.eco-institut.de/en/portfolio/afsset/
[41] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000024909119&categorieLien=id
[42] https://cdnmedia.eurofins.com/corporate-eurofins/media/1069182/italian_environmental_criteria_for_construction_works_and_products.pdf
[43] https://m1.rts.fi/en/m1-criteria-and-the-use-of-classified-products-2d03887d-aa6a-4a66-ad3c-ce25a512cf38
[44] https://m1.rts.fi/en/emission-classification-of-building-materials-836edfcc-8e39-4ec5-abe1-ca2d52f78998

system only applies to relevant construction products for interior use, including wallboard, floor covering, sealing, paint, wallpaper, caulking, adhesive and putty. The recommended formaldehyde emission limit for such products is < 0.05 mg/m³ (according to EN 717-1), however formaldehyde concentrations of 0.05-0.124 mg/m³ are accepted for certification[45]. Certified products are marked with a green (recommended), yellow (accepted) or red (to be avoided) arrow pointing up, sideways or down respectively. On the product card the overall assessment is shown with a big arrow, while the respective content assessment is shown with a small arrow.

Members of the German Association of German prefabricated construction (Qualitätsgemeinschaft Deutscher Fertigbau; QDF) must comply with a rather strict formaldehyde emission standard (QDF Statue, 2015)[46]. Instead of E1, certified members are obliged to use wood composites e.g. for ceilings, walls or roofs that do not exceed a formaldehyde emission limit of 0.03 ppm (0.037 mg/m³; close to ⅓E1 or E0.33), measured in accordance with EN 717-1. For additional interior constructions (e.g. panels, parquet flooring, laminate flooring), wooden composite materials need to comply RAL-UZ 38 „Blue Angel".

The RAL UZ-38 "Blue Angel" eco-label refers to ready-to-use indoor furniture and slatted frames made predominantly (> 50 % by volume) of wood and/or wood-based materials (chipboards, core boards, fibreboards, veneer-faced boards, each non-coated or coated)[47]. For manufacturing RAL-UZ 38 conform product, only wood-based materials marked with the RAL-UZ 76 "Blue Angel" eco-label are allowed or E1 conform materials can be used. The finished products, however, must not exceed a limit emission of 0.05 ppm (0.062 mg/m³) (after 28 days according to the BAM test method, which is based on EN ISO 16000-9).

The RAL-UZ 76 "Blue Angel" eco-label, in turn, refers to all panel-shaped materials used for interior construction and furnishing[48], specifically to chipboards, fibreboards, MDF, plywood panels, solid wood panels, OSB panels (OSB - oriented strand board), wood-component panels, as well as high-pressure decorative laminates (HPL) and boards from expanded glass. Those materials must not exceed a formaldehyde emission level of 0.08 mg/m³ after 28 days if measured according to EN 16516 (loading factor of 1.4 m²/m³ for all products). If measured according to EN 717-1, a limit value of 0.03 ppm (0.037 mg/m³) shall not be exceeded. Thus, formaldehyde emission limits for RAL-UZ 76 panels comply with the Japanese emission class F**** (close to ⅓E1 or E0.33).

Similarly, the RAL-UZ 176 "Blue Angel" eco-label was specifically developed for ready-to-use interior floor coverings as well as to panels and interior door elements, if those products consist predominantly (> 60 % by volume) of wood and/or wood-based materials (chipboards, core boards, fibreboards, veneer-faced boards, each non-coated or coated), including parquets, laminates, linoleum, cork and other materials on wood-based substrates)[49]. For manufacturing such products, the same emission limit values apply as for RAL-UZ 38 products.

The German TÜV PROFiCERT system was developed specifically for wooden and wood-based construction products used indoors and interior superstructures[50]. The system proposes four different standard classes: the TÜV PROFiCERT-product Interior Standard, the TÜV PROFiCERT-product Interior Standard with additional quality assessment, the TÜV PROFiCERT-product Interior PREMIUM standard, as well as the TÜV PROFiCERT-product Interior PREMIUM standard with additional quality assessment. Besides meeting other quality criteria, the formaldehyde emission of certified products is limited. For receiving the TÜV PROFiCERT-product Interior Standard (with and without additional quality assessment), a formaldehyde emission limit of 0.06 mg/m³ according to EN 16516 is required. A limit of 0.01 mg/m³ according to EN 16516, on the other hand, is mandatory for the TÜV PROFiCERT-

[45] https://byggvarubedomningen.se/globalassets/engelska/criteria-3.0.pdf
[46] https://www.fertigbau.de/bdf/wer-wir-sind/qualitaetsgemeinschaft/
[47] https://www.eco-institut.de/wp-content/uploads/2017/04/038-1301-e.pdf
[48] https://produktinfo.blauer-engel.de/uploads/criteriafile/en/DE-UZ%20076-201602-en%20Criteria.pdf
[49] https://www.eco-institut.de/wp-content/uploads/2017/04/176-1301-e.pdf
[50] https://www.proficert.de/content/e1556/e3460/VergabekriterienTVInterior-V10_2016-09_ger.pdf

product Interior PREMIUM class (with and without additional quality assessment).

The Austrian Ecolabel can be received for wood in general, for wood-based (construction) materials and floorings made of wood, if a formaldehyde limit value of 0.062 mg/m³ is not exceeded after 28 days acc. to EN 717-1 (Austrian Ecolabel Guideline UZ 07)[51,52]. For surface-treated wood-based materials a concentration limit of 0.037 mg/m³ (acc. to EN 717-1) is applied.

For receiving the "top" and "premium" mark of the German Qualitätsgemeinschaft Holzwerkstoffe e.V. a formaldehyde emission of 0.124 mg/m³ and 0.062 mg/m³, respectively, must not be exceeded for chip and particle boards (acc. to EN 717-1)[53].

The eco-institute-label developed formaldehyde emission limits for wooden and wood-based floorings, laminate and panels. The limit value is 0.036 mg/m³, according to EN 717-1[54].

The international "natureplus" eco-label system requires that every building product which is awarded this label has to fulfil several minimum criteria for the relevant product category. "In the case of products which are comprised of several system components e.g. thermal insulation composite systems, floor coverings on carrier boards, bricks/blocks with integrated insulation etc., the criteria contained within the product guidelines for the individual components shall also apply"[55]. For plywood boards, porous and hard/medium wood-fibre bards, chip and particle boards, OSB for construction purposes, laminated wood-based boards, as well as MDF boards a formaldehyde emission limit of 0.036 mg/m³ (acc. to TM-01) is needed to get certified. The same holds true for interior doors made from wood, wood-based materials and adhesive-bonded wood products for construction purposes. For wood and wood-based flooring two categories are distinguished: solid un-glued products with an emission limit of 0.036 mg/m³ and glue-laminated products with a formaldehyde emission threshold of 0.048 mg/m³. The proposed test method is the "TM-01 for Volatile Organic Compounds VOC/TVOC, formaldehyde, acetaldehyde and TSVOC" (DIN EN ISO 16000 series expanded by the natureplus implementation rules).

The Indoor Air Comfort and Indoor Air Comfort Gold label by Eurofins can be received for glues, sealing compounds and paints, textile and elastic flooring, but also for wood-based flooring and plasterboards[56]. These materials need to emit lower formaldehyde levels than 0.06 mg/m³ and 0.01 mg/m³ (according to EN 16516) to get certified with the Indoor Air Comfort and Indoor Air Comfort Gold mark, respectively.

The internationally accepted UL GREENGUARD Certification Program was developed introducing formaldehyde and other VOC emission standards for products designed for indoor use, incl. construction materials. It is divided into two classes, the UL GREENGUARD standard and the UL GREENGUARD Gold standard. The latter "includes health-based criteria for additional chemicals, and also requires lower total VOC emissions levels to ensure that products are acceptable for use even in the most sensitive environments such as schools and healthcare facilities"[57]. Product-specific requirements specify that "hardwood plywood (HWPW), particle board (PB), and medium density fibreboard (MDF) used by panel manufacturers, third party certifiers, distributors, importers, fabricators, retailers and in finished goods certified under this standard shall meet the California Air Resources Board (CARB) Airborne Toxics Control Measure (ATCM) to Reduce Formaldehyde Emissions requirements for Composite Wood Products" to comply and get certified[58]. Finished products shall not emit higher formaldehyde levels than 0.062 mg/m³ and 0.009 mg/m³ to receive the UL GREENGUARD standard and the UL GREENGUARD Gold standard, respectively (measured

[51] https://www.umweltzeichen.at
[52] https://www.umweltzeichen.at/file/Richtlinie/UZ%2007/Long/UZ07_R9.0a_Holzwerkstoffe%20und%20Holzfu%C3 %9Fb%C3 %B6den_2019.pdf
[53] https://qg-holzwerkstoffe.de/wp-content/uploads/2016/12/Qualitaetsbestimmungen-Spanplatten.pdf
[54] https://www.eco-institut-label.de/wp-content/uploads/2017/10/eco-INSTITUT-Label_Pruefkriterien_Holzfussbo%cc%88den-20170928-CV.pdf
[55] https://www.natureplus.org/index.php?id=43&L=2
[56] https://www.eurofins.com/media/1899/specifications_indoor_air_comfort_v5-3a-de.pdf
[57] https://legacy-uploads.ul.com/wp-content/uploads/sites/2/2017/01/10435-EPA-Formaldehyde-White-Paper_FINAL-2.pdf
[58] http://cromarbo.be/documentsPDF/certification-greenguard.pdf

acc. to UL 2821: GREENGUARD Test Method for Building Products and Furnishings)[59, 60].

In addition to the product-specific voluntary certification systems, several voluntary certification standards exist with regard to indoor air quality in buildings, in general.

The non-profit organisation U.S. Green Building Council (USGBC), for instance, has developed the LEED (Leadership in Energy and Environmental Design) Green Building Rating System. By using the LEED one can collect points by fulfilling "credits" for proper consideration of environmental aspects, like saving of energy and of resources, recyclability, but also indoor air quality, e.g. by using low-emitting materials (Oppl and Augustin). LEED is becoming more and more accepted worldwide. However, LEED does not apply to products but only to buildings. Building projects that want to consider LEED can follow the product approach, where “all products out of several product categories are evaluated” separately[61]. The product approach implies that 100 % of each of the installed product categories, such as composite wood or furniture, must comply with the requirements on low VOC emissions in order to get LEED points. On the other hand, the system approach can be followed, where emission limits are not established for single products but rather for “all products going into a surface, e.g. a floor or a wall”[62]. To receive LEED “points”, composite wood materials shall comply with CARB specifications for formaldehyde emissions.

Similarly, the British BREEAM (Building Research Establishment's Environmental Assessment Method) is an approach for promoting and certifying sustainable buildings, ranking them from A+ to E, where A+ represents the best environmental performance/least environmental impact, and E the worst environmental performance/most environmental impact[63]. Here again, products cannot be certified but rather buildings can receive certification for sustainability. However, a product can be certified by BRE and listed in BRE Global's Green Guide based on its environmental profile for showing that the product can be used in a BREEAM assessment to help achieve credits, but low emissions are not an element of that certification. Thus, the use of low emitting materials in general can be helpful to receive credit points and fulfilment of certain requirements is obligatory for receiving BREEAM certification. For wooden panels the minimum requirement is the E1 formaldehyde emission standard.

The French Haute Qualité Environnementale (HQE) is a similar approach for promoting and certifying sustainable buildings in accordance with the HQE approach. Using this approach four certification levels can be distinguished with regard to formaldehyde emission: all products on floor, wall and ceiling must emit lower formaldehyde levels than 0.063, 0.04, 0.02 and 0.01 mg/m³, respectively. The lower the emission the more points can be granted[64]. Specific limitations for wood composites are not mentioned.

Likewise, the Green Star program, an internationally recognised sustainability rating system, is available in Australia[65], New Zealand[66] and South Africa[67]. Again, products cannot be certified, but the use of compliant products can help building projects to collect additional points for a higher sustainability rating. Minimum criteria are the use of 100 % E1 (or lower) wood composite materials (including particle board, plywood, MDF, laminated veneer lumber (LVL), high-pressure laminate (HPL), compact laminate and decorative overlaid wood panels)[68].

The German Society for sustainable construction (Deutsche Gesellschaft für Nachhaltiges

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[59] https://www.ul.com/sites/g/files/qbfpbp251/files/2019-04/Watching-your-CARBs-Webinar-FINAL-for-posting.pdf
[60] http://cromarbo.be/documentsPDF/certification-greenguard.pdf
[61] https://www.eurofins.com/certifications-international-approvals/voc/leed/
[62] https://www.eurofins.com/certifications-international-approvals/voc/leed/
[63] http://interfaceinc.scene7.com/is/content/InterfaceInc/Interface/EMEA/WebsiteContentAssets/Documents/Certificates/BREEAM/wc_eu-breeamcontribution.pdf
[64] https://www.certivea.fr/uploads/documents/3b5504-GP_REF_NFHQEBT_NEUF_20150619.pdf; https://www.eurofins.com/media/1956/leed-a-new-challenge-for-low-voc-emitting-materials.pdf
[65] https://new.gbca.org.au/green-star/
[66] https://www.nzgbc.org.nz/GreenStar
[67] https://gbcsa.org.za/
[68] https://new.gbca.org.au/green-star/rating-system/; https://www.gbca.org.au/uploads/147/35475/IEQ_Reduced%20Exposure%20to%20Pollutants_DRAFT_D1_distributed.pdf; https://www.eurofins.com/certifications-international-approvals/voc/sustainable-buildings/;

Bauen, DGNB) is an association for promoting and certifying sustainable buildings. Complying with these standards include a strict compliance with rather high indoor air quality. The concentration limit for complying with regard to formaldehyde is set to 0.1 mg/m³ air, measured within the area that shall be certified according to DIN ISO 16000-3 maximum 4 weeks after completing the building. Limit values for specific product categories do not exist, but the use of low emitting products inside the building is recommended for earning certification[69]. One exception is flooring installation, which has to be labelled with the "Blue Angel" and/or EMICODE.

The EMICODE® is a label to certifying low VOC emissions into indoor air from adhesives, sealants, parquet varnishes and other construction products, including wood flooring coatings[70]. The specific formaldehyde emission limit for EMICODE®-labelled products is identical for all 3 EMICODE classes (EC1plus, EC1 and EC2): 0.05 mg/m³ (measured after 3 days in a test chamber according to[71]). Wood-based materials and panels are not subject to EMICODE labelling.

Furniture, toys and other relevant materials

Mandatory and voluntary national limit values within and outside the EU

The Danish government imposes a formaldehyde emission limit of 0.124 mg/m³ for wood-based materials used in the manufacture of furniture and related parts. However, the limit value does not apply to existing furniture and parts that comply with current Danish standards, and those manufactured for export to non-EU countries. Moreover, construction products and furniture padding and upholstery are also excluded and an additional limit value of 0.134 mg/m³ was added for sales of fixed and movable objects, which also includes furniture and kitchen elements (both limit values according to EN 717-1)[72].

The French authorities notified the European Commission in 2017 on a draft order[73] and a decree[74] regarding the labelling of wood-based furniture products with respect to their formaldehyde emission levels. As outlined in the proposal, the Regulation will apply on 1 January 2020, for products placed on the market after that date. For products placed on the market before this, it will apply from 1 January 2021. As with wood-based construction materials, the proposed regulation distinguishes four different classes based on their formaldehyde emission: A+ (< 0.003 mg/m³), A (< 0.005 mg/m³), B (< 0.01 mg/m³) and C (≥ 0.01 mg/m³). The method for characterising formaldehyde emissions from furniture products in indoor air is EN 16000-9.

In 2014, Russia implemented the so far strictest formaldehyde emission limit known specifically for the safety of furniture: 0.01 ppm (0.012 mg/m³) formaldehyde (according to TP/CU TC 025/2012)[75]. The Technical Regulation CU TR 025/2012 on safety of furniture was adopted in the framework of the Customs Union between Russia, Belarus and Kazakhstan by the Decree No 32 of 15 June 2012 of the Commission of the Customs Union and came into force on 1 February 2014[76].

For furniture that complies with the EU-ecolabel the following applies, specifically with regard to formaldehyde emission, and only if the content of wood-based panels in the final furniture product (excluding packaging) exceeds 5 % w/w[77].

"Formaldehyde emissions from all supplied wood-based panels, in the form that they are used in the furniture product (in other words, unfaced, coated, overlaid, veneered), and which were

[69] https://static.dgnb.de/fileadmin/de/dgnb_system/Nutzungsprofile/innenraeume/kriterien/04-SOC1.2-Innenraumluftqualitaet.pdf
[70] https://www.emicode.com/wp-content/uploads/2019/05/EMICODE_Webbroschur2015_engl_2.pdf
[71] https://www.emicode.com/methode/
[72] https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2017&num=89
[73] https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2017&num=23
[74] https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2017&num=22
[75] https://ivth.org/content/download/taho2014/Vortrag_Schwab.pdf
[76] http://www.ccis-expertise.com/pdf/cu-tr-025-2012.pdf
[77] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D1332&from=EN

manufactured using formaldehyde-based resins shall either:

- Be lower than 50 % of the threshold value allowing them to be classified as E1.
- Be lower than 65 % of the E1 threshold value, in the case of Medium Density Fibreboard (MDF) panels.
- Be lower than the limits set out in the CARB Phase II or the Japanese F-3 star or F-4 star standards."

For textile floor coverings, formaldehyde concentration of 0.01 mg/m³ shall not be exceeded in the chamber test according to ENV 13419-1 (with EN ISO 16000-3 or VDI 3484-1 for air sampling and analysis).

The European Furniture Industries Confederation (EFIC) agreed to the EPF's statement regarding a common EU-wide legislation for the production, import and marketing of wood-based panels and of products made from them and recommended a formaldehyde emission limit that is in line with the E1 emission class at the maximum (EPF/EFIC, 2015). Recently, they further indicated that a formaldehyde emission limit below E1, i.e. ½E1 (E0.5, according to EN 717-1) should be mandatory within the EU[78].

The Austrian Ecolabel can be received for (textile covered) furniture, if the used wood-based materials emit lower formaldehyde levels than 0.062 mg/m³ according to EN 717-1 (Austrian Ecolabel Guideline UZ 06)[79]. In the specific case of textile covered armchairs, a limit value of 0.06 mg/m³ (acc. to EN 16516)[80] applies to the finished product and not to the materials used (Austrian Ecolabel Guideline UZ 54). Toys made of glued wood cannot emit higher formaldehyde concentrations than 0.037 mg/m³ (acc. to EN 717-1; Austrian Ecolabel Guideline UZ 73)[81].

The RAL UZ-38 "Blue Angel" eco-label refers to ready-to-use indoor furniture and slatted frames made predominantly (> 50 % by volume) of wood and/or wood-based materials (chipboards, core boards, fibreboards, veneer-faced boards, each non-coated or coated)[82]. For manufacturing RAL-UZ 38 conform product, only wood-based materials marked with the RAL-UZ 76 "Blue Angel" eco-label are allowed or ½E1 conform materials can be used. The finished products, however, must not exceed a limit emission of 0.05 ppm (0.062 mg/m³) (after 28 days according to the BAM test method (Method for the measurement of emissions of formaldehyde and other volatile organic compounds based on DIN EN ISO 16000-9)). The RAL UZ 120 was designed for elastic floorings[83], while RAL UZ 119 and 117 cover matrasses[84] and upholstered furniture[85]. Formaldehyde emission limits are 0.06 mg/m³ (acc. to EN ISO 16000-9), 0.02 mg/m³ and 0.06 mg/m³, respectively, the latter two measured according to the BAM test method. The RAL UZ 128 for textile floorings (carpets) sets a formaldehyde emission limit of 0.02 ppm (0.025 mg/m³), measured according to DIN ISO 16000-28 in combination with VDI 4302[86].

The German TÜV PROFiCERT system, which is available for wooden and wood-based construction products with its four standard classes (TÜV PROFiCERT-product Interior Standard, TÜV PROFiCERT-product Interior Standard with additional quality assessment, TÜV PROFiCERT-product Interior PREMIUM standard, TÜV PROFiCERT-product Interior PREMIUM standard with additional quality assessment; see above) is also available for textile flooring. For receiving TÜV PROFiCERT-product Interior PREMIUM certification, the formaldehyde

[78] https://europanels.org/wp-content/uploads/2019/07/EUWID-Special-June-2019-EPF-plans-to-introduce-voluntary-emission-class-for-formaldehyde.pdf
[79] https://www.umweltzeichen.at/file/Richtlinie/UZ%2006/Long/UZ06_R9.0a_M%C3 %B6bel_2019.pdf
[80] https://www.umweltzeichen.at/file/Richtlinie/UZ%2054/Long/UZ54_R4a_Polsterm%C3 %B6bel_2019.pdf
[81] https://www.umweltzeichen.at/file/Richtlinie/UZ%2073/Long/UZ73_R1.0a_Spielzeug_2017.pdf
[82] https://www.eco-institut.de/wp-content/uploads/2017/04/038-1301-e.pdf
[83] https://produktinfo.blauer-engel.de/uploads/criteriafile/de/DE-UZ%20120-201102-de%20Kriterien.pdf
[84] https://produktinfo.blauer-engel.de/uploads/criteriafile/de/DE-UZ%20119-201801-de%20Matratzen.pdf
[85] https://produktinfo.blauer-engel.de/uploads/criteriafile/de/DE-UZ%20117-201801-de%20Kriterien.pdf
[86] https://produktinfo.blauer-engel.de/uploads/criteriafile/de/DE-UZ%20128-201602-de%20Kriterien.pdf

emission of such products is limited to 0.004 mg/m³ (acc. to EN 16516)[87].

The Golden M ("Das Goldene M") label was developed by the Deutsche Gütegemeinschaft Möbel e.V. particularly for furniture but is also applicable for matrasses. The formaldehyde emission limit required for certification with the best class (A) is 0.06 mg/m³ according to EN 717-1[88,89].

To receive the Nordic Swan Ecolabel for furniture and fitments the average emissions of formaldehyde must not exceed 0.124 mg/m³ air for MDF panels (E1) and 0.07 mg/m³ air for all other types of panels as determined by the current version of EN 717-1. The Nordic Swan Ecolabel is implemented in Sweden, Norway, Iceland, Denmark and Finland.[90] For toys, the "emission of formaldehyde shall on average not exceed 0.09 mg formaldehyde/m³ air for MDF boards and 0.07 mg/m³ air for all other boards when this is determined by the current version of EN 120 or similar methods approved by Nordic Ecolabelling"[91].

The Indoor Air Comfort and Indoor Air Comfort Gold label by Eurofins can also be received for furniture and textile flooring[92]. Furniture products need to emit lower formaldehyde levels than 0.06 mg/m³ and 0.01 mg/m³ (according to EN 16516) to get certified with the Indoor Air Comfort and Indoor Air Comfort Gold mark, respectively. Textile floorings even need to adhere to a formaldehyde limit value of 0.004 mg/m³ (acc. to EN 16516) for receiving the Indoor Air Comfort Gold mark. Testing of furniture includes the testing of a whole (complex) article; in the course of certification, a realistic scenario is being defined, incorporating the number of furniture pieces that would be located in a room of the size of the European Reference Room (12 m²). If more than one piece of the respective furniture category would be located in such a room, the formaldehyde emission rates of a single piece will be multiplied by the number of furniture pieces that is expected in the room. Using the resulting final emission rates, the formaldehyde air concentration in a European Reference Room is calculated.

The UL GREENGUARD Certification Program with its two classes (UL GREENGUARD standard and the UL GREENGUARD Gold standard) is also available for interior furnishing and cleaning and personal care products[93]. UL GREENGUARD certified products must not exceed a formaldehyde emission limit of 50 ppb (0.061 mg/m³), while UL GREENGUARD Gold certified products must exhibit a formaldehyde emission limit below 7.3 ppb (0.009 mg/m³) when using the UL 2821 GREENGUARD Test Method for Building Materials, Finishes and Furnishings[94,95]. For office seating there are specific rules in place for certification, including a formaldehyde emission limit of ≤ 0.0045 mg/m³ (≤ 0.00365 ppm)[96].

The Oekotex label covers textile products, but also includes matrasses, and upholstery. It distinguishes amongst others between materials with no direct contact with skin and decoration materials. Formaldehyde concentration limits are 150 mg/kg and 300 mg/kg, respectively. Formaldehyde emission limits are identical for both: 0.1 mg/m³ [97]. The test method of choice is not mentioned on the website, but according to a consultation comment is ISO 16000-9 or ISO 16000-11, plus ISO 16000-3 for formaldehyde determination by HPLC/UV. According to another consultation comment (No 2064), the National Bed federation

[87] https://www.proficert.de/content/e1556/e3460/VergabekriterienTVInterior-V10_2016-09_ger.pdf
[88] https://www.dgm-moebel.de/de/emissionslabel
[89] https://www.dgm-moebel.de/de/gesundes-wohnen
[90] https://www.svanen.se/contentassets/446952e937b44ba3b0ecb636d4875267/criteria-document_031_furniture-and-fitments-031_english.pdf
[91] https://www.svanen.se/contentassets/0b6f152941774e2e8ebe7dd97c93a989/criteria-document_095_toys-095_english.pdf
[92] https://www.eurofins.com/media/1899/specifications_indoor_air_comfort_v5-3a-de.pdf
[93] http://cromarbo.be/documentsPDF/certification-greenguard.pdf
[94] https://www.ul.com/resources/ul-greenguard-certification-program
[95] https://www.ul.com/sites/g/files/qbfpbp306/files/2019-05/GG_VOC_tables.pdf
[96] https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=2ahUKEwjajdm4jOXIAhUNNOwKHYJ-ANoQFjAAegQIAhAC&url=http%3A%2F%2Fgreenguard.org%2FLibraries%2FGG_Documents%2FGGPS_007_GGSelect.sflb.ashx&usg=AOvVaw2KbPdrNpU2P7XNeyos3fnq
[97] https://www.oeko-tex.com/importedmedia/downloadfiles/STANDARD_100_by_OEKO-TEX_R__-_Standard_de.pdf

supports the voluntary Oekotex certification system.

The CertiPUR (EuroPur) certification system measures a.o. VOC, including formaldehyde for flexible polyurethane foams used in comfort applications (bedding and furniture). A limit value of 0.01 mg/m³ formaldehyde shall not be exceeded for receiving certification. The following test methods are listed: ISO 16000-9 and ISO 16000-11, plus ISO 16000-3 for formaldehyde determination by HPLC/UV[98].

The Association of Environmentally Friendly Carpets e.V. (Gemeinschaft umweltfreundlicher Teppichboden; GUT) was developed by leading European carpet manufacturers in 1990[99]. Certification aims for improvement of environmental and consumer protection issues from the production process up to the phase of use and eventually recycling. According to GUT standards, carpets must not exceed a formaldehyde emission limit of 0.004 mg/m³ after 28 days in a chamber test. If the formaldehyde concentration is lower than 0.01 mg/m³ at day 3 of testing, the chamber test might be terminated, as it is considered "guaranteed that in such a case also the 28-day criteria will be complied with"[100].

IKEA informs on their internet platforms to have lowered formaldehyde content and emissions from their products since 1986 aiming average emissions of 0.05 ppm (½E1), banned the use of formaldehyde in paints and removing formaldehyde from adhesives used for gluing veneer coatings[101, 102].

A producer of office furniture voluntarily applies specific standards (ANSI/BIFMA M7.1 emission standards for testing on office workstations and furniture products. Consumer exposure scenarios are considered as office furniture is also used in private homes) (comment No 2060).

Several consultation comments were received (e.g. No 2604 and 2622), in which it was reported or even requested to introduce a ½E1 formaldehyde emission limit for wood-based panels. It was further indicated that by doing so, the production costs will be higher, but implementation of a mandatory ½E1 level would be feasible even without transition period. On the contrary, numerous consultation comments indicate that even a mandatory ½E1 level would have severe negative financial impacts (e.g. Nos. 2644, 2718, 2740, 2741).

Vehicle cabin interior

No legally binding limit exist which would guarantee that cars placed on the European market have formaldehyde cabin interior emissions as low that the RAC DNEL would not be exceeded.

Car manufacturers comply with a voluntary limit of 0.1 mg/m³ for cars placed on the European market. The limit value refers to measurement in the interior of the vehicle. A range of methods have been developed by ISO/TC 146/SC 6 for sampling of VOC and SVOCs from vehicle interiors and the materials used.

For other interior environments, public bus transport and other road vehicles, rail and water vehicles, and aircraft cabin, no information on binding or voluntary measures is available.

[98] https://www.europur.org/images/CertiPUR_Technical_Paper_-_Full_Version_-_2017.pdf
[99] http://www.pro-dis.info/about_gut.html?&L=0
[100] http://www.pro-dis.info/emission-test00.html?&L=0
[101] https://www.wki.fraunhofer.de/content/dam/wki/de/documents/Mediathek/themen/qa/puez/QA_IOS-MAT_2015-11_deutsch.pdf
[102] https://www.din.de/blob/75220/620e26748c603a7188312dd9e5ab0277/2010-03-formaldehyd-konformitaetssysteme-data.pdf; http://www.holzforschung.at/uploads/media/Mag0408_CH2O.pdf; https://de.scribd.com/document/376884574/IOS-MAT-0003

JUSTIFICATION IF ACTION IS REQUIRED ON A UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter states that risks associated with articles that may release formaldehyde in indoor environments need to be addressed on a Union-wide basis because of the following factors:

- Exposure takes place in all Member States from articles produced in the EU as well as from imported articles manufactured with the addition of formaldehyde or formaldehyde releasing substances and these goods are free to move within the Union.

- A number of Member States have established legislation to prevent or reduce the risk associated with indoor consumer exposure to formaldehyde from articles (in particular wood-based products). However, to date no EU-wide harmonised regulation of formaldehyde emissions from articles exists.

- Voluntary agreements to self-restrict formaldehyde emissions are in place in major EU industry sectors. European manufacturers of wood-based panels adopted a voluntary industry agreement to produce only panels complying with the formaldehyde emission class E1 as defined in the harmonised European Standard EN 13986. The voluntary emission limit adopted by European manufacturers of wood-based panels is also supported by the European furniture industry. Non-compliant articles can however still be placed on the EU market, due to manufacturers that have not subscribed to such voluntary agreements and/or extra-EU imports. A voluntary agreement is also in place by the automotive industry to limit the formaldehyde concentration in the interior of road vehicles to a maximum of 0.1 mg/m^3.

- The risks of health issues for consumers exposed to formaldehyde released from articles in indoor environments are considered not adequately controlled EU-wide.

SEAC and RAC conclusion(s):

SEAC and RAC agree that the health risks for consumers exposed to formaldehyde released from articles should be controlled on an EU-wide basis.

Based on the key principles of ensuring a consistent level of protection of human health across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that risks associated with formaldehyde should be addressed in all Member States.

Key elements underpinning the SEAC and RAC conclusion(s):

SEAC

The potential for consumer exposure to formaldehyde levels above the WHO guideline value persists in indoor environments under certain circumstances.

In the absence of a legally binding EU-wide measure, voluntary agreements to self-restrict formaldehyde emissions from articles might not be able to prevent producers who have not subscribed to such voluntary agreements and importers of articles produced outside the EU from placing high formaldehyde releasing materials on the EU market.

Moreover, at present, the existing national legislations can prevent only at national level the placing on the market of non-compliant wood-based panels releasing formaldehyde. These disparities may result in different levels of risk reduction across the EU.

RAC

RAC agrees with the Dossier Submitter's justification on the need of a Union-wide legislation. Due to Union-wide similarities in building construction and the Union-wide distribution of the broad range of articles, indoor exposure will occur in all Member States. RAC notes that the risk level should be equally low across all Member States. Available legislation concerns mainly construction materials/wood-based panels. Although some Member States have national regulations in place to limit formaldehyde emissions or to indicate emission classes (which alone has no effect on the placing on the market of formaldehyde-emitting articles), there is no enforceable EU-wide legislation. In line with the view of the Dossier Submitter, RAC supports the need of an EU-wide legislation.

For the same reasons (Union-wide use of vehicles, lack of legislations) an EU-wide legislation that covers vehicles of all kind (within the scope) will be the only option for vehicles.

JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

Non-REACH legislation and other measures have not been considered suitable by the Dossier Submitter for managing the identified risks. For this reason, a number of potential restriction options under REACH have been considered:

- RO1 – Full ban of formaldehyde releasing articles and mixtures: RO1 is disregarded by the Dossier Submitter as this option is considered neither consistent with the risk assessment nor proportionate to the risk.

- RO2 – Concentration limit for formaldehyde or specific formaldehyde releasing substances in articles and mixtures: RO2 is disregarded by the Dossier Submitter due to a number of uncertainties that make it difficult to link a concentration limit for formaldehyde and known (to date) formaldehyde releasers to formaldehyde emissions. In addition, an emission limit is considered more closely linked to inhalation exposure and hence to the actual risk.

- RO3 – Emission limit for wood-based panels consistent with formaldehyde emission class E1: The Dossier Submitter considers RO3 consistent with the risk assessment as wood-based panels are the major (permanent) source of formaldehyde emissions to indoor air and it would effectively reduce risks by preventing that high formaldehyde emitting class E2 wood-based panels are placed on the EU market. RO3 is considered proportionate, implementable and manageable. The Dossier Submitter states that while RO3 would ensure that only class E1 panels are used for the manufacturing of finished products such as furniture or laminate flooring in the EU, high formaldehyde emitting articles made from non-compliant panels could still be imported from outside the EU. RO3 is therefore disregarded in favour of RO4.

- RO4 – Emission limit for articles consistent with formaldehyde emission class E1: RO4 extends the emission limit described in RO3 to other articles (including, but not limited to, wood-based panels) as a further precaution against producing and importing additional formaldehyde emitting articles, in particular wood-based products such as furniture and laminate flooring.

Under both options, RO3 and RO4, the Dossier Submitter considers an emission limit lower than the one defined by the E1 emission class as not consistent with the risk assessment,

because indoor air formaldehyde concentrations measured in the EU are in the majority of cases below the WHO guideline value (0.1 mg/m^3). The Dossier Submitter concludes that, compared to the E1 emission limit, a lower emission limit would also not be supported by the available information from a proportionality point of view.

The proposal covers consumer articles that are used in indoor environments[103] as well as articles for both indoor and outdoor use (e.g. wood-based panels). Articles that are only meant to be used in outdoor environments are not included in the restriction proposal. The proposal covers articles where formaldehyde or formaldehyde releasing substances (formaldehyde releasers) are used in their production (either as such or in mixtures) and where formaldehyde is released during use as a result of either the "off-gassing" of residual formaldehyde or from the degradation and chemical reactions of other substances used in the production. The proposal does not cover articles produced without the use of formaldehyde or formaldehyde releasing substances. In such articles formaldehyde is either not released (because it is not present in the article, e.g. glass articles) or it can be only released by decomposition of substances that are naturally present in the material of the article (e.g. lignin degradation in solid wood) or as a result of combustion.

As well as in the interiors of buildings, the proposal aims also to reduce consumer exposure to formaldehyde in the interiors of vehicles (road, rail, air and water vehicles). In the specific case of road vehicles (e.g. cars, trucks, vans, buses and motor-homes) and aircraft the proposal is intended to restrict the placing on the market of articles where the interior concentration of formaldehyde exceeds 0.1 mg/m^3 under reasonably foreseeable conditions of use.

Formaldehyde concentrations in textiles worn on or near the skin are already limited by the restriction on CMR substances in clothing and footwear, i.e. Regulation (EU) 2018/1513 (implemented as entry 72 of Annex XVII of REACH). The Dossier Submitter therefore proposes to exempt articles subject to entry 72 of Annex XVII of REACH from the current restriction proposal. Articles not subject to the restriction on CMR substances in clothing and footwear, such as wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners, would however fall into the scope of the proposed restriction.

The Dossier Submitter also proposes an exemption for substances used as biocides under the Biocidal Products Regulation (BPR), i.e. Regulation (EU) 528/2012, because the Commission is already developing regulatory activities under BPR. BPR does however not apply to imported articles releasing formaldehyde from the use of substances for other purposes than biocide. Such articles would therefore be in the scope of the proposed restriction.

Based on the information received from stakeholders during the consultation and further advice from ECHA's Forum for Exchange of Information on Enforcement (Forum), the Dossier Submitter proposes additional derogations for articles subject to Regulation (EU) 2017/745 on medical devices, articles subject to Regulation (EU) 2016/425 on personal protective equipment (PPE), articles subject to Regulation 2011/10 on food contact materials, articles subject to Directive 2009/48/EC on toy safety, articles exclusively for industrial and professional use, as well as second-hand articles.

RAC conclusion(s):

The assessment performed by RAC has shown that the (P95/Max) indoor air concentrations of formaldehyde in houses/dwellings exceed 0.05 mg/m^3 in the majority of the available studies (see Table 5) and thus indicated an elevated RCR > 1. The existing voluntary agreements (e.g. to comply with formaldehyde emission class E1) did not succeed to demonstrate that sufficiently low concentrations were achieved.

RAC supports a broad restriction with an emission limit for all articles.

[103] Indoor environments are not limited to buildings but also include other environments such as cars, trucks, buses, trains, aircraft, mobile homes, or container homes.

Key elements underpinning the RAC conclusion(s):

RAC concludes that a restriction using an emission limit of 0.05 mg/m³ either measured in chamber experiments for articles used in building interiors (wood-based panels and other consumer products releasing formaldehyde within the scope of the restriction, e.g. furniture, flooring, wall coverings, etc.) under the conditions specified in Appendix X) or measured as cabin interior air concentration for vehicles of any kind in the scope of the restriction is consistent with the risk assessment as outlined in this document.

RAC judged the emission limit of 0.124 mg/m³ proposed by the Dossier Submitter measured under the conditions specified in Appendix X as insufficient (too high) to protect consumers against the risks. The Dossier Submitter proposal presents the status quo in several Member States and the voluntary target of industry sectors in place. Therefore, no significant improvement in consumer protection is expected by RAC by imposing the E1 level, while the risk of consumers in relation to the RAC DNEL of 0.05 mg/m³ has been identified. Therefore, RAC proposes a more stringent emission limit of 0.05 mg/m³ in the air of a test chamber (conditions prescribed in Appendix X) for building interior articles and 0.05 mg/m³ as concentration limit for cabin interior of vehicles of all kind.

The Dossier Submitter proposal and consideration of additional data by RAC documented that measured formaldehyde concentrations in conventional buildings exceed 0.05 mg/m³ under certain conditions.

In line with the Dossier Submitter, wood-based panels used as construction material and for the production of other articles (such as furniture or flooring material) have been identified as major sources that (in additional to additional short-term exposures not intended to be covered by this restriction proposal) pose a long-term risk for carcinogenicity and other health effects from formaldehyde exposure.

While some Member States have implemented a mandatory emission limit (E1) for wood-based construction products, no binding EU-wide limit exists. The Dossier Submitter indicated that European manufacturers agreed on a voluntary E1 standard that means that manufacturers in the EU and imported goods of non-EU-production may not comply with the E1 standard. Overall, RAC takes note of a rather complex situation with various limits and labelling schemes introduced in the countries, most on voluntary basis (see Table 19).

As RAC agreed on a DNEL of 0.05 mg/m³ and as a consequence derived a lower emission limit of 0.05 mg/m³ expressed as concentration in the test chamber measured under conditions of Appendix X, the established voluntary standard E1 in place since years is no longer considered as sufficiently protective. With regards to wood-based panels, the emission limit proposed by RAC corresponds largely to a number of voluntary formaldehyde emission classes (e.g. EU wide (EU Ecolabel E1/2 (0.06 mg/m³), or other labels in France (0.062 mg/m³), Sweden (< 0.05 mg/m³), Belgium (0.03 mg/m³), Finland (M1 < 0.01 mg/m³, M2 0.01-0.25 mg/m³ developed by the Finnish Society of Indoor Air Quality and Climate (FiSIAQ, 2001) and from other national/multinational organisations (see Table 19).

Lower obligatory emission limits than those proposed by RAC are in place in Japan (0.03 mg/m³), Australia and New Zealand agreed on emission limit of comparable size (0.06 mg/m³), from 2024 also binding for plywood and laminated products in the United States of America. Mandatory emission limits (above E1) can be observed in some nations (e.g. China, USA (for thin MDF only).

The majority of comments on behalf of European industry associations/manufacturers of wood-based panels expressed their agreement with the restriction as initially proposed by the Dossier Submitter (additional comments on the impact of lower emission values were only requested during the last phase of the consultation). This broad agreement on a restriction proposal that corresponds to the E1 standard is not surprising as the 97 % of the EU's total wood-based panel production shows already compliance with the E1 standard. A number of them are suggesting the deletion of the E2 level (which would to a larger extent affect the EU importers (32 % is the Dossier Submitter's estimate on total imported volume of E2 wood-based panels) and some propose a mandatory or voluntary ½E1 standard.

Some comments on behalf of companies recognised customer requirements and initiatives from some Member States and see an EU-wide need for an emission class below E1 (e.g. consultation comment No 2604). Although additional production costs due to slower operation are expected they suggest ½E1 (0.062 mg/m³) as technically feasible (consultation comments No 2604, 2622).

One producer of furniture proposed ½E1 for wood-based panels used in furniture production in order to guarantee the WHO guideline value without any further testing of their end product (consultation comment No 2615).

Numerous associations of producers/distributors of furniture, mattresses, textiles, toys have committed to lower emission rates than the E1 level. While some manufacturers of furniture declared to seek a level in the range/slightly below of E1, others aim to comply with the criteria of voluntary labels at much lower levels than 0.05 mg/m³ (minimum 0.01 mg/m³ or even lower 0.004 mg/m³ for textile floorings).

In conclusion, RAC notes that several EU countries already apply a mandatory formaldehyde emission limit for wood-based panels that is slightly lower than the E1 standard. However, no EU-wide harmonised regulation of formaldehyde emissions from articles exist, which may result in different levels of risk reduction across the EU.

At this level (~ E1), RAC expects exceedance of the RAC DNEL and RCR > 1 as assessed in the previous sections. Considering the RAC long-term DNEL, the existing E1 standard (0.124 mg/m³ as proposed by the Dossier Submitter) is not considered to represent an appropriate regulatory risk management measure for consumer protection from formaldehyde releasing articles, instead 0.05 mg/m³ (i.e. 40 %-E1, measured under the conditions specified in Appendix X) is proposed by RAC as emission limit (see previous section).

The numerous types of voluntary certification labels and marks further indicate that the production and use of wood-based panels with formaldehyde emission significantly lower than E1 (i.e. ½E1, ⅓E1 or even lower) is in fact already possible and common. With respect to furniture and other articles, such as matrasses or toys, considerably lower limit values are already in place on a mandatory and voluntary basis, respectively.

RAC agrees that other measures are not considered applicable to reduce the identified risks from articles placed on the market for consumer use. Concentration limits may actually be effective in reducing formaldehyde releases. However, the emission behaviour under the various article use conditions and types of materials and articles do not allow establishing a safe concentration limit, while what matters is the actual inhalation exposure resulting from the emissions. Other measures on parameters that have significant influence on the level of formaldehyde indoor concentrations like humidity, temperature and air ventilation may be taken into consideration, however, achieving EU-wide building performance guaranteeing permanent low levels of humidity, low temperature and effective ventilation is neither realistic nor practicable. Generally, preventing emission from the sources is the measure of first choice to control indoor air quality and user-dependent risk management measures (such as ventilation) to reduce air concentrations resulting from source emissions are not the most appropriate regulatory options.

Although limited, data for road vehicles (automobiles) also indicate frequent exceedance of the DNEL in the interior. The Background Document and consultation comments received informed on test methods following ISO 12219-1 standards and a voluntary approach to limit the interior air concentration to 0.1 mg/m³, which would be in line with Dossier Submitter proposal.

RAC agrees on a broad scope as proposed in RO4 including vehicles, but instead proposes a concentration limit of 0.05 mg/m³ for vehicle cabin interior. RAC agrees with the European Automobile Manufacturers Association (ACEA) that testing of the vehicle cabin air instead of testing individual construction components is the most suitable way to control formaldehyde concentrations in vehicles' interiors. As formaldehyde may be released from a wide range of vehicle components (articles and mixtures used in the production of vehicles), the options proposed under RO1, RO2 and RO3 will not be effective to control the formaldehyde

concentration in the interior of vehicles. Compliance with an appropriate concentration limit of 0.05 mg/m^3 will ensure that consumer risk arising from a multiplicity of potentially formaldehyde releasing components will be adequately controlled in the vehicles within the scope of the restriction proposal.

However, in order to ensure protection of passengers and drivers, RAC supports the broad scope of the restriction – as compared to the mutual resolution UNECE (2017) – applicable to various kind of passenger road vehicles including cabin interior of trucks, buses, caravans and other road vehicles. RAC is not aware of specific industry standards for these vehicles and points out that the necessary flexibility as regards to the development, implementation and application of appropriate harmonised testing standards in the EU and also used internationally by non-EU manufacturers should be granted for. ISO 12219-10 on Interior air of road vehicles (Part 10: Measurement methods of diffused volatile organic compounds (VOC) - Trucks and buses) is under development (drafting start date: June 2019[104]).

No information on established test methods and standards is available for passenger ships, trains or aircraft. Indoor (cabin) measurements in vehicles have been established by the automotive industry and are considered to be adaptable to other vehicles. Starting from the ISO norms for automobiles specific adaptations are needed for road vehicles other than automobiles, and, if inclusion is decided by the Commission, also for rail and water vehicles to develop standard testing procedures specific for these vehicle types. These new standards could be developed as EU (ISO) norms that include the relevant conditions of testing (temperature, ventilation rate, closed doors, etc.).

Justification for the opinion of SEAC

Summary of proposal:

See summary of proposal under *Justification for the opinion of RAC* above.

SEAC conclusion(s):

Risk management options

SEAC considers that, among the Union-wide risk management options analysed by the Dossier Submitter, the proposed restriction under REACH (referred to as RO4) seems to be the most practical, effective and efficient option to prevent consumer exposure to formaldehyde from high formaldehyde emitting articles.

SEAC agrees that a full ban of formaldehyde releasing articles and mixtures (RO1) would have substantial economic impacts, which would be disproportionate to the resulting benefits.

Similarly, SEAC agrees that setting a concentration limit for formaldehyde releasing substances in articles and mixtures (RO2) would not be effective in order to control emissions.

RO3 and RO4 appear to be similar options since they both propose an emission limit consistent with formaldehyde emission class E1 and since wood-based panels seem to be the main permanent sources of formaldehyde emissions.

However, SEAC considers RO4, including not only wood-based panels, more protective for human health than RO3.

In SEAC's view, taking into consideration the flexibility introduced by the Appendix X of the proposed restriction on the use of testing methods, RO4 can be considered as a proportionate risk management option.

Scope

SEAC agrees with the Dossier Submitter's revised and clarified text of the scope as defined in

[104] https://standardsdevelopment.bsigroup.com/projects/2018-02385

the Background Document, in which:

- only articles in which formaldehyde or formaldehyde releasing substances have been intentionally added in their production process are restricted;

- it is proposed road vehicles produced with the intentional addition of formaldehyde or formaldehyde releasing substances, where exposure to consumers can occur in their interior, shall not be placed on the market if the formaldehyde in their interior exceeds a concentration of 0.1 mg/m^3 as measured in accordance with the conditions specified in Appendix X;

- Appendix X on testing methods has been added;

- the "use" of articles exceeding the emission limit is not restricted due to the complexity of enforcement in line with the Forum advice;

- articles that are only for outdoor use under reasonably foreseeable conditions are derogated;

- articles exclusively for industrial and professional use, if formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use, are derogated;

- second-hand articles are exempted; and

- articles already regulated under other EU regulations are exempted.

Regarding aircraft, SEAC agrees with RAC that a concentration limit is not applied.

Regarding paragraph 10 of the restriction proposed by the Dossier Submitter (i.e. a derogation for articles subject to Directive 2009/48/EC on toy safety), SEAC supports a reference to Appendix C to Annex II Directive 2009/48/EC to avoid a regulatory gap for children over 36 months. SEAC has also assessed other requests for derogations received from industry (e.g. POM, tyres) but did not find sufficient grounds for further exemptions.

Limit values

SEAC supports the limit values proposed by the Dossier Submitter set at a level of 0.124 mg/m^3 for articles in scope and at a level of 0.1 mg/m^3 for interiors of road vehicles.

SEAC takes note that RAC does not agree with the Dossier Submitter that the WHO guideline value is sufficiently protective for the general population. Instead RAC derived a DNEL of 0.05 mg/m^3 (0.04 ppm; relevant equally for all indoor environments) for use in its evaluation. On this basis, RAC proposes limiting emissions exceeding 0.05 mg/m^3 in the air of a test chamber used under the conditions specified in Appendix X for articles in scope and a concentration limit of 0.05 mg/m^3 for interiors of road vehicle cabins.

SEAC recognises the higher protective potential of the limit values set by the RAC at the level of 0.05 mg/m^3 for articles included in the scope of the proposed restriction and for interiors of road vehicles. However, SEAC lack information on the additional health benefits associated with the lower limit values proposed by RAC.

SEAC notes that, in some applications, emission limit values lower than the existing E1 class proposed by the Dossier Submitter have already been implemented by part of the industry. SEAC notes that RAC shows in Table 19 (of the RAC opinion) the availability of selected products in accordance with the RAC proposal. However, SEAC notes that, in most cases, the main issue for industry to comply with a lower limit value, as proposed by RAC, seems to be mainly the economic feasibility and much less the technical feasibility if the transition period is large enough for industry to comply. The related economic consequences of a switch to a lower limit value are discussed in detail below in the section on costs.

From the information gathered during the consultation, SEAC notes that a limit value of 0.05 mg/m^3 as proposed by RAC seems technically feasible in some cases through the consistent use of a new generation resins/glues (melamine based aminoplast resins or resins based on MDI) and/or the use of special formaldehyde scavengers. However, this limit value also entails far-reaching changes in technology including modifications in production processes and new construction of industrial plants.

As discussed in the sections concerning costs and proportionality of the RAC proposal, SEAC considers that the limit value proposed by RAC appears to entail major socio-economic impacts for the whole EU society. In the consultation on the SEAC draft opinion, several industry stakeholders provided information on impacts of intermediate limit values between the RAC and the Dossier Submitter proposal – in particular, 0.08 mg/m^3 and 0.062 mg/m^3 (i.e. "half E1"), measured in accordance with the conditions specified in Appendix X. SEAC sees the adoption of an intermediate limit value as a possible compromise solution since it would potentially bring higher benefits than the proposal of the Dossier Submitter in front of technical challenges and socio-economic costs that seem to be considered bearable by several industry sectors, particularly if an adequate transition period was granted and specific time limited derogations foreseen.

SEAC considers that such intermediate limit values would potentially better protect particularly sensitive populations, such as children in kindergartens or in schools, residents of old people's homes and patients of hospitals who have almost 24 hours exposure to formaldehyde emitting articles. For such niches, there are already specialist suppliers of products that meet or fall below the RAC limit. SEAC is of the opinion that, if these niche products are available, solutions for special situations are on the market. Therefore, it seems unnecessary to impose the RAC limit as a general limit value for the whole EU economy.

Transition period

SEAC supports a transition period of 24 months in general and 36 months for trucks and buses for a restriction as proposed by the Dossier Submitter. If the RAC proposal were to be applied, the transition period would have to be tailored sector by sector and extend up to 10 years.

Testing methods and Appendix X

SEAC supports the Appendix X on testing methods as proposed by the Dossier Submitter. SEAC expects a greater need for method development to establish correlations between sector-specific measurement methods and the reference conditions proposed in Appendix X which are comparable to those specified in EN 717-1. For testing of very small articles that are demonstrably used at very low loading factors, SEAC supports the amendment of Appendix X to allow for more realistic loading factors. Further details are provided in the section *Key elements underpinning the SEAC conclusion(s)* below.

Alternatives

SEAC considers that, for the wood-based panels industry, limit values of formaldehyde emissions as proposed by the Dossier Submitter, can be reached without a switch to any alternative resin but a longer curing time may be needed in some cases.

For some articles other than wood-based panels (e.g. furniture, longitudinal beams for construction), SEAC notes that other formaldehyde-based or formaldehyde-free resins might have to be used to substitute UF resins in order to reduce formaldehyde emissions. SEAC notes that polyoxymethylene (POM) and rubber mixtures for tyres make only a very small contribution to the emission of formaldehyde. SEAC therefore sees no reason to replace POM and rubber mixtures for tyres in general.

If the RAC proposal was to be applied, a major change in the composition/chemistry of resins and formaldehyde scavengers is to be expected. Suitable alternatives do not appear to be available for all applications and, where they are, their availability may be limited.

Key elements underpinning the SEAC conclusion(s):

agreements and national regulations in some Member States, already exist and that formaldehyde concentrations measured in indoor environments in the EU are, in most cases, below the WHO Guideline for Indoor Air Quality (2010) of 0.1 mg/m^3. However, SEAC recognises that, in some Member States, consumers may still be exposed to formaldehyde concentrations exceeding the WHO guideline value. This is because the placing on the market of high formaldehyde emitting materials, such as class E2 wood-based panels used in construction (e.g. in ceilings and walls) or finished articles (e.g. furniture) is still allowed.

SEAC recognises that the proposed restriction is intended as a preventive measure that would lead to the harmonisation of national risk management measures related to the formaldehyde release from articles (mainly wood-based panels but also many others) across the EU.

After assessing all possible risk management options, SEAC considers RO1 (full ban of formaldehyde releasing articles and mixtures) not to be consistent with the risk assessment and with the unavailability of substitutes for all uses.

In SEAC's view, RO2 (concentration limit for formaldehyde or specific formaldehyde releasing substances in articles and mixtures) would not be effective to control emissions due to the uncertain link between formaldehyde emissions and a concentration limit.

RO3 (emission limit for wood-based panels consistent with formaldehyde emission class E1) leaves a regulatory gap for high formaldehyde emitting articles made from non-compliant wood-based panels imported from outside the EU (e.g. imported furniture) and non-wood-based articles in general. RO3 is therefore disregarded in favour of RO4.

Scope

SEAC notes that the scope of the restriction, as proposed by the Dossier Submitter, clearly indicates which articles are restricted and which ones are out of scope.

Articles in scope

SEAC agrees that the scope includes articles produced using formaldehyde or formaldehyde releasing substances as such or in a mixture if the formaldehyde released from them exceeds a concentration of 0.124 mg/m^3 as measured in accordance with the conditions specified in Appendix X.

SEAC agrees that the proposal should cover only articles in which formaldehyde or formaldehyde releasing substances have been intentionally added in their production process and where releases may occur as a result of off-gassing of residual formaldehyde present in the article or from degradation of the substances used in the production process.

SEAC notes that the scope includes the placing onto the market of road vehicles and aircraft produced with the intentional addition of formaldehyde or formaldehyde releasing substances where exposure to consumers can occur in their interior, if the formaldehyde in their interior exceeds a concentration of 0.1 mg/m^3 (i.e. the WHO guideline value) as measured in accordance with the conditions specified in Appendix X. With regard to aircraft, SEAC takes note of RAC's assessment that passenger risk is adequately controlled and agrees with RAC's conclusion that a concentration limit for aircraft is not applied.

SEAC notes that the proposed restriction affects in particular the wood-based panels industry as well as industry sectors that rely on wood-based materials:

- sector of wood-based panels (e.g. plywood, particleboard (PB), oriented strand board (OSB), medium density fibreboard (MDF)) and their downstream users, such as:

- furniture sector;

- construction sector;
- wood and wood-based panels recycling sector.

Different sectors manufacturing other articles are concerned by the scope of the proposed restriction. These include:

- the mineral wool insulation sector;
- automotive sector for articles in car interiors, for example flexible moulded foams for seat cushioning and parts for acoustic insulation, interior trim and foam sheets for headliners and lining for seats, armrests, door panels out of polyurethane and for the very small articles of polyoxymethylene (POM);
- manufacturers of complex articles (e.g. upholstered furniture with textile and leather) with foams made of polyurethane foam (PUF);
- textile sector (clothing, carpets, curtains, carpet flooring or wallcovering);
- leather sector;
- non-textile accessories, closures and trim elements;
- rubber tyres.

Derogations and articles out of scope

Articles produced without the addition of formaldehyde or formaldehyde releasing substances

SEAC agrees that articles produced without the addition of formaldehyde or formaldehyde releasing substances should be out of the scope. Such articles either do not release formaldehyde because it is not present in the article (e.g. metals, minerals, plastic materials produced from non-formaldehyde-releasing polymers, glass, ceramics etc.) or formaldehyde can be released by decomposition of substances naturally present in them (e.g. lignin degradation in grown solid wood) or as a result of burning processes.

Articles exclusively used outdoor

SEAC agrees with the exclusion from the scope of articles exclusively used in outdoor environments since risk concerns mostly indoor environments and these articles do not contribute to formaldehyde exposure in indoor air. The following non-exhaustive list includes examples of articles, which in SEAC's view, are exclusively for outdoor use: trellises, pagodas, wooden play equipment, car ports, equipment sheds, etc.

In their response to the consultation on the SEAC draft opinion, the European Insulation Manufacturer Association (EURIMA, ref. 486), confirmed that, for the limit value proposed by RAC, the inclusion of outdoor products in the restriction would trigger significant costs for the mineral wool insulation sector. EURIMA underlined that substantial investments and research would be needed to ensure the same performance in terms of e.g. conductivity and durability. The mineral wool sector supplies for indoor and outdoor applications. If this sector would not get an exemption for outdoor applications, according to EURIMA estimates, it would have more than eight times the annual costs if all products (indoor and outdoor) together had to meet the limit value proposed by RAC (€2 304 million) compared to the situation in which only indoor products would have to meet this limit value (€282 million). With the limit value proposed by RAC, SEAC sees a case for an exemption for outdoor grades of insulation material without risk of exposure to consumers. The outdoor grades could be sold to competent trade professionals via specialist retailers. The indoor grade of insulation materials should still be subject to the restriction. Accordingly, in the do-it-yourself sector, only quality for indoor use should be provided. Details on economic impacts are discussed in the section on *Costs* further below.

Regarding the comments of the European Tyre and Rubber Manufacturers' Association (ETRMA, ref. 465) SEAC sees a need for clarification with regard to the indoor and outdoor use of tyres. Apart from industrial tyres (see section on *Articles for industrial and professional use* below), other types of tyres more closely associated with consumer use exist. Tyres for children's pushchairs, wheelchairs, folding bikes and toys, including children's bicycles and scooters, can in SEAC's view be considered for both indoor storage/use and outdoor use. SEAC does not consider these types of tyres to be exempted from the proposed restriction. On the other hand, tyres for bicycles (e.g. larger than 24"), wheelbarrows, motorcycles, motor scooters, cars, motorhomes, vans, light trucks are, in SEAC's view, intended for outdoor use although SEAC acknowledges that there might be cases of seasonal storage of tyres intended for outdoor use in/near the home. SEAC supports an exemption according to paragraph 3 of the Dossier Submitter's proposal as far as these types of tyres intended for outdoor use are concerned.

Articles for industrial and professional use

SEAC supports the derogation for articles exclusively for industrial and professional use, if formaldehyde released from them does not generate exposure to consumers (paragraph 4 of the proposed restriction).

SEAC considers this derogation also covers articles which undergo further processing before being sold to industrial/professional end users, such as:

- articles for the core of sealed doors for fire-protection, noise reduction and anti-burglar resistance,
- transportation plywood/OSB boxes for packaging valuable and/or fragile cargo and dangerous goods,
- plywood/wooden composite materials for EURO pallets for transportation,
- poplar plywood, peeled wood strips, etc. for the packaging of fruits and vegetables,
- OSB, plywood and chipboard for shielding of outdoor construction sites,
- panels treated with fire retardants solely for industrial use,
- rubber for industrial tyres.

Certified doors for fire-protection, noise reduction and anti-burglar resistance cannot be drilled into or mechanically altered or there is a threat of losing the relevant certification. This ensures permanent sealing against possible formaldehyde emissions. In contrast to the exemption for such gas-tight sealed articles, SEAC considers that the core boards of laminated/coated boards for furniture and carpenter use should already be of E1 quality. This is important in view of the fact that, often, during the further processing of such articles to furniture and/or fixed wood-based installations in apartments (e.g. walk-in cupboards), the surface is opened by drilling holes in the panels to allow more flexibility in affixing fasteners in consumer use.

In addition, SEAC welcomes the derogation for industrial and professional use also with regard to the packaging industry. Valuable and/or fragile cargo is often packed in large plywood or OSB boxes. There are also certified plywood/OSB boxes for the transport of dangerous goods which have to pass several tests to be granted a certification. Essential points of the testing and approval requirements for wooden packaging are contained in the regulations of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) Volume II, Appendix A, Part 6. The test requirements for rail, sea and air transport do not differ significantly. These packaging materials are intended for the industrial sector and not for individual end users. The function of maintaining safety/security outweighs the risk of exposure to formaldehyde. There should also be no exposure for customers to formaldehyde in the intended use.

A comparable industrial/professional application without consumer exposure is the provision of wood-based materials (plywood, OSB, chipboard) for transportation. EURO pallets are standardised equipment for handling a vast range of products and consist of boards made of grown, natural softwood and spacers between the boards. These spacers are made of light poplar wood or composite materials consisting of pressed wood sawdust and a binder/glue.

In this context, SEAC supports a derogation for articles (e.g. poplar plywood, peeled wood strips, etc.) for the packaging of fruits and vegetables. With regard to food contact, these articles are not excluded from the scope of the proposed restriction per se since they are not regulated under Regulation 2011/10 on food contact materials since this regulation only relates to the use of plastics as food contact materials. For this reason, SEAC supports an exemption from the restriction for these light and flexible wood-based packaging materials. SEAC also considers it very unlikely that consumers would permanently store empty packaging of fruit and vegetables inside their dwellings. SEAC sees this example as an opportunity to reflect on whether the exemption should be extended to other food contact materials (i.e. those covered by Regulation 1935/2004). Apart from these lightweight plywood and chipboard packaging, so-called alternative "bio-packaging", which is not made of plastic, is coming more and more into the market. With this, SEAC would like to draw the Commission's attention to the fact that the current exemption only applies to plastics and that the Commission should possibly consider exempting other food contact materials.

During the consultation on the SEAC draft opinion, the European Panel Federation (EPF, ref. 461) underlined the reason for an exemption for packaging articles. EU requirements for wood packaging material are based on the 2002 FAO International Standard for Phytosanitary Measures (ISPM) n° 15. Under ISPM n° 15, all non-manufactured wood packaging materials – including wood pallets, crating and loose wood dunnage – must be treated, either by heat or fumigation. When used for packaging, manufactured wood products such as MDF, plywood, OSB, and particleboard, have the advantage to be exempted from the need to be treated since any pests are destroyed during the manufacturing process, avoiding in this way additional chemical load to the products.

The situation is similar when using e.g. OSB, plywood and chipboard for shielding of outdoor construction sites. This is also an industrial application without consumer exposure to formaldehyde. The application for construction sites is in the temporary protection of neighbouring areas against dust and noise as well as to restrict access. In the same way, large plywood boards are used as a basis for the labelling/explanation of construction site projects. In addition, formwork for concrete construction is often also made of various wood-based materials.

SEAC supports the derogation proposed in paragraph 4 also with respect to panels treated with fire retardants solely for industrial use. If this exemption would not be there, then all formulations of fire-retardant treated panels would have to be modified and new tests would have to be carried out. In terms of safety, protection against fire seems more relevant than protection against emissions of formaldehyde.

SEAC sees a similar situation for certain types of tyres and considers the exemption proposed in paragraph 4 to cover tyres for open mines, stone quarries, mines, agriculture, construction machinery, forklift truck, aircraft, heavy trucks, buses, etc. since these constitute industrial applications without consumer exposure.

In SEAC's view, the exemption for articles for industrial and professional use applies also to heavy trucks and special military and civil vehicles as these. Such vehicles appear to be more like workplaces rather than indoor environments that expose consumers to formaldehyde. On the other hand, light trucks are also often offered in rental car fleets as moving aids for private use. Such road vehicles can expose consumers to formaldehyde via indoor air comparable to the use of cars and buses. It seems useful to SEAC to distinguish between light and heavy trucks. A limit to draw this distinction could be a total vehicle mass of 7.5 t, as many private driving licenses in the EU allow the use of vehicles up to 7.5 t total mass without additional training as professional drivers.

Exemption for second-hand articles

For second-hand articles, available information from stakeholders indicates that:

- used wood-based panels and construction materials, for instance after demolition, are unlikely to be placed on the second-hand market,

- furniture is more likely to be placed on the second-hand market via Internet or in specialised shops,

- in most cases, formaldehyde emissions from other types of articles are below the limit of the restriction proposal already when they are first placed on the market.

In the majority of cases, formaldehyde releases decrease over time (as off-gassing of residual formaldehyde occurs) hence releases from articles sold (or transferred) as second-hand articles, are expected to be very limited. However, SEAC notes that the available information, was not enough for the Dossier Submitter to perform a quantitative assessment of the risks posed by second-hand articles.

In addition, based on advice received from ECHA's Forum for Exchange of Information on Enforcement (Forum), the enforcement of second-hand articles seems extremely problematic.

For these reasons, SEAC supports the exemption of second-hand articles from the proposed restriction.

Exemptions for articles already regulated under other regulations

Issues concerning potential double regulation have been raised during the consultation in particular for toys (ref. 2002), construction materials (ref. 2081 and 2207), food contact materials, medical devices and personal protective equipment (ref. 2173, 2444).

By introducing some exemptions, in the Background Document, the Dossier Submitter clarified which articles are already subject to other regulations and thus do not fall under the scope of the proposed restriction.

The proposed exemptions concern the following articles:

- Articles subject to Regulation (EU) 2017/745 on medical devices because such devices have to fulfil specific requirements in terms of safety and functionality.

- Articles subject to Regulation (EU) 2016/425 on personal protective equipment (PPE), because such equipment needs to fulfil specific safety requirements and to ensure their functionality.

- Articles in the scope of Regulation 2011/10 on food contact materials, as emitting substances used in food contact materials (mostly MF plastics) are expected to have a very low potential of releasing formaldehyde in indoor environments and it can be reasonably assumed that their use by consumers will be limited to short periods. Drinking water is considered the number one foodstuff. In this respect, SEAC expects that components of water meters and brewing heads of coffee machines, e.g. made of polyoxymethylene (POM), are primarily subject to Regulation 2011/10 and are not subject to the formaldehyde restriction. As already mentioned above, SEAC sees room to reflect on whether the exemption should be extended to other food contact materials (i.e. those covered by Regulation 1935/2004).

- Articles subject to Directive 2009/48/EC on toy safety. The emission limit in resin-bonded wooden toy materials coincides with the emission limit of the current restriction proposal by the Dossier Submitter.

- Articles subject to the existing restriction on CMR substances in clothing and footwear (Entry 72 of Annex XVII of REACH implementing the Regulation (EU) 2018/1513). In fact, entry 72 already established limits on formaldehyde concentrations in textiles worn on or near the skin. Since formaldehyde is very unlikely to cause cancer through dermal exposure unless present at very high concentrations, the limits established by Regulation (EU) 2018/1513 are considered to be protective enough. These articles are significantly below the concentration of 0.2 % for skin sensitisation. In addition, the contribution of articles subject to entry 72, is unlikely to significantly contribute to inhalation exposure. Textile articles (such as wall-to-wall

carpets and textile floor coverings for indoor use, rugs and runners) not subject to Regulation (EU) 2018/1513 will be subject to this current restriction proposal and they will have to comply with the emission limit proposed.

- Substances used as biocides under the Regulation (EU) 528/2012 (BPR) on Biocidal Products because the Commission is already developing regulatory activities. Specifically, formaldehyde is listed in Annex II to the Review Programme Regulation to be evaluated by Germany for the disinfectants and algaecides not intended for direct application to humans or animals, veterinary hygiene, and embalming and taxidermist fluids. However, included in the scope of the current restriction proposal are articles to which BPR does not apply such as imported articles releasing formaldehyde from the use of substances for other purposes than biocide.

SEAC notes that for PPE potentially there could be inhalation exposure of individual consumers. However, as pointed out by the Dossier Submitter in the Background Document, SEAC considers that such equipment needs to fulfil specific safety requirements to ensure protection of EU workers.

As far as food contact materials are concerned, SEAC notes that in the Background Document the derogation is proposed by the Dossier Submitter because food contact materials are considered unlikely to significantly contribute to the formaldehyde concentration in indoor environments. This is due to the low release potential of the formaldehyde emitting substances used in food contact materials (mostly MF plastics) and it can be reasonably assumed that use by consumers is not continuous and limited to short periods.

In conclusion, SEAC supports the above-mentioned derogations for articles subject to other EU regulations but, in view of comments received in the consultation on the SEAC's draft opinion, SEAC sees the need for the following modifications/clarifications:

SEAC notes the comment from Denmark (ref. 460) that proposes to fill the regulatory gap for emissions of formaldehyde for toys for children over 36 months.

The derogation related to Directive 2009/48/EC on toy safety is considered too broad according to the comment by Denmark. The Commission Directive amending Appendix C to Annex II to Directive 2009/48/EC on toy safety (adopted in November 2019) establishes an emission limit of 0.1 ppm for formaldehyde in resin-bonded wood toy materials which corresponds to the proposed limit value in the SEAC draft opinion of 0.124 mg/m^3. However, the limit values in Appendix C to Annex II to Directive 2009/48/EC are only applicable for toys for children under 36 months or in other toys intended to be placed in the mouth.

Consequently, by derogating Directive 2009/48/EC from the restriction, toys for children above 36 months and toys not intended to be placed in the mouth, will be allowed to emit formaldehyde in high concentrations, as these toys are outside the scope of both the proposed REACH restriction and the restriction in Directive 2009/48/EC. According to Denmark, the most obvious solution would be to introduce the restriction in Directive 2009/48/EC, but it is not possible to amend Directive 2009/48/EC with new limit values for chemicals for toy for children above 36 months or toys not intended to be put in the mouth. Since the intention of the proposed restriction is to protect consumers exposed to formaldehyde against adverse health effects, SEAC considers it important to close this gap by ensuring that toys for children above 36 months are covered too. Therefore, SEAC supports the Danish proposal and suggests that the derogation related to Directive 2009/48/EC on toy safety (i.e. paragraph 10 of the restriction proposed by the Dossier Submitter) is phrased as follows: "By way of derogation, paragraph 1 shall not apply to articles covered by Appendix C to Annex II to Directive 2009/48/EC on toy safety."

SEAC notes that the European leather industry (ref. 471, 491, 462, 463, 496) is concerned by the potential "double regulation" regarding formaldehyde in leather. It was also highlighted that the proposal foresees an exemption for textiles articles subject to the existing restriction on CMR substances in clothing and footwear (entry 72 of Annex XVII of REACH). Moreover, it was underlined that textile, leather and hide articles will be soon regulated by the restriction on skin sensitisers currently under evaluation. The restriction proposal on skin sensitisers

intends to limit the formaldehyde concentration in textile and leather at 75 mg/kg (as proposed by the Dossier Submitter) or at 30 mg/kg (as proposed by RAC).

SEAC notes that the skin sensitisers restriction proposal is still in the opinion development phase and it is therefore difficult to deal with the issue of future double regulation. Nevertheless, SEAC notes that the proposed restriction is focused on the formaldehyde emissions to prevent risks related to inhalation exposure while the skin sensitisers proposal is to restrict the content of formaldehyde (as well as other substances) in articles in contact with the skin to prevent risk of skin sensitisation. Therefore, the two restrictions are not overlapping in the sense that they are intended to address different risks. SEAC therefore recommends the Commission to take this into account when taking their decisions.

SEAC notes that the proposed derogation for substances used as biocides would apply to articles visibly labelled as biocidal products. Such biocidal products have been subjected to a risk assessment for consumers and the environment as part of the biocidal product authorisation procedure.

Treated articles are usually only labelled as biocidal products if they have an “external” biocidal effect on humans and animals, e.g. an insecticide-treated horse blanket to protect horses against insect bites.

In the case of articles that are treated with substances containing biocidal products (e.g. preservatives, see Annex V of BPR), the presence of the biocidal substance in the product may have, in many cases, only an “internal”, i.e. purely material protective, effect. For this reason, treated articles are, in many cases, not labelled as biocidal products. In SEAC’s view it is appropriate that such articles remain within the scope of the proposed restriction.

The term "biocide" as such is not mentioned in Regulation (EU) 528/2012. “Biocidal product”, on the other hand, would be clear. The word “biocide” in paragraph 6 of the proposed restriction entry could therefore be changed to “biocidal products”.

Exclusion of temporary sources

SEAC acknowledges that formaldehyde emissions from temporary combustion sources, such as cooking, smoking, burning wax or incense candles and ethanol fireplaces, cannot be addressed by an emission limit on articles. However, SEAC notes that temporary formaldehyde emission sources which are outside the scope of this restriction proposal further increase formaldehyde concentrations in indoor air, at least in the short term.

Exclusion of consumer mixtures

SEAC notes that formaldehyde can also be released from consumer mixtures such as resins, glues, adhesive, fillers, stabilizers, foaming agents, paints, lacquers, etc. Since 2018, mixtures cannot be supplied to consumers in a concentration of ≥ 0.1 % w/w due to the classification of formaldehyde as CMR substance (Carc. 1B) and its subsequent inclusion in entry 28 of REACH Annex XVII. SEAC notes that the Dossier Submitter’s assessment shows that risk from consumer mixtures is adequately controlled at such a concentration limit. Therefore, the proposed restriction does not include per se mixtures for consumer use, but it covers articles treated with mixtures that may generate exposure to consumers.

Other exemptions requested by industry

SEAC notes that, during the consultation on the SEAC draft opinion, the European Tyre & Rubber Manufacturers Association (ETRMA, ref. 465) requested an exemption for consumer tyres.

According to ETRMA, tyres and general rubber goods are articles implicitly included in the restriction proposal by the Dossier Submitter, since formaldehyde releasing resins are used in the formulation of specific rubber mixtures. Formaldehyde is generated by the reaction of the hardener resins with phenolic resins and is mainly released during the industrial manufacture process of articles. ETRMA further stated that, once the article is finished, the

residual formaldehyde is embedded in the cured rubber matrix and there is no identified risk from the presence of formaldehyde and its potential emissions from rubber articles.

SEAC sees no reason for exempting tyres per se. From a scientific and technical point of view, phenolic resins, in particular, are known for a permanent phenol-formaldehyde compound which, in comparison to urea-formaldehyde compounds, cannot be hydrolysed after curing and hence it cannot release formaldehyde. It seems that only few tests with chamber test methods are necessary to eliminate possible doubts concerning the presence of formaldehyde. However, in SEAC's view, certain tyre types are covered by the derogations relating to articles exclusively used outdoor and articles for industrial and professional use (see relevant sections above).

During the consultation on SEAC's draft opinion, a request for an exemption of flexible polyurethane foam (PUF) was received from the European Association of Flexible Polyurethane Foam Blocks Manufacturers (EUROPUR, ref. 450). EUROPUR stated that their PUF can emit formaldehyde and hence they can be considered as formaldehyde releaser. Flexible PUF are mainly used in upholstered furniture and in bed mattresses. EUROPUR provided measured data on formaldehyde emissions from 166 foam samples taken in the years 2014-2019. The measurement results, obtained using chamber tests according to a specific industry standard (CertiPUR), were converted into results according to EN 717-1 by extrapolation. The majority of the measurements show that formaldehyde emissions from flexible PUF from raw materials and/or photochemical degradation are very low (in general below 0.0125 mg/m^3 according to EN 717-1). Only four of the measurement values were around 0.02 mg/m^3 (according to EN 717-1). CertiPUR standards, used by EUROPUR members for testing PUF, can be partially correlated to the EN 717-1 testing method. For the measurements provided in the consultation according to the CertiPUR standard, measurement values according to EN 717-1 were derived as follows: CertiPUR result * 1.25 = extrapolated EN 717-1 chamber concentration. Even though CertiPUR and EN 717-1 test results can be correlated, EUROPUR is concerned that customers of PUF producers might ask for additional testing (at costs between €1 300 and €1 450 per test) because the reference test method proposed in the restriction is different from the industry-specific standard.

SEAC considers that, according to the internal standard of CertiPUR with a limit value of 0.01 mg/m^3 (= 0.0125 mg/m^3 EN 717-1), no action would be triggered with respect to the restriction proposal. SEAC also sees that only a few optional tests would have to be carried out to clarify the cases above 0.0125 mg/m^3 with EN 717-1. If the sources of these higher formaldehyde emission peaks are detected, further tests do not seem necessary.

Therefore, SEAC sees no reason for an exemption from the scope of the proposed restriction. In general, SEAC notes that the case shows that formaldehyde emissions from articles made of flexible PUF, such as bed mattresses and upholstered furniture, can even stay below the limit value of 0.05 mg/m^3 proposed by RAC.

PlasticsEurope (ref. 502) requested a derogation for articles containing POM on the basis that these are typically very small articles with only a minor contribution to formaldehyde emissions in indoor environments. SEAC considers that POM as material should not be derogated per se but sees room for added flexibility when it comes to testing of small articles used at very low loading factors (see section *Testing small articles made of POM* below).

Limit values

SEAC notes that the WHO Guideline for Indoor Air Quality for formaldehyde, adopted by the Dossier Submitter as a DNEL in the proposed restriction, sets an exposure limit to 0.1 mg/m^3 (0.08 ppm) for all indoor environments and that the Dossier Submitter assessed its proposed limit values against this DNEL. As such, SEAC welcomes a concentration limit of 0.1 mg/m^3 for interiors of road vehicle cabins. SEAC's detailed assessment of the costs, benefits and proportionality related to the limit values proposed by the Dossier Submitter is presented in the relevant sections of this opinion.

With regard to aircraft, SEAC takes note of RAC's assessment that passenger risk is adequately controlled and therefore agrees with RAC's conclusion that a concentration limit for aircraft is not applied.

SEAC notes that RAC carried out an extensive overview at global level of the currently existing mandatory and voluntary formaldehyde emission limits as well as voluntary certification labels and markings for wood-based construction materials, furniture and for other products (see Table 19 of RAC's opinion).

SEAC agrees with RAC that some EU (and non-EU) countries have already in place mandatory formaldehyde emission limits for wood-based panels that are lower than the E1 standard. Moreover, SEAC notes that recently Germany, while nominally maintaining a limit value of 0.124 mg/m^3 for wood-based panels, set testing conditions that impose de facto a formaldehyde emission limit value which corresponds to "half E1" when measured according to EN 717-1. However, SEAC is not aware of any European nor extra-European country that imposes formaldehyde emission limit values as stringent as the limit proposed by RAC.

SEAC acknowledges that, for enhancing the emissions reduction, countries such as France and Japan require information on formaldehyde emissions on the labels of wood-based panels. However, SEAC notes that these requirements can be considered as a labelling rewarding lower emissions and not as a ban on emissions beyond the E1 threshold.

Moreover, around the world, there are many different voluntary agreements and multiple forms of eco-labelling certifying lower formaldehyde emissions compared to E1. In SEAC's opinion, indeed voluntary certification labels and markings represent an additional way, on the one hand, to make consumers care about the indoor air quality at home and become more aware of their choices and, on the other hand, for providing incentives to companies to differentiate their products from those of competitors by reaching lower emission levels.

In agreement with RAC, SEAC acknowledges that in the EU only few panels with emissions higher than the E1 standard are produced. SEAC notes that this fact further indicates that the production and use of wood-based panels with formaldehyde emission lower than E1 (e.g. ½ E1, ⅓ E1) seems feasible at least for some kind of panels and applications and it is becoming more and more common on a voluntary basis.

Nevertheless, during the consultation on SEAC's draft opinion, SEAC received information regarding technical challenges related to the limit value proposed by RAC.

In fact, many industry sectors (wood-based panels, furniture, construction, mineral wool) indicated that, to maintain the current technical performances required in some specific applications, the use of different and more advanced resins, glue systems, adhesives systems or scavengers might be technically challenging. Besides responding to the demand from the market, the need to guarantee the same technical performances and structural functions (such as stability, duration, resistance to humidity, thermal efficiency, fire-protection, noise reduction, anti-burglar resistance, acoustic insulation, strength, flexibility, stiffness, thickness, low swelling, etc.) for some specific applications stems from the obligation to fulfil safety requirements of the final articles.

The same industry sectors indicated that, although very challenging in terms of materials and production processes particularly for some critical applications, technical feasibility is reachable but at very high investment and production costs.

EPF (ref. 461) claimed that for some wood-based panel types the limit proposed by RAC is not achievable with formaldehyde-based resins. With lower formaldehyde limits the board and processing properties are negatively influenced. The board properties become worse. This is particularly noticeable in the case of moisture resistance (thickness swelling and long-term behaviour under strongly humid conditions) and strength properties (long-term loads must also be taken into account). The proposed limit can be technically achieved "by extremely advanced non-formaldehyde-based resins", but the availability of these resins is very limited, and few resin suppliers have the necessary technology and formulations. Furthermore, according to EPF, upscaling the production and use of these resins will be a long and slow

process with supply bottlenecks that will also lead to likely substantial shortages of essential additives that are required for these advanced resins, in particular melamine.

Certain fibreboards (thin MDF, HDF boards with low swelling as core boards for flooring) can only be made with melamine reinforced UF adhesives. The use of PMDI as an alternative would entail severe production problems as well as much higher costs. It seems not clear which adhesives can be used at industrial scale for this product group, if melamine reinforced UF adhesives cannot be further used due to the restriction on formaldehyde emissions as proposed by RAC.

Glued wood-based products like structural finger jointed timber, glued solid timber, glulam, cross laminated timber and laminated veneer lumber (LVL) would be forced to change the adhesive system and this may cause costs of some €100 000 per factory. Should the RAC proposal of 0.05 mg/m³ be implemented, industry would face problems with such glued wood-based products, and this could end up in severe market losses which EPF was unable to quantify. The development of different adhesive systems will take 4-5 years. The production cannot influence the emission-behaviour of their products in the same way as particleboards can. EPF expects that such solid wood products would probably disappear from the market.

According to EPF, in the plywood sector up to 50 % of the products could not be produced anymore, especially in the building sector where strength requirements cannot be reached if formaldehyde emissions have to limited to 0.05 mg/m³ (0.04 ppm). The technical requirements regarding humidity (EN 636-2) cannot be met. EPF assumes that plywood panels in applications with structures that are thicker than 40 mm will have to leave the market. That would affect building products as well as all other applications – even products that are encased like in the area of furniture or sports equipment, where the structural properties/strength requirements are also crucial.

Fedustria (ref. 455) explained that particleboards are divided into 7 technical classes going from P1, general dry use conditions, to P7, heavy duty construction under humid conditions. Standard furniture panels and DIY boards are categorised under P1 and P2. P1 and P2 panels are also produced with lower emission values. However, values of ½ E1 can be obtained by reducing strength and stiffness values of the panels, by raising the panel densities. Structural boards from P3 to P7 have problems to reach lower emissions without influencing negatively their panel characteristics in a significant way. Setting ½ E1 as limit (even though the nominal limit value is 0.124 mg/m³, this has effectively implemented by the German Chemikalienverbotsverordnung regulation through the use of more stringent testing conditions in accordance with EN 16516) is already a major challenge for all producers. Fedustria explained that lowering the emission limit further down to 0.05 mg/m³ (i.e. 40 % of E1) will mean a huge challenge that not only implies a change of glue type (from aminoplast resin towards isocyanate or PU resin systems), but also serious investments in production equipment. The effort to reduce another 20 % below ½ E1 seems extremely difficult. The closer the emission limit is to the emissions of natural wood, the more difficult it becomes. Fedustria stated not one producer in the world would have experience with ultra-low emitting boards for heavy duty purposes, nor with low density or flame-retardant particleboard. This implies a big challenge for R&D in the wood-based panel sector and a transition period of at least 4 years would be necessary. According to Fedustria, compliance with the RAC proposal would necessitate a shift towards other glue systems such as PMDI, PU or PF reducing the production speed by 20 to 50 %. According to Fedustria, the most feasible option to produce ultralow emitting panels would be the use of PMDI which is formaldehyde-free so emission would be close to the emissions of natural wood. However, a lack of production capacity worldwide for PMDI resin is expected and 5 years for an adjustment of the necessary production capacity will be needed.

The European Phenolic Foam Association (EPFA[105], ref. 497) underlined that, given the broad range of products manufactured, its members will struggle to meet the lower limit of 0.05 mg/m³ proposed by RAC. Phenolic foams consist of fully-cross-linked polymeric matrices

[105] EPFA explained that phenolic foams use between 30 000 and 40 000 tons of phenolic resins each year to produce approximately 0.9-1.4 million m³ of thermal insulation foam per year with a minimum market value of €400-620 million. According to EPFA, due to their excellent fire performance, phenolic foams are often used in specialised applications which offer additional design flexibility and a high level of thermal efficiency.

manufactured from phenolic (PF) resins. The phenol-formaldehyde reaction of PF resins is irreversible and there is very limited possibility for significant formaldehyde emission following the initial curing process. Nevertheless, EPFA members, operating under the provisions of the European Product Standards EN 13166 and EN 14314, ensure that their products are currently tested for formaldehyde emissions using EN 16516 in accordance with the requirements of the Construction Products Regulation (CPR). Even with the uncertainties of the correlation between EN 16516 and the testing conditions outlined in Appendix X (which broadly correspond to EN 717-1), there is clear evidence that the products would fulfil the requirements of a 0.124 mg/m^3 limit as proposed by the Dossier Submitter. EPFA claims that up to 90 % of its current production by volume could be under threat if outdoor applications are included as proposed by RAC. However, SEAC notes that outdoor articles should be excluded from this restriction.

The European Insulation Manufacturer Association (EURIMA, ref. 486) considers that achieving an emission limit of 0.05 mg/m^3 would possibly be technically feasible but only in case a sufficient transition period was granted. This emission limit would potentially require also investments into manufacturing plants for process changes, worker protection, etc. It will also include completing compliance testing according to EN 717-1 and generating compliance proofs as requested by the market or by authorities.

The European leather industry (ref. 471, 491, 462, 463 and 496) stressed the fact that the RAC emission limit of 0.05 mg/m^3 represents a significant challenge since currently no alternative chemical process exists that is capable to keep the performances required by customers.

As far as the automotive sector is concerned, during the consultation on SEAC's draft opinion, EUROPUR and EURO-MOULDERS also submitted a joint comment (ref. 453). EURO-MOULDERS produce flexible polyurethane foam used in seat cushioning, acoustic insulation, arm rests, head rests, energy absorption behind the bonnet and moulded carpet underlay (together about 15 kg in a passenger vehicle). EUROPUR manufactures foam sheets used in headliners, textile lining, acoustic insulation and other minor parts of the vehicle (together about 2.5 kg included in a passenger vehicle). Both associations represent companies (most Tier-2 suppliers, some of them are Tier-1 suppliers)[106] that are suppliers to the automotive industry.

SEAC takes note that implementation of an emission limit of 0.05 mg/m^3 for polyurethane parts would in theory be technically feasible over the long term with the use of a combination of low formaldehyde polyols, specific additives and the use of formaldehyde scavengers in formulations. However, the following challenges are expected by industry:

- Formaldehyde scavengers are not yet commercially available for all types of flexible polyurethane foams.
- When they exist, the main consequence of using formaldehyde scavengers is increased emissions of acetaldehyde, which is a substance strictly limited in OEM specifications due to Chinese vehicle indoor air legislation.
- Adding scavengers to foam formulations is not a minor operation. Other issues arise as well in terms of the production process, mechanical properties of PU parts and compliance with humid ageing specifications.
- The development of a completely new generation of aldehyde scavengers by additive suppliers would be required.

The European Automobile Manufacturers Association (ACEA, ref. 484) sees a challenge and costs of up to €100 000 per model and year for the change from voluntary to mandatory

[106] A supply pyramid is the structure of a supply chain, headed by the producer of the end product (Original Equipment Manufacturer, OEM). The suppliers of modules and systems are located downstream. The OEM is followed by a so-called Tier-1 supplier for modules and whole systems. Further down the pyramid follows a Tier-2 supplier for components and at the base of the pyramid acts the Tier-3 supplier for simple components.

testing with an unchanged limit value of 0.1 mg/m³ alone. Regarding the lower value of 0.05 mg/m³, ACEA explained that it is difficult to have a full picture of the possible consequences within a short period of time without involving the whole supply chain. In ACEA's view, RAC's proposal will cause significant costs in the order of millions of euros for each OEM and model, non-recurring R&D costs as well as recurring costs for the optimized raw materials. This affects different material concepts like wood, leather, fibre enforced material, interior paintings, POM, several seat coverings, insulations, noise absorbing materials and many more. Due to the circumstances that in most cases formaldehyde is not an integrated part of material recipes but a degradation product, it will need to, for example, develop new ways of stabilization for some materials. This needs time on one hand and causes generally high costs for R&D on the other hand.

Overall, SEAC notes that for almost all sectors (except leather) lowering the emission limit down to the RAC limit seems to be technically feasible in most cases only after substantial investment to develop suitable production processes and provide proper reagents in the necessary amount. In some cases, commercial availability of the alternative resins and scavengers can be an issue.

Several industry sectors (e.g. Formacare, ref. 458 and 514; EPF, ref. 461; EPFA, ref. 497, EPRA, ref. 472, and EURIMA, ref. 486) provided information on impacts of two other potential limit values (0.08 mg/m³ and 0.062 mg/m³ measured in accordance with the conditions specified in Appendix X) both lower than the limit proposed by the Dossier Submitter but higher than the limit proposed by RAC.

On the one hand, SEAC recognises that a restriction with an intermediate limit value would potentially entail higher benefits than the limit proposed by the Dossier Submitter in terms of consumer health protection (but lower benefits than the limit proposed by RAC). However, the potential risk reduction was not quantified and the magnitude of any additional benefits of an intermediate limit relative to the limit proposed by the Dossier Submitter is not known.

On the other hand, generally speaking, SEAC considers that for industry the lower the limit value the higher are the increases in investment and R&D costs as well as costs related to production process changes including substitution. However, SEAC also notes that, from the comments received during the consultation on the SEAC draft opinion, several industries did not expect major disrupting impacts from the two intermediate limit values.

Transition period

Transition period of the restriction proposed by the Dossier Submitter

The Dossier Submitter proposed a 12-month transition period for the restriction on the consideration that, at least for the wood-based panels industry, all members of EPF are already producing E1 class wood-based panels and that regulations are in place in eight Member States.

Based on the comments received in the consultation on the SEAC draft opinion (see Table 20), SEAC supports a transition period of 24 months in general for the restriction proposed by the Dossier Submitter. This is to allow necessary adjustments in production processes and the development/validation of specific test methods.

On the basis of a comment received from the automotive sector (ACEA, ref. 484) in the consultation on the SEAC draft opinion, SEAC agrees that a transition period of 36 months would be more appropriate to allow industry to comply with the 0.1 mg/m³ concentration limit for interiors of trucks and buses. The measurement methods for trucks and buses have been under development only since June 2019 (ISO 12219-10).

In the case of POM articles, SEAC does not understand the long transition period of 4-8 years requested by PlasticsEurope (ref. 502) for the restriction proposed by the Dossier Submitter. The submitted measurement results show emission values well below 0.124 mg/m³ even when applying a loading factor of 1 m²/m³ which PlasticsEurope deems to be unrealistically high given that POM articles are typically very small and used and much lower loading factors

(see section on *Testing small articles made of POM* below). It appears that the publicly available measurement results provided are examples of selected qualities of POM, as PlasticsEurope considers that 10-20 % of POM articles would exceed the limit value proposed by the Dossier Submitter.

SEAC considers that, in case industry would have to comply with limit values lower than proposed by the Dossier Submitter, an even longer transition period after entry into force would be needed.

Table 20: Transition period requested by industry concerning the restriction proposed by the Dossier Submitter

Sector/type of article	Source of information	Transition period request (years)
Wood-based panels	EPF	1
Boards for heavy duty purposes, low density flame-retardant PB	FEDUSTRIA	2
Furniture	FEDUSTRIA	2
Furniture	AMEUBLEMENT FRANÇAIS	1
Phenolic resin industry	EPRA	2
Phenolic foams	EPFA	1
POM	PlasticsEurope	4-8
Mineral wool	EURIMA	2
Leather	COTANCE, VDL	2
Car hard/soft foams	EUROPUR, EURO-MOULDERS	2
Passenger cars	ACEA	2
Trucks and buses	ACEA	3

Transition period of the restriction proposed by RAC

SEAC notes that, many sectors claimed that they would need additional time to make investments in R&D, new production equipment and for developing new processes, as well as to adjust the production capacity, perform testing and comply with the requirements by authorities and to respond to the demand from the market.

According to a survey carried out by Formacare (ref. 514), the formaldehyde sector group of the European Chemical Industry Council (CEFIC), to be able to comply with the limit value proposed by RAC, several industry sectors would need a transition period of 36 to 60 months after entry into force of the restriction.

Based on the information provided by CEFIC, SEAC notes that, to comply with the limit values proposed by RAC, the wood-based panels industry would need a minimum transition period of 24 months after entry into force of the restriction in order to adjust the production capacity of MDI.

The furniture sector also provided information on the transition period. The Belgian Federation of the Woodworking, Furniture and Textile Industries (Fedustria, ref. 455) explained the need of a 5 years transition period to comply with the 0.05 mg/m^3 limit. In fact, Fedustria indicated that the most feasible option to produce ultra-low emitting panels would be the use of PMDI, for which a lack of production capacity is expected worldwide.

Furthermore, Fedustria expects that for the R&D for ultra-low emitting boards for heavy duty purposes and low-density flame-retardant particleboard there is a need for at least 4 years transition period.

The European Mineral Wool Manufacturers Association (EURIMA, ref. 486) considers that the emission limit of 0.05 mg/m^3 can be reached only if a transition period of up to 7 years is granted in order to make investments for completing compliance testing according to EN 717-1 and generating compliance proofs as requested by the market and by authorities. For instance, the curing process would need to be changed to work with formaldehyde-free binder types. Other technology used in fibre manufacturing would be affected and require new machines to perform the operations. Buying, installing and optimizing new machines for all EU plants will require more than the proposed 2 years.

For polyoxymethylene (POM), PlasticsEurope (ref. 502) underlined that, in order to comply with a limit of 0.124 mg/m^3 proposed by the Dossier Submitter, 4-8 years transition period would be needed for developing new grades with new technologies, for testing and for obtaining the certifications required to ensure safety of products. PlasticsEurope also stressed that to comply with the limit of 0.05 mg/m^3 proposed by RAC, 6-10 years would be needed.

The European phenolic resin industry (EPRA, ref. 472) underlined that, regardless the emission limit (including 0.124 mg/m^3 proposed by the Dossier Submitter), a 24 months transition period will be needed for the further R&D to be carried out by downstream manufacturers of articles.

The European Phenolic Foam Association (EPFA, ref. 497) considers that a 12 months transition period would be enough for the Dossier Submitter's proposal of 0.124 mg/m^3 but doubts that even 24 months would be sufficient to comply with RAC's proposal to prevent significant loss of market for phenolic foams.

The automotive sector (ACEA, ref. 484) considers that the transition period should be 5 years for the 0.05 mg/m^3 limit value proposed by RAC. SEAC notes that RAC indicates that a transition period of 24 months for all articles and interiors of road vehicles would be enough for industry to comply with the lower limit value proposed.

SEAC summarised in Table 21 the information received by the different industry sectors during the consultation on SEAC's draft opinion in terms of transition period needed to comply with the restriction as proposed by the Dossier Submitter and by RAC, respectively.

Table 21: Comparison of the transition periods requested by industry

Sector / type of article	Source of information	Transition period request for Dossier Submitter proposal (years)	Transition period request for RAC proposal (years)
Wood-based panels	EPF	1	up to 5
Boards for heavy duty purposes, low density flame-retardant PB	FEDUSTRIA	2 *	up to 4
Furniture	FEDUSTRIA	2 *	up to 5
Furniture	AMEUBLEMENT FRANÇAIS	1	unable to quantify
Phenolic resin industry	EPRA	2	2
Phenolic foams	EPFA	1	2
POM	PlasticsEurope	4-8	6-10
Mineral wool	EURIMA	2	5-7
Leather	COTANCE, VDL	2	at least 2
Car hard/soft foams, glued wood-based products	EUROPUR, EURO-MOULDERS, EPF	2	up to 5
Passenger cars	ACEA	2 **	3-5
Trucks and buses	ACEA	3 **	3-5

*) 0.062 mg/m³ or ½ E1 if tested in accordance with EN 717-1
**) 0.1 mg/m³

SEAC considers that different sectors and, within the same sector, companies of different sizes (SMEs, medium size companies and big companies) in different European countries might need more (or less) time depending on the (limited) resources available to make organizational and technical adjustments and on the eventual limit value set. Therefore, it cannot be excluded that other specific sectors or companies not mentioned here might need longer transition periods.

Testing methods and Appendix X

Before the introduction of the Appendix X a large number of comments were received during the consultation on the Annex XV dossier. For many industry sectors testing methods were considered to be the most critical issue of the restriction proposal (for example, ref. 2002, 2023, 2050, 2055, 2060, 2071, 2090, 2099, 2114, 2159, 2173, 2178, 2198, 2214, 2217, 2275, 2334, 2349, 2350, 2444, 2494,2483, 2569,2570, 2583, 2604, 2615, 2622, 2644, 2657, 2665, 2677).

SEAC notes that, among all these comments, some were in favour of the use of other methods than EN 717-1, which was specifically referred to by the Dossier Submitter in the original proposed wording of the restriction entry (ref. 2002, 2060, 2206 2023, 2071, 2114, 2604, 2615, 2622, 2644, 2665, 2677), a number of comments suggested the use of EN 16516 (ref. 2217, 2275, 2334, 2349, 2350, 2494, 2569), others proposed to allow to continue using current methods for different sectors such as automobile (ref. 2067, 2083, 2133, 2136), leather (ref. 2133, 2136), office furniture as well as for the flexible polyurethane foam industry (ref. 2211).

SEAC agrees with the Dossier Submitter that, taking into consideration the comments received during the consultation, Appendix X on testing methods introduces flexibility for industry hence reducing the additional costs of the proposed restriction.

According to Appendix X, emissions from articles in the restriction proposal refer to a concentration in the air of an emission test chamber (expressed in mg/m^3). The test chamber is the reference method and Appendix X defines the conditions (temperature, relative humidity, air exchange rate, loading factor, etc.) for the test chamber. Analytical methods and sampling methods used to determine the formaldehyde concentration are defined in specific test standards. Therefore, other standard test methods (e.g. gas analysis) or non-standard test methods can be performed if a reliable correlation to the reference test chamber can be established.

In the case of road vehicles for the transportation of people, Appendix X considers that testing of formaldehyde concentrations in the interior of the vehicle is acceptable to guarantee compliance with the current restriction proposal. Therefore, in such a case, the concentration of formaldehyde in vehicle interiors, measured in accordance with the conditions specified in Appendix X, shall not exceed 0.1 mg/m^3. Appendix X makes similar considerations for passenger aircraft but SEAC agrees with RAC's conclusion that a concentration limit for aircraft is not applied.

It seems essential to SEAC that the methods are in accordance with Quality Management (QM) requirements in general:

- The reference test chamber measurements will be done at certified/accredited test laboratories (e.g. GLP/EN 17025).

- Other (not reference chamber testing) standard test methods (e.g. gas analysis, perforator) are used routinely by the producers for daily production checks. Such kind of self-control needs a traceable QM and if required a certification/accreditation too.

- The operators of factory test methods should be responsible for validated correlation to the chamber test methods for the articles concerned.

- In cooperation with the Forum for Exchange of Information on Enforcement (Forum), responsible actors should be assigned for those cases where there are questions.

In conclusion, SEAC considers that the proposed limit value of 0.124 mg/m^3, as measured in accordance with the conditions specified in Appendix X, ensures the enforceability of the proposed restriction, allowing industry to reduce the costs of compliance by using all suitable test methods, provided that results can be correlated to the reference conditions specified in Appendix X.

As explained in a comment received in the consultation on the SEAC's draft opinion (ref. 486), EN 717-1 is not the method used by the construction/mineral wool sector to test formaldehyde emissions into indoor air (tests in this sector are rather performed using EN 16516). Moreover, according to this comment, EN 717-1 is not designed for outdoor applications scenarios. SEAC notes that although test methods would not be an issue for articles used exclusively in outdoor applications (as these articles are proposed for an exemption), in the case of articles that can be used both indoor and outdoor (and hence would fall within the scope of the restriction), there will be a need to establish testing conditions and a correlation with factory production control measurements.

SEAC thanks EPF (ref. 499) for describing in the consultation on SEAC's draft opinion how alternative methods can be used on the basis of correlations, primarily in the wood-based panels sector for accelerated factory production control methods.

For the flexible PUF sector, EUROPUR stated in the consultation on the SEAC draft opinion (ref. 450) the possibility to convert measurements obtained through chamber tests according to a specific industry standard (CertiPUR) into results according to EN 717-1 by extrapolation, as follows: CertiPUR result * 1.25 = extrapolated EN 717-1 chamber concentration. SEAC considers it appropriate to include the industry's internal CertiPUR standard in Appendix X.

Testing complex articles

Many comments submitted in the consultation expressed concern about the need to test complex big articles like furniture, which indeed are produced in such a large variety that testing all of them would be extremely expensive.

Taking into consideration these challenges, SEAC agrees with the clarification made by the Dossier Submitter in Section 2.2.2.2 of the Background Document that testing of complex articles (e.g. pieces of furniture) is not needed if their components do not contain formaldehyde or formaldehyde releasing substances or if formaldehyde emissions of individual components are within the limit established by the current proposal. However, when formaldehyde or formaldehyde releasing substances or mixtures (e.g. lacquers or glues) are added during the production process of complex articles, testing is required.

SEAC considers that compliance testing with the emission limit value is necessary at the beginning of the supply chain because with increasing size and complexity of the final products, tests become more difficult and expensive. SEAC notes that, for instance, formaldehyde emissions from upholstered furniture cannot be measured adequately with EN 717-1, in this case EN 16516 seems to be more suitable. SEAC points out that the development of adapted test methods and the correlation to EN 717-1 as a reference method is a task for industry.

Vehicles are also examples of complex articles. For the automotive industry, ACEA underlined in the consultation on the SEAC draft opinion (ref. 484) that the whole complex approach from the material and part specification to the final vehicle procedure testing (according to ISO 12219-1, ambient mode) involving the entire supply chain, is based on a limit value of 0.1 mg/m^3 and this is set up in different regions of the world. Any changes affecting this concentration limit or in the way it is currently tested would inevitably question the whole approach and would have significant consequences requiring a long period of time to be fully evaluated.

Testing small articles made of polyoxymethylene (POM)

Articles made of POM, engineering thermoplastic used in precision parts requiring high stiffness, low friction, and excellent dimensional stability, are used in a wide range of industrial and automotive applications, inside homes, offices and vehicles.

SEAC takes note that, during the consultations on the Annex XV dossier and on the SEAC draft opinion, some comments (ref. 2083, 2214, 2731, 502) raised the issue of and requested a derogation for small articles made of POM mainly due to high testing costs. In fact, POM articles are claimed by industry to be low formaldehyde releasing materials and to have a low loading factor.

PlasticsEurope (ref. 502) mentioned that the expected contribution to the formaldehyde concentration in indoor air by small articles containing POM plastic is so low (0.0002 mg/m^3), that POM should be considered part of the indoor background formaldehyde concentration, rather than being included in this restriction proposal. PlasticsEurope stated that at a loading factor of 1 m^2/m^3, 10-20 % of POM articles would be rendered non-compliant under the Dossier Submitter proposal and 80 % of POM articles would be rendered non-compliant under the RAC proposal. However, PlasticsEurope considers a loading factor of 1 m^2/m^3 unrealistically high given that POM articles are typically very small and used at much lower loading factors (< 0.01 m^2/m^3). Therefore, according to PlasticsEurope, POM should either be out of scope or, in case POM remains within the scope, its low loading factor should be taken into account.

SEAC agrees that each small part would only slightly contribute to the total load of formaldehyde emitting equipment indoors and in vehicles. SEAC has not taken POM per se out of the scope because no one can predict future uses of larger items. In connection with the future restriction, it is important to minimize testing costs by having the test at the beginning of the supply chain on the material side, not at the producer of the final product alone. As previously stated, a large part of the still volatile formaldehyde is off-gassed during

thermal processing on the injection moulding machine. SEAC expects residual outgassing at the end customer is negligible. SEAC can imagine that with the experience available in the industry, it should be possible to grant a corresponding certificate of harmlessness to customers while adhering to various technical parameters (temperature, pressure, dwell time in the pressing tool etc.). POM seems to be suitable for high precision injection moulded plastic parts, so there seems to be no need for re-certification of safety relevant components too.

Even though SEAC considers that POM as material should not be derogated per se, SEAC supports an amendment of Appendix X to allow more realistic loading factors for testing of small articles that are demonstrably used at very low loading factors. A possible solution could be to allow, in justified cases, the use of the various loading factors related to the European Reference Room as set out in section 4.2.2 of the European Standard EN 16516: 1.0 m^2/m^3 for walls, 0.4 m^2/m^3 for floor and ceiling, 0.05 m^2/m^3 for small surfaces (e.g. door, window, heating system) and 0.007 m^2/m^3 for very small surfaces (e.g. sealants). SEAC therefore proposes to amend point 1.c of Appendix X in the following way:

The loading factor, expressed as the ratio of the total surface area of the test piece to the volume of the test chamber, shall be (1 ± 0.02) m^2/m^3. In cases where such a loading factor would clearly not be realistic under reasonably foreseeable conditions of use, loading factors in accordance with section 4.2.2 of EN 16516 could be used when fully justified.

Alternatives

In order to comply with the emission limit proposed by the Dossier Submitter, at least for wood-based panels, SEAC sees no need for switching to formaldehyde-free alternatives since a longer curing time of UF resins should be enough to reduce formaldehyde emissions in indoor air. The commitment of the European wood-based panels industry to only produce class E1 panels by continuing using UF resins demonstrates the technical and economic feasibility of the use of UF resins in such a way as to be in line with the proposed restriction.

On the other hand, to achieve an emission limit lower than the Dossier Submitter's proposal, a switch to alternative resins/glues/adhesives may be necessary, depending on the required emission level. Some alternatives are reported here.

<u>Formaldehyde-based resins</u>

Urea formaldehyde (UF) resins

SEAC notes that currently the most used resins in the production of wood-based panels and of other articles concerned by this restriction are urea formaldehyde (UF) resins.

As stated in Annex D.4 of the Background Document, UF resins are very cheap and fast curing but are not suitable for damp conditions and are typically used for panels intended for non-structural use such as particleboard and hardwood plywood. UF resins are also non-staining and therefore do not blemish the high-quality expensive face veneers used for hardwood panels for interior finish applications. Since the formaldehyde component of UF resins is not completely chemically fixed by the urea, some formaldehyde remains free to dissipate and, as such, UF resins are associated with the highest releases of formaldehyde when compared with other formaldehyde-based resins.

Newly developed and used UF resins (mUF with added melamine but a melamine content of < 8 %) are also able to meet the "new" E1 class according to the German Chemikalienverbotsverordnung ("German E1" with limit 0.1 ppm according to EN 16516 or 0.05 ppm according to EN 717-1). Addition of melamine has positive effects with respect to cross-linking and curing behaviour. Further decreasing the content of formaldehyde in the aminoplast resins seems possible only by introducing major changes in the chemistry to compensate for the lower content of formaldehyde. This would require to significantly increase the content of melamine (MUF with > 10 % melamine) to replace a substantial part of the urea. According to a comment submitted by Kronospan (ref. 487) in the consultation on the SEAC draft opinion, new types of aminoplast resins need to be developed. These new resins would not be comparable to established melamine fortified resins (mUF) nor to established

MUF resins for moisture and water-resistant boards. This means a substantial addition of melamine, from a melamine-fortified mUF resin to rather a MUF resin with more melamine compared to urea. Another possibility is to use a significant amount of additional crosslinkers for the aminoplast resin, such as isocyanate (PMDI), as discussed below.

Other formaldehyde-based resins

Other formaldehyde-based resins such as phenol formaldehyde (PF), melamine formaldehyde (MF), melamine urea formaldehyde (MUF), resorcinol formaldehyde (RF), and phenol resorcinol formaldehyde (PRF) resins release little to no formaldehyde from the cured product and can be considered as substitutes for UF resins. However, each of these resins has some shortcomings:

MF and MUF (> 10 % melamine) resins have a comparably good weather and water resistance like PF resins. MF resins are up to 3 times more expensive than UF resins. MUF resins are cheaper than MF resins but more expensive than UF resins too. Melamine capacity to meet demand of the wood-based panels industry to comply with the E1 formaldehyde emission class seems sufficient. MF and MUF resins belong to the class of resins with low/no formaldehyde emissions from cured products. EPF explained in the consultation on the SEAC's draft opinion (ref. 461) that melamine stabilizes an aminoplast resin when the proportion of formaldehyde is decreased to very low levels. For the emission levels needed to fulfil the limit value proposed by RAC, a high proportion of melamine will be needed in these aminoplast resins. The demand for melamine for new types of adhesive resins for the production of particleboard and MDF as main types of wood-based panels for furniture and various indoor applications is expected to increase by a factor of 30 if the RAC proposal was implemented (EPF, ref. 461). According to EPF, this would mean a need for about 600 kilotons melamine or two to three new big melamine plants, most probably outside the EU, entailing high transport costs. According to Formacare (ref. 514), a restriction as proposed by RAC, would result in a significant increase of melamine consumption. According to Formacare's most conservative estimate, which assumes 6 % melamine content in the resin, EU demand for melamine to be used for resins would increase by 140 000 tons/year, from 40 000 tons (current situation) to 180 000 tons.

PF resins[107] show low or no formaldehyde emissions form the cured product but there may be a concern for worker health due to the use of phenol. There are environmental concerns when using phenol too. PF resins require high temperature for curing and long press times and are 2-3 times more expensive than UF resins but cheaper than other formaldehyde-based resins like RF and PRF resins. PF resins have a wide application beyond their use in the wood-working industry. A comment submitted in the consultation on the Annex XV dossier (ref. 2483) shows other uses in different industry sectors. SEAC notes that PF resins can only be used in limited cases as a replacement for UF resins due to their 2-3 times higher price and its dark colour. SEAC has no information whether the availability on the market is sufficient to cover a larger demand for PF resins. RF and PRF resins have a comparably good weather and water resistance but a very dark (dark brown to black) colour. According to Annex D.4 of the Background Document, RF and PRF resins have around four times the price of UF resins and the supplies of resorcinol may not be sufficient to meet the needs of the wood-based panels industry. Worker health concerns regarding both phenol and resorcinol should be comparable to PF resins. According to Formacare (ref. 514), a restriction along the lines of the RAC proposal could trigger the replacement of MUF resins for construction products by PRF resins. Formacare estimates that for such a replacement 8 520 tons resorcinol would be needed, that is, compared to the estimated current (2019) resorcinol market of 640 tons for wood adhesives in the EU, more than 13-fold bigger.

In SEAC's view, at least in the short run, it seems very unlikely that the market could meet this extra demand and a price increase can be expected. SEAC considers that, beyond wood-based panels, PF resins have a wide range of applications such as in mineral wool binders, in

[107] According to Formacare (ref. 514), the category of PF also covers a variety of phenolic monomers including styrenated phenol, resorcinol and some of the alkyl phenols, so the inclusion of, for example, RF resins as a separate category is not necessary. Most importantly, for all these phenolic structures, the phenol-formaldehyde bond is not susceptible to hydrolysis and the polycondensation (curing) process is therefore non-reversible. As a result, PF resins should be considered as ultra-low emitters of formaldehyde (ULEF) in service.

brake pads/linings, in refractory applications, in coatings and adhesives applications, and in abrasives applications (both coated and bonded).

Formaldehyde-free alternatives – isocyanate resins and biobased glues

Isocyanate resins

One theoretical alternative to formaldehyde-based resins are based on isocyanates, mainly the so-called PMDI (Polymeric Diphenylmethane Diisocyanate; CAS: 9016-87-9). PMDI is a mixture of MDI and higher molecular weight forms of MDI. PMDI even gives so-called NAF ("no added formaldehyde") solutions.

According to a comment received in the consultation on the SEAC draft opinion (ref. 488), when using pure PMDI adhesives, the formaldehyde emissions of boards will reduced to the natural emission of wooden particles, strands and fibres with emission values between 0.015 and 0.030 mg/m³ when tested in accordance with EN 717-1.

According to EPF (ref. 461), there are several issues in terms of availability of PMDI as well as production and storage capacity to be solved for the immediate and generalised use of PMDI as alternative adhesive for the production of wood-based panels. In fact, according to EPF:

- a complete switch of the whole European production of particleboard and MDF to PMDI is currently not possible, due to the limited availability of PMDI on the market since an amount of up to 2 million tons of PMDI will be needed. The actual demand for PMDI for these types of boards can be estimated by a factor 100 lower, because PMDI is used in very limited amounts in particleboard and MDF; only in OSB mainly PMDI are used as adhesives.

- the use of PMDI requires investments in wood-based panels production plants, in storage areas (storing PMDI is more complicated than storing aminoplast resins due to health concerns and the need to eliminate moisture in the tank) and in terms of production costs (type of blenders, use of release agents in the presses against PMDI steel adhesion).

SEAC takes note that, according Formacare (ref. 514), the current PMDI consumption for the wood-based panel sector for 2018 was estimated at 250 kilotons (solid dry mass) in comparison with approximately 3.5 megatons for UF/MUF resins and 90 kilotons for PF resins. In case a full switch of the European production of particleboard and MDF to PMDI takes place, this would create a substantial additional MDI demand between a lower bound estimate of 1 megaton (with PMDI used as a crosslinker in addition to UF resins) and an upper bound estimate of 2 megatons in the case of a full switch to pure PMDI glues. This potential demand increase would require the construction of 2 to 4 world scale plants to supply exclusively the European wood panel industry.

SEAC notes that PMDI resins could be used as a substitute to UF resins in MDF/particleboard and in Composite Wood Products (CWP) in buildings. SEAC takes note of the positions of EPF and Formacare regarding the use of PMDI. SEAC doubts that only formaldehyde free resins have to be used to reach the demanding RAC limit. In SEAC's view the gap in the availability of PMDI resins seems to be smaller than expected by EPF and Formacare. There are at least five PMDI resin producers in Europe which, according to the European Diisocyanate & Polyol Producers Association (ISOPA, ref. 459), are investing regularly into new capacities to meet growth assumptions.

Biobased glues

In principle, alternative biobased glues such as lignins, tannins or sugar-based glues could be used, but these glues are not sufficiently available on the market. Boards made by using these kinds of glues are subject to problems such as insufficient general technical properties, discoloration, inacceptable swelling or even decomposition when used in humid conditions (Fedustria, ref. 455). Apart from technical issues, there are ethical concerns to be faced before

proposing a wider use of these products, in relation to competing for agricultural products for raw material generation for technical purposes vs. food generation. At present, there are only two kinds of wood-based panels (but limited volumes) produced with such adhesives, which are tannin bonded boards and soy protein bonded plywood. These two examples so far are significantly below 0.5 % of the total board production (EPF, ref. 461).

All natural-based adhesives are, on the one hand, too high in content of substances without adhesive properties and, on the other hand, they have a high water demand. All adhesives for wood-based panels are water-borne systems and formulations with a higher water content than about 50 % requires a long “curing” time. The water can also cause bursting of the freshly pressed hot panels due to the high gas pressure of the water vapour within the core layers of the panels.

Lignins are available in large amounts as by-products of pulping of wood. The costs are also on a low level but the adhesive force of lignin-based systems as well as curing time have proven to be unsuitable for the manufacture of high-quality wood-based panels. Even the use of lignin as extenders is limited to some PF resins used in plywood production (Prof. R. Marutzky, ref. 488).

Casein and bone glues are proteins that were used for structural bonding of solid wood in the past, but nowadays have been substituted by white glues (PVAc systems). Due to their high viscosity and low curing characteristics, they are unsuitable for the production of wood-based panels. Other protein-based adhesives such as soybean proteins give high viscous glue systems as well and are principally only suitable for adhesion of wooden veneer products but unsuitable for particleboards, fibreboards and OSB (Prof. R. Marutzky, ref. 488).

Tannins are natural products widely distributed in plant materials. There are different types of tannins but only two types can be used as binders of particleboards. These tannins are extracted from some wood species endemic in southern parts of Africa. The availability of these tannins is restricted, estimated to not more than about 50 000 tons per year. Their main use is the tanning of leather. Utilisation of tannins from pine bark have been tried as well but the content of non-bonding compounds (about 50 %) is far too high for sufficient bonding. Pine tannins also are highly sensible to oxidation and pre-condensation. A principle drawback in the context of the present restriction proposal is the fact that tannins have to be cross-linked with an excess of formaldehyde causing significant formaldehyde emissions of tannin-bonded panels after pressing. Therefore, low emitting tannin-based particleboards require time-consuming post-curing and flash off measures (Prof. R. Marutzky, ref. 488).

Other chemicals

Another alternative would be the replacement of formaldehyde by other chemicals, such as furfural, glyoxal, dimethoxyethanal, glutyraldehyde, or 5-hyhroxymethyl-furfural. A lot of scientific results about this have been reported, but currently no industrial nor even semi-industrial application exists. This is also not to be expected for the next couple of years (EPF, ref. 461).

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter expects the proposed restriction to be an effective measure for addressing the identified risks, in particular with regard to new articles imported into the EU. The overall risk reduction potential is however expected to be limited given that the measured indoor air formaldehyde concentrations in the EU are already today below the WHO guideline value in the majority of cases.

The exposure reduction expected from the proposed restriction is assessed quantitatively in the dossier. This assessment is based on the estimations of formaldehyde concentrations in indoor air which the Dossier Submitter performed as part of the exposure assessment. The conclusions from the Dossier Submitter were that formaldehyde concentrations in indoor environments can exceed the WHO guideline value if high emitting articles, such as class E2 wood-based panels, are used in large quantities but that such exceedances could be avoided if emissions from panels and other articles do not exceed the proposed emission limit of 0.124 mg/m³.

The Dossier Submitter also states that formaldehyde emissions decline over time and that formaldehyde concentrations are typically found to be higher in new homes. The analysis presented in the proposal focuses on newly built homes. It is therefore expected that, with the passing of time, formaldehyde concentrations in homes above the WHO guideline value fall below the guideline value simply as a result of formaldehyde decay. Even if this is the case, the proposed restriction could help to avoid periods in the order of up to several months in which people in newly built homes are exposed to formaldehyde concentrations above the WHO guideline value.

RAC conclusion(s):

RAC agrees that a restriction will be an effective measure for addressing the identified risks.

The restriction measure as proposed by RAC is considered as effective to reduce the risks (as identified by RAC) from continuous exposure from articles in the scope.

RAC concludes that compliance with the restriction appears to be monitorable in general, although additional practical advice may need to be issued to enforcement authorities for composite articles. The restriction under REACH, as proposed by RAC, would lead to a harmonisation of risk management measures related to the release of formaldehyde from articles across EU Member States at a level sufficient to address the identified risks for consumers.

The risk reduction effects, however, are not monitorable directly due to the complex nature of the exposure scenario. Multiple parameters have significant influence on the amount of risk reduction. RAC finds it difficult to demonstrate the quantitative reduction, however RAC has attempted to estimate exposure reduction by modelling. This was identified as the only approach available and was also followed by the Dossier Submitter. As a result, it is concluded that an emission limit significantly lower than the Dossier Submitter proposed emission level is needed to achieve RCR < 1, and to prevent those exposure situations that are frequent and matter most, i.e. several articles are present simultaneously emitting formaldehyde in relevant amounts, and often high loading situations add up to high formaldehyde concentrations. While the restriction cannot guarantee to prevent all situations of concern (i.e. RCR > 1) due to the multitude of sources adding up and individual characteristics and exposure determinants (e.g. occupant dependent lack of ventilation), a significant reduction of emission from the most important sources is needed to effectively reduce the risk. The restriction serves to prevent high formaldehyde emitting articles from being placed on the EU market and according to available information, the exposure of consumers via formaldehyde releasing articles is then sufficiently controlled below the by RAC defined DNEL of 0.05 mg/m³.

RAC conducted an additional assessment and based thereon RAC does not agree that the concentration limit proposed by the Dossier Submitter will be sufficiently effective for risk reduction.

With regard to alternatives to formaldehyde/formaldehyde releasing substances, the Dossier Submitter concludes that due to limited information on availability, cost and performance of formaldehyde free products as alternatives to UF resins, a level of uncertainty remains with respect to the applicability of ULEF and especially NAF resins. Currently, however, scientific effort is made to identify and assess the feasibility, applicability and potential risk of further alternatives to formaldehyde-based resins. Hence, in the near future it is considered possible to replace the currently used formaldehyde-based resins with ULEF or NAF resins, which would contribute to increase indoor air quality, as intended by the restriction on hand.

Key elements underpinning the RAC conclusion(s):

Buildings

RAC concludes that employed materials (construction materials and other articles), which are compliant with the E1 class emission limit of 0.124 mg/m³ according to EN 717-1 chamber test, may lead to significantly high formaldehyde air concentrations in indoor environments that may exceed the long-term DNEL and also the WHO guideline value.

RAC expects that lowering the emission limit for construction materials to 0.05 mg/m³ (measured under the conditions specified in Appendix X) will lead to a significant reduction of mean and maximum concentrations.

Furniture

As furniture products significantly contribute to the indoor formaldehyde concentrations it is expected that the proposed restriction will effectively reduce the risks.

Producers/importers of furniture could produce/import low emitting furniture products as several national and union-wide labels are available (Nordic Ecolabel, Blue Angel, EU-Ecolabel). Without any mandatory legislation and as of 2013, the compliance was found to be negligible. Only two furniture companies held licenses for the EU-Ecolabel (1 in Poland and 1 in Italy), covering a total of some 39 products (1 in Poland 38 in Italy) (JRC, 2017).

Vehicles

Based on the literature data (see above) and the limited measurement data on cars submitted during the consultation, RAC expects a reduction of exposure in cars from the implementation of the RAC proposal. As cabin concentrations in aircraft are already below 0.05 mg/m³ (assumed that data are representative), no risk reduction effect is expected for this area. No statement on risk reduction is possible for other types of vehicle due to the lack of data.

RAC notes that the effectiveness of the proposed restriction can only be assessed for uses within the scope as outlined in the proposal. The Dossier Submitter identified other temporary sources of formaldehyde release (mainly as combustion product or from mixtures). RAC supports not to address these short-term risks within this restriction proposal, instead RAC indicates to consider the need of other risk measures for ethanol fireplaces.

Risks from alternatives to formaldehyde-based resins

As noted in the Background Document, the use of formaldehyde-based resins (in particular UF and MUF resins) in the production of articles (particularly wood-based panels) represents one of the most relevant sources of formaldehyde exposure for consumers.

In the US the use of ultra-low emitting formaldehyde (ULEF) resins or even no-added formaldehyde (NAF) resins are already encouraged, as manufacturers who plan to only use NAF or ULEF based resins can apply for an exemption from the third party certification requirements, which are mandatory in general. ULEF resins usually emit ≤ 0.062 mg/m³

formaldehyde; however, the industry is continuously searching for other formaldehyde-based alternatives with formaldehyde emission in the same range as for raw timber (≤ 0.012 mg/m³). Accordingly, for phenol formaldehyde resins (PF), melamine formaldehyde (MF) and melamine urea formaldehyde (MUF) resins, as well as resorcinol formaldehyde (RF) and phenol resorcinol formaldehyde (PRF) resins, the Dossier Submitter concludes that only low or even no formaldehyde emits form cured products, yielding no risks to consumers. In the Background Document it is further specified that while urea formaldehyde (UF) resins emit 8.6-1 580 µg/(m²h) (mean: 164 µg/m³), MF and MUF emit only half of this concentration. For RF, no specific emission values were reported in the Background Document, but PF was reported to emit even lower formaldehyde concentrations, namely 4.1-9.2 µg/(m²h). Hence, all of these alternative resins emit formaldehyde, although to a lower extent than UF.

For Melamine, however, there is a CLH proposal on the way proposing a harmonised Carc. 2 (H351) classification for this substance. Moreover, melamine is self-classified as Skin Corr. 1C (H314), Eye Irrit. 2 (H319), Skin Sens. 1 (H317) and STOT SE 3 (H335), indicating that melamine may be hazardous after skin and eye contact, as well as after ingestion and inhalation. Such harmonised classification might exclude MF and MUF from the list of valid alternatives to UF resins. Phenol, which is used in PF, is harmonised classified as Muta. 2 (H341), besides its harmonised STOT RE 2* (H373**), Skin Corr. 1B and Acute Tox. 3 (oral, inhalation and dermal) classification. Although it is questionable whether consumers of articles made using PF would be actually exposed to phenol, it is clear that workers will be exposed and, in addition, environmental concerns arise. Resorcinol is harmonised classified for Acute Tox. 4 (H302), Skin Irrit. 2 and Eye Irrit. 2 (H315 and H319), which would put RF at the top of the list of alternative (ultra) low-emitting formaldehyde-based resins. In the Background Document, however, the high costs and the limited supply of recorcinol are highlighted. Moreover, resorcinol was being evaluated in the course of a substance evaluation under REACH, which concluded that this substance is likely an endocrine disruptor affecting the human thyroid system[108]. This substance is further known to be toxic to the aquatic environment.

Besides the above mentioned ULEF resins, NAF resins are already available on the market, which are composed of e.g. either using biomass products or by-products, such as soy, tannin, lignin and proteins, respectively, or using isocyanates like polymeric methylene diphenyl diisocyanate (p-MDI) (see Background Document, Annex Table D.4). Furthermore, polyurethanes, emulsion polymer isocyanates (EPI), polyvinyl acetate (PVA) and ethyl vinyl acetate (EVA), as well as epoxy adhesives represent potential alternatives to formaldehyde-based resins, when focusing on solid wood lamination, laminated beams or bonding applications between wood/wood-based panels and other materials. Such NAF resins will not emit formaldehyde and thus would not constitute human health risks via formaldehyde release. However, these alternative NAF resins were reported to be significantly more expensive (Annex to the Background Document, Table D.4) and in addition, some of them must be considered toxicologically relevant[109]. For assessment of human health risks, the individual ingredients need to be examined in more detail (see Table 22).

Table 22: Known hazards of potential NAF alternatives (Grøstad and Pedersen, 2012; ANSES, ROMA on Formaldehyde, 2016)[110,111]

Alternative	Basic ingredients	CAS number	EC number	Known hazards (HH) acc. to C&L inventory
Polymeric methylene diphenyl diisocyanate (p-MDI; usually using a mixture of the three different isomers)	4,4'-methylene diphenyl diisocyanate (4,4'-MDI)	101-68-8	202-966-0	CLH: Acute Tox. 4* (H332) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Skin Sens. 1 (H317) Resp. Sens. 1 (H334) STOT SE 3 (H335) STOT RE 2* (H373**; resp. tract) Carc. 2 (H351)
	2,2'-methylene diphenyl diisocyanate (4,2'-MDI)	2536-05-2	219-799-4	
	2,4'-methylene diphenyl diisocyanate (2,2'-MDI)	5873-54-1	227-534-9	
	Mix of isomers	26447-40-5	247-714-0	

Emulsion polymer isocyanates (EPI)	Two-part system based on acrylate (e.g. vinyl acetate-acrylate copolymerized (VAAC)emulsion), polyurethane or vinyl acetate (i.e. PVA or EVA) and an isocyanate hardener (i.e. MDI) See below for hazard info on polyurethane, PVA and EVA and above for MDI.	Vinyl acrylate: 2177-18-6	Vinyl acrylate: 218-538-1	Self-classification: Acute Tox. 1 (H300) Acute Tox. 3 (331) Skin Irrit. 2 (H315) Eye Dam. 1 (H318)
		Vinyl acetate-acrylate copolymer: 25067-02-1	-	No hazard data available, but can contain 1-5 % nonylphenol, branched, ethoxylated (CAS: 68412-54-4) and 0.5-1 % vinyl acetate (CAS: 108-05-4)[112] Nonylphenol is a known SVHC.
Polyurethanes	Polyurethane adhesives are formed by the reaction of various types of isocyanates with polyols. Isocyanates (MDI) can be emitted from PU resins. (Cuno et al., 2015) For hazard info on isocyanates see above.	Polyurethane: 9009-54-5 (EPA)	Poly-urethane: 618-449-1	Not classified acc. to CLP Acc. to IARC, however, there is limited evidence of a carcinogenic effect of polyurethanes, and they are classified as an IARC group 3 substance (unclassifiable as to carcinogenicity in humans)[113].
		Ethylurea: 625-52-5	Ethylurea: 210-898-8	Self-classification: Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE (H335)
		Polyurethane Resin (example 1): 9018-04-6	Poly-urethane Resin (example 1): 618-503-4	Not classified for HH acc. to CLP
		Polyurethane Resin (example 2): 109159-24-2	Poly-urethane Resin (example 2): 695-277-3	Self-classification: Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)
Epoxy adhesives	Created by polymerizing acrylic or methylacrylic acids using a suitable catalyst The most common epoxy resins are produced from a reaction between epichlorohydrin (for hazards see below) and bisphenol A, a known endocrine disruptor (SVHC)[114], also classified as Repr. 1B.	Acrylic acid: 79-10-7	Acrylic acid: 201-177-9	CLH: Acute Tox. 4* (H302, H312; H332) Skin Corr. 1A (H314)
		Methylacrylic acid: 79-41-4	Methyl-acrylic acid: 201-204-4	CLH: Acute Tox. 4* (H302, H312) Skin Corr. 1A (H314)
		Epoxy resins (e.g.): 61788-97-4 932396-47-9 68334-76-9	Epoxy resins (e.g.): 920-018-0 612-377-4 692-835-8 690-887-6	Self-classification: Skin Irrit. 2 (H315) Skin Sens. 1 (H317) Eye Irrit. 2 (H319)
Polyvinyl acetate (PVA) Ethyl vinyl acetate (EVA)	Acetic acid ethenyl ester, homopolymer	9003-20-7	618-358-7	Self-classification: Acute Tox. 4 (H301, H332) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)
	Ethyl vinyl acetate (but-3-	24937-78-8	607-457-0	Self-classification:

[108] ECHA dissemination website: https://echa.europa.eu/de/advanced-search-for-chemicals
[109] https://www.wecobis.de/en/service/sonderthemen-info/voc-und-formaldehyd-aus-holz-und-holzwerkstoffen/voc-holz-3-info.html
[110] http://www.subsportplus.eu/wp-content/uploads/data/formaldehyde.pdf
[111] ECHA dissemination website: https://echa.europa.eu/de/advanced-search-for-chemicals
[112] https://hazmap.nlm.nih.gov/category-details?id=21841&table=copytblagents
[113] https://monographs.iarc.fr/list-of-classifications/
[114] https://echa.europa.eu/de/proposals-to-identify-substances-of-very-high-concern-previous-consultations?diss=true&search_criteria_ecnumber=201-245-8&search_criteria_casnumber=80-05-7&search_criteria_name=4 %2C4 %27-isopropylidenediphenol

	enoic acid; ethene)			Skin Sens. 1 (H317) Carc. 2 (H351)
	Vinyl acetate	108-05-04	203-545-4	CLH: Acute Tox. 4 (H332) STOT SE 3 (H335) Carc. 2 (H351)
	Vinyl acetate copolymer	-	925-954-3	No hazard information available, not listed in C&L inventory
Protein glues	Mainly soy-protein-based (soybean oil), but also made from linseed, rapeseed or blood Can be blended "with a very small amount of proprietary resin" or combined with a "liquid cationic amine polymer-epichlorohydrin amine called polyamide-epichlorohydrin (PAE)." (PAE considered to be completely consumed in batch manufacturing process used to make resin) Risks may arise when inhaled, as many people are allergic to particular proteins.	Soybean oil: 8001-22-7	232-274-4	Self-classification: Eye Irrit. 2 (H319)
		Epichloro-hydrin (1-chloro-2,3-epoxy-propane): 106-89-8	203-439-8	CLH: Acute Tox 3* (H301, H311, H331) Skin Corr 1B (H314) Skin Sens. 1 (H317) Carc. 1B (H350) Self-classification: Suspected ED Repr. 2 (H361)
Tannin-based and lignin-based adhesives	Polyhydroxypolyphenolics isolated from plants (e.g. glyoxalised lignin, mimosa tannin, hexamine)	Tannins: 1401-55-4	215-753-2	Self-classification: Eye Irrit. 2 (H319) Skin Irrit. 2 (H315)
		Lignin: 9005-53-2	232-682-2	Not classified for HH acc. to CLP
		Hexamine (methen-amine): 100-97-0	925-145-5 202-905-8	CLH: Skin Sens. 1 (H317)
Blood-based adhesive	Additional cross-linkers needed to produce technically suitable boards (no specifics available)	-	-	Health and safety concerns exist over the use of blood

RAC notes that although no formaldehyde is assumed to be emitted when using NAF resins, other potential hazards can be expected due to various different chemicals used for making these resins. Some of these potential hazards comprise CMR properties (e.g. PVA, EVA, EPI, pMDI), while others are limited to e.g. irritating properties. Only a very limited number of considered alternatives seem to not pose a risk to consumers, i.e. as they do not elicit any adverse human health effects. These include lignin-based adhesives. Furthermore, resins which would rather unlikely elicit adverse effects in consumers are tannin-based and soy-based (without addition of epichlorohydrin). However, especially for these natural/bio-based adhesives, it was reported that they can be more expensive, as their supply is considered limited. They are further likely not as effective as formaldehyde-based resins, particularly when used for plywood, particleboard, OSB, MDF production[115]; Background Document, Annex Table D.4). PU, on the other hand, was reported to be not applicable for particleboard and MDF. Furthermore, the emission of isocyanates (MDI) cannot be excluded when using this type of adhesive. Thus, PU does not seem to be an adequate alternative for formaldehyde-based resins, as it is the case with p-MDI.

[115] https://www.wecobis.de/en/service/sonderthemen-info/voc-und-formaldehyd-aus-holz-und-holzwerkstoffen/voc-holz-3-info.html

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of proposal:

Although all consumer articles for indoor or indoor/outdoor use in which formaldehyde or formaldehyde releasing substances have been used in their production process would fall under the scope of the proposed restriction, the impact assessment carried out by the Dossier Submitter focuses on wood-based panels. This is because wood-based panels used in both construction and finished articles have been identified as the main permanent formaldehyde emission sources in indoor air; hence they are expected to be the class of articles most affected by the proposed restriction.

The economic impact of the proposed restriction is expected to be limited, given that a voluntary agreement is in place in the EU's wood-based panels industry to only produce panels with formaldehyde emissions complying with the restriction proposal. Since the proposed emission limit is already legally binding in a number of Member States for wood-based panels, additional enforcement costs are only expected for authorities in Member States without national regulations to ensure compliance with the restriction and the imposed emission limit. Investment costs and additional testing costs are expected to be negligible and were not estimated by the Dossier Submitter. For the reference year 2016 costs to EU society are estimated to be in the order of €28 million (central estimate).

SEAC conclusion(s):

Costs associated with the restriction proposed by the Dossier Submitter

Considering the limit value proposed by the Dossier Submitter, in line with the comments received during the consultations on the Annex XV dossier and on the SEAC draft opinion, SEAC agrees with the Dossier Submitter that costs are expected to be limited both for the European wood-based panels and for the furniture sectors.

Overall, SEAC concludes that the restriction proposed by the Dossier Submitter entails additional costs for the EU society in terms of production, sampling, testing and enforcement costs in the order of some tens of millions of euros. Additional costs to EU consumers will depend on the extent to which non-EU manufacturers are able to pass through production cost increases in the form of higher prices.

Costs associated with the restriction proposed by RAC

SEAC concludes that the restriction as proposed by RAC would entail major additional economic costs in terms of investments in research and development, new technologies or plants, higher production costs, sampling and testing costs in the order of billions of euros.

For most of the impacted sectors, even if reaching the limit value proposed by RAC seems technically feasible, the main issue appears to be the economic feasibility, especially if combined with a too short transition period and the need to establish correlations between test methods in accordance with Appendix X.

SEAC based its conclusion on the comments received during the consultations by several sectors (chemicals sector, wood-based panels and furniture sectors, leather producers, rubber and tyres sector, insulation manufacturers, construction sector and many of their downstream users). Industry considers that high investment in R&D and high costs related to substitution and changes in production processes as well as, in some cases, unemployment has to be expected for European society in case of a restriction as proposed by RAC.

However, SEAC notes that part of industry such as, for instance, European manufacturers of alternative resins or materials or producers of the new equipment needed by industry to

comply, might benefit from the restriction. This would decrease the overall costs for the EU society of a potential restriction as proposed by RAC.

Therefore, even if SEAC agrees that major socio-economic impacts have to be expected, SEAC considers that the negative consequences related to the RAC proposal, as claimed by industry, tend to overestimate the magnitude of the impacts.

Key elements underpinning the SEAC conclusion(s):

Relevant information on the technical issues and socio-economic impacts associated with a potential implementation of either the Dossier Submitter proposal or the RAC proposal was provided to SEAC by industry stakeholders during the consultation on the Annex XV dossier as well as in the course of the consultation on SEAC's draft opinion.

As part of the consultation on the Annex XV dossier, the ECHA Secretariat, on behalf of SEAC, invited industry stakeholders (email sent on 2 September 2019) to submit information about the possible impacts of an emission limit lower than the value proposed by the Dossier Submitter should RAC propose a lower limit value following its derivation of a lower DNEL. SEAC notes that not all impacts reported in the comments received from industry in response to this invitation referred to the specific limit value proposed by RAC. This is because the exact limit value proposed by RAC, following its derivation of a lower DNEL, was not yet known at the time when industry stakeholders were invited to submit additional information on the possible impacts of a lower limit value. In addition, RAC also proposed a lower limit value of 0.05 mg/m^3 for formaldehyde concentrations in the interior of road vehicles and, during the consultation on the Annex XV dossier, no information from the automotive industry was received on the impacts of such a limit value. On the other hand, information on socio-economic costs provided by industry during the consultation on the Annex XV dossier could have overestimated in some cases the negative impacts of a lower limit value since this data was provided before the introduction of Appendix X, which reduces additional testing costs, and the introduction of the exemption for industrial and professional uses.

In the consultation on its draft opinion, SEAC invited industry, Member States, NGOs and any other relevant stakeholder to provide specific information on potential socio-economic impacts related to production changes, substitutions of resins, sampling and testing and enforcement of a restriction with the limit value proposed by RAC. Furthermore, SEAC invited stakeholders to provide information on the transition period needed to comply with the limit values proposed by the Dossier Submitter as well as with the limit values proposed by RAC.

In this context, without neglecting the added value of the information provided during the consultation on the Annex XV dossier, SEAC considers that the additional information provided during the consultation on SEAC's draft opinion seems more relevant since it is indeed more focused on the socio-economic impacts of the specific limit value proposed by RAC.

During the consultation on the SEAC draft opinion, comments were received from a number of industry associations of the following sectors:

- Formaldehyde sector (Formacare, ref. 458 and 514)
- Resin producing sector (Formacare ref. 514), including:
    - Phenolic resin industry and phenolic foams industry (EPRA, ref. 472; EPFA, ref. 497)
    - Aminoplast resin sector
    - Diisocyanate and polyol industry (ISOPA, ref. 459)
- Woodworking sector and in particular the wood-based panel industry (EPF, ref. 461 and 499; Fedustria, ref. 455; Confindustria, ref. 477)
- Furniture sector (Ameublement Français ref. 495; VDM, ref. 466; CBM, ref. 490; TMI ref. 493)
- Construction sector
- Mineral wool insulation sector (EURIMA, ref. 486)

- European leather industry (COTANCE, ref. 471; Fédération Française de la Chaussure, ref. 491; VDL, ref. 462; CTC, ref. 463; Nordic Leather Research Council, ref. 496)
- Automotive sector (ACEA ref. 484), including:
    - Moulded polyurethane parts industry (*EURO-MOULDERS,* ref. 453; *EUROPUR,* ref. 450; Formacare, ref. 514)
    - POM and plastic sector for automotive sector (PlasticsEurope, ref. 502)

All responding industry associations or companies claimed that several technical challenges can be expected entailing socio-economic costs. Such costs reported by industry include increased production and investment costs, revenue and job losses, reduced technical performances, loss of competitiveness on extra EU markets, negative impacts on the circular economy and even, in some cases, shutdowns.

Costs associated with the restriction proposed by the Dossier Submitter

SEAC notes that the most concerned sectors by this restriction are the wood-based panels industry and their supply chain such as, for instance, furniture producers and construction sector. The resin producing industry and the wood recycling industry as suppliers to the wood-based panels industry are affected in the same way.

SEAC notes that economic impacts on the sectors of other articles emitting formaldehyde were not further assessed by the Dossier Submitter since such impacts are assumed to be negligible compared to those related to wood-based panels which represent the articles most affected by the proposed restriction.

SEAC further notes that its analysis of the various cost elements is based on the evaluation of the Dossier Submitter's assessment on costs of substitution, investment, production, sampling, testing and for enforcement, calculated using the limit value of the restriction proposal.

SEAC considers that industry sectors producing other articles in the scope of the proposed restriction such as curtains, carpets and interior furnishings of road vehicles would not bear significant socio-economic impacts, given that these industry sectors will be able to continue using their current testing methods as foreseen by Appendix X.

Overall, SEAC agrees with the conclusions of the socio-economic assessment carried out by the Dossier Submitter for the proposed restriction. The information received in the consultations appears to confirm the limited socio-economic costs to industry associated with the proposed restriction.

In particular, EPF (ref. 2627 and 461) considers that the limit value of 0.124 mg/m^3, proposed by the Dossier Submitter and corresponding to the E1 class, is the most appropriate and proportionate value to guarantee safety to the European citizens, while minimizing the additional costs for the wood-based panels industry.

According to Formacare (ref. 458 and 514), the formaldehyde sector group of the European Chemical Industry Council (CEFIC), at the level of the limit value proposed by the Dossier Submitter, applicability is immediate and socio-economic impact is minimal.

<u>Compliance costs associated with the restriction proposed by the Dossier Submitter</u>

In terms of compliance costs (substitution costs, investment costs, production costs, sampling and testing costs), the main impacts are expected for the wood-based panels industry, the aminoplast resins and for POM, but other industry sectors (e.g. furniture, construction, insulation, leather and automotive industry) might also have to bear additional costs to comply with the proposed restriction.

Substitution costs

SEAC agrees with the Dossier Submitter that, to comply with the proposed restriction, no

major substitution of formaldehyde is expected due to the specific technical properties and economic aspects related to each formaldehyde and formaldehyde-based resin as well as formaldehyde-free resins, as described further above in the opinion.

Investment and production costs

SEAC considers that the proposed restriction could entail only very limited new investment costs.

SEAC based its conclusion on investment costs on the fact that, during the consultation on SEAC's draft opinion, it was indicated by several industry sectors, including the wood-based panels sector, that no or only very limited research and development, changes in technology, new machinery or modification of existing equipment seem to be necessary to switch from the production of class E2 to that of class E1 panels. For other articles concerned by the proposed restriction, SEAC cannot exclude some minor investment costs.

However, SEAC considers that there could be an increase of production costs for those EU companies still producing class E2 panels as well as for non-EU manufacturers producing class E2 panels for the EU market. For the EU actors in the supply chain of class E2 wood-based panels, as well as for EU importers of class E2 wood-based panels, if they do not want to lose their market, the proposed restriction is expected to increase production costs to reach the class E1 emission level.

In fact, producing class E1 panels is more expensive than producing class E2 panels because reducing formaldehyde emission implies the use of lower quantities of UF resins or the use of resins with a lower content of formaldehyde, entailing longer curing time and higher costs than the relatively inexpensive and fast curing UF resins. This also means that, when switching to the production of class E1 panels, the production volume will shrink compared to the production of class E2 panels, and this will further increase production costs. This increase in production costs has been estimated by the Dossier Submitter on the basis of information provided by the European Panel Federation (EPF). According to EPF, the production costs of E.LES[116] wood-based panels would be 10-15 % higher than those for class E1 panels[117]. As the exact difference in production costs between class E1 and E2 panels is not known, this range was used by the Dossier Submitter as an approximation for the difference in production costs between E1 and E2 panels. The lower end of this range (10 %) was used by the Dossier Submitter in the calculation. In the consultation on the SEAC draft opinion, EPF (ref. 461) specified the cost increase to comply with the E1 emission limit especially concerns PB/MDF production and is estimated at €79 million. This estimate corresponds to the upper end of the cost estimate provided by the Dossier Submitter (i.e. €28-79 million).

Costs of changing EU production of wood-based panels from class E2 to class E1 will be borne by EU society, either by EU manufacturers or by EU consumers, depending on the extent to which EU manufacturers will be able to pass through these costs. SEAC considers the impact of higher production costs on EU manufacturers of wood-based panels to be minimal as the vast majority of them already produce E1 panels. In fact, for the EU manufacturers of wood-based panels, who have already subscribed to a voluntary agreement to only produce class E1 panels, no negative impacts are expected in terms production costs due to the proposed restriction.

For non-EU-manufactured wood-based panels which are placed on the EU market, the costs associated with a switch from class E2 to class E1 panels will depend on their ability to pass through increased production costs to the EU consumers. The part of extra costs that non-EU manufacturers are able to pass through to EU consumers represents a cost to EU society. However, in case a pass through is not possible, the extra costs are borne by non-EU

[116] In December 2016, EPF announced the so called (E.LES), which sets different emission limits for different product groups. Under E.LES the formaldehyde emission limit for fibreboard and OSB is consistent with E1 (= 0.1 ppm or 0.124 mg/m^3) but is set to a lower value of 0.065 ppm (= 0.08 mg/m^3) for particleboard and plywood. E.LES is available to all EPF members for use but without any form of obligation (EPF, 2017).

[117] According to EPF, the price difference depends on the panel characteristics, with the price difference being smaller for standard grade boards and higher for boards that need high mechanical performance and/or strong resistance to humidity.

manufacturers. SEAC notes that the Dossier Submitter considers a pass through of costs as not very likely since non-EU manufacturers are assumed to compete on price.

Anyway, even if there is a strong price competition in the wood-based panels sector, SEAC considers that it cannot be excluded that non-EU manufacturers would pass through some of these extra costs to EU consumers.

On the basis of a survey among its resins producing members, Formacare (ref. 514) estimated that the 0.124 mg/m³ limit will imply more quality control and R&D investments that could be quantified between €200 000 and €500 000 per year and per company. While only a few companies reported this impact, there is at least one respondent for which the loss of turnover will raise up to €4 million, representing a yearly production decrease of 9 000 tons of resins.

EUROPUR and EURO-MOULDERS also submitted a joint comment (ref. 453). EURO-MOULDERS stated that to comply with the limit value of 0.1 mg/m³ for the indoor air of vehicles as proposed by the Dossier Submitter, the cost for industry would be relatively limited, since for a long time a large part of the automotive supply chain had implemented a voluntary limit at that level. Only a limited number of OEMs that currently do not maintain specifications for formaldehyde emissions from polyurethane parts will have engineering and R&D costs for the plants. From a technical point of view, it would be possible to comply with such new specifications if set at 0.1 mg/m³ with existing formaldehyde-mitigation technologies.

Stakeholders from the furniture sector (French furniture sector, ref. 495; Confindustria, ref. 477) underlined that the Dossier Submitter's proposal to limit formaldehyde emissions from articles to an "E1" level (i.e. 0.124 mg/m³ or 0.1 ppm) constitutes real progress for the health of European consumers and the single furniture market. This value nevertheless remains technically and economically sustainable due to the availability of quality materials at a reasonable price which can respect this limit and the know-how of European furniture companies.

Sampling and testing costs

SEAC considers that for the wood-based panels sector additional sampling and testing costs are likely to be limited since formaldehyde emissions testing is already part of routine production control. Nevertheless, some sectors such as the automotive sector (e.g. EURIMA, ref. 458; EPRA, ref. 472; ACEA, ref. 484; EPFA, ref. 497) reported testing costs as the main cost element to comply the restriction proposed by the Dossier Submitter.

Concerning sampling costs of wood-based panels, the Swedish Chemical Agency (KEMI) underlined that sampling using EN 717-1 (or EN 14080 for glue laminated timber and glued solid timber) and sampling preparation according to EN 326-1 are quite complicated as several fresh samples (5) are needed and several pieces from the board have to be tested. The samples should be wrapped up and hermetically sealed until being tested by specialists.

As far as testing costs of wood-based panels are concerned, in order to comply with national regulations with respect to formaldehyde emissions, industry already developed reliable chamber test methods for formaldehyde and other compounds using large (up to 48 m³) or smaller chambers (0.225 m³ and 1 m³). In addition, wood-based panel producers control formaldehyde emissions during production via smaller scale derived test methods, in accordance with quality control limits based on correlations with chamber test methods.

Taking into consideration the information gathered on other articles during the consultations, SEAC considers that, given the flexibility with regard to test methods introduced in the Background Document through Appendix X of the restriction proposal, testing the compliance with the proposed formaldehyde emission limit would imply minor additional costs for manufacturers of these articles.

SEAC notes that such additional sampling and testing costs would depend on the type and number of articles that will have to be tested (which should be limited since only articles where formaldehyde or formaldehyde releasing substances have been intentionally added are

within the scope of the proposed restriction), as well as on the testing methods and testing conditions used. Even though SEAC concurs with the Dossier Submitter's assessment that additional testing costs would be limited, SEAC also considers that, at least during the initial phase after entry into force of the proposed restriction, there will be additional costs related to the need to establish correlations between testing methods in order to keep using the testing methods already in place.

SEAC notes that the European phenolic resin industry (EPRA, ref. 472) provided information indicating that testing costs would primarily be associated with the development of robust correlations between EN 717-1 (which are comparable to the reference conditions specified in Appendix X) and other analytical methods mandated by existing regulations and industry standards required to confirm compliance with emissions limits.

The European Mineral Wool Manufacturers Association (EURIMA) is in a similar situation. EURIMA stressed that EN 717-1 is not the method used by the construction/mineral wool sector to test formaldehyde emissions into indoor air (test in this sector are rather performed using EN 16516). Moreover, EN 717-1 is not designed for outdoor application scenarios, and therefore there will be a need to establish testing conditions and a correlation with factory production control measurements. SEAC does not understand this concern for outdoor items because they are not within the scope of the restriction. This may be relevant for articles that can be used both indoor and outdoor.

SEAC does not anticipate sampling and testing costs additional to those currently incurred by industry in the following cases:

- Companies producing materials as well as their downstream users manufacturing consumer articles in which formaldehyde or formaldehyde releasing substances were not intentionally added during the production processes, as defined in the scope. Only in cases of doubt downstream users will afford costs to check the formaldehyde emissions in accordance with the conditions specified in Appendix X (see below).

- Sectors with established pre-testing or factory standard testing methods. The requirements for routine checks to ensure a reliable correlation between the used in-house testing methods and testing in accordance with the conditions specified in Appendix X remain unchanged.

SEAC anticipates some additional sampling and testing costs in the following cases:

- Industries without sector-specific testing methods in place for formaldehyde emissions will have to develop specific methods and to establish the correlation with the conditions specified in Appendix X.

- Companies in doubt about whether their suppliers could have used formaldehyde or formaldehyde releasers in their production processes would have to test if formaldehyde can be released from their articles.

- Industry still making use of very old correlations of some derived test methods (e.g. EN 120 and WKI flask method) which are probably not valid anymore and need to be re-evaluated on the basis of the conditions specified in Appendix X.

However, based on the information available, SEAC doesn't have sufficient data to quantify any of these sampling and testing costs nor for assessing the need for specific derogations.

SEAC notes that European Automobile Manufacturers Association (ACEA, ref. 484) stated that, even though the way to measure the limit value of 0.1 mg/m^3 is in line with their current approach, the Dossier Submitter's proposal would regardless entail extra testing costs. According to ACEA, the essential number of tests to reach satisfying confidence levels depending on model variation elevate testing costs up to €100 000 per model and year. Besides the needed external capacities, OEMs will be forced to expand the necessary in-house test facilities to ensure conformity of production. ACEA stated that this will create non-recurring costs between €500 000 and 1 000 000 per OEM/site depending on the still existing

test facilities and analytical devices.

SEAC is surprised about this order of magnitude of additional costs, because the established limit value of 0.1 mg/m^3 for indoor air measurement should be an established good practice in industry and with suppliers in their QM.

Concerning testing costs, PlasticsEurope (ref. 502) mentioned an example of a typical SME with an average consumption of 10 tons/year of POM producing small items like gears. On the basis of two measurements per year and €1 800 per measurement according to EN 717-1 that means €1 600 per SME/year. Based on the annual quantity of POM (around 264 000 tons) over all injection moulding sites, this means additional testing costs of €54 million per year. With an actual average price of around €3 000/ton and at 264 kilotons this refers to a turnover of €792 million. That means a cost increase of at least 7 %. This does not include additional costs for workforce for administration purposes or lower throughputs to reduce the formation of formaldehyde during processing. As outlined in the section *Testing small articles made of POM* above, SEAC supports the amendment of Appendix X to allow for more realistic loading factors for testing of very small articles.

Enforcement costs associated with the restriction proposed by the Dossier Submitter

Regarding enforcement, SEAC considers that some costs can be expected for the National Enforcement Authorities.

Considering the Forum advice, based on information provided by KEMI on the costs of sampling, sampling preparation and testing by the enforcement authorities and taking into consideration that the Dossier Submitter's analysis does not include articles other than wood-based panels, SEAC considers that the generic value for enforcement costs of €60 000 per year, suggested by the Dossier Submitter, could be considered as an underestimation of the administrative costs incurred by Member State authorities to ensure compliance with the emission limit of the proposed restriction.

However, SEAC notes that enforcement costs in those Member States already enforcing national regulations for wood-based panels cannot be considered as additional costs of the proposed restriction since they are already incurred in the baseline scenario.

Taking into consideration both these arguments, overall, SEAC concludes that the generic order of magnitude estimate of around €60 000 per year, could be a good indication of the enforcement costs also for this restriction.

Costs associated with the restriction proposed by RAC

SEAC based its conclusion on the comments received during the consultation on the SEAC draft opinion from a number of industry stakeholders covering several sectors. The industry considers that high investment in R&D, high costs related to substitution and changes in production processes as well as social costs of unemployment have to be expected for European society in case of a restriction as proposed by RAC.

Compliance costs associated with the restriction proposed by RAC

Based on the information received in the consultations, SEAC highlights that for most industries (such as the wood-based panels and furniture industry, the mineral wool industry, the resin producing industry, and the phenolic foams industry) research and development, changes in processes, production lines (technology, new machinery or modification of existing equipment) and in products seem to be needed to be able to comply with the 0.05 mg/m^3 emissions limit value proposed by RAC, while maintaining the same or similar performances of the final products.

According to several comments received during the consultation on the Annex XV dossier and on SEAC's draft opinion (ref. 2622, 2627, 2677, 461 and 477), the main issue to comply with the limit value proposed by RAC mainly concerns the cost increases related to the need to change to alternative resins, binders, or glue systems and/or scavengers and all related issues

concerning commercial availability, production and associated additional investment and production costs.

As far as resins are concerned, SEAC considers that manufacturers would have to face serious additional costs to switch from UF resins to other formaldehyde-based resins containing less free formaldehyde (such as MF and PF) or to the use of formaldehyde-free resins (such as PMDI) which is in general more expensive and technically more complex.

In addition to providing information relating to the Dossier Submitter's proposal (0.124 mg/m^3) and to RAC's proposal (0.05 mg/m^3), several comments from different industry sectors (ref. 458, 461, 466, 472, 477, 486, 487, 490, 493, 495, 497 and 514) provided also information on impacts associated with two other potential limit values: 0.08 mg/m^3 and 0.062 mg/m^3 ("half E1"), both lower than the one proposed by RAC but higher than the one proposed by the Dossier Submitter.

SEAC acknowledges that very clear and self-explanatory tables, summarizing the relevant impacts associated with these four different limit values, were provided by Formacare (ref. 458 and 514), the wood-based panel industry (EPF, ref. 461), the European Phenolic Foam Association (EPFA, ref. 497), the European Phenolic Resins Association (EPRA, ref. 472) and the mineral wool sector (EURIMA, ref. 486).

Wood-based panels and furniture industry

For the wood-based panels sector, the European Panel Federation (EPF, ref. 461) estimated that the limit value proposed by RAC, i.e. 0.05 mg/m^3, which corresponds to 40 % of the E1 emission limit, would entail economic cost to the EU society close to €13 billion and social impacts in terms of 514 000 jobs lost throughout the supply chain, while providing only negligible additional benefits in terms of protection of human health. However, EPF also reported that costs are not clearly predictable because they depend on the existence of relevant technical solutions and on their commercial availability, for example PMDI or melamine.

According to EPF, PMDI are not considered available and, in addition, no wide experience exists with such productions, except of a certain European production of PMDI bonded wood-based panels (which are mainly OSB and only certain special particleboards and MDF) and a restricted volume of so-called F**** boards for the East Asian market (but based on fully different quality and test method standards, especially concerning formaldehyde emission).

EPF claims that, since the volumes of PMDI currently available on the market will not be sufficient to produce all wood-based panels in Europe (particleboards, OSB, MDF), two new MDI plants with a capacity of 600 000 tons each would be needed. This would imply investment costs of approximately €800 million and a time period of 8 years for construction and 5 years for implementation. In addition, EPF reported that full PMDI production of particleboard is expected to entail additional cost for chemicals of €30/m^3, plus the cost of investments and additional costs for increased downtime and maintenance. For multi-daylight presses that are still mostly used by SMEs, the additional cost is estimated to be higher, in the order of €40/m^3 which could in some cases lead to the non-viability of the factory.

Furthermore, EPF estimated that the increase in melamine content in the aminoplast resins formulations to make up for the lower content of free formaldehyde, would imply a supply cost increase of €200-650 million (see section on *Alternatives* for further details on MF resins).

Table 23 provides the summary of the cost estimates provided by EPF for the wood-based panels industry for the RAC proposal as well as for other limit values.

Table 23: EPF (ref. 461) summary of the impacts of the four limit values

Limit value according to EN 717-1 (mg/m³)		Costs (million €)								
		Annual					One-time			Total
		PB/ MDF Prod. costs	PB/ MDF Lost business	Ply-wood Prod. costs	Ply-wood Lost business	Sub-total	Panel producer Invest.	Supplier Invest.	Sub-total	Grand total
E1	0.124	79	-	-	-	79	-	-	-	79
E1 Plus	0.08	437	-	75	-	512	-	-	-	512
1/2 E1 (50% E1)	0.06	1 008	348	88	125	1 568	-	1 600	1 600	3 168
RAC final proposal (40% E1)	0.05	2 016	2 085	126	625	4 852	100	8 000	8 100	12 952

EPF underlined that a limit value corresponding to 0.062 mg/m³ (i.e. “half E1”) is feasible, but it would cost close to €3 168 million in total. From a practical point of view, however, EPF also noted that such a legal limit can only be complied with by targeting even lower limits in production. To ensure compliance with the E1 limit of 0.1 ppm (i.e. 0.124 mg/m³) the real target value in an industrial production must be in the range of 0.08 ppm (i.e. 0.1 mg/m³) in order to compensate for production variations which can occur, including seasonal parameters. With “half E1” the daily target value in the wood-based panel production is at least 0.05 mg/m³ or even lower, because production variations will become more pronounced, and also formaldehyde test procedures are getting close to their limits of validity and reliability. The practical production target of 0.05 mg/m³ would be very close to the legal proposal of RAC.

SEAC notes that as of 1 January 2020, through the German Chemicals Prohibition Ordinance (“Chemikalienverbotsverordnung”), the German authorities require to measure formaldehyde emissions of wood-based panels according to EN 16516 instead of EN 717-1. In practice, even if the limit of 0.1 ppm (i.e. 0.124 mg/m³) for formaldehyde was not changed, the new German test conditions effectively mean that the limit value for formaldehyde emissions measured according to EN 717-1 are halved to 0.05 ppm (i.e. 0.062 mg/m³). This national effort is an indication that “half E1” is technically and economically feasible for wood-based panels. However, Formacare (ref. 514) points out an important aspect in its comment on the SEAC draft opinion. The significant difference between the RAC proposal of 0.05 mg/m³ (measured in accordance with Appendix X) and the German legislation (Appendix 1 to the German Chemicals Prohibition Ordinance), which effectively corresponds to a limit of 0.062 mg/m³ when measured in accordance with Appendix X, is not only the value itself but also the scope. According to the German legislation the limit value does not have to be met for wood-based panels that are covered later (e.g. by plastic, natural wood, etc.) in another company (to produce furniture, for instance) as long as the covered panel meets the limit value. Therefore, under the German legislation, it is actually possible to produce panels of the “former” E1 emission class and to place them on the market for use by the furniture industry because after covering the boards will meet the new “half E1” limit value.

In the current restriction proposal, the situation is different because this possibility does not exist. As soon as raw wood-based panels are placed on the market the relevant limit value has to be met, even if further processed later on to produce a piece of furniture. Formacare (ref. 514) referred to the fact that about two-thirds of the raw boards are produced for furniture industry this difference is very significant and thus, the current German market cannot be used as an accurate forecast of the effects of the proposed restriction, neither for the 0.062 mg/m³ nor for the 0.05 mg/m³ scenario.

During the consultation on the SEAC draft opinion, Confindustria (ref. 477), on the behalf of the Italian wood-based panels industry indicated that in Italy high investments were done in the past in particleboard production to develop technologies allowing to meet the E1 emission class by using 100 % recycled wood (see section on *Wider economic impacts related to the circular economy*). As such, no impacts are foreseen by Confindustria for the emission limit value proposed by the Dossier Submitter. A limit value as low as 0.062 mg/m³ can also

be achieved with 100 % use of recycled wood although with losses in productivity and at a significant cost increase. Confindustria underlined that for the Italian wood-based industry alone, the “half E1” scenario would imply an estimated increase of costs of around €32 million for particleboard, around €15 million for MDF and more than €10 million for plywood. Confindustria also emphasized that a large proportion of Italian manufacturers are unable to achieve the required emission level for certain classes of panels while retaining the same performance characteristics. This lower emission level could be reached with phenol-formaldehyde resins but would require structural changes to manufacturing plants, creating environmental issues relating to the handling of the phenol during production and in managing waste.

According to Confindustria, it is very difficult to fulfil the limit proposed by RAC with recycled wood, therefore a partial substitution with virgin wood will be necessary. A further reduction of the formaldehyde emission limit can only be achieved by using PMDI resins. Considering that formaldehyde scavengers are needed when using recycling wood, even when using a formaldehyde free resin for the production of new panels, panels with recycled wood may not reach the required values. This would prevent the development of the circular economy and put almost all Italian industry out of business. Moreover, the use of PMDI plus scavengers will lead to a large cost increase, estimated for the Italian particleboard industry alone at €125 million compared to the costs of complying with the E1 emission class. Moreover, the additional costs of the chipboard alone would result in a cost increase for the furniture sector, which would seriously impact the competitiveness of Italian furniture exports.

SEAC notes that a limit value of 0.062 mg/m^3 was also supported by a comment received in the consultation on the SEAC draft opinion from Kronospan Lampertswalde GmbH (ref. 487), a producer of wood-based panels.

The Belgian Federation of Woodworking, Furniture and Textile Industries (Fedustria, ref. 2597 and 455) underlined that to reach the emission limit value of 0.05 mg/m^3, its members would have to shift to other glue systems such as PMDI, PU or PF. This would reduce the production speed by 20 to 50 %. With a view to the OEL for MDI (5 ppb), Fedustria highlighted the need for further investment in other production lines with a closed cabinet, e.g. gluing of particles, diffusing and spreading of the glued particles on the belt, pre-press, press, diagonal saw and the glue kitchen. According to Fedustria, the size of the investment would also depend on the availability of free building space around the existing production sites. If no extra space is available, then production must be stopped to make the necessary changes. The association estimated in both cases several millions of euros are needed. Even for one production line they estimated investment costs in the order of tens of millions of euros. In addition, Fedustria stated that producers do not have experience with ultra-low emitting boards for heavy duty purposes, nor with low density or flame-retardant particleboard. According to Fedustria this would imply a big challenge for R&D in the wood-based panel sector and a transition period of at least 4 years would be necessary.

SEAC notes that all comments received from the European furniture industry are in favour of the “half E1” (0.062 mg/m^3) limit. National furniture industries, including Germany (VDM, ref. 466), Denmark (TMI, ref. 493) and the Netherlands (CBM, ref. 490) support the proposal of a general binding limit value across the whole European market of 0.05 ppm (i.e. 0.062 mg/m^3 or “half E1”) measured in accordance with EN 717-1 (which broadly corresponds to the conditions specified in Appendix X). SEAC shares the view of VDM, CBM and TMI that in Europe there is a need to harmonize limit values to support the internal market. The French furniture sector (Ameublement Français, ref. 495) underlined that, taking into account the new requirements in force in Germany since 1 January 2020, for wood-based panels and wood-based furniture, the limit value of formaldehyde should be set at 0.062 mg/m^3. The use of “half E1” wood-based panels would directly put the finished furniture article in compliance with the emission requirements without the need for testing, provided that no formaldehyde releasing substances are added during their production. However, SEAC acknowledges that technical and economic feasibility considerations related to the obligations for the German market are only valid for a subset of wood-based panels manufacturers which already serve the German market. The technical and economic consequences for other sectors of the economy can be more complex.

The French furniture sector (ref. 495) underlined that the emission limit proposed by RAC will induce an increase in their supply costs, risks on the performance levels (safety and durability) in use of the final furniture piece and, sometimes, a re-design of products, as well as uncertainties with regard to the availability of materials and mixtures. Ameublement Français underlined that, even if the emission limit of 0.05 mg/m^3 were to be technically feasible, this would only be the case if a sufficient transition period is granted and heavy investments would be done. This new technology would potentially require also investments into manufacturing plants for process changes, worker protection, etc. It will also include completing compliance testing according to EN 717-1 and generating compliance proofs as requested by the market, customers or authorities.

Construction sector

Construction panels for structural use seem to be particularly affected by the limit value proposed by RAC. Boards intended for use in construction fall under the scope of the harmonised standard EN 13986. Since July 2013, CE marking has become mandatory in all EU countries under the Construction Product Regulation (CPR). This imposes greater obligations on the whole supply chain to ensure that materials comply with the applicable standards and relevant technical information is provided. In case the limit proposed by RAC was to be implemented, EPF expects substantial additional costs for construction panels for structural use (system 1, 2+, table ZA.2, EN 13986), fire retardant panels and acoustic panels made with fire retardant non-structural panels (system 1, table ZA.2, EN 13986). In this context, SEAC stresses the importance of the exemption in paragraph 4 of the proposed restriction to articles exclusively for industrial and professional use if the formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use (see section on *Derogations and articles out of scope* for further details).

Construction products for outdoor use will face some difficulties with the application of the intermediate limit of 0.08 mg/m^3. Additional costs and a longer transition period (between 4 to 7 years) are expected to be needed to carry out R&D to find an alternative solution and to redesign the product portfolio. In addition, industry claims that companies will need to establish the correlation between the test conditions outlined in Appendix X and the EN 16516 method, as the latter is mainly used for outdoor application products, and to perform testing in external labs to generate compliance proofs required by the market. However, as explained in the section on *Derogations and articles out of scope*, SEAC supports an exemption for articles exclusively used in outdoor.

Mineral wool industry

The European Insulation Manufacturer Association (EURIMA, ref. 486) indicated that complying with the emission limit of 0.05 mg/m^3 could be technically feasible, but only when a sufficient transition period was granted (5 to 7 years) and heavy investments were done to redesign or reprocess the entire portfolio of insulation products while ensuring the same level of performances. There would be a need to switch to formaldehyde-free binders, implying changes in plants, as well as curing and production processes. In addition, the spinning technology of fibres, the mixing and spraying of the binder would require new machines to perform the operations. According to EURIMA, the 0.05 mg/m^3 limit proposed by RAC especially for outdoor products would imply research and heavy investments to ensure conductivity and durability. Based on the available information, Formacare (ref. 458) estimated, for the insulation industry, costs of investment in the range of €9-164 million per company and for the whole sector an annual cost of €1 257.1-1 419.8 million per year.

The mineral wool sector supplies for indoor and outdoor applications and requested a derogation for its outdoor applications at least. The transition to the limit value proposed by RAC would create €282 million additional costs annually for the indoor sector (in addition to one-time costs of €232 million). If all products (indoor and outdoor) together had to meet the RAC proposal, €2 304 million would be added annually (in addition to one-time costs of €383 million) according to EURIMA. Therefore, SEAC supports an exemption for outdoor grades of insulation material without risk of exposure to costumers (see section on *Derogations and articles out of scope*). For details see the costs overview presented by EURIMA (Table 24). Concerning the information provided by the European mineral wool sector

(EURIMA, ref. 486), SEAC notes that the derogation for outdoor articles highly reduce the potential loss of sales.

Table 24: Consolidated costs for the mineral wool sector associated with the four limit values (EURIMA/Formacare, ref. 514)

Scenario [mg/m³]	Overall costs
0.124	Total cost for the mineral wool industry under the Dossier Submitter proposal will be mainly related to the implementation of Appendix X: €2-3 million covering R&D, additional testing, quality control, external testing, factory control and the potential impact on employment
0.08	The cost includes investment costs of €3.5-60.5 million per company + €827.1-892.4 million per year for the whole sector The cost impact is an assumption based on the available information. This estimation takes into account the outdoors products as well.
0.062	The impact is comparable to the 0.05 mg/m³ scenario.
0.05	The costs include the investment costs of €9-164 million per company + €1 257.1-1 419.8 million per year for the whole sector The cost impact related to the RAC proposal is an assumption based on the available information.

Resin producing industry

Formacare's analysis (ref. 458 and 514), based on the survey conducted, also includes the impact of each of the four scenarios on its members in the resin industry. According to Formacare, the impact intensifies gradually over the four scenarios, with the aminoplast resins producers most impacted (see Table 25 and Table 28). Although less severe, significant impacts are expected for the acetal producers too (see Table 28).

Acetal resins

While facing little to no impact from a limit set at 0.124 mg/m³, acetal producers are expected to be only marginally affected by a 0.08 mg/m³ limit and to face slightly higher costs under a 0.062 mg/m³ limit, mainly due to the need for stricter quality control and measurement of samples. As far as the RAC proposal is concerned, acetal resins' sales would be affected. In fact, according to Formacare, compliance with a 0.05 mg/m³ limit under the conditions outlined in Appendix X appears compromised with a loading factor of 1 which is not realistic for acetal resins.

Aminoplast resins

Formacare (ref. 458 and 514) expects more severe impacts for aminoplast resins producers. The impacts of the four scenarios on the aminoplast resins sector were assessed in terms of investments (namely in extra R&D efforts), turnover loss, plant closure and price increase of alternatives.

According to Formacare, under the Dossier Submitter's proposal (0.124 mg/m³), the aminoplast resins producers will only be slightly impacted in terms of additional investments in R&D and some markets loss. Many members of Formacare flagged a need for more quality control and R&D investments which could be mean extra costs in the order of €200 000-500 000 per year and per company.

A limit value of 0.08 mg/m³ is considered economically feasible by the majority of companies of the aminoplast resins sector. However, according to industry, given the current development stage of alternatives, the 0.08 mg/m³ scenario would be challenging, mainly for SMEs, resulting in increased costs for both resin and wood-based panel manufacturers and raising the prices of aminoplast resins by about 6-10 %. Besides additional R&D investments (in the range of €0.5-2 million per company), industry claims that for specific products there would be negative impacts in terms of quality, energy consumption and competitiveness,

potentially entailing losses of profitability and employment.

The technology to reduce emissions to comply with a limit of 0.062 mg/m^3 appears to be available as similar provisions for wood-based panels are already in place in Germany. Formacare estimated that for large companies, production cost increases would be in the order of 5-10 %. Companies of intermediate size would face production cost increase in the order of 20-25 %. This price increase is one of the consequences of the loss of productivity resulting from a greater energy consumption (bigger carbon footprint and source of costs for producers), a slower batch cycle and overall increased supply costs caused by the lower volumes sold. Under the 0.062 mg/m^3 limit scenario the foreseen loss of sales is in the range of 15-30 % for most companies responding to the Formacare survey.

To meet the RAC emission limit, aminoplast resins producers would face R&D costs for new formulation (€5-16 million per company according to some of the respondents to the Formacare survey). Both small and large companies warn that, for aminoplast chemistry, technology to comply with the RAC limit is not available on the market. Turnover losses are estimated to range from 30 % in the best-case scenario, to virtually 100 % for the worst-case scenario and would at least reach €1.376 billion. According to the Formacare survey, in the EU, the vast majority of the aminoplast resin producers would go out of business, while three aminoplast resins manufacturers companies claimed to be able to comply with the RAC's emission requirement, facing only limited economic impacts (€1-4 million per company) but, according to Formacare, this might raise resin prices by 150 %. For the members of Formacare, regardless of the transition time, the RAC proposal would push more than half of the aminoplast resins producers out of the market.

Table 25: Summary of the impacts of the four restriction scenarios on the aminoplast resins producers (ref. 514)

Effects / Scenario	Investments	Turnover loss	Employment effects	Plants closure	FA derivatives price increase
1= 0,124mg/m^3 (DS)	Minor	Minor, if existing	None	None	0-5%
2= 0,08mg/m^3	Medium	5-10%	None	None	5-10%
3=0,062mg/m^3	High	5-25%	Around 600 jobs threatened	Some	5-25%
4=0,05mg/m^3 (RAC)	Technology not even available	Above 50%	10,600+ jobs threatened	Majority	5-50%

In general, according to Formacare, the limit value proposed by RAC, which is about 40 % of the limit value proposed by the Dossier Submitter, is the most difficult to assess, because there would be no precedent[118] for such a low emission class.

Formacare explained that, since the emission levels of the RAC proposal appear largely impossible to reach with current technology/chemistry for the respondents of the survey, converting current aminoplast resins to Ultra-Low Emission of Formaldehyde (ULEF) resins relies on the availability of three commodities: either melamine (for tweaked MUF), or resorcinol (for replacement of MUF in specific uses), or PMDI (whether as full replacement of UF/MF/PF resins or as an additional crosslinker). Table 26 gives an overview of the commercial availability of these three commodities.

[118] Formacare underlined that the Japanese F**** standard is considered far from being comparable because it only affects formaldehyde emissions from furniture used in public buildings.

Table 26: Commercial availability of melamine, resorcinol and PMDI (Formacare, ref. 514)

	Melamine	Resorcinol	pMDI
Current Market	Available, long market.	Very tight market, low number of producers, competing applications.	Balanced market, scarce availability of pMDI.
Estimated future market (RAC proposal, 0,05mg/m³)	Strong European demand increase of at least 25%. Current market able to supply increased demand from WBP industry, but price increase very likely.	13-fold increase for Wood adhesives in Europe. Current market unable to supply extra demand from WBP industry.	Strong increase of demand (insulation) & increase of supply to balance out as well. Current & foreseeable future markets unable to absorb extra demand either for mixed use or full replacement by p-MDI (4-8fold increase of current demand for WBP).
Trend forecast from restriction at 0,05mg/m³	Tightening. Visibility is very limited due to lack of large scale experience to produce ultra low emission resins.	Tightening	Tightening

In addition, Formacare claims that there could be a risk of increased market concentration negatively affecting competition. As a consequence, for the whole wood industry, there could be an underinvestment on innovation and a decrease in productivity. Consumers might also face a reduction of choice, as well as higher prices. Formacare underlined that even if there are technical alternatives, these would also have to be economically feasible throughout the whole supply chain.

PMDI resins

According to the European Diisocyanate & Polyol Producers Association (ISOPA, ref. 459), at least five European PMDI resin producers are investing regularly into new capacities to meet future growing demand. SEAC considers that if the RAC limit would be in place additional production capacity European PMDI resins producers would be able to serve part of the wood-based industry. Therefore, under the RAC proposal, PMDI resins producers would gain at least part of the market loss of producers of other resins.

Phenolic resins

With regard to phenolic resins, the European Phenolic Resin Association (EPRA, ref. 472) explained that downstream users estimate that, where product and process development costs are prohibitive, or where no viable alternative is available, between 2 % and 7 % of manufacturing capacity may be lost. EPRA adds that sales would be lost translating into additional costs for the sector (between €16 million and €55 million per year). For EPRA members, the intermediate scenarios 0.08 mg/m³ and 0.062 mg/m³ would imply a loss of resins' sales at the same costs as estimated for the RAC proposal (see Table 28).

Phenolic foams industry

Phenolic foams consist of fully-cross-linked polymeric matrices manufactured from phenolic (PF) resins. According to the European Phenolic Foam Association (EPFA, ref. 497), industry is testing formaldehyde emissions of their products according to EN 16516. While the products would clearly comply with the Dossier Submitter's proposal, annual testing costs would at least double over the first two years after the entry into force of the restriction in order to become confident in the correlation between testing according to EN 16516 and the testing requirements outlined in Appendix X. These additional testing costs will cause at least €225 000 over the first two years.

Table 27: Impacts of the different limit values on the phenolic foam sector (EPFA, ref. 497)

Proposed Threshold Limit (mg/m^3)	Loss of Sales (%) (Indoor Products Only)	Loss of Sales (%) (Both Indoor & Outdoor)
0.124	0	0
0.080	0-5	30-50
0.062	5-10	50-70
0.050	15-20	70-90

Table 28, prepared by SEAC, summarizes the impacts on the resin producing sector.

Table 28: Summary of the impacts of the four scenarios on producers of different resins

	0.124 mg/m³	0.08 mg/m³	0.062 mg/m³	0.05 mg/m³
aminoplast resins producers	slight impact	significant financial impacts	R&D investments; increase in production costs (5-10 %); distributional impacts	R&D investments (€5-16 million); loss of turnover (30 %); plant closures; market concentration
acetal producers	little to no impact	only marginally affected	slightly higher costs for quality control and measurement of samples	sales would also be hindered (loading factor issue); market concentration
phenol resin producer	little to no impact	loss of resin sales for phenolic resin manufacturers 2-7 % (€16-55 million/year).		

Source: SEAC summary of the information received

Automotive industry

EUROPUR and EURO-MOULDERS (ref. 453) indicated that the limit proposed by RAC over a 4 year period would impose costs of €96.7-126 million for moulded and slabstock foams used in vehicle interiors, in terms of engineering, R&D and for the formulation of a new generation of formaldehyde scavengers (see Table 29). SEAC takes note of the provided estimates but also considers that incremental improvements in the production of formaldehyde scavengers decrease such costs.

It is claimed that, as a consequence of the concentration limit proposed by RAC for car interiors, in order to guarantee the safety of all polyurethane parts of vehicles (such as for instance airbag sensors included in the seat), in principle requalification (costs not included in Table 29) would be required by OEMs. Based on the experience from previous cases of changes in additives in foam formulations, the associations indicate that the typical one-time requalification cost in such situations is about €40 000 to €50 000 per OEM or foam type for each supplier. Regarding the limit of 0.05 mg/m³, the two associations requested to extend the current transition period of 2 years to at least 5 years to allow industry to adapt.

Table 29: Costs associated with the concentration limit proposed by RAC for car interiors (EUROPUR and EURO-MOULDERS, ref. 453)

	2021-2022 [million €]	2023 [million €]	2024 [million €]
MOULDED FOAMS			
Engineering	3.90	0	0
R&D	5.13-7.37	0	0
Formulation	4.95-6.19	19.8-24.75	19.8-24.75
SLABSTOCK FOAMS			
Engineering	2.17	0	0
R&D	31.69-45.56	0	0
Formulation	1.03-1.29	4.12-5.15	4.12-5.15
TOTAL	48.9-66.5	23.9-29.9	23.9-29.9

The European Automobile Manufacturers Association (ACEA, ref. 484) noted the difficulties to get a complete picture within a short period of time of the consequences associated with the RAC proposal for the whole supply chain. According to ACEA, RAC's proposal will cause significant costs in the order of millions of euros for each OEM and model, including one-off R&D costs as well as recurring operating costs for the optimized raw materials. This affects different material concepts like natural materials (e.g. wood, fibre enforced material), interior paintings, POM, seat coverings, insulations and many other materials. ACEA referred for PUF to the comments submitted by EURO-MOULDERS (see above) as an example for a material which is contributing to formaldehyde emissions in vehicle cabin interiors. ACEA underlined that in most cases formaldehyde is not an integrated part of material formulations but a degradation product. For instance, developing new ways of stabilization will be needed for some materials, which requires time and in general it entails high R&D costs.

Sampling and testing costs

SEAC notes that, in general, regardless of the level of the emission limit (either the level proposed by the Dossier Submitter or the value recommended by RAC), costs for testing should be the same. However, in some cases, a lower limit value could potentially lead to higher sampling and testing costs for industry since the lowered emission limit could imply the need to carry out additional tests to obtain product certifications following composition changes and the need to increase testing efforts in cases where companies suspect their products could exceed the emission limit.

During the consultations, Fedustria and one company (ref. 2604) indicated that, if the composition of the used materials changes, for fire protection doors, anti-theft or sound proof doors, currently produced with wood-based panels, new tests would be necessary to get new certifications to test the technical performance of these articles. This cost was indicated to be between €5 000-10 000 per test (depending on the article to be tested). This indicates that fire tests, smoke tests, destruction tests and sound tests are very expensive.

The French furniture sector (ref. 495) underlined that the RAC's proposal would increase the number of emission tests to be carried out on final articles or on complete furniture to ensure compliance, which will represent additional costs and delays.

SEAC notes that the leather industry (COTANCE, ref. 471) highlighted that since there is no experience with test methods that can monitor leather articles below a level of 0.05 mg/m^3, the consequences for the leather industry cannot be predicted.

<u>Enforcement costs associated with the restriction proposed by RAC</u>

SEAC only considered the cost estimate of €60 000 per year expected for the Dossier Submitter's proposal. As the Forum has only been involved at the beginning of the process and only with the proposal of the Dossier Submitter, SEAC is lacking information on the implementability and enforceability of the limit value proposed by RAC and, as such, is not in

a position to assess the extent to which the €60 000 estimate is transferable to the RAC proposal.

Benefits

Summary of proposal:

The Dossier Submitter states that the proposed restriction would limit exposure to formaldehyde in indoor environments by restricting the placing on the market of high formaldehyde releasing articles, including from imports. This would contribute to keeping indoor air formaldehyde concentrations below the WHO guideline value and would help to prevent detrimental health effects linked to formaldehyde inhalation exposure.

While the Dossier Submitter expects the proposed restriction to be an effective measure for addressing the identified risks, in particular with regard to new articles imported into the EU, the overall risk reduction potential, and hence the benefits of the proposal, are expected to be limited, given that the formaldehyde concentrations measured in indoor air environments in the EU are already below the WHO guideline value in the majority of cases.

For a reference year, 2016, the Dossier Submitter estimates that around 300 000 homes or 690 000 individuals could potentially benefit from reductions in formaldehyde concentration to values below the WHO guideline value as a result of the proposed restriction. In addition, the proposed restriction would serve as a preventative measure that bans high formaldehyde emitting articles from being placed on the EU market and it would harmonise the existing rules on formaldehyde emissions for the entire Union.

SEAC conclusion(s):

Benefits associated with the restriction proposed by the Dossier Submitter

SEAC considers that benefits of this restriction will derive from reducing the exposure to formaldehyde in indoor environments. Adverse health effects from indoor exposure to formaldehyde relate to irritation of the eyes, upper airways and nasopharyngeal cancer.

SEAC notes that the benefits have been assessed by the Dossier Submitter in terms of number of new dwellings and individuals for which formaldehyde exposure could potentially be brought below the WHO guideline value.

SEAC agrees with the Dossier Submitter that benefits will mainly come from the reduction of exposure to formaldehyde from wood-based panels (and articles made from them, such as furniture), which are the main consumer articles releasing formaldehyde.

However, SEAC considers that the benefits of the proposed restriction could be higher than assessed by the Dossier Submitter since it also reduces formaldehyde releases from articles other than wood-based panels.

Benefits associated with the restriction proposed by RAC

SEAC acknowledges the potential additional benefits arising from the RAC proposal in terms of reduced exposure that may lead to a reduction in eyes and upper airways irritations and nasopharyngeal cancers. SEAC notes, however, that the risk reduction was not quantified, and that the magnitude of any additional benefits is not known.

Key elements underpinning the SEAC conclusion(s):

Benefits associated with the restriction proposed by the Dossier Submitter

SEAC based its conclusions on benefits on the following considerations:

- RAC, despite proposing more stringent limit values, expects some health benefits from the Dossier Submitter's proposal, in particular due to the restriction of imports of class

E2 panels.

- Even if the exposure from other permanent sources has been considered as a background exposure, the analysis of the benefits carried out for this restriction only focuses on class E2 wood-based panels assumed to be installed in new homes without considering that such panels could be installed in old homes being renovated. However, SEAC recognises that such an assumption does not affect SEAC's conclusion on benefits.

- Additional benefits, which were not included in the assessment made by the Dossier Submitter, could come from avoiding the exposure resulting from other consumer articles releasing formaldehyde in indoor air.

- Benefits were not monetized in the Background Document by, for instance, calculating the avoided costs of illness related to the main endpoints (skin and eyes irritations) or by using estimates of willingness-to-pay for formaldehyde emission reduction.

Benefits associated with the restriction proposed by RAC

SEAC notes that the additional human health benefits from the lower limit value proposed by RAC remain unquantified since the reduction in risk associated with lowering the limit value was neither quantified by RAC nor by the Dossier Submitter. Therefore, SEAC does not have sufficient information to assess the magnitude of the additional human health benefits associated with the limit value proposed by RAC.

SEAC notes that, during the consultation on the SEAC draft opinion, little information was gathered on additional benefits that would arise from a potential restriction with the limit value proposed by RAC.

Other impacts

Summary of proposal:

Social impacts: Although the proposed restriction applies to all articles that may release formaldehyde in indoor environments, the Dossier Submitter has limited the assessment of potential impacts of the proposed restriction to various relevant actors in the supply chain of wood-based panels. This choice is justified by the fact that this is expected to be the sector most affected by the proposed restriction. Relevant impacts are identified for both EU and non-EU manufacturers of non-compliant wood-based panels as well as downstream users of panels. To the extent that impacts on these actors lead to costs for EU society, they are considered as economic impacts. Other actors discussed are producers of formaldehyde and formaldehyde-based resins, exporters of wood-based panels and SMEs. Any effect of the proposed restriction on these actors is however expected to be limited.

Wider economic impacts: According to the Dossier Submitter, the proposed restriction would have minor impacts on article prices of class E1 wood-based panels. As such, international trade flows are likely to remain unchanged and no substantial wider economic impacts are expected as a result of the restriction. No wider impacts on the economic growth or development, changes to competition with the EU or direct impacts on the macroeconomic stabilisation have been identified by the Dossier Submitter for the case that the proposed restriction was implemented.

Distributional impacts: The Dossier Submitter expects any negative impacts on manufacturers and importers of class E2 wood-based panels to be offset by gains by manufacturers and importers of class E1 wood-based panels. As the vast majority of wood-based panels placed on the EU market already complies with the formaldehyde emission class E1 and therefore with the proposed restriction, these distributional impacts are expected to be limited.

SEAC conclusion(s):

Other impacts of the restriction proposed by the Dossier Submitter

SEAC notes that from the proposed restriction only limited social impacts can be expected, namely for actors of the wood-based panels industry.

SEAC considers that only minor wider economic impacts on the international and European competitiveness (very limited changes on article prices, as well as on trade flows) can be expected from the proposed restriction. SEAC considers that no impacts can be expected on the macroeconomic stability and growth of the European economy.

SEAC considers that distributional impacts can be expected to be limited with some negative impacts on manufacturers and importers of class E2 wood-based panels and some positive impacts on manufacturers and importers of class E1 panels. SEAC notes that the proposed restriction is expected to have limited impacts on small and medium-sized enterprises as most wood-based panels producers in the EU already subscribed to the voluntary industry agreement of producing only class E1 panels.

Therefore, overall, SEAC concludes that social, distributional and wider economic impacts of the restriction as proposed by the Dossier Submitter are negligible.

Other impacts of the restriction proposed by RAC

SEAC considers that RAC's proposal would result in social impacts in terms of job losses, mainly in the wood-based panels industry and its supply chain. However, it seems realistic to SEAC that jobs will be lost also in other industry sectors. Unemployment is expected mainly due to the fact that some companies will have to reduce or stop their activities if they cannot bring their production in compliance with the RAC proposal.

SEAC expects that the limit proposed by RAC might entail some wider economic impacts in terms of changes in competitiveness of European companies, such as the producers of resins, potentially partially in favour of extra-European companies. Moreover, SEAC considers that the RAC proposal would also entail negative impacts for the European circular economy reducing the recycling of wood and wood-based materials.

Regarding distributional impacts, SEAC considers that in particular small and medium-sized enterprises, as well as consumers would be affected.

SEAC concludes that, overall, the restriction, as proposed by RAC, would entail significant negative socio-economic impacts on almost all industry sectors affected by this restriction. The RAC proposal would also have wider economic impacts and distributional implications for the EU society.

Key elements underpinning the SEAC conclusion(s):

Other impacts of the restriction proposed by the Dossier Submitter

Concerning social impacts, SEAC conclusions are based on the fact that the proposed restriction mainly concerns the supply chain of wood-based panels. No unemployment effects are expected as a result of the proposed restriction, because wood-based panel factories will not stop their activity while putting their production in conformity with the proposed limit since only minor economic impacts are expected. Accordingly, the supply chain should not be affected by unemployment. The consultations did not contradict this view.

The economic impacts for the EU associated with the switch from class E2 to class E1 panel production will depend on the capacity of non-EU manufacturers to pass through increased production costs down to EU consumers. Only the part of the extra costs passed through to EU consumers represents an additional cost to EU society. However, even if the distribution of these costs between non-EU manufacturers and EU consumers is not known, most probably, due to international competition, extra costs of imported articles would be mainly

borne by non-EU manufacturers rather than EU consumers.

According to a survey carried out by Formacare among its members (ref. 514), the socio-economic impacts of the restriction proposed by the Dossier Submitter are limited to a need for more quality control and R&D investments (€200 000-500 000 per year and per company), some market losses and a price increase of 3 % implemented by some aminoplast resins producers.

Moreover, the economic impacts of the proposed restriction are not of such a magnitude to imply wider economic impacts in terms of article prices, as well as on international trade and on macroeconomic stability and growth.

Concerning distributional impacts for the wood-based panels industry, SEAC conclusions are based on the fact that most wood-based panels placed on the EU market already comply with the emission limit of the proposed restriction since a vast majority are already class E1 panels. For manufacturers and importers of class E1 panels some positive impacts are to be expected as they have already consolidated markets in terms of, for instance, clients, point of sales, marketing activities, etc.

As far as downstream users of class E2 wood-based panels, such as construction industry, furniture manufacturers, producers of laminate flooring, and final consumers are concerned, some higher costs are expected for purchasing more expensive class E1 panels, as reflected in the estimate of production costs by the Dossier Submitter.

Other impacts of the restriction proposed by RAC

Social impacts related to job losses

During the consultations, direct and indirect job losses were claimed by different sectors in the case of RAC's proposal as a consequence of loss of sales and high investments that could lead to plant closures. However, detailed figures on the actual number of jobs lost was made available to SEAC only by a few sectors such as the wood-based panels industry (EPF, ref. 461) and by the chemicals industry (Formacare, ref. 458 and 514).

EPF indicated that the estimate of 514 000 potential jobs lost is based on the assumption that maximum 50 % of the PB/MDF production could switch to PMDI due to a lack of PMDI availability. However, EPF claimed that probably this could be an underestimation. If the PMDI industry would not be able to provide the required capacity, EPF calculated that 857 000 jobs would be lost.

Formacare indicated approximately 10 600 job losses for the chemical industry in the EU and Norway. SEAC has no information on whether these 10 600 job losses estimated by Formacare for the chemical industry are included in the figure of 514 000 provided by EPF. Therefore, in order to avoid possible double counting, SEAC did not add up the Formacare and the EPF figures and only considered the number of jobs lost as estimated by EPF in its assessment of social impacts.

SEAC does not have sufficient information to assess if the claimed number of job losses can be considered realistic. However, based on the information received by industry during the consultations, SEAC attempted to assess the social impacts of job losses associated with the proposal from RAC. In order to monetise these impacts, SEAC applied the methodology on social costs of unemployment outlined in Dubourg (2016)[119] and endorsed by SEAC (2016)[120].

In the absence of specific figures concerning the average salary for the impacted European industries, SEAC based its assessment on the average monthly salary for the year 2019 in

[119] Dubourg (2016): https://echa.europa.eu/documents/10162/13555/unemployment_report_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554
[120] SEAC (2016): https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

the EU (i.e. €1 857 equal to an annual salary of €22 284)[121]. Following the methodology outlined in Dubourg (2016), SEAC multiplied the average annual salary with the number of jobs potentially lost and multiplied the result with the default welfare factor of 2.7, i.e. 514 000 * €22 284 * 2.7. This results in estimated social costs of unemployment of €30 926 million.

SEAC considers that, while the job losses could be overestimated for the wood-based sector, since the EPF assumptions on which they are based seem rather pessimistic, the total social costs could be underestimated since they only include the jobs that could be lost by the wood-based and by the chemical industry, neglecting potential unemployment in other sectors that did not provide quantified estimates.

Taking into account the above-mentioned considerations and uncertainties, SEAC considers that, at European level, total social cost of unemployment associated with the RAC's proposal can be expected to be in the order of tens of billions of euros.

Wider economic impacts on the European competitiveness

SEAC considers that some limited negative impacts can be expected in terms of international competitiveness of the European products and trade.

SEAC notes that EPF, in their comments on the SEAC draft opinion, underlined that, to achieve compliance with the RAC proposal, there is not sufficient capacity of melamine and PMDI. According to EPF, there is already now a strong competition on the melamine raw material market, with large and growing demand in particular from the Asia-Pacific region. Increasing demand in Europe, which would be driven by the restriction as proposed by RAC, could have a strong impact on product availability and lead to price increases.

On the side of input supply, SEAC considers that, given the increased demand, the limited availability of melamine and PMDI in Europe might entail the need to purchase these alternative resins at higher prices. If EU companies producing such resins would not be able to expand their capacity, non-EU companies (mainly Asian) might gain additional market share. However, SEAC considers that the gap in the availability of PMDI resins from European producers might be smaller than expected by EPF. In fact, the European Diisocyanate & Polyol Producers Association (ISOPA, ref. 459) underlined that regular investments are made by European PMDI resin producers to increase their production capacities to meet additional demand. Therefore, SEAC considers that only a use of PMDI-based resins by the whole wood-based industry would require additional plant capacity. However, in SEAC's view, this is not the case since a switch to PMDI does not seem necessary for all applications.

In addition, SEAC notes that, should the RAC limit be adopted, producer surplus losses for manufacturers of formaldehyde-based resins would be compensated, at least partially, by the producer surplus gains of the PMDI resin manufacturers. This would then represent mainly a distributional impact for the EU society.

On the side of sales, the competitive position of EU producers vis-à-vis non-EU competitors could be affected in case European manufacturers would have to increase final prices of their articles in order to cover these higher costs. In fact, in case, on their side, non-EU manufacturers would not increase prices of their articles, there might be a reduction of competitiveness of European exports in terms of prices.

In SEAC's view, in terms of macroeconomic stability and overall growth of the European economy, no impacts can be expected.

Wider economic impacts related to the circular economy

Several stakeholders, namely from the wood-based panel industry (EPF, ref. 461) and the main association of manufacturing and service companies in Italy (Confindustria, ref. 477) highlighted the major negative impacts that the proposal made by RAC would entail for the

[121] Data on average monthly salary taken from Eurostat.

recycling sector and the circular economy.

According to the comments received on this subject, wood-based panels contain a substantial share of recycled wood and the limit value proposed by RAC would reduce the ability to use recycled wood-based materials containing formaldehyde-based resins. Moreover, the RAC proposal may result in lower production volumes of wood-based panels leading to a lower demand for recycled wood. As a result, the use of virgin wood, glass or plastics in several applications (such as, among others, packaging and transportation), as well as the use of steel and cement in the construction sector would increase and wood waste that is currently recycled would need to be disposed of in a different way (for instance by incineration).

SEAC shares the view that wood is an important renewable resource namely for packaging, construction material but also in many other applications and that a low emission limit value could have negative impacts on wood recycling.

Distributional impacts among sectors and companies (including SMEs)

Besides the distributional impacts among producers of resins discussed above, SEAC notes that, according to the survey carried out by Formacare (ref. 514), mainly five sectors would be negatively impacted by the RAC proposal. These sectors are the woodworking sector (in particular the wood-based panel industry), the POM supply chain, the mineral wool insulation sector and the automotive sector. SEAC notes that, according to Formacare, lowering the limit down to the value proposed by RAC would entail different impacts on companies depending on their size.

SEAC considers that negative impacts can be expected not only for manufacturers and importers of class E2 wood-based panels, as under the Dossier Submitter's proposal, but also for manufacturers and importers of class E1 and E.LES wood-based panels and other articles.

In addition, SEAC considers that, in other sectors, such as the resins producers and leather manufacturers, the most affected companies would be SMEs with lower capacity of making the necessary investments to stay on the market.

SEAC notes that Formacare (ref. 458 and 514) evaluated that, even with an emission limit of 0.062 mg/m^3 resin producing SMEs might be forced to close their business units with significant reductions in employment. Similarly, the European leather industry (COTANCE, ref. 471) provided information on the impacts on the about 1 600 SMEs directly employing some 30 000 workers. These companies generate business to some 40 000 enterprises and work to about 2 million people downstream of tanning.

SEAC considers that switching to an alternative resin chemistry in order to comply with the RAC proposal could potentially entail benefits for manufacturers of alternative resins. In general, these gains related to the production and sales of alternative resins would benefit other European companies than those producing classic resins (distributional impact) or companies based outside the EU (net loss for the EU economy). However, SEAC is unable to assess to what extent the gains related to the production and sales of alternative resins would take place within the EU or not.

Distributional impacts on consumers

SEAC notes that the RAC proposal might increase prices of consumer articles. This distributional impact would affect end users only if manufacturers would pass along their supply chain at least a portion of their additional investment and production costs.

Overall proportionality

Summary of proposal:

The Dossier Submitter considers the proposed restriction as proportionate to the risk. This conclusion is based on an examination of the proposed restriction's cost-effectiveness, which compares compliance costs with the number of homes or individuals in the EU that could

potentially benefit from formaldehyde concentrations below the WHO guideline value. For a reference year, 2016, the resulting costs of achieving formaldehyde concentrations below the WHO guideline value – €93 per affected home and €41 per affected individual (central estimates) – are considered marginal compared to the costs of a new dwelling.

RAC and SEAC conclusion(s):

RAC

RAC indicates that proportionality should also be weighed against the risk based on the proposed DNEL of 0.05 mg/m³. It notes the difficulties for SEAC as the Dossier Submitter has not taken into account additional considerations to reflect options for lowering the emission limit. RAC expects more tailored information may become available in the consultation on the SEAC draft opinion with regards to cost-effectiveness for (consumer) articles that are within the scope of the restriction proposal and considering the emission/concentration limit as proposed by RAC weighed against the health risks identified above.

SEAC

Proportionality of the restriction proposed by the Dossier Submitter

As far as the proposal of the Dossier Submitter is concerned, SEAC considers that the benefits deriving from limiting formaldehyde emissions from consumer articles can be achieved at limited costs for EU society, given the exemptions included in the proposal, as well as Appendix X on testing conditions which minimises the potential additional costs for industries other than the wood-based panels industry.

SEAC notes that, during the consultations, almost all affected industry sectors that provided comments, viewed the proposal of the Dossier Submitter as proportionate to the risk. SEAC has no reason to challenge this view.

In conclusion, based on the information provided in the Background Document, on the comments received in the consultations and on SEAC's assessment thereof, SEAC considers that the restriction proposal of the Dossier Submitter is proportionate to the risk. SEAC further considers that it is affordable.

Proportionality of the restriction proposed by RAC

Based on the information received by industry and on a break-even analysis carried out by the SEAC rapporteurs, SEAC considers that the RAC proposal, given the high socio-economic burden for industry, would break even only if it could avoid several thousand cases of nasopharyngeal cancer per year. This would require an incidence of nasopharyngeal cancer among the EU population living in new dwellings that is more than 200 times higher than the actually observed incidence in the EU (IARC, 2018)[122]. This supports the conclusion that implementing a restriction based on the limit values proposed by RAC does not appear to be proportionate to the risk.

Key elements underpinning the RAC and SEAC conclusion(s):

RAC

As to the monitoring of articles/vehicles within the scope the restriction, cost effectiveness will not be affected by the emission/concentration limit as proposed by RAC, because the concentration level does not affect the frequency or cost of the monitoring per se. RAC assumes that the same methods can be applied (the concentration limit is not lower than the detection limit of standard analytical methods). Irrespective of the level of the concentration limit, correlation factors of internally used test methods with the standard parameters of Appendix X have to be established for each article/article group. If the production of articles has changed, producers/importers are responsible to show that their article still complies with

[122] IARC (2018). Cancer Today. Available: https://gco.iarc.fr/today [Accessed 18 May 2020]

the restriction.

RAC notes from the consultation that the proposed limit value of 0.05 mg/m³ will affect production processes, however, considers adaption to the lower concentration as feasible especially in view of the numerous available voluntary limits on a broad spectrum of articles with the scope.

The already by EU manufacturers of wood-based panels voluntarily implemented E1, which is mandatory already in a range of Member States and even undercut by many voluntary labels and certification schemes for a range of articles, is considered by RAC to bring no significant benefits for those aforementioned groups of articles/countries. In case the limit proposed by the Dossier Submitter would be implemented, some health benefits are expected in particular due to the limitation of E2 panel imports. Even if only very minor risk reduction effects will be gained with an emission limit of E1, RAC considers such a restriction preferable to no EU-wide restriction measure.

SEAC

Proportionality of the restriction proposed by the Dossier Submitter

SEAC based its conclusions on its assessment of the information gathered during the consultations, as well as on the data provided for the proposed restriction by the Dossier Submitter in the Background Document.

The considerations that can be made from the comments received during the consultations are the following:

- The vast majority of the European industries of wood-based panels and furniture are already complying with the E1 limit value proposed in the restriction due to the existence of several national regulations and self-commitments.

- Only few other consumer articles on the EU market release formaldehyde over the proposed limit value and their contribution to the overall emissions in indoor environments is expected to be minor.

- The automotive sector already has voluntary agreements and stringent standards in place which are in line with the Dossier Submitter's proposal.

- Sectors of other articles are expected to be affected by limited impacts, if any, since either formaldehyde-based substances are not added in the production process or because they already comply with the E1 limit value proposed by the restriction or because they are exempted.

- During the consultations, the restriction as proposed by the Dossier Submitter has generally received support from the affected industry sectors, with almost all affected industry sectors that provided comments viewing the proposal of the Dossier Submitter as proportionate to the risk.

Overall, the information received during the consultations seems to confirm the Dossier Submitter's assessment that the costs of implementing the proposed restriction are expected to be limited.

In addition, SEAC considers that some health benefits associated with limiting formaldehyde emissions from articles can be expected from the proposed restriction. Despite proposing more stringent limit values, RAC expects some health benefits from the Dossier Submitter's proposal in particular due to the restriction of imports of class E2 panels.

Therefore, SEAC is of the view that the health benefits associated with limiting formaldehyde emissions from articles can be achieved at limited costs, which supports the Dossier Submitter's conclusion that the proposed restriction is proportionate to the risk.

Proportionality of the restriction proposed by RAC

SEAC acknowledges that a restriction with a lower limit value would potentially entail higher health benefits.

However, on the side of costs, SEAC notes that, from the comments received during the consultations, significant socio-economic impacts are anticipated by different industry sectors to attain the limit value of 0.05 mg/m³.The comments received during the consultations can be summarised as follows:

- All European industry sectors indicated that the limit value proposed by RAC would imply considerable challenges due to technical changes in their production processes and substantial socio-economic costs both in terms of new investment and annually recurring costs;

- RAC's limit value would particularly imply negative impacts on the small and medium size enterprises;

- Negative impacts on the circular economy have to be expected;

- At a minimum, longer transition periods would be needed to comply with the limit proposed by RAC.

In order to get a better understanding of the proportionality of the RAC proposal versus the Dossier Submitter proposal, SEAC carried out a break-even analysis focusing on the annual impacts (in the sense of annually recurring costs, excluding any social costs and one-off costs such as investments) associated with the different proposals. The analysis aims at comparing the different proposals as a means to illustrate and put into perspective the health benefits that would be required for the different proposals to break even, i.e. to generate more benefits than costs. The analysis uses avoided nasopharyngeal cancer cases as a proxy for benefits. It should be noted, however, that nasopharyngeal cancer might not be the most relevant endpoint (unless formaldehyde exposure at very high concentrations is considered) and that irritation of the eyes or upper airways could be more relevant endpoints. Nasopharyngeal cancer cases were used for illustrative purposes because the required data are readily available. For the sake of completeness, SEAC also included in the analysis the two intermediate limit values for which information was received in the consultation on the SEAC draft opinion, i.e. 0.08 mg/m³ and 0.062 mg/m³. However, for these two limit values SEAC did not carry out a full impact assessment.

Taking into consideration issues of data availability and the fact that the Dossier Submitter in its analysis only focused on interior air of newly built dwellings, SEAC limited its assessment to the impacts on the wood-based panel industry. SEAC recognises that the focus on this sector does not fully account for the economic impacts of other sectors (such as leather, resin producing, mineral wool and automotive industries), but many of these sectors did not provide monetised data that could be used by SEAC in a meaningful way. In fact, data concerning the percentages of lost business (e.g. turnover losses) or business losses at company level were not easily usable by SEAC. In some cases, the data provided by industry did not specify if it referred to annual production cost increases or to one-off costs for investments. This complicated SEAC's decision on what data to include in its assessment.

As mentioned above, in terms of economic impacts, the main cost elements taken into account by SEAC are the annually recurring impacts relating to increased production costs, as well as lost business as provided for the wood-based panel sector (data from the consultations) expected in case each of the assessed limit values was in place. SEAC recognises that this approach highly underestimates the costs of a limit value lower than the one proposed by the Dossier Submitter since it does not consider investment costs, which according to industry are substantial.

In addition, as indicated already in the section on *Social impacts* above, it is anticipated that RAC's proposal would entail job losses. SEAC recognises that the social impacts related to job losses should be taken into consideration when assessing the total socio-economic costs

of the RAC proposal but, for the purpose of the break-even analysis, SEAC did not add them to the annually recurring economic impacts since the social impacts do not represent recurring impacts. Moreover, EPF provided information on job losses only for the limit value proposed by RAC and not for any other limit values.

In sum, considering issues of data availability and in order to be conservative in its analysis, SEAC only considered the annually recurring economic impacts on the wood-based panel industry as outlined in Table 23 above.

On the side of benefits, SEAC assumes that effects will occur on an annual basis since after each year the articles in a new home (wood-based panels, furniture, etc.) will have off-gassed. In its assessment SEAC focused on nasopharyngeal cancer while other endpoints, such as eyes and upper airways irritation, were not considered. For nasopharyngeal cancer, SEAC monetised DALYs/case (3.5 DALYs/case[123]) using the VSLY[124] (€175 000-250 000) to calculate a welfare proxy for one case of nasopharyngeal cancer of €612 500-875 000 with a mean of €743 750.

SEAC used the information on costs outlined in Table 23 above and the welfare proxy of an avoided nasopharyngeal cancer case derived in the previous paragraph to obtain information on the number of nasopharyngeal cancer cases that would need to be avoided for each of the different limit values to break even.

As shown in Table 30, 6 522 nasopharyngeal cancer cases would have to be avoided each year for the RAC proposal to break even. For the Dossier Submitter proposal, 106 nasopharyngeal cancer cases would have to be avoided each year to break even. For limit values of 0.08 mg/m^3 and 0.062 mg/m^3, 688 and 2 108 would have to be avoided, respectively.

To put these values into perspective, SEAC calculated the nasopharyngeal cancer incidence that would have to be observed among the EU population living in new dwellings each year for the different scenarios to break even and compared this with the nasopharyngeal cancer incidence rate actually observed in the EU according to IARC (2018).

In section 3.2 of the Background Document it is estimated that the EU had a housing stock of about 250 million dwellings in 2015 with an estimated 0.7 % of the EU's housing stock, or 1.75 million, coming from newly built/completed dwellings. In addition, according to section 2.5.2 of the Background Document, the average household in the EU had 2.3 members in 2016. Based on these numbers, SEAC assumed that 4 million individuals live in newly built dwellings each year (= 1.75 million dwellings built per year with 2.3 individuals per dwelling). This means that for the RAC proposal to break even, 6 522 nasopharyngeal cancer cases would have to be avoided among these 4 million individuals. In other words, 1 631 in 1 million (= 6 522 nasopharyngeal cancer cases in 4 million individuals) would have to suffer nasopharyngeal cancer for the RAC proposal to break even. However, according to IARC (2018) data, in 2018 the incidence rate of nasopharyngeal cancer in the EU was only 7.5 in 1 million (crude rate). This means that one would need to see a more than 217 times higher incidence rate than is actually observed for the RAC proposal to break even. The same reasoning can be applied to the other limit values.

[123] The number of Disability Adjusted Life-Years (DALYs) associated with a nasopharyngeal cancer case has been derived from the results of the Global Burden of Disease Study 2017 (IHME, 2018). The total number of DALYs for nasopharyngeal cancer in the EU in 2017 (101 401) has been divided by the total number of nasopharyngeal cancer cases (prevalence) in the EU in 2017 (28 820) resulting in a value of 3.5 DALYs/case. See also IHME (2018), Global Burden of Disease Study 2017 (GBD 2017) Results, Available: http://ghdx.healthdata.org/gbd-results-tool [Accessed 18 May 2020].

[124] The "Value of Statistical Life-Year" (VSLY) is based on ECHA's reference "Value of Statistical Life" (VSL) in the context of cancer of €3.5-5 million (ECHA, 2017). Using standard annuitization the VSLY can be derived as follows: VSLY = r*VSL/(1-(1+r)^-LE) = 0.04*VSL/(1-(1.04)^-35) = €175-250 thousand for individuals with an average remaining life expectancy of 35 years and for a discount rate of 4 %. See also ECHA (2017), Willingness-to-pay values for various health endpoints associated with chemicals exposure, SEAC/32/2016/05.2 Rev.1, Available: https://echa.europa.eu/documents/10162/13637/seac_reference_wtp_values_en.pdf [Accessed 18 May 2020].

Table 30: Break-even analysis for different limit values

Scenario	Annually recurring economic impacts on wood-based panel industry (million €)	Value of an avoided naso-pharyngeal cancer case (million €)	Number of naso-pharyngeal cancer cases to be avoided each year to break even[1]	EU population living in new dwellings each year (million)[2]	Naso-pharyngeal cancer incidence among EU population living in new dwellings each year to break even[3]	Actual naso-pharyngeal cancer incidence rate according to IARC (2018)
Dossier Submitter limit 0.124 mg/m³	79	0.744	106	4	27 in 1 million	7.5 in 1 million (crude rate)
Limit 0.08 mg/m³	512		688		172 in 1 million	
Limit 0.062 mg/m³	1 568		2 108		527 in 1 million	
RAC limit 0.05 mg/m³	4 852		6 522		1 631 in 1 million	

1. Annually recurring economic impacts divided by the value of an avoided nasopharyngeal cancer case.
2. SEAC estimate (for details refer to the text above the table).
3. Number of nasopharyngeal cancer cases to be avoided each year to break even divided by the EU population living in new dwellings each year (million)

In conclusion, the results of SEAC's assessment under the conservative assumptions outlined above, suggest that:

- a restriction with the Dossier Submitter limit value (0.124 mg/m³) would break even if it would avoid 106 nasopharyngeal cancer cases among individuals living in new dwellings each year, which represents an incidence among the EU population living in new dwellings that is 3.5 times higher than the incidence actually observed in the EU according to IARC (2018). SEAC notes that this finding is based on annually recurring economic impacts of €79 million as estimated by EPF in the consultation on SEAC's draft opinion. This estimate corresponds to the upper end of the cost estimate provided by the Dossier Submitter (i.e. €28-79 million). Using the Dossier Submitter's central estimate of €28 million instead would let the proposal break even if it would avoid 38 nasopharyngeal cancer cases, which represents an incidence among the EU population living in new dwellings that is 1.3 times above the observed incidence.

- a restriction with a limit value of 0.08 mg/m³ would break even if it would avoid 688 nasopharyngeal cancer cases among individuals living in new dwellings each year, which represents an incidence among the EU population living in new dwellings that is 29 times higher than the incidence actually observed in the EU according to IARC (2018).

- a restriction with a limit value of 0.062 mg/m³ ("half E1") would break even if it would avoid 2 108 nasopharyngeal cancer cases among individuals living in new dwellings each year, which represents an incidence among the EU population living in new dwellings that is 70 times higher than the incidence actually observed in the EU according to IARC (2018).

- a restriction with the RAC limit value (0.05 mg/m³) would break even if it would avoid 6 522 nasopharyngeal cancer cases among individuals living in new dwellings each year, which represents an incidence among the EU population living in new dwellings

that is 217 times higher than the incidence actually observed in the EU according to IARC (2018).

Due to a number of limitations and uncertainties relating to both costs and benefits (as outlined further above in this section), the break-even analysis presented here can only be considered as a means to compare the different proposals. This analysis does not provide a measure of the benefits of the different proposals. As such, in itself, the finding that the break-even incidence of nasopharyngeal cancer among the EU population living in new dwellings would be higher than the observed incidence does not render the Dossier Submitter's proposal disproportionate. In SEAC's view this finding has to be seen within the context of the limited costs associated with the restriction proposed by the Dossier Submitter expected by industry.

In SEAC's view, the substantial difference between the RAC proposal and the Dossier Submitter proposal in terms of health benefits to break even provides a strong indication that the RAC proposal is not proportionate. This finding is also consistent with the high socio-economic impacts expected by industry for implementing a restriction based on the limit values proposed by RAC.

In SEAC's view, the adoption of intermediate limit values (such as 0.08 mg/m³ or 0.062 mg/m³) would potentially entail higher benefits than those associated with the Dossier Submitter proposal while implying less severe technical challenges and socio-economic costs for several industry sectors than the RAC limit. SEAC considers that coupled with adequate transition period and specific time limited derogations for each industry sector, these limits deserve to be carefully evaluated by decision makers as potential compromise solutions.

Uncertainties in the proportionality section

RAC

The Dossier Submitter mainly assessed proportionality of risks from newly built homes and did not consider living conditions in existing building stock. RAC identifies, in addition to residents of new homes, additional groups of consumers potentially at risk which have not yet been addressed: residents of newly renovated homes with/without tight ventilation, residents of existing homes who (re-)furnish one or more rooms in their home resulting in high loading factors/high emission concentrations in that room, residents with existing homes at a high loading summed up from other articles (e.g. decoration articles, textiles, mattresses, carpets, etc.) at insufficient ventilation, and passengers in vehicles (road vehicles incl. public transport, rail, ships).

In order to assess proportionality of health risk (related to irritation, other precursor events and cancer by formaldehyde) and costs should be considered for each group of consumers separately (as the size of groups of new homeowners will be significantly smaller than the other groups).

SEAC

Uncertainties on proportionality of the restriction proposed by the Dossier Submitter

SEAC considers that several uncertainties characterise this socio-economic analysis (see dedicated section on uncertainties below), nevertheless, in SEAC's view, such uncertainties do not challenge the overall conclusion on costs, benefits and proportionality of the proposed restriction.

SEAC acknowledges that, in the development of this restriction proposal, in order to reduce the existing level of uncertainties, the Dossier Submitter made several plausible assumptions both for the exposure and for the assessment of socio-economic impacts related to wood-based articles.

SEAC considers that, overall, the socio-economic impacts, which were calculated by the

Dossier Submitter only for the wood-based panels, are underestimated because the proposed restriction does not affect only the wood-based panel sector but also other industries manufacturing or companies importing articles emitting formaldehyde above the proposed limit.

Uncertainties on proportionality of the restriction proposed by RAC

SEAC considers that the assessment of the proportionality of the restriction proposed by RAC is subject to a high degree of uncertainty both due to uncertainties relating to the socio-economic impacts claimed by industry stakeholders and due to the lack of information with regard to health benefits.

SEAC notes that the industry stakeholders themselves underlined the difficulty to assess the potential impacts related to the RAC proposal. Therefore, SEAC considers that a high degree of uncertainty is associated with the information on socio-economic costs, at least for some industry sectors that contributed to the consultations.

Uncertainties also exist on the side of benefits since the risk reduction associated with the RAC proposal was not quantified, hence the magnitude of any additional benefits is not known.

Uncertainties and limitations related to the break-even analysis

The uncertainties and limitations related to the data used and the assumptions made by SEAC to carry out the break-even analysis concern:

- the cost data provided by industry that could be overestimated;
- the fact that only newly built dwellings are taken into account, hence neglecting any use of wood-based panels for renovation purposes (same assumption made by the Dossier Submitter);
- the fact that only data concerning the wood-based panel sector are used, hence neglecting impacts on sectors of other articles not in the supply chain of the wood-based panels (same assumption made by the Dossier Submitter);
- the fact that only nasopharyngeal cancer cases are taken into account, hence neglecting other relevant endpoints, such as irritation to eyes and upper airways;
- the consideration in the assessment of only annually recurring costs, hence neglecting any one-off and social cost;
- the absence of any quantitative information on benefits.

The break-even analysis, due to the above-mentioned incomplete or not verifiable data and strong assumptions, suffers a high level of uncertainty. However, since the same datasets and assumptions are used for each of the four potential scenarios, the limitations related to the break-even analysis equally affect each scenario. Therefore, such uncertainties should not challenge the overall conclusions on the comparison of the Dossier Submitter's and RAC's proposal in terms of proportionality.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers the proposed restriction practical, because it is implementable, manageable and enforceable.

The restriction proposal is considered implementable (within the timeframe of 12 months) and manageable because the measures proposed are, to a large extent, already applied in

the EU as a result of voluntary agreements in specific industry sectors and national legislation in a number Member States that is broadly in line with the restriction proposal.

It is considered enforceable because some Member States (e.g. Austria, Denmark, Germany, Italy and Sweden) have already implemented or are planning to implement legislation to limit formaldehyde emissions from specific categories of articles, in particular wood-based products. Formaldehyde emission limits are therefore already enforced in a number of Member States and chamber tests (performed in accordance with EN 717-1 or under similar conditions) are prescribed to enforce the legislative requirements. Chamber tests as well as other test methods exist to monitor the release of formaldehyde from articles and enforcement authorities have already experience in applying them. Enforcement authorities of other Member States can therefore set up an efficient supervision mechanism to monitor compliance with the proposed restriction.

RAC and SEAC conclusion(s):

RAC and SEAC consider that enforcement authorities of Member States without national regulations in place to limit formaldehyde emissions from articles can monitor compliance with the proposed restriction in the same way as Member States already having such national regulations in place by know-how transfer.

SEAC

Implementability and enforceability of the restriction proposed by the Dossier Submitter

SEAC considers that for the wood-based panels industry, the emission limit proposed by the Dossier Submitter (0.124 mg/m^3) is implementable within the timeframe of 24 months and for trucks and buses within 36 months after entry into force of the proposed restriction, providing sufficient time for the market to comply. Moreover, based on the comments received during the consultations, SEAC considers that compliance with the proposed restriction will be manageable also by the other main European industry sectors affected by the proposed restriction.

For the enforceability of the limit of the proposed restriction for the wood-based panels, SEAC concludes that enforcement authorities of other Member States will also be able to enforce.

In line with the Forum advice, SEAC considers that enforceability for other types of articles is possible taking into consideration that the introduction of Appendix X provides enough flexibility by allowing different testing methods provided that they are correlated to the reference conditions.

SEAC considers that, after initial efforts to establish suitable correlations, the restriction will be practicable without major negative long-term impacts on industry sectors.

Implementability and enforceability of the restriction proposed by RAC

SEAC considers that the emission limit proposed by the RAC (0.05 mg/m^3) would not be implementable within the timeframe of 12 months neither by the European wood-based panels industry nor by any other industry sector. In fact, all sectors that have submitted comments during the consultations underlined the need of additional time in case they would have to comply with the RAC proposal. Therefore, SEAC considers that, should the proposal made by RAC be implemented, longer and sector-specific transition periods, tailored to the situation of each of the affected industry sectors, would have to be allowed.

As the Forum has only been involved at the beginning of the process and gave its advice only on the basis of the Dossier Submitter's proposal, SEAC is not in a position to draft conclusions on the implementability and enforceability of the RAC proposal by different sectors. However, SEAC sees no reasons why enforcement authorities of Member States should not be able to enforce a restriction as proposed by RAC. With regard to the availability of test methods and specific correlations between sector-specific methods and the reference conditions (as

specified in Appendix X), SEAC expects that national enforcement authorities might require similar transition periods as the affected industry sectors.

Key elements underpinning the RAC and SEAC conclusion(s):

RAC

Implementability and enforceability

RAC agrees with the options included in the Appendix X for the measurement of formaldehyde releases from articles and on the measurement of formaldehyde concentration in the interior space of vehicles. The outline of applicable test methods and the conditions of their applications allows testing of a broad range of articles. It gives also flexibility and, if established, allows the use of already applied standard test methods preventing double testing if other test methods based on different conditions than those outlined in Appendix X are preferred. As described in point 2 of Appendix X, if a test method based on different conditions is uses, compliance shall be demonstrated based on an acceptable correlation with the prescriptions outlined in point 1 of Appendix X. The text of Appendix X may be extended with regards to the applications for rail and water vehicles and others road vehicles than cars.

Testing of construction elements, furniture, flooring or other articles made from E1 panels and carrying the CE label is needed as formaldehyde may not only be released from the E1 (or E2) panel but can also be released from paints, glues, fillers, foam, coatings/varnish, impregnations and other products to which formaldehyde or formaldehyde releasers were added during production and which were used in the production of the articles. The measures to demonstrate compliance with the EU-wide E1 standard has been considered as to a large extent already being applied by the EU manufacturers (in particular for the manufacturers of wood-based panels). Instead of the previously certified (voluntary) concentration limits producers and importers have to ensure that their test method complies with the provisions of the restriction (as outlined in Appendix X). In order to comply with a lower emission limit as proposed by RAC (instead of the level proposed by the Dossier Submitter), it is assumed that no additional effort is needed or, to the knowledge of RAC, no limitations are given.

RAC agrees that no additional effort is needed for manufacturers of articles who have already adopted test methods based on EN 717-1. Manufacturers of construction products under CPR may continue to use their existing test methods (based on EN 16516 for CE marking) and product standards provided that they are able to confirm the equivalency to the reference conditions outlined in Appendix X for the article of concern.

Manufacturers and importers who have not yet established test methods for their articles because no mandatory emission limit exists at present (e.g. as it is the case in many Member States for furniture) or because test methods are not yet available at all for some articles (e.g. carpets or matrasses), will have to establish an appropriate testing method for their articles and set up adequate quality assessment criteria for the comparison of the chosen method with the reference conditions outlined in Appendix X, if a test method based on these conditions cannot be applied by them. If methods based on different conditions are used, an acceptable correlation with other monitoring methods that are internally preferred by manufacturers has to be derived in order to continue with the preferred test method. It is to note that such a correlation will be specific for the article tested and the test method used in comparison to the reference method. Additional explanation should be added to the Appendix X to indicate that the correlation factor of 1.6 that was derived by Wilkes and Jann (2018) for their particular wood-based panels cannot be applied to other articles or article groups. Correlation factors of 1.4-1.8 for different types of panels were indicated by a Forum comment.

According to the Dossier Submitter's proposal, testing of complex articles (e.g. pieces of furniture) is not needed if their components do not contain formaldehyde or formaldehyde releasing substances or if formaldehyde emissions of individual components are within the limit established in the current proposal. However, when formaldehyde or formaldehyde releasing substances or mixtures (e.g. lacquers or glues) are added during the production process of complex articles, testing requirements apply. It is the responsibility of producers

and importers of articles to guarantee that articles placed on the market comply with the provisions of this restriction proposal. As it is the responsibility of the producers and importers to guarantee the compliance with the restriction, this needs every actor to pass the information within the supply chain. A declaration of conformity, as proposed by a consultation comment (No 2677), may not be sufficiently informative, as 'article-type' components of a complex article may be in compliance with the restriction. A declaration of conformity alone on article-type components, however, will not guarantee that the final product is in compliance with the restriction as other components (like glues) will not be covered by the restriction. In response to the question on the need of testing on whole furniture there was a suggestion that if no sufficient information on formaldehyde release is available (to the manufacturer), testing cannot be avoided. RAC suggests adding advice to Appendix X on the conditions when testing on (whole) complex articles can be avoided.

With regards to the testing of articles, the Dossier Submitter considered the proposed restriction as implementable. This assessment will not change through a lower emission limit as derived by RAC. To the Dossier Submitter's view the implementation of the restriction (with emission limits as initially proposed by the Dossier Submitter) should be possible within 12 months.

In the initial view of RAC, a 12-month transition time as proposed by the Dossier Submitter was considered to be feasible for the sector producing wood-based panels (as test methods are assumed to be already in place). One producer indicated that alternative glue systems are available without transition time to comply with lower emission limits than E1 (consultation comment No 2622). CECE, the organisation representing the European construction equipment manufacturers and related industry indicated that a longer transition time is needed to identify for all articles and components the use of formaldehyde and formaldehyde releasers across the supply chain (consultation comment No 2626). The spectrum of products in relation to their potential exposure to consumers is not specified by CECE, however, it should be noted that articles with industrial/professional use *only* are exempted from the restriction. In the same line of argumentation, an industry representative mentioned during RAC-52 that a 12-months transition may not be feasible taking into account the limitations on laboratory capacities and the need to test the articles after production changes not only on the emission of formaldehyde (and possibly other substances) but also in relation to other essential properties/performance criteria. RAC finally agrees that a transition period of 24 months is appropriate.

For other sectors (producing articles other than wood-based panels) it is unknown to RAC to what extent manufacturers have already established appropriate test methods on testing of articles. Limitations of governmental laboratories to cope with additional test requirements for articles that have not been tested before have to be taken into account as well. There may also be a need for enforcement bodies to establish new test methods in their laboratories for other articles than wood-based panels; the extent is unknown to RAC. RAC therefore recommends considering a transition period of 24 months after entry into force for all articles including wood-based panels.

In addition, the same constraints as for the wood-based panel industry may apply to vehicle producers due to changes in production, design and supplier. RAC acknowledges that test methods are in place for voluntary measurements for automobiles and aircraft (note: RAC does not support the restriction proposal on aircraft). Industry sectors producing other road vehicles than cars have to establish compliance with the concentration limits for cabins. Although it can be assumed that cabin measurements can easily be introduced and is expected to be already in place for certain types of road vehicles in order to meet non-EU regulations for their global businesses, it may take more than 12 months to organise a compliant supply chain. Since June 2019, standard test methods for trucks and buses are under development (ISO 12219-10).

Using sampling and measurement provisions from existing ISO norms on automobiles it is thought that adaptations for rail and water vehicles may be needed to develop standard testing procedures specific for these vehicle types. The development of new EU (ISO) norms including the relevant conditions of testing (temperature, ventilation rate, duration of closed doors before testing, etc.) specific for measurements in cabins of rail or water vehicles may

also take more than 12 months in case of inclusion of rail and water vehicles.

According to the Forum's advice testing of vehicles interiors appears not to be established by enforcement authorities. This also justifies deviating from 12 months transition time for the sector of producers of vehicles. In conclusion, a transition time of 24 months is considered appropriate for all vehicles within the scope.

SEAC

Implementability and enforceability of the restriction proposed by the Dossier Submitter

SEAC based its conclusions on the compliance with the proposed transition period and on the manageability of the proposed restriction on the following elements:

- Large part of the wood-based panels industry is already in compliance due to the fact that voluntary agreements and national legislations already exist.
- Other relevant industry sectors such as furniture and automotive have already signed voluntary agreements to reduce formaldehyde emissions.
- It appears from the consultation that there are other sectors which do not yet follow voluntary agreements or are not yet subject to national rules with regard to formaldehyde emissions (e.g. POM, mineral wool industry, amino resin producers). These sectors will be affected by this restriction for the first time.

For wood-based panels and for other categories of articles, SEAC based its conclusions on the enforceability of the proposed limit value by EU enforcement authorities on the fact that eight Member States, having national regulations in place, are already enforcing similar limit values by using already existing test methods such as chamber tests and other testing methods in accordance with EN 717-1 or under similar conditions. Therefore, SEAC is of the opinion that for such articles National Enforcement Authorities of other Member States will also be able to enforce this restriction.

In line with the Forum advice on sampling and sampling preparation, SEAC based its conclusions on the enforceability of the proposed restriction for articles other than wood-based panels on the following elements:

- EN 717-1 is a complicated and expensive method and for the enforcement authorities not suitable for every article, because it is specifically designed for wood-based panels.
- For sampling and sampling preparation, EN 326-1 referred to by EN 717-1 is adapted to wood-based panels (or at least flat samples).
- EN 14080 is a sampling method available for glulam beams, nevertheless no further standards are established for sampling other articles.
- For specific purpose sampling and testing for other types of articles, for instance articles with large dimensions/very small pieces, it seems important to set up technical rules how to get representative samples from these articles.

Implementability and enforceability of the restriction proposed by RAC

SEAC based its conclusions on the manageability and on the compliance of the limit proposed by RAC within the transition period proposed by the Dossier Submitter on the fact that, supported by the information gathered during the consultations, very few European industry sectors (including wood-based panels industry) are currently in compliance with the RAC limit.

SEAC notes that the Forum has only been involved at the beginning of the process of development of the opinion of SEAC and only concerning the proposal of the Dossier Submitter, In the absence of an advice from the Forum on the enforceability of the limit value

proposed by RAC, concerning wood-based panels and other categories of articles, SEAC is not in a position to conclude on the implementability and enforceability by EU enforcement authorities of the limit value proposed by RAC. However, SEAC sees no specific elements indicating the fact that the enforcement of the limit value proposed by RAC would create additional enforcement difficulties for Member States, namely for articles for which appropriate methods already exist according to Appendix X. SEAC underlines that, during the consultations on the SEAC draft opinion, none of the Member States indicated any potential issue for such enforcement.

Some industries that are currently not concerned by the proposal of the Dossier Submitter since they manufacture articles emitting less than 0.124 mg/m^3 might find out that their articles might be affected by a potential restriction having the RAC limit. In this respect, the affected industry, as well as National Enforcement Authorities, might be confronted with some difficulties and additional testing or other actions might be required.

Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

According to the Dossier Submitter, the effectiveness of the proposed restriction could be monitored by quantifying, over time, the amount of EU-manufactured and imported articles with compliant formaldehyde emissions compared to the current situation.

RAC and SEAC conclusion(s):

Based on the information provided in the Background Document as well as on the information gathered during the consultation, RAC and SEAC agree that monitoring compliance of wood-based panels, furniture and other EU-manufactured and imported articles with the formaldehyde emission limit as set in paragraph 1 of the restriction entry can be done over time by using test methods in accordance with the conditions specified in Appendix X.

Key elements underpinning the RAC and SEAC conclusion(s):

RAC

RAC agrees that available test methods will allow monitoring of formaldehyde release from the EU-manufactured and imported articles, provided that data are published or made available to enforcement bodies or by enforcement authorities. RAC also notes that monitoring is already in place in Member States who have adopted national regulations (mainly on wood-based panels/construction products) and on a voluntary basis by EU producers of wood-based panels and cars. Monitorability of the emission and concentration limit as proposed by RAC will not differ from monitorability of the initially proposed emission and concentration limits by the Dossier Submitter.

Comparison with the current situation will be limited for articles within the scope for which there is currently no mandatory testing. According to the Dossier Submitter proposal the amount of E2 panels and articles made of high emitting wood-based panels should decrease after entry into force. The actual low amount should disappear from the EU-market.

Monitoring enables to show compliance with the emission and concentration limits as proposed by RAC. In addition, monitoring allows identifying the developments in the produced volumes of wood-based panels following the introduction of a new market class with lower emission limit based on the proposal by RAC. For articles or vehicles without previous mandatory concentration limits a comparison with the current (non-regulated) situation is largely not possible.

SEAC

Monitorability of the restriction proposed by the Dossier Submitter

For wood-based panels, and consequently for wood-based furniture, SEAC's conclusions on monitorability of the restriction proposed by the Dossier Submitter are mainly based on the fact that, at present, the limit of this restriction is already monitored due to the existing national regulations and testing standards.

In SEAC's view, the restriction proposed by the Dossier Submitter is monitorable also for other articles since appropriate test methods for other articles exist and can be applied in accordance with Appendix X.

Monitorability of the restriction proposed by RAC

SEAC based its conclusions on the monitorability of the restriction proposed by RAC on the fact that testing standards for monitoring activities exist and can be applied to limit values as low as those proposed by RAC.

Regarding other articles, SEAC considers that the restriction proposed by RAC is monitorable since appropriate test methods for other articles exist and can be applied in accordance with Appendix X.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter identified a number of uncertainties in the exposure assessment. On the one hand, these uncertainties relate to the assumptions made in setting up the exposure scenario, in particular assumptions regarding loading factors, emission reductions from covering materials and climatic conditions. On the other hand, they concern the scoping choices made, particularly with regard to the non-consideration of temporary emission sources and mixtures.

RAC conclusion(s):

RAC has identified a number of uncertainties. Some of them have been identified and described by the Dossier Submitter and relate to the definition of exposure scenario and the scope which excludes temporary emission sources and mixtures. The potential for peak exposure and elevated exposure arising from other sources not in the scope of the restriction, such as combustion sources, is an uncertainty which RAC acknowledges. Further uncertainties are related to the exposure and risk assessment: in particular concerning the measurement data, their representativeness for a realistic worst case versus an average exposure situation and, on the other hand, the likely overestimation of indoor air concentrations obtained with Monte Carlo simulations. For certain vehicle interior situations, no exposure data is available at all (trains, passenger ships, road vehicles other than cars). In contrast to vehicles (where a concentration limit in the vehicle's interior is proposed), the derivation of an appropriate emission limit for building interior articles, is based on calculation/simulation with its uncertainties due to the complexity of the emission scenario and its individual determinants. Equally the actual risk reduction effects by limiting emissions at the level proposed by RAC with the proposed restriction are somewhat uncertain due to the difficulties in quantification. While the restriction will affect those indoor situations of most concern and significant risk reduction is assumed, there may still be situations of concern with RCR > 1. The potential risk shifts by switching to 'no added formaldehyde' (NAF) alternatives which contain hazardous substances is acknowledged as an uncertainty because an in-depth toxicological and human health risk assessment is needed to come to robust conclusions for the individual alternatives.

Key elements underpinning the RAC conclusion(s):

The following table provides an overview of the uncertainties identified by RAC:

Table 31: Uncertainties identified by RAC

Source	Description	Effect on risk characterisation
1. Scope of the restriction		
Exposure due to temporary emission sources	The Dossier Submitter excluded temporary emission sources from the scope of the restriction. Temporary sources can contribute to high peak concentrations that alone could exceed the concentration limits. Consideration of peak exposure in the exposure scenario would make it difficult to reach any conclusion on the need to limit emissions from articles as peak exposure from temporary sources would be mostly unaffected by a measure targeting permanent articles. Formaldehyde emitted from different combustion processes may have a high short-term impact on indoor quality. RAC notes that formaldehyde emissions arising as by-product from combustion of incenses and ethanol fireplaces show considerable high concentrations exceeding the long-term DNEL of 0.05 mg/m³ and the WHO guideline value of 0.1 mg/m³. In the view of RAC, regulatory measures should be considered to limit formaldehyde emissions and consumer risk arising from ethanol fireplaces.	↑

Exposure due to use of mixtures	The Dossier Submitter assessed risk from use of mixtures containing formaldehyde or formaldehyde releasers up to 0.09 % (just below the SCL), including all-purpose and floor cleaning, furniture polishing, brush and roller paint, bottled glue and two-component glue. Exposure estimates were in the range of 0.014-0.059 mg/m^3, the upper range estimate for application of furniture polishing liquid exceeds the RAC DNEL, however presents an infrequent short-term scenario, which does not raise a long-term concern.	-
2. Hazard		
Correctness of NOAEC	Objective data on humans exposed long-term to monitored concentrations of formaldehyde would have been the preferred type of data which are not available. While sensory irritation assumed to be the most sensitive effect preceding subsequent steps in tumour development can only be measured for humans, allow animal data to screen for (cytotoxic) irritation effects accompanied by inflammation, local genotoxic effects and followed by hyper/metaplasia and tumour formation. Although irritation and subsequent precursor events were seen consistently across several species (including monkeys) showing concentration and duration-related effects, there are always remaining uncertainties for extrapolations from animal data (even from data on monkeys) to humans which should be covered by AF.	↑↓
Correction of DNEL values for exposure duration	There are indications from other eye irritants than formaldehyde that prolongation of exposure may lower the threshold concentration for sensory irritation in humans. It has also been shown that prolonged formaldehyde exposure increases the extension/frequency of squamous metaplasia/hyperplasia in rats/monkeys in long-term experiments. Although it is attempted that the formaldehyde concentration is the major driver for cytotoxicity and subsequent events, it cannot be ruled out that prolonged exposure intensifies cell damage and the risk for tumours.	↑
Representativeness of DNELs for the general population	The database on sensitive subgroups of the general population is still – after decades with publications on a variety of subgroups (asthmatics, so-called hypersensitives) with limited reliability – very limited as studies under controlled conditions on volunteers in subgroups of concern (e.g. children, elderly people who no longer leave their home) prohibits for ethical reasons. No difference in severity and symptoms of irritation effects were seen between 'healthy' volunteers and e.g. asthmatics at high formaldehyde concentrations. However, uncertainties remain whether sensitive subgroups respond at lower concentrations than 'healthy' adult volunteers.	↑
3. Exposure		
Building exposure scenario	The Dossier Submitter estimated formaldehyde concentrations under a residential exposure scenario that reflects the situation of a newly built private home that uses wood-based panels as construction material and feature a number of other formaldehyde emitting articles.	
General uncertainties in formaldehyde exposure assessment	Emission of formaldehyde from various treated articles made from different materials is dependent on a variety of parameters, including inherent material characteristics (material type, formaldehyde amounts incorporated and bound to matrix, and diffusion resistance) and external factor including room volume and material loading (m^2/m^3), air ventilation, humidity, temperature, ageing of material, further contributing factors (indoor chemistry, sink effect, coverage of material). Emission rates are therefore only indirectly related to indoor air concentrations via the exposure scenario.	↑↓
Representativeness of measurement data	While overall availability and reliability of measurement data is considered well by RAC, the following uncertainties are noted: - Data may not be representative for all EU countries due to different national construction standards and national legislations in place limiting formaldehyde emissions, - Formaldehyde sources are and formaldehyde emission class (sub-E1, E1, E2) of wood-based panels used in these homes for construction is unknown, thus air concentrations measured cannot be attributed to particular sources and correlated with emission classes,	↑↓

	- Data reflect average situation but reasonable worst-case situations are not covered, such as: renovated existing buildings with improved energy-efficiency (with tighter building envelope), small sleeping chambers and particular small homes.	
Monte Carlo simulation: choice of modelling parameters	The exposure estimations are based on Monte Carlo simulations for the European reference room. RAC identified uncertainties in the choice of modelling approach, parameters and assumptions: - well-mixed room, probabilistic modelling using mean emission rates and distributions, considered acceptable an approach for a realistic higher tier estimation of possible variations, - sink effect: unusual in the regulatory context, limited information on the concept of sink effects has been made available by the Dossier Submitter, - 75 % reduction in emission rates applied although literature reports a rather wide range of emission reduction of 70-98 %, - fixed air exchange rate of 0.5 h^{-1} used, which may lead to underestimation of exposure (Noted: Dossier Submitter considered ACH distribution upon recommendation as an uncertainty assessment). - The use of constant temperature and humidity in the modelling may underestimate higher seasonal and regional release rates.	↑
Monte Carlo simulation: emission sources	Overestimation likely exists, in particular due to the variety of emissions simply added up in the Monte Carlo simulations.	↓
Monte Carlo simulation: representativeness of the European Reference Room	The room dimensions, loading factor, and materials assumed in the European reference room do not cover reasonable worst-case situations, such as very small urban flats (e.g. Paris). In particular small sleeping chambers with low ACH may not be covered.	↑
Monte Carlo simulation: emission rates	The emission data are rather rare for certain sources in particular furniture. Emission rates used in the model by the Dossier Submitter show quite high Geometric Standard Deviations for furniture, laminates, doors, and outdoor air. This results in high exposure estimates in the high percentiles of the simulation, which evidently exceed the range seen in actual measurement data by far. Adapted modelling by RAC confirmed significant overestimation of indoor air concentration is likely.	↓
Exposure assessment: Ageing due to off-gassing	An evolution of formaldehyde with time is not reflected in the Dossier Submitter assessment. Decrease of formaldehyde emissions due to ageing of materials is likely and upon recommendation an ageing factor has been considered by the Dossier Submitter in an uncertainty analysis by applying a decrease factor of 0.4 ± 0.1. However, formaldehyde releasing materials may show different behaviour in particular seasonal variations with strong increase of emissions due to humidity and temperature rise. Data to derive a robust ageing factor is not available.	↓ ↑
State-of-the art construction standard – energy-efficiency	The Dossier Submitter assessment is limited to new residential buildings. For renovation of existing building stock to meet energy-performance requirements (Directive 2018/844/EU, EPBD) significantly lower ventilation rates may lead to reasonable worst-case indoor concentrations exceeding health-based guidance value.	↑
Non-resident and public buildings such as schools	The Dossier Submitter did not assess a dedicated exposure scenario for non-resident private office buildings, public buildings, in particular in schools. Upon recommendation, the Dossier Submitter compared the exposure scenario of a classroom with the European reference Room scenario parameters, and RAC assessed literature studies on public buildings incl. schools. It is concluded that uncertainties seem fairly low.	-
Vehicle cabin interior scenario	The Dossier Submitter proposed the restriction for interior situations including vehicle cabins:	
Consumer risk from road vehicles interior other than cars (public transport, trucks, caravans)	According to ACEA, road passenger vehicles are tested according to ISO 12219-1 and UNECE (2017) mutual resolution. This includes passenger cars and light duty trucks used as passenger cars (but buses for public transport and trucks used only for transport of goods are here excluded). Accordingly. RAC has no information on formaldehyde emissions and applicable standards for these specific road vehicles and contribution to consumer risk is not known. RAC agrees with the precautionary way forward chosen by the Dossier Submitter to include articles used in all kind of road vehicles for passenger transport in the scope of the restriction.	↑ ↓

Consumer risk from the interior of vehicles other than road vehicles	Rail and water vehicles and aircraft cabins are in the scope of the restriction proposed by the Dossier Submitter, but no specific exposure scenarios for these interior environments has been assessed. Unlike for aircraft, no data for rail and water vehicle cabins became available during the consultation and consumer risk remains uncertain. RAC notes that commuting via railway and ferry ships is a relevant means of daily transportation of consumers.	↑↓
4. Risk		
General uncertainties linked to the exposure assessment	A variety of uncertainties in the exposure assessment have been identified by RAC. These concern both, the availability, robustness and representativeness of the available measurement data, as well as the evident limitations and uncertainties in modelling formaldehyde indoor air concentrations by taking into account only some variables in a linear well-mixed room model. Acknowledging these uncertainties, RCR for buildings are estimated by RAC as an approximation as close as possible.	↑↓
RCR for vehicles	No assessment is possible for rail vehicles, passenger ships and other road vehicles than cars as no exposure data became available.	↑↓
5. Evidence if the risk management measure and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk		
Assessment of the voluntary emission limit E1	RAC has concluded that the E1-limit is not sufficient for protecting consumers against health effects of formaldehyde. Due to the complexity of the emission process with the multitude of exposure determinants and articles used interior, an appropriate (lower) emission limit can only be derived as approximation by means of calculation and simulation. Uncertainties include e.g. the different emission characteristics for the various articles, the use of various articles in combination, ageing/off-gassing, secondarily reduced emissions from furniture built from wood-based panels, a non-linear relationship between air ventilation and room concentrations, insufficient ventilation leading to DNEL exceedance, climatic conditions leading to higher emissions, and high background exposure (e.g. due to temporary emission sources and ambient air).	↑↓
6. Risk from alternatives		
Human health risk assessment No-added formaldehyde (NAF) resins	Limited information has been presented by the Dossier Submitter on potential risk from alternatives to formaldehyde-based resins. RAC compared hazards of the various NAF based on C&L data (harmonised and self-classification), but for an assessment of human health risks, the individual ingredients need to be examined in more detail. Potential hazards can be expected due to various different chemicals used for making these resin alternatives.	↑
7. Effectiveness in reducing the identified risks		
Risk reduction effects of the RAC proposed restriction - buildings	For the proposed limit of 0.05 mg/m^3, RAC concludes that it may be effective in reducing formaldehyde concentrations significantly. The risk reduction effects, however, are not monitorable directly (see also 4. above). An emission limit significantly lower than the emission limit for articles proposed by the Dossier Submitter is needed and in many living situations it can be expected that the air concentrations will be reduced in a way that RCR < 1, while the restriction cannot guarantee to prevent all situations of concern with RCR > 1.	↑
Risk reduction effects of the RAC proposed restriction - vehicles	RAC expects a reduction of emissions for cars based on limited measurement data available. No statement on risk reduction is possible for other types of vehicle due to the lack of data.	−
8. Uncertainty in the proportionality assessment		
	RAC proposes the assessment of proportionality of health risk (related to irritation, other precursor events and cancer by formaldehyde) in relation to costs should be considered for each group of consumers separately (as the size of groups of new home owners will be significantly smaller than the other groups). a) residents of new homes certain other groups of consumers potentially at risk have not yet been addressed in the restriction	↑

	proposal. These are: b) residents of newly renovated homes with/without tight ventilation, c) residents of existing homes who (re-) furnish one or more rooms in their home resulting in high loading factors/high emission concentrations in that room, d) residents with existing homes at a high loading summed up from other articles (e.g. decoration articles, textiles, mattresses, carpets, etc.) at insufficient ventilation, and e) passengers in vehicles (road vehicles incl. public transport).	

Justification for the opinion of SEAC

Summary of proposal:

Uncertainties in the impact assessment, as identified by the Dossier Submitter, mainly relate to the lack of information about class E2 wood-based panels in terms of market volume, emissions and productions costs. Other sources of uncertainty concern the ability of non-EU manufacturers to pass through costs to EU consumers, testing costs, as well as the extent to which class E2 panels are concentrated in a number of homes. The Dossier Submitter also recognises that the focus of the impact assessment on wood-based panels, despite the wider scope of the restriction proposal, introduces some relevant uncertainties.

SEAC conclusion(s):

Uncertainties related to the restriction proposed by the Dossier Submitter

SEAC considers that some of the uncertainties associated with the restriction proposed by the Dossier Submitter were clarified during the consultations, namely on the (minor) impacts on different industry sectors manufacturing or importing articles other than wood-based panels.

SEAC considers that the remaining uncertainties do not challenge the overall conclusion on costs, benefits and proportionality of the restriction as proposed in the Background Document by the Dossier Submitter.

Uncertainties related to the restriction proposed by RAC

SEAC considers that, even if the overall magnitude of socio-economic impacts associated with the RAC limit and, subsequently, the level of (dis)proportionality of RAC's proposal are highly uncertain, based on the submissions received during the consultations, relevant negative impacts will almost certainly affect a number of industry sectors.

In SEAC's view, the remaining uncertainties do not challenge the overall conclusion on costs, benefits and proportionality of a potential restriction including the limit value proposed by RAC.

Key elements underpinning the SEAC conclusion(s):

Uncertainties related to the restriction proposed by the Dossier Submitter

The uncertainties related to the socio-economic assessment carried out by the Dossier Submitter concern the extent to which:

- the assumption made by the Dossier Submitter in terms of emissions and production costs on the EU total market volume of manufactured and/or imported class E2 panels is reliable in the absence of exact information.

- the assumption made by the Dossier Submitter on production costs difference of 10 % between E1 and E2 panels is a reliable figure in the absence of market information for class E2 panels. To quantify the production cost, the Dossier Submitter made an approximation based on industry information that class E1 panels are 10-15 % cheaper in production than lower emitting E.LES panels. In the absence of more precise information on this difference, the Dossier Submitter assumes it to be 10 %. SEAC concludes that it is reasonable to assume that the 10 % cost difference is an upper bound and hence it represents a conservative estimate of economic impacts as an emission reduction from E2 level to E1 level is more easily achievable than from E1 level to the even lower E.LES level.

- non-EU manufacturers will pass through the additional costs to EU consumers. Even if it seems reasonable to consider that, due to price competition, non-EU manufacturers will not be able to pass through any additional costs to EU consumers, SEAC notes that this possibility cannot be excluded. To address this uncertainty, the Dossier Submitter carried out a sensitivity analysis for the estimation of economic impacts assuming different shares of extra costs passed through to EU consumers (50 % or 100 %) which brings the estimation of economic impact amounts to €53 million and €79 million, respectively. The costs per home to ensure the WHO guideline value would be €178 (50 % pass through) and €263 (100 % pass through). These values are still considered marginal relative to the costs of a new dwelling.

- all the class E2 wood-based panels are used only in indoor building and construction and not outdoor.

- the entire volume of class E2 panels for building and construction purposes is concentrated in a number of new houses as assumed by the Dossier Submitter. However, even if the installation of a mixture of E1 and E2 panels for construction purposes cannot be excluded, usually panels can be expected to be bought in batches.

- the class E2 panels would be installed only in newly built homes and not in the recent renovation of ancient houses. This would result in a different stock of dwelling to be taken as a basis for the calculations.

- the assumption made by the Dossier Submitter that costs and benefits for producers and importers of wood-based panels for the reference year 2016 would be representative for impacts occurring in future years taking into consideration that trends in the construction sector might change quite quickly.

Uncertainties related to the restriction proposed by RAC

SEAC's conclusions on the proportionality of the RAC proposal suffer from the unavailability of complete and symmetric information, on both the benefit and the cost side.

On the cost side, SEAC considers that the information provided by industry related to the RAC proposal (as well as for the two intermediate limit values), seems to be rather uncertain. In SEAC's view, the uncertainties mainly concern the overall magnitude of the socio-economic impacts collected during the consultation on the SEAC draft opinion due to industry's lack of experience with such a limit. In fact, with the exception of a small part of the wood processing industry, most industry sectors claiming high costs reported having no experience in achieving formaldehyde emissions as low as the limit proposed by RAC. Moreover, there is a lack of information from other actors, for instance producers of alternative resins or glue systems or scavengers, suppliers of new machinery or producers of alternative materials such as plastic, which would potentially benefit from a restriction as proposed by RAC hence reducing the net impact on the EU society.

On the benefit side, for RAC's as well as for the other scenarios, there is indeed a high degree of uncertainty since the risk reduction was not quantified and the magnitude of any associated health benefits is not known.

Therefore, even if SEAC's assessment has a sufficient scientific basis, SEAC considers that, in

this specific case, taking into account the large number of sectors affected and given the complex technical and economic issues involved, the qualitative information on potential consequences of the different restriction scenarios provided by industry become of crucial importance for taking policy decisions.

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ה' באדר, התשפ"ה
05 מרץ 2025
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לכבוד
מר יואל בריס
יושב ראש רשות האסדרה, יושב ראש ועדת החריגים

פניית שר הכלכלה להוספת תנאי לאסדרה האירופית המאומצת – Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) - דרישה להשלמות

בהמשך לבקשת יושב ראש רשות האסדרה לקבל "עמדת גורמי המקצוע ..בדבר קיומו של חשש לפגיעה בבריאות הציבור ותוכנה של פגיעה כזו, וביסוס האמור במחקרים ובנתונים" להלן חוות דעת בנושא המצאות פורמלדהיד ברהיטי תינוקות וילדים.

פורמלדהיד נמצא בשימוש בייצור מוצרי עץ, רהיטים, וטקסטילים ועוד; מוצרים אלו עלולים לשחרר פורמלדהיד לאוויר. פורמלדהיד הוא גז רעיל שגורם לגירוי למערכת הנשימה העליונה ונספג במערכת הנשימה העליונה. ההשפעות העיקריות של פורמלדהיד הם בחשיפה נשימתית. ארגון בריאות העולמי קבע ערך סף טוקסיקולוגי לפורמלדהיד באוויר (0.1 מק"ג לשלושים דקות) על בסיס השפעות של גירוי נשימתי בחשיפה אקוטית וכרונית לפורמלדהיד. מדובר בערך שנותן הגנה גם לאוכלוסיות רגישות (כולל ילדים) וכן נותן הגנה מהשפעות כרוניות אחרות של פורמלדהיד כולל סרטן.[1]

פורמלדהיד מסווג כרעיל בבליעה, בחשיפה עורית וכן בחשיפה נשימתית (Acute Tox. 3; H331; Acute Tox. 3; H311; Acute Tox. 3; H301); מגרה את מערכת הנשימה (STOT SE 3); בנוסף פורמלדהיד מסווג כמוטגן (Muta 2 H341) וכן חומר מסרטן (Carc 1B H350).[2] על פי הסוכנות למחקר על סרטן (International Agency for Research on Cancer) פורמלדהיד מסווג כמסרטן בבני אדם (קבוצה 1) על בסיס ממצאים בבני אדם וחיות מעבדה. [3]

מספר מחקרים בדקו האם חשיפה לפורמלדהיד גורמת לריגוש נשימתי בקרב ילדים כולל אסתמה. הסוכנות להגנת הסביבה בגרמניה פרסמה הערכה ב 2016 והגיעה למסקנה שאין קשר סיבתי ברור בין חשיפה תוך מבני לפורמלדהיד ואסתמה בקרב ילדים.[4] לעומת זאת בהערכת סיכונים של הסוכנות להגנה על הסביבה שפורסם ב 2024 נקבע כי חשיפה כרונית לפורמלדהיד עלולה לגרם לאסתמה בקרב ילדים וכן תסמינים הקשורים לאלרגיה.[5]

על פי ההערכה של הסוכנות להגנה על הסביבה (2024), מספר מחקרים מעידים על רגישות מיוחדת של ילדים להשפעות של פורמלדהיד על מערכת הנשימה, לעומת מבוגרים. התפתחות הריאות ממשכיה עד גיל שש/שמונה, דרכי הנשימה בקרב ילדים יותר צרים וכן יש הבדל בין ילדים ומבוגרים ברמת האנזימים שמפרקים את פורמלדהיד. [5]

Department of Environmental Health
Ministry of Health
P.O.B 1176 Jerusalem 91010
call.habriut@moh.health.gov.il
Tel: * 5400 **Fax**: 025655914

קול הבריאות *5400

המערך הארצי לבריאות הסביבה
משרד הבריאות
ת.ד.1176 ירושלים 91010
call.habriut@moh.health.gov.il
טל: 5400* **פקס:**02-5655914

על פי הערכת סיכונים שנעשתה במסגרת הוועדה להערכת סיכונים של ECHA, הגורמים העיקריים שתורמים פורמלדהיד לאוויר תוך מבני כוללים פאנלים ורהיטים העשויים מעץ. במודלים של ריכוז תוך מבני של פרומלדהיד, הימצאות רהיטים שפולטים פורמלדהיד עלולה לגרום לריכוזים באוויר שחורגים מערך הסף שנקבע על ידי ארגון בריאות העולמי. בתרחישים מסוימים, רהיטים תורמים עד 50% מהפורמלדהיד באוויר. חשוב להדגיש שריכוז באוויר תוך מבני של פורמלדהיד מושפע מגודל החדר ומידת האוורור, כאשר ריכוז פורמלדהיד עלול להיות יותר גבוה בחדרים קטנים ולא מאווררים (כגון ממ"דים).

לסיכום, רהיטי עץ לתינוקות וילדים עלולים לפלוט פורמלדהיד לאוויר, מה שתורם לריכוז התוך מבני של פורמלדהיד. מדובר בגז רעיל שנספג דרך מערכת הנשימה וגורם לגירוי למערכת הנשימה. בנוסף פורמלדהיד נמצא קשור להשפעות ארוכות טווח כולל אסתמה וסרטן. תינוקות וילדים עלולים להיות יותר רגישים לפורמלדהיד בגלל שמערכת הנשימתית כולל הריאות נמצאים בתהליכי התפתחות. כאשר רהיטים נמצאים בחדרים קטנים ולא מאווררים, כגון ממ"דים, הסיכוי להמצאות פורמלדהיד באוויר עולה. הערכת סיכונים שנעשה בוועדה להערכת סיכונים בסוכנות לכימיקלים באירופה (ECHA) מצא שבתרחישים מסוימים הימצאות רהיטים חדשים עלולה לגרום לריכוז פורמלדהיד באוויר שעולה מעל ערך הסף הטוקסיקולוגי שנקבע על ידי ארגון בריאות העולמי ולכן הוחלט להגביל את ריכוז הפורמלדהיד ברהיטים ומוצרים נוספים.

כדי למנוע פגיעה בבריאות הציבור ובמיוחד בקרב תינוקות וילדים (גירוי מערכת הנשימה ואסתמה) חשוב להגביל את הריכוז של פליטת פורמלדהיד מרהיטי תינוקות וילדים. משרד הבריאות תומך בבקשת משרד הכלכלה להוסיף תנאי עד לכניסה לתוקף של הדרישה באירופה, ולפיו חובת העמידה בסף מקסימאלי של שחרור פורמלדהיד תהיה לפי אחת משתי חלופות לדרישה :א. בהתאם לדרישה הקיימת בתקינה הישראלית הרשמית .ב. בהתאם לתקנה 1464 EU2023/המעדכנת את הוראה מחייבת REACH .

בכבוד רב,

ד"ר תמר ברמן,
מנהלת תחום הערכת סיכונים בבריאות הסביבה

העתקים:
מר משה בר סימן טוב, מנכ"ל משרד הבריאות
ד"ר שרון אלרעי פרייס, ראש שירותי בריאות הציבור
מר איגור דוסקולוביץ', הממונה על התקינה

Department of Environmental Health
Ministry of Health
P.O.B 1176 Jerusalem 91010
call.habriut@moh.health.gov.il
Tel: * 5400 **Fax**: 025655914

קול הבריאות *5400

המערך הארצי לבריאות הסביבה
משרד הבריאות
ת.ד.1176 ירושלים 91010
call.habriut@moh.health.gov.il
טל: 5400* **פקס:**02-5655914

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משרד הבריאות
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call.habriut@moh.health.gov.il
טל: *5400 **פקס:**02-5655914