Comments of the Commission on the European Ombudsman's Own initiative inquiry - Ref. OI/2/2023/MIK

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

The Ombudsman's own initiative inquiry concerns the risk management of hazardous chemicals by the European Commission. In particular, it refers to the time taken for the Commission to adopt measures under the REACH Regulation[1], based on recommendations and opinions of the European Chemicals Agency ('ECHA'), as well as the transparency of the 'comitology procedures'. The Ombudsman highlights that it is of utmost importance for public health and the environment that the Commission fulfils its role as the risk manager as swiftly and transparently as possible, recalling the recent REACH evaluation and the ambitions of the 'Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment', where the Commission emphasised the need to respond rapidly to scientific findings regarding dangerous chemical substances.

In a recently conducted public consultation, the Ombudsman received concerns by civil society on the time taken by the Commission to regulate hazardous substances under REACH. Preliminary investigations by the Ombudsman's team confirmed the concerns raised as regards the time taken for inclusion of substances in Annex XIV ("the authorisation list") and adoption of restrictions.

In addition to the concerns regarding the time taken by the Commission to adopt the above types of measures under REACH, the Ombudsman highlights concerns about the lack of transparency of the 'comitology procedures', which the Commission has to follow in the adoption of implementing regulations and decisions under REACH. The concerns put forward are that these procedures provide for limited information being made publicly available, which makes it difficult for the public to hold the Commission and the Member States to account for their actions.

II. THE INQUIRY

Based on the information received in its public consultation concerning the time it has taken the Commission, following receipt of ECHA recommendations or opinions, to include substances in Annex XIV, adopt restrictions and grant authorisations, the Ombudsman is concerned about the impact these delays may have on the protection of human health and environment. The Ombudsman is therefore seeking further clarity on the facts of the matter and requests the Commission's reply to the following questions:

1. Regarding the time taken by the Commission to process the files:
    a. What was the median time for the Commission to include substances on the authorisation list, to grant authorisations, or to introduce restrictions, counting from the date the Commission received the file from ECHA to the date of the

[1] 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

official publication of the relevant act? Please include all the procedures launched since the REACH Regulation entered into force.

b. What has the median time been for the Commission to process pending files concerning the three procedures listed under point (a), counting from the date the Commission received the file from ECHA to the date of this letter?

c. Please provide the breakdown of files that took or have been pending for six, twelve, eighteen, twenty-four, thirty, thirty-six etc. months (i.e. the six-month breakdown). Please report separately on the closed and pending files like under points (a) and (b).

d. Please provide data showing whether the time taken to complete the above procedures has been increasing or decreasing over time, since the REACH Regulation entered into force.

2. What are the different steps that the Commission takes to process the abovementioned files after receiving them from ECHA? At which step(s) of that process do delays occur? For example, is there a delay between the receipt of the file from ECHA and putting it on the agenda of the REACH Committee? If so, why?

3. Does the Commission systematically publish all documents listed in Article 10 of the Comitology Regulation (when it comes to the REACH Committee)? How long does it take for such documents to be published in the Comitology Register? Could the Commission make available additional documents and information during comitology procedures to better enable the public to trace the progress of the discussions and understand the reasons for possible delays, especially considering the content of requests for public access to documents the Commission receives concerning these procedures?

III. THE COMMISSION'S COMMENTS TO THE INQUIRY

After making preliminary remarks on the context of the inquiry, the Commission will address each of the questions put to it by the Ombudsman.

Preliminary remarks

Time to adopt measures under REACH

At the outset, we would like to note that REACH is the most advanced and comprehensive chemical legislation in the world and that many other jurisdictions have followed the EU's lead in regulating chemicals. Accordingly, the Commission takes human health and the protection of the environment extremely seriously.

The Commission would like to acknowledge the practical and technical challenges for preparing a draft for an individual authorisation decision, the inclusion of new substances or additional properties in the authorisation list or a restriction, and for adopting the final measure in accordance with the 'comitology procedures', as required by the REACH Regulation. According to that regulation, decisions granting/refusing authorisations are adopted following the examination procedure in accordance with Article 5 of Regulation (EU)

No 182/2011 ('the Comitology Regulation'); for inclusions of substances or additional properties in the authorisation list and restrictions, the applicable procedure is the regulatory procedure with scrutiny ('RPS procedure') in accordance with Article 5a of Council Decision 1999/468/EC ('the Comitology Decision'). Working procedures partly account for those challenges, but the complexity and, in the case of authorisation decisions, the number of individual cases constitute important factors contributing to the time it takes for the Commission to adopt measures under REACH.

The challenges for the Commission's preparation of draft authorisation decisions were recognised in the 2018 REACH Review Report[2] which found that there was room for improvement in the quality of authorisation applications, which would be key in making the process work efficiently. The opinions of the Risk Assessment Committee ('RAC') and the Socio-economic Analysis Committee ('SEAC') did not always provide all the elements necessary for efficient decision-making by the Commission, or did not always do so with sufficient clarity. Concerns were also raised about the quality of restriction dossiers initiating the restriction process, and its consequences for the functioning of the restrictions process.

Being mindful of this situation, the Commission services already took some measures to speed up the preparation of draft authorisation decisions and draft restrictions, as follows:

(i) overall, working with ECHA to further improve the opinions of RAC and SEAC, so that they better address the needs of a swifter decision-making, without undermining the full independent assessment by the two ECHA Committees;

(ii) regarding authorisations, working on further tools and guidelines with ECHA and Member States to increase the quality of the applications, with the aim to also facilitate and streamline the decision-making step;

(iii) in the restrictions area, working with Member States as Dossier Submitters to facilitate the preparation of the restriction dossiers and benefit from their involvement during the opinion-making process.

The Ombudsman letter indicates that the Commission adopts or draws up draft measures 'based on ECHA's opinions and recommendations' and seems to reflect the understanding of some kind of 'automatism' between ECHA recommendations or opinions and Commission decisions. However, it should be clarified that Commission decisions are not bound[3] by ECHA opinions and recommendations and therefore, there is no automatism between the content of a recommendation or opinion from ECHA and listing a substance or additional properties in the authorisation list, adopting an authorisation decision or adopting a restriction. ECHA recommendations constitute an 'advice' to the Commission and ECHA's Committees'

[2] Commission Staff Working Document accompanying the Commission General Report on the operation of REACH and review of certain elements (SWD(2018)58 final).

[3] As regards authorisations, Article 60(2) and 60(4) REACH require that the Commission 'takes into account' the relevant opinions of ECHA's Committees, which is not the same as 'to be based on them' (See also Case T-837/16, paragraph 66). As regards restrictions, Article 73(1) REACH foresees the possibility that ECHA's Committees' opinions are not taken into account by the Commission (Case T-226/18, under appeal, paragraph 213). As regards listing of substances in the authorisation list, Article 58(3) REACH requires that prior to a Commission decision to include a substance in the authorisation list, ECHA recommend priority substances to be included in the authorisation list. However, this does not bind the Commission, who may decide to not to include substances prioritised by ECHA or to include other substances not prioritised by ECHA (see also Case T-610/17, paragraph 129).

opinions are the views of scientific committees in the areas within their remit which provide input for the Commission in its decision-making. Furthermore, the Commission may also take into account information and aspects not contained in ECHA recommendations or opinions. Thus, the Commission, although taking into account ECHA's scientific committees' assessments and ECHA recommendations, bears the responsibility to ensure that all authorisation decisions, restrictions and inclusions in the authorisation list it proposes and adopts are well-substantiated and legally sound. This requires the Commission to take into account all relevant factors and assess the sufficiency and adequacy of the information provided, to carry out the Commission's own robust assessment. This need is getting even stronger in light of the increasing number of authorisation decisions and restrictions being challenged in Court. In some cases, in striving to present well-substantiated and legally sound decisions, the Commission has sent opinions back to ECHA for further clarification and/or assessment of additional information[4]. Moreover, every measure proposed by the Commission needs to be first agreed by both services responsible for REACH (DG GROW and DG ENV) and then go through appropriate internal consultation with all relevant Commission services, and the political discussions and validation may also add to the time of the process.

As regards the inclusion of substances in the **authorisation list**, the Commission has in two instances grouped two ECHA recommendations in one inclusion in the authorisation list, effectively creating each time a longer time between the first of the two recommendations and inclusion. A third grouping is currently ongoing for the two most recent ECHA recommendations. The Commission groups recommendations when only a limited number of the substances recommended by ECHA is considered appropriate for inclusion in the authorisation list at that moment. The justification for not including all the recommended substances is explained in the recitals of the Commission regulations amending Annex XIV. Those recitals provide justification not only on the substances included in Annex XIV (as legally required), but for transparency reasons, also on those not included. Examples of substances from ECHA recommendations not included in Annex XIV are, e.g., dechlorane plus, bisphenol A, and terphenyl hydrogenated, where restriction dossiers were planned or under preparation by Member States and inclusion in the authorisation list would have prevented the restriction processes. Another example includes several lead compounds, where the Commission decided to postpone a decision in view of ongoing discussions on a restriction and, taking into account that one of the main identified concerns was workers' exposure, on the possible adoption of additional measures under the occupational safety and health legislative framework.

As regards **restrictions**, one can observe that the time needed to adopt measures is increasing over time. This relates inter alia to the increased complexity of restrictions. While restrictions in the past often covered one substance and/or a specific use, many recent restrictions are wide in scope, covering groups of substances and/or a wide range of uses (for example, the restriction on hazardous chemicals in tattoo inks covers some 4000 substances; the restriction on microplastics intentionally added to products, addressing risks posed by a group of similar substances (all synthetic polymers sized below 5 mm which are synthetic, insoluble, not biodegradable and organic) covers a wide range of uses). The advantage of addressing risks from many substances and/or uses under a single measure is that economies of scale allow considerable time-saving compared to the time that would have been needed to individually restrict each substance or use covered by the wide-scope restriction. It also allows avoiding

[4] In e.g., the applications for authorisations TCE Microporous, TCE Entek and TCE Blue Cube, or in the case of the draft restriction on microplastics.

regrettable substitution. However, a wide-scope restriction unavoidably takes longer to be processed than a "classic" restriction targeting a single substance and/or a specific use, because its scope is much broader, impacting many more uses and sectors, and that timing was not properly foreseen when the REACH Regulation was adopted.

As for decisions **granting or refusing authorisations**, there is a considerable saturation of the system created by hundreds of applications for authorisations for a very limited number of substances. Significant delays were caused by the outcome of the 'lead chromates pigment case'[5] which triggered a need to revise all pending authorisation applications, resulting in a request for additional information to certain applicants (e.g. in particular for certain old applications for uses of chromium trioxide). Moreover, lengthy discussions at the REACH Committee, where in many cases the Commission's draft decisions required several discussion rounds (e.g. during more than a year for certain applications regarding 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated) before adoption, and European Parliament resolutions, taking the view that draft decisions exceeded the Commission's implementing powers, on other files, added further delays. The Commission services are not managing to process the applications to the speed required, in particular applications submitted for uses of chromium trioxide. The solution for those challenges will be proposed in the upcoming REACH revision, which should also address the question of reasonable and realistic deadlines for the preparation of a Commission decision, which in hindsight was not sufficiently considered at the time when REACH was proposed and adopted (because of lack of on-the-ground experience at that time).

The **Covid pandemic** added delays in terms of procedures, as REACH Committee meetings overnight went from in-person meetings to – at first - virtual and - currently - hybrid meetings. The result has been an increased use of written votes following meetings instead of on-the-spot oral votes at physical meetings (for more details, see the reply to question 2).

Transparency and comitology

The inquiry appears to suggest that the Comitology Register does not provide sufficient information on the status of each case and that it is impossible to know at which stage of the Commission's internal procedure a draft is. Firstly, we would like to recall that Article 4 of Regulation (EC) No 1049/2001[6] regarding public access to European Parliament, Council and Commission documents ('Regulation (EC) No 1049/2001') allows the institutions to refuse access to a document in certain circumstances, including when disclosure would undermine the institution's decision-making process. In this context, in the *ViaSat* judgment[7], the General Court duly took note of the confidentiality attached to certain documents in the rules of procedure of comitology committees in order to assess the applicability of the exceptions in Article 4 of Regulation (EC) No 1049/2001. Secondly, the content of the Comitology Register is regulated by Article 10 of the Comitology Regulation. The Commission, willing to ensure the biggest possible transparency, goes beyond what it is obliged to make available under Article 10 of the Comitology Regulation and uses the Register to make publicly available the text of draft individual authorisation decisions, draft inclusions in the authorisation list and draft restrictions on which the opinion of the REACH Committee is sought even before the REACH Committee has voted on them. Finally, the Commission provides for additional

[5] Case C-389/15 P, European Commission v Kingdom of Sweden.

[6] OJ L 145, 31.5.2001, p. 43.

[7] Judgment of 28 May 2020, ViaSat v Commission, T-649/17, EU:T:2020:235, p.86.

transparency through other means than the Comitology Register (for more details, see the reply to question 3).

Question 1

a. What was the median time for the Commission to include substances on the authorisation list, to grant authorisations, or to introduce restrictions, counting from the date the Commission received the file from ECHA to the date of the official publication of the relevant act? Please include all the procedures launched since the REACH Regulation entered into force.

- Include substances on the authorisation list[8]: median time **24 months**
- Grant/refuse authorisations[9]: median time **18 months**
- Introduce restrictions[10]: median time **16 months**

b. What has the median time been for the Commission to process pending files concerning the three procedures listed under point (a), counting from the date the Commission received the file from ECHA to the date of this letter?

- Since ECHA recommendations for inclusion of substances on the authorisation list pending adoption[11]: median time **14 months**
- Since ECHA Committees' opinions on applications for authorisations pending adoption[12]: median time **13 months**
- Since ECHA Committees' opinions on restrictions pending adoption[13]: median time **18 months**

[8] Data on eight regulations (ten ECHA recommendations), published in the Official Journal until 8 June 2023.

[9] Data on 189 applications for authorisations, with summaries of decisions granting or refusing authorisation published in the Official Journal until 8 June 2023.

[10] Data on 26 restrictions adopted in accordance with the Article 68(1) procedure under REACH and published in the Official Journal since the entry into force of REACH until 8 June 2023. The eight restrictions adopted in accordance with the Article 68(2) procedure under REACH and the four amendments of Annex XVII based on the transitional measures of Article 137 of REACH are not included, as they did not entail the involvement of ECHA's scientific committees.

[11] Data concerning two ECHA recommendations, received on 14 April 2021 and 12 April 2023 respectively.

[12] Data concerning 78 applications for authorisations, pending with the Commission on 8 June 2023. In the meantime, summaries of decisions on nine of those applications for authorisation were published in the Official Journal, with the REACH Committee having given a favourable opinion on them in February and April 2023. For another six pending decisions on authorisation applications, the written voting procedure in the REACH Committee was terminated without result at the request of a Member State; they will be discussed and possibly voted upon in the upcoming REACH Committee meeting of 14 September 2023.

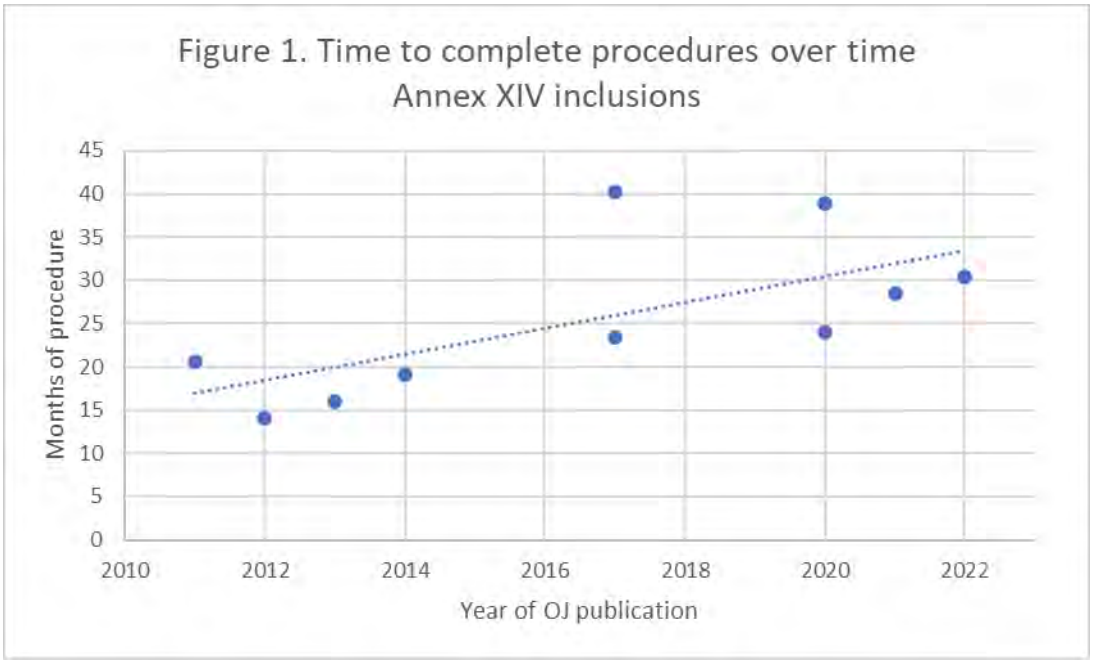
[13] Data concerning nine restriction files, pending with the Commission on 8 June 2023. In the meantime, one of those restrictions (on formaldehyde and formaldehyde releasers) was published in the Official Journal, while another restriction (on microplastics) undergoes the scrutiny of the European Parliament and the Council until 5 August 2023.

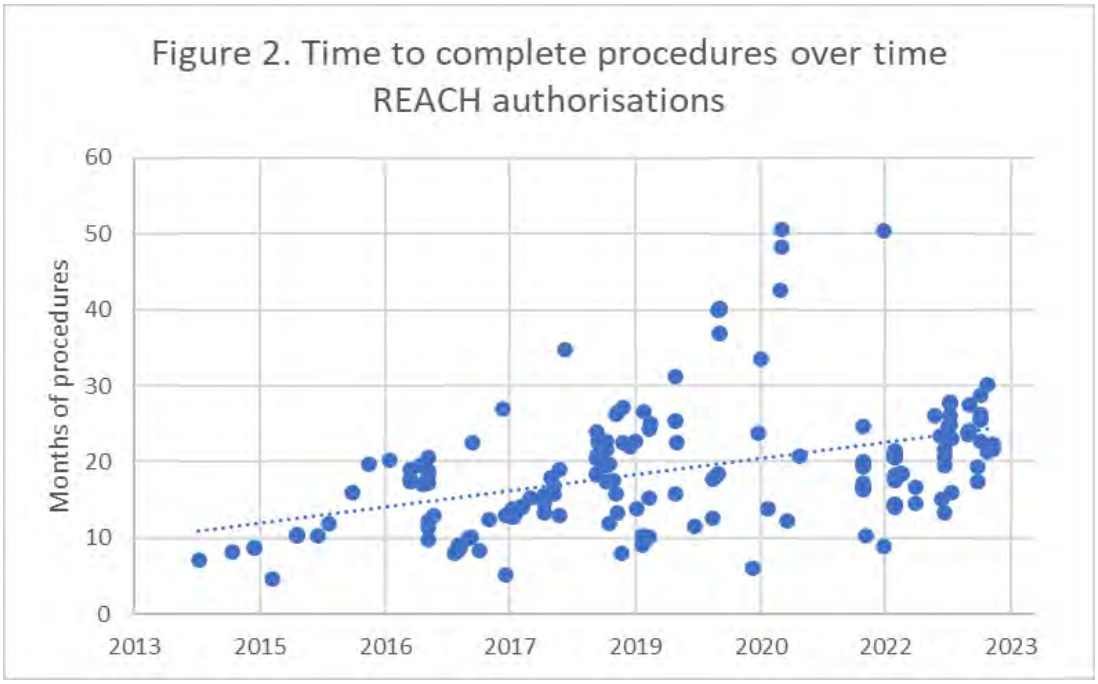
c. Please provide the breakdown of files that took or have been pending for six, twelve, eighteen, twenty-four, thirty, thirty-six etc. months (i.e. the six-month breakdown). Please report separately on the closed and pending files like under points (a) and (b).

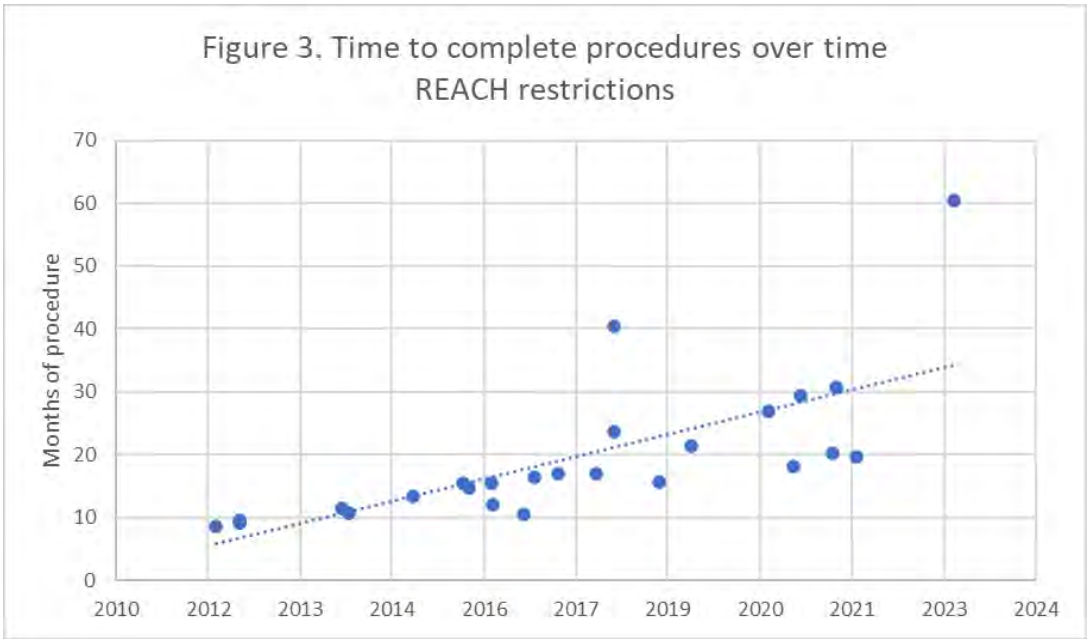
Table 1. Adopted measures			
Intervals	Inclusion Annex XIV	Authorisations	Restrictions
0-6 months		3	
6-12 months		35	8
12-18 months	2	62	9
18-24 months	4	50	4
24-30 months	2	24	2
30-36 months		3	1
36-42 months	2	8	1
42-48 months		2	
48-54 months		2	
54-60 months			1

Table 2. Pending measures			
Intervals	Inclusion Annex XIV	Authorisations	Restrictions
0-6 months	1	25	3
6-12 months		14	
12-18 months		8	2
18-24 months		13	1
24-30 months	1	8	2
30-36 months		2	
36-42 months			1
42-48 months		4	
48-54 months		2	
54-60 months		1	
60-66 months			
66-72 months			
72-78 months		1	

d. Please provide data showing whether the time taken to complete the above procedures has been increasing or decreasing over time, since the REACH Regulation entered into force.







Question 2

What are the different steps that the Commission takes to process the abovementioned files after receiving them from ECHA? At which step(s) of that process do delays occur? For example, is there a delay between the receipt of the file from ECHA and putting it on the agenda of the REACH Committee? If so, why?

After receipt of the ECHA opinions or recommendations, the process to adoption can be summarised in the following steps, further detailed below.

i. Analysis and assessment of the file by the lead Commission services (DG GROW and DG ENV[14]) and discussion between them to find a common understanding and agreement on the measure, including the drafting of the legal text;
ii. Seeking formal agreement of the two responsible Directorates-General as well as the two responsible Cabinets to launch an inter-service consultation;
iii. Inter-service consultation (10 working days, plus time to resolve comments received and to elaborate a revised and agreed legal text);
iv. Notification under the terms of the Agreement on Technical Barriers to Trade ('TBT') (60 days, for restrictions and inclusions in the authorisation list);
v. Publication for public feedback (4 weeks, for inclusions in the authorisation list);
vi. Discussion in the REACH Committee;
vii. Vote (oral or written) in the REACH Committee;
viii. In the case of positive opinion of the REACH Committee, scrutiny by the European Parliament and the Council (under the RPS procedure: 3 months for restrictions and inclusions in the authorisation list; under the examination procedure: any time for authorisation decisions before adoption, limited to whether a draft implementing act exceeds the implementing powers provided for in the legislative basic act);

[14] Both services are jointly responsible for REACH, following the related Commission decision taken at the Commission's meeting of 29 October 2003, PV(2003)1632 final.

ix. Adoption of measure by the College of Commissioners through written procedure, after formal agreement of the two Directorates-General as well as the two responsible Cabinets.

i. Files received from ECHA are not draft measures proposed by the Commission and cannot therefore be put on the agenda of the REACH Committee as such[15]. As explained in the preliminary remarks, ECHA recommendations and ECHA's scientific committees' opinions are not binding on the Commission. The Commission considers the recommendations and opinions for the purposes of its decisions, but can also take into account further aspects or information not contained in those recommendations or opinions. The Commission, as the policy maker, has also a margin of discretion.

ECHA recommendations on priority substances for inclusion in the authorisation list include an annex with the motivation of the ECHA recommendation. In addition, the Commission receives all the information submitted to ECHA during the public consultation leading to the preparation of the recommendation as well as the replies to the call for socio-economic data that ECHA launches in parallel to the consultation on behalf of the Commission. This input could include hundreds of replies that the Commission needs to assess to understand the impact of potential measures. For example, in the last recommendation from ECHA, more than 500 replies were received for a single substance, i.e., lead metal. All information has to be analysed before the Commission takes a decision on the appropriateness of the listing of a substance at a given time and the precise terms of the inclusion, before drafting a Commission regulation, including recitals justifying the Commission's decision. In the case of restrictions, files received from ECHA consist of the scientific opinions of RAC and SEAC on the restriction dossier prepared by the Dossier Submitter (ECHA or (a) Member State(s)), accompanied by a Background Document with annex(es) as well as an explanatory note describing the main changes made during the opinion-making process of RAC and SEAC compared to the dossier submitted. Especially in cases of wide-scope restrictions covering groups of substances and/or a wide range of uses, the file often contains a very thorough and voluminous analysis and assessment of risk-related and socio-economic aspects by the Dossier Submitter, RAC and SEAC. It is for the responsible Commission services to analyse and assess the file, in particular whether the conditions of Article 68(1) of REACH are met, and to discuss and agree on a common understanding on the draft measure to be proposed, including the drafting of the legal text. Decisions granting or refusing authorisations have to be drafted after considering technically complex application files and RAC and SEAC opinions.

In all cases, negotiations between the two responsible services (DG GROW and DG ENV) are required. Moreover, as any generally applicable measures of EU law must be published in the official languages of the EU and be clear and precise with regard to their content, original versions of draft inclusions into the authorisation list and draft restrictions have to be clearly worded in order to produce correct versions in other languages[16].

[15] Article 3(3) of the Comitology Regulation requires that 'the draft implementing act' be submitted to the Committee; Article 5a(2) of the Comitology Decision requires that 'a draft of the measures to be taken' be submitted to the Committee.

[16] The Commission services strive to prepare and update translations in parallel to the other processes as much as possible, so as not to cause unnecessary delays.

The General Court clarified in a judgment of 30 June 2021[17] what the responsibilities of the Commission are in the preparation of draft restrictions:

- The Commission is to prepare the draft amendment to Annex XVII (paragraph 198 of the abovementioned judgment);
- The Commission has a broad discretion, in particular as to the assessment of highly complex scientific and technical facts, in order to determine the nature and the scope of the measures which it adopts. This broad discretion applies not only to the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts. The Commission must therefore be able to show that in adopting the act it actually exercised its discretion, which presupposes that it took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate (paragraphs 74 and 75 of the abovementioned judgment);
- The Commission is not bound by the opinions of RAC and SEAC (paragraph 213 of the abovementioned judgment);
- The procedure provided for in Title VIII of REACH is intended to provide the Commission with the necessary scientific information to enable it to determine, in full knowledge of the facts, whether or not there is an unacceptable risk to health and the environment and to lay down restrictions in order to address such a risk (paragraph 217 of the abovementioned judgment);
- The notion of "unacceptable risk" in Article 68(1) of REACH is different from that of "risk that is not adequately controlled and needs to be addressed" in Article 69 of REACH. Unacceptable risk depends on several factors which include, in particular, the risk assessment, the appropriateness of a restriction in reducing the risks assessed and the socio-economic impact of such a restriction (paragraph 199 of the abovementioned judgment).

As regards decisions granting or refusing authorisations, Case T-837/16 (confirmed in appeal by Case C-389/19 P) provided important clarifications on the following aspects:

- The applicants need to discharge their burden of proof in their applications for authorisation. The Commission cannot remedy substantial shortcomings in the application, or in the Commission assessment on whether the requirements for granting an authorisation are met, by setting conditions in the authorisation. In assessing the applications, the Commission should take into account all relevant information available, not only ECHA's scientific assessment, and ensure that, if uncertainties still remain, they are negligible, before granting an authorisation (paragraphs 79, 81 to 83, 86 and 89 among others of the judgment in case T-837/16);
- It is for the Commission alone to verify whether the conditions for authorisation are fulfilled and it has an obligation to consider on its own initiative the relevant information. In taking its decisions, the Commission should take into account ECHA's opinions but it is not bound by them. If it relies on ECHA's scientific opinions it should ensure that their reasoning is full, consistent and relevant. In the event that the Commission opts to disregard substantially an opinion or to substitute, in relation to technical or economic points, its opinion for the opinion issued by one of the ECHA committees, it must provide specific reasons for its findings by comparison with those made in the ECHA opinion and its statement of reasons must explain why it is disregarding the latter. The statement of reasons must be of a scientific level at least commensurate with that of the opinion in question (paragraphs 64-69 of the judgment in case T-837/16);

[17] Case T-226/18, Global Silicones Council and others, under appeal.

- On the assessment on suitability of the alternatives (by the applicant and thus, by ECHA and the Commission), there is the need to take into account alternatives available 'in general' and not only 'feasible for the applicant' as done previously (paragraphs 74-75 of the judgment in case T-837/16). Consequently, the standard language of the decisions as well as the ECHA opinion template and relevant guidance had to be updated accordingly;
- On the requirement to submit a substitution plan: if suitable alternatives are available but not (yet) for the applicant, the applicant needs to submit a substitution plan. The judgement clarified the applicability of that legal requirement beyond the limited number of cases to which the Commission had applied it until that moment[18]. Consequently, ECHA guidance needed to be edited and a substitution plan was requested in a number of cases which had to be subsequently assessed by SEAC.

Furthermore, it should be clarified that REACH provides for two routes of granting authorisations: (1) the adequate control route, according to which if the risk is adequately controlled, the Commission must grant an authorisation (Article 60(2) REACH). (2) Where the risk is not adequately controlled, the socio-economic route where, subject to compliance with two conditions (socio-economic benefits outweigh the risk arising from the use of the substance and there are no suitable alternatives) the Commission 'may' grant an authorisation (Art. 60(4) REACH). This means that within this route of authorisation, even if the conditions are met, the Commission has a wide margin of discretion on whether to grant an authorisation and it can decide not to grant it based on any legitimate and proportionate public interest considerations. Most applications for authorisations concern the use of substances for which risk arising from their use cannot be adequately controlled and therefore an authorisation can only be granted under the socio-economic route. Therefore, time for discussion on how to apply this discretion and whether and which grounds to use for this purpose has also been needed within the overall process for certain applications, between the receipt of ECHA's opinions and putting draft authorisation decisions on the agenda of the REACH Committee for discussion and vote.

In the area of listing of substances in Annex XIV, the General Court in Case T-610/17 also confirmed the purely advisory nature of ECHA recommendations on priority substances, so that even if the Commission decides to follow the ECHA recommendation, that fact does not mean in itself that the Commission does not carry out its own assessment (paragraphs 104 and 129). The General Court also recalled in this context the broad discretion the Commission has in the assessment of highly complex scientific and technical facts (paragraph 158). Thus, the Commission's margin of discretion requires also in this area time for necessary deliberations prior to the decision to include a substance in Annex XIV.

The responsible Commission services are usually approached by stakeholders (including economic operators as well as NGOs) wishing to communicate their views on pending files in a meeting or by submitting a written document. For example, in the case of the lead shot in wetlands restriction, several dozens of letters were received from Members of the European Parliament[19], hunters' and shooters' associations, environmental protection NGOs, international organisations, scientists and individual citizens submitting views and/or evidence directly to the Commission; moreover, the Commission responded favourably to several meeting requests from Members of the European Parliament, government

[18] Only in the adequate control route for authorisation.

[19] In addition to more than 25 formal Parliamentary Questions received and responded to by the Commission.

representatives, industry, hunters' and shooters' associations and environmental NGOs. All of the input provided had to be processed, analysed and responded to[20], and taken into account for the drafting and decision-making on the restriction. Also in the case of the wide-scope microplastics restriction, it was necessary to gather and assess much more information and evidence, meet more stakeholders and reply to many more letters and questions than for a restriction addressing one substance and/or a specific use. All this is in line with the great value which the Commission attaches to being informed of stakeholders' views, so that they can be made part of its analysis and assessment.

ii.-iii. Seeking formal agreement of the respective Directorates-General and responsible Cabinets before launching an inter-service consultation, as well as agreement of other services through inter-service consultation, are standard internal procedures, as collegiality is the guiding principle of all the work of the Commission, and responsibility for the coherence and quality of the Commission proposals is shared throughout the cycle from policy planning to adoption[21]. Practical experience since the entry into force of the REACH Regulation shows that seeking formal agreement of the respective Directorates-General and responsible Cabinets before launching an inter-service consultation in the REACH restrictions and authorisation area usually takes a minimum of 4 to 6 weeks. In inter-service consultation, other services normally have a deadline of 10 working days to submit their (dis)agreement or comments; the latter have to be taken into account by the responsible services in the elaboration of an agreed new legal text for the draft measure.

The above timelines show that the 3-month deadline, laid down in 2006 in Article 64(8) REACH for preparation of a draft authorisation decision and Article 73(1) REACH for preparation of a draft restriction, has proven unrealistic in the light of the Commission's responsibilities under the authorisation and restrictions titles of the REACH Regulation, also taking into account the Commission's internal procedures and the increasing number of wide-scope restrictions. The Commission is reflecting on how to address this in the REACH revision.

iv.-v. As regards restrictions and inclusions in the authorisation list, the Commission is bound by international obligations as well as obligations of EU law. Draft restrictions and draft inclusions of substances in the authorisation list have to be notified to the World Trade Organisation under the terms of the TBT. The notification triggers a mandatory standstill of 60 days, during which the draft cannot be processed further by the Commission and, in particular, it cannot be put to a vote by the REACH Committee. Any comments from third countries have to be taken into account and are discussed with Member States before the vote. In addition, the Commission's commitment to Better Regulation requires that stakeholders have the possibility to provide feedback on the draft texts of implementing acts and regulatory procedure with scrutiny measures, with exceptions[22]. Exceptions are foreseen, inter alia, for individual authorisation decisions (in the REACH area, this exception applies to decisions to grant or refuse authorisations) and for acts based on scientific opinions from an agency or scientific committee on which a public consultation has already taken place where the Commission follows the agency/scientific committee findings (in the REACH area, this

[20] Where appropriate in accordance with the Commission's Code of Good Administrative Behaviour.

[21] P(2019)2, Communication from the President to the Commission, The Working methods of the European Commission, 1.12.2019, pages 8 and 11.

[22] Better Regulation Toolbox, November 2021, Tool #51, pages 451 and following.

exception applies to restrictions). Accordingly, Commission draft proposals for decisions to include substances or additional properties in the authorisation list are published on the 'Have Your Say' portal for a four-week public feedback period and all stakeholders' comments received are taken into account. This ensures transparency towards the general public and provides stakeholders and the general public with a possibility to comment on the draft act. The Commission ensures efficiency by making the timelines of 60 days and 4 weeks coincide.

vi. The limited availability of suitable meeting rooms at Commission premises and the many other meetings taking place in the REACH area[23] imply that REACH Committee meetings have to be planned very long in advance and can only exceptionally be organised ad-hoc. This explains why occasionally several weeks have passed between the draft measure being ready (as witnessed by the date of the TBT notification) and it being discussed in a REACH Committee meeting, for which invitations and agendas are usually sent to members at least 21 calendar days in advance[24], in line with Article 3(1) of the Rules of Procedure of the REACH Committee[25].

Article 3(4) 2nd subparagraph of the Comitology Regulation requires the chair of a committee to 'endeavour to find solutions which command the widest possible support within the committee.' Moreover, the Commission in principle avoids proceeding to votes if there is no reassurance of sufficient support from Member States in the REACH Committee, as negative or 'no opinion' votes would trigger further procedural steps implying longer timelines in decision-making[26].

In the first years after entry into force of REACH, restrictions, some decisions on authorisation applications and inclusions in the authorisation list could usually be voted upon in the first REACH Committee meeting in which they were tabled, or in the next meeting. For inclusions in the authorisation list, this changed with the 5th inclusion; since then, at least two separate meetings devoted to discussion only (i.e. no vote taken) usually have to take place before an inclusion obtains sufficient support to ensure a positive REACH Committee vote. In the area of restrictions, a similar trend can be observed: the draft restriction on methanol was the first to require discussions during four separate meetings, before a positive vote could be ensured in the 5th meeting; since then it is not unusual for three, four or even five discussion rounds to be necessary to ensure a positive vote. In the case of authorisation decisions, for many decisions, one or two discussions in the REACH Committee are still sufficient to obtain the necessary support for the Commission's proposal. However, during the past year some decisions have been tabled for discussion in four or five meetings, but this is rather the exception than the rule. The agendas of the REACH Committee have become more

[23] Several of the persons designated to represent the Member States in the REACH Committee, and several members of Commission and ECHA staff participating in the REACH Committee, may also be called to participate in meetings of RAC and SEAC, meetings of ECHA's Member State Committee, CARACAL meetings and other meetings in the REACH area, so that overlaps between such meetings and the REACH Committee are avoided as much as possible. The Commission teams responsible for authorisations and restrictions are also responsible for the ongoing REACH revision, which together with keeping chemicals risk management under the current REACH Regulation running, including by defending it in Court and towards stakeholders, is implying huge demands on them in terms of workload.

[24] The 21-day deadline is particular to the REACH area; the normal deadline foreseen by the Comitology Regulation is in principle 14 days.

[25] https://ec.europa.eu/transparency/comitology-register/screen/committees/C34200/consult?lang=en

[26] In the case of restrictions or inclusions in the authorisation list, Article 5a(4) of Council Decision 1999/468/EC. In the case of authorisation decisions, Article 5(3) or (4) of the Comitology Regulation.

charged with authorisation decisions over the years, reflecting their increased numbers: whereas, in 2014, only one draft authorisation decision was put on the agenda for each meeting, recent agendas routinely included 7 to 15 draft authorisation decisions.

vii. Article 73(2) REACH requires the Commission to send the draft restriction to the Member States at least 45 days before voting. This requirement is a special feature of the REACH restrictions area, which was included by the legislator to ensure appropriate coordination within each Member State. The Commission understands the 45-day timeline as only applying to the first version of the draft restriction submitted to the REACH Committee.

The Covid pandemic triggered significant changes in REACH Committee voting practices. Before the pandemic, in most cases, votes were taken in meetings and only rarely in written procedure[27]. This allowed making last minute changes to the draft measure to ensure sufficiently wide Member State support and then immediately proceeding to the vote. As the pandemic did not allow for in-person meetings, virtual meetings had to be held, which evolved into hybrid meetings, with all the well-known constraints of remote connection. The chair may obtain the committee's opinion by written procedure in accordance with Article 3(5) of the Comitology Regulation, when for example based on Article 8 of the Rules of Procedure of the REACH Committee, 'the draft implementing act has already been discussed during a committee meeting'. Such written votes were often preferred in particular during the pandemic, as the voting results could be cast, counted and registered more reliably in a written procedure than in a virtual meeting when such meetings were used more frequently due to COVID19 related circumstances, and continue to be preferred due to the virtual or hybrid meeting format[28] in which REACH Committee meetings have been taking place since the pandemic[29]. The benefits gained in terms of legal certainty by relying on a written vote imply, however, disadvantages in terms of timing: when the discussion in the meeting ensures sufficiently wide Member State support, the vote cannot be taken in the meeting, but the text of the draft act has to be sent to the Member States who have 21 calendar days to cast their written vote[30]. Moreover, Member States can request that the written voting procedure be terminated without result, in which case a REACH Committee meeting has to be convened within a reasonable time[31]. This happened in the case of the draft restriction on lead in gunshot in wetlands, as well as for certain authorisation decisions which are still pending, adding to the time needed for processing the measures.

viii. After the positive vote in the REACH Committee, draft restrictions and inclusions in the authorisation list have to be submitted to a three-month scrutiny by the European Parliament and the Council as they are adopted under the RPS procedure[32]. This implies a three-month standstill during which the draft measures cannot be adopted. In the case of the draft restriction on lead in PVC, the European Parliament opposed the adoption of the restriction

[27] Cf Article 3(3) and (5) of the Comitology Regulation.

[28] As some Member States, in the context of greening government, no longer allow their representatives to travel to Brussels by air.

[29] Even after the pandemic, virtual or hybrid meetings take place and the chair of the committee can take a vote via the written procedure under the conditions of the Comitology Regulation.

[30] Article 8 of the REACH Committee Rules of Procedure.

[31] Cf Article 3(5), second subparagraph, of the Comitology Regulation.

[32] Article 5a(3) of the Comitology Decision.

during the three-month period[33], leading the Commission to submit an amended draft to the REACH Committee. This necessitated repeating steps i.-iv., as the reasons for the European Parliament's objection required in-depth consideration within the Commission, careful drafting and committed negotiating, to ensure that the amended draft would be agreeable to both the European Parliament and the Member States. Discussions in five REACH Committee meetings were needed to be able to proceed to the vote on the draft as amended following the European Parliament's objection.

With regard to authorisation decisions which are adopted in accordance with the examination procedure, the scrutiny right of the European Parliament or the Council is more limited as they can at any time only indicate that in their view the draft exceeds the Commission's implementing powers, obliging the Commission to review the draft and to inform the European Parliament and the Council of its intended course of action[34]. The European Parliament has passed resolutions for the following draft authorisation decisions:

- DEHP (Vinyloop)[35]: Decision adopted on 16 June 2016, 6 months after resolution; total time needed to process 20 months, mostly due to extensive discussions in the REACH Committee;
- Sodium dichromate (Ilario Ormezzano)[36]: Decision still pending, since the Commission requested the applicant to submit a substitution plan following the judgment in Case C-389/19 P;
- DEHP (DEZA)[37]: Application withdrawn in March 2023, 3 years after resolution, after having been pending for 97 months, initially due to extensive discussions in the REACH Committee and, at a later stage, since the Commission requested the applicant to submit a substitution plan following the judgment in Case C-389/19 P;
- DEHP (Grupa Azoty)[38]: Application withdrawn in March 2020, one year after resolution, after having been pending for 79 months, mostly due to extensive discussions in the REACH Committee;
- Chromium trioxide (Chemservice)[39]: Decision adopted on 15 December 2020, nearly 18 months after resolution; total time needed to process 51 months, initially due to

[33] European Parliament resolution of 12 February 2020 on the draft Commission regulation amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead and its compounds (OJ C 294, 23.7.2021, p. 2).

[34] Article 11 of the Comitology Regulation.

[35] European Parliament resolution of 25 November 2015 on draft Commission Implementing Decision XXX granting an authorisation for uses of bis(2-ethylhexhyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (OJ C 366, 27.10.2017, p. 96)

[36] European Parliament resolution of 29 November 2018 on the draft Commission implementing decision granting an authorisation for certain uses of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Ilario Ormezzano Sai S.R.L.) (OJ C 363, 28.10.2020, p. 98)

[37] European Parliament resolution of 27 March 2019 on the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (DEZA a.s.) (OJ C 108, 26.3.2021, p. 75)

[38] European Parliament resolution of 27 March 2019 on the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.) (OJ C 108, 26.3.2021, p. 80)

[39] European Parliament resolution of 27 March 2019 on the draft Commission implementing decision granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Lanxess Deutschland GmbH and others) (OJ C 108, 26.3.2021, p. 85)

extensive discussions in the REACH Committee and, at a later stage, since the Commission requested the applicant to submit a substitution plan following the judgment in Case C-389/19 P;

- Chromium trioxide (Cromomed)[40]: Decision adopted on 18 December 2020, nearly 14 months after resolution; total time needed to process 48 months, mostly due to extensive discussions in the REACH Committee.

ix. Only after a decision granting or refusing authorisation has received a favourable opinion by the REACH Committee, or after a draft restriction or inclusion in the authorisation list has successfully passed the scrutiny of the European Parliament and the Council, it can be adopted by the Commission. This implies, for the purpose of ensuring proper political validation, seeking formal agreement of the respective Directorates-General and responsible Cabinets before launching the adoption process[41]. Practical experience since the entry into force of the REACH Regulation shows that seeking formal agreement of the respective Directorates-General and responsible Cabinets before launching the adoption process in the REACH restrictions area can take 3 to 5 weeks, while it can take 2 weeks to 2 months in the case of authorisation decisions and 6 to 8 weeks for inclusions in the authorisation list. Adoption of a measure under the REACH Regulation takes place through the so-called written procedure, in which Commissioners and their Cabinets have five working days to request extension of the time limit, or suspension or termination of the procedure, absent which the measure is automatically adopted. So far, all restrictions, inclusions in the authorisation list and authorisation decisions have been automatically adopted at the end of the five working days' period.

Question 3

Does the Commission systematically publish all documents listed in Article 10 of the Comitology Regulation (when it comes to the REACH Committee)? How long does it take for such documents to be published in the Comitology Register? Could the Commission make available additional documents and information during comitology procedures to better enable the public to trace the progress of the discussions and understand the reasons for possible delays, especially considering the content of requests for public access to documents the Commission receives concerning these procedures?

Although Article 10(5) of the Comitology Regulation only requires the Commission to publish the *references* of the documents referred to in Article 10(1), the Commission systematically publishes those documents *in full* when it comes to the REACH Committee.

All agendas, draft acts on which the committee is asked to give an opinion and final draft acts following delivery of the opinion are included in the Comitology Register in principle at the same time as they are made available to the members of the REACH Committee, as required by Article 10(4) of the Comitology Regulation, although occasional delays of a few days may occur due to internal validation procedures. They are, as a rule, made publicly available upon

[40] European Parliament resolution of 24 October 2019 on the draft Commission implementing decision partially granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Cromomed S.A. and others) (OJ C 202, 28.5.2021, p. 68)

[41] P(2019)2, Communication from the President to the Commission, The Working methods of the European Commission, 1.12.2019, pages 8 and 10.

inclusion in the Register, so that the public is put on an equal footing with the European Parliament and the Council to whom those documents are transmitted.

The voting results and the information concerning the adoption of the acts by the Commission are published in principle within a few days from the vote or adoption respectively, although delays of a few days may occur also here due to internal validation procedures. In the case of summary records (including the lists of the authorities/organisations to which the persons designated by the Member States belong), delays are longer, usually ranging from 1 to 3 weeks, again due to internal validation processes.

In addition, the Commission publishes lists of all adopted restrictions, inclusions in the authorisation list and adopted authorisation decisions, with hyperlinks to the full texts, on its website[42]. Moreover, the Commission prepares, for each CARACAL meeting[43], a rolling work plan of the REACH Committee with tentative dates for submission of draft restrictions, inclusions in the authorisation list and authorisation decisions. This work plan is made publicly available on CircaBC, without need for registration or log-in[44]. Draft restrictions and inclusions in the authorisation list can also be consulted on the Commission website dedicated to the TBT database[45], where all drafts notified under the terms of the TBT are publicly available.

The Comitology Register allows the public to see for each draft measure when it was put on the REACH Committee agenda for the first time as well as all subsequent times, whether the measure was put up for discussion only or for discussion and (possible) vote, whether the discussion at any of those meetings was conclusive or not, when the draft measure was tabled for another discussion and (possible) vote, and when it was voted, passed on to the European Parliament and the Council for scrutiny, and adopted. The Comitology Register also enables the public to see and, if they so wish, compare different versions of each draft measure on which the REACH Committee is asked to give an opinion in successive REACH Committee meetings and/or written vote[46]. Hence the Commission trusts that the public is fully able to trace the progress of discussions, bearing in mind that the REACH Committee's discussions, like all comitology discussions, are confidential[47].

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[42] https://single-market-economy.ec.europa.eu/sectors/chemicals/reach_en. Direct links for the list of restrictions: https://ec.europa.eu/docsroom/documents/54798, for the list of additions to the authorisation list: https://ec.europa.eu/docsroom/documents/49975, for the list of authorisation decisions: https://ec.europa.eu/docsroom/documents/54725.

[43] Meeting of the Competent Authorities for REACH and CLP.

[44] https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/84998de9-01ff-4434-b566-85367d2fae5b

[45] http://ec.europa.eu/growth/tools-databases/tbt/en/search/

[46] The Annex provides, by way of example, the three different versions published in the Comitology Register of the latest restriction adopted by the Commission (on formaldehyde and formaldehyde releasers). The version with reference D084710/01 was published ahead of the REACH Committee meeting of October 2022; the version with reference D084710/02 was published ahead of the REACH Committee meeting of December 2022; the version with reference D084710/03 was published at the launch of the written REACH Committee vote in January 2023.

[47] Article 13(2) of the Rules of Procedure of the REACH Committee, in line with Article 13(2) of the Standard Rules of Procedure for Committees (OJ C206, 12.7.2011, p.11).

As suggested by the Ombudsman's question, the Commission has examined requests for access to documents received in the last three and a half years in order to ascertain whether they suggest a need to make available additional documents and information during 'comitology procedures'.

Since 1 January 2020, the Commission has received 29 requests for access to documents relating to procedures covered by the Ombudsman's first question, as follows:

- 24 requests asked for access to the final adopted text of authorisation decisions. 23 of them were answered by referring the requester to the abovementioned list of authorisation decisions available at the Commission's website; one request asked for a non-existent language version.

- Two requests asked for access to the final text of inclusions in the authorisation list and were answered by referring the requester to the publication in the Official Journal.

- One request asked for access to the detailed outcome of the vote on a particular restriction, specifying how the individual Member States and their representatives voted.

- Finally, two requests asked for access to the correspondence with a particular Member State on the same particular restriction.

Accordingly, the content of requests for public access to documents received by the Commission since 1 January 2020 concerning the procedures covered by the Ombudsman's first question does not suggest a need to make available additional documents and information during comitology procedures.

IV. CONCLUSIONS

The Commission fully understands that the time it needs to actually process draft restrictions, inclusions in the authorisation list and authorisation decisions from receipt of the file from ECHA may appear slow. However, a close analysis of the procedures which the Commission is bound to comply with, as well as the practical constraints under which these procedures take place, shows that large parts of the timelines are not within the control of the Commission, while other parts are inextricably linked to the Commission's commitment to Better Regulation and to the Commission's responsibilities in laying down measures, clarified in particular in the restrictions area by the General Court and in the area of authorisation decisions by the Court of Justice, and considered also in the area of inclusions in the authorisation list. The complexity of recent files, especially due to the tendency towards wide-scope restrictions as well as the number of authorisation decisions, is also becoming an increasingly significant factor affecting timelines. In any event, the Commission is willing to examine how standard internal procedures could be applied in a more efficient manner, while still safeguarding the principles of collegiality and shared responsibility for the coherence and quality of the Commission proposals.

The Commission attaches great value to transparency and publishes information on REACH 'comitology procedures' well beyond what the Comitology Regulation obliges it to make public. Access to documents requests received do not suggest a public need for such detailed information.

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION

Annex:

Three different versions of the draft restriction on formaldehyde and formaldehyde releasers published in the Comitology Register.

ANNEX

EUROPEAN
COMMISSION

Brussels, XXX
D084710/01
[…](2022) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 68(1) thereof,

Whereas:

(1) Formaldehyde is a highly reactive gas at ambient temperature and atmospheric pressure conditions. It is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2] as carcinogen category 1B, mutagen category 2, acute toxicant category 3, skin corrosive category 1B and skin sensitiser category 1.

(2) Formaldehyde is a high production volume chemical with a wide array of uses. It is also produced endogenously in humans and animals, and it is an essential metabolic intermediate in all cells. 98 % of the formaldehyde manufactured or imported in the Union is used as a chemical intermediate in the production of formaldehyde-based resins, thermoplastics and other chemicals, which are further used in a broad range of applications. Formaldehyde-based resins are used in the production of a wide variety of articles, which, as a result, may release formaldehyde. 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 like furniture and flooring, and for wallpapers, foams, parts for vehicles and aeroplanes, textile and leather products.

(3) On 20 December 2017[3], pursuant to Article 69(1) of Regulation (EC) No 1907/2006 the Commission asked the European Chemicals Agency ('the Agency') to prepare a dossier which conforms to the requirements of Annex XV to that Regulation

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1 OJ L 396, 30.12.2006, p. 1.

2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

3 https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e

(hereinafter 'the Annex XV dossier'), in order to assess the risk to human health from formaldehyde and formaldehyde releasing substances in mixtures and articles for consumer uses.

(4) On 11 March 2019, the Agency (to be known as 'the Dossier Submitter' in the context of submission of a dossier) submitted the Annex XV dossier[4], which demonstrated that the risk to human health from formaldehyde released from consumer articles in indoor environments is not adequately controlled under all scenarios, and that action on a Union-wide basis is necessary to address that risk.

(5) The Dossier Submitter assessed the hazard of formaldehyde by considering the effects of the substance on several endpoints, concluding that the risk from inhalation leading to sensory irritation is the most sensitive effect in humans. The Annex XV dossier assessed the risks from inhalation of formaldehyde associated to consumer exposure against the World Health Organization (WHO) Guideline for Indoor Air Quality for formaldehyde (30-minute average concentration based on sensory irritation in humans)[5]. The Guideline provides for a short-term value (0,1 mg/m^3) with a view to preventing detrimental effects on lung function, as well as long-term health effects, including nasopharyngeal cancer. The Dossier Submitter used that value as the level above which humans should not be exposed (derived no-effect level ('DNEL') and to calculate the proposed emission limit of 0,124 mg/m^3.

(6) Based on available literature and the outcome of the exposure estimation, the Dossier Submitter concluded that human health risks from formaldehyde release from mixtures for consumer use are adequately controlled.

(7) The Dossier Submitter therefore proposed to prohibit the placing on the market of formaldehyde and formaldehyde releasing substances in articles generating consumer exposure where the formaldehyde releases lead to concentrations exceeding 0,124 mg/m^3 in the air of a test chamber. Moreover, the Dossier Submitter specified that formaldehyde in road vehicles and aircraft, where formaldehyde or formaldehyde releasing substances were intentionally added during their production to confer a sought-after function, should not be placed on the market if the formaldehyde measured in their interior exceeds a concentration of 0,1 mg/m^3 and where exposure of formaldehyde to consumers can occur there[6].

(8) The Dossier Submitter's original proposal established EN 717-1 as the standard method to measure in a test chamber the emissions for formaldehyde released from wood-based panels. To clarify that other suitable test methods can also be used and to cover articles other than wood-based panels, the Dossier Submitter replaced the reference to standard EN 717-1 in its proposal by a wider description of conditions and methods. Ambient conditions may have an influence on formaldehyde emissions from articles and therefore relevant testing parameters were also listed in the Annex XV dossier.

(9) On 13 March 2020, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion. In its opinion, RAC considered the WHO guideline value not sufficiently protective for the general population and concluded in particular that short-term sensory irritation effects in humans cannot be used to predict long-term effects such as

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4 https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182439477

5 WHO 2010-WHO Guidelines for Indoor Air quality: Selected Pollutants. Geneva. World Health Organization, p. 103.

6 ECHA (2020). Background Document to the Opinion on the Annex XV report proposing restrictions on formaldehyde and formaldehyde releasers

cancer. RAC instead set a DNEL of 0,05 mg/m^3 derived from data on chronic effects in animals for the inhalation route and concluded that a limit value of 0,05 mg/m^3 for formaldehyde released from articles and for formaldehyde in the interior of road vehicles was needed to control the risk.

(10) RAC concluded that the risk to passengers from formaldehyde in aircraft is adequately controlled.

(11) RAC recommended a transitional period of 24 months from the entry into force until the application of the proposed restriction, compared to the 12 months suggested by the Dossier Submitter, as a longer time was considered necessary to allow for the development of standard analytical methods in all sectors affected. RAC concluded that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks to human health arising from consumer exposure to formaldehyde, in terms of its effectiveness in reducing the risk, its practicality and the manner in which it can be monitored.

(12) On 17 September 2020, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion, concluding on the Dossier Submitter's proposed restriction and the modifications proposed by RAC.

(13) In its opinion, SEAC acknowledged that the Dossier Submitter's proposal entails costs in terms of production, sampling, testing and enforcement in the order of tens of millions of euros. However, SEAC concluded that those costs are expected to be limited for the concerned sectors, as most of the articles, including road vehicles, placed on the market in the Union today are already compliant with the proposed limit value. SEAC also concluded that benefits from the Dossier Submitter's proposed restriction would result from restricting the placing on the market of articles emitting high concentrations of formaldehyde, including imports. The restriction would result in reduced adverse health effects related to irritation of the eyes, upper airways and nasopharyngeal cancer, mainly for individuals living in new dwellings.

(14) SEAC considered that the benefits deriving from limiting formaldehyde emission from consumer articles indoors and in the interior of vehicles, as proposed, could be achieved at limited costs for society. Therefore, SEAC concluded that the Dossier Submitter's proposal is the most appropriate Union-wide measure to address the identified risk to human health, in terms of its socio-economic benefits and its socio-economic costs, if certain derogations are included and proposed testing conditions accepted.

(15) To provide sufficient time for stakeholders to implement the restriction, SEAC recommended a deferral of 24 months for all sectors as regards the application of the restriction. For trucks and buses, however, SEAC recommended 36 months due to the need to develop standard analytical methods for measuring formaldehyde concentrations in the interior of these vehicles.

(16) SEAC concluded further that the proposed restriction, as modified by RAC, entails major socio-economic costs, in the order of tens of billions of euros, in terms of investment in research and development, new technologies, higher production costs, sampling and testing costs, as well as job losses. Furthermore, it potentially has negative effects on recycling sectors and the circular economy. SEAC recognised that to achieve the limit proposed by RAC, technically feasible alternatives exist for certain applications; however, they require far-reaching technological changes and, in specific cases, the use of less sustainable alternatives.

(17) SEAC acknowledged that RAC's proposal has potential additional benefits in terms of reduced exposure that may lead to a greater reduction in eye and upper airway irritation and nasopharyngeal cancers compared to the Dossier Submitter's proposal. However, RAC did not quantify the risk reduction associated with lowering the limit value; hence, the magnitude of the additional health benefits remains unknown. Furthermore, as part of its assessment, SEAC carried out an analysis by which it calculated that, given the high socio-economic costs, the incidence of nasopharyngeal cancer among the population in the Union living in new dwellings would have to be 200 times higher than the actual observed incidence, for the RAC proposal to break even. Taking into account this break-even analysis, the information received from industry during the consultations, and the absence of data or information that would allow the quantification of additional health benefits, SEAC concluded that the restriction based on the limit value proposed by RAC does not appear to be an appropriate measure to address the identified risk in terms of socio-economic benefits and socio-economic costs.

(18) The Forum for Exchange of Information on Enforcement was consulted on the Dossier Submitter's proposal and its recommendations on its implementability and enforceability have been taken into account; the Forum did not consider the modifications recommended by RAC, as they were presented after the consultation of the Forum.

(19) On 23 February 2021, the Agency submitted the opinions of RAC and SEAC to the Commission[7]. The opinions of RAC and SEAC concluded that there is a risk to the health of consumers that is not adequately controlled and needs to be addressed on a Union-wide basis due to the emissions of formaldehyde from articles into indoor air and from road vehicles into their interior.

(20) The Commission notes that, while the proposed restriction by the Dossier Submitter as well as the opinions by RAC and SEAC refer to consumers, the assessment underpinning the proposal addresses the risk to the population that could be exposed to formaldehyde in indoor air other than workers, including persons that are not direct consumers. For the sake of legal clarity, it is therefore appropriate to refer to the general public as the population targeted by the restriction.

(21) The Commission, taking into account the Annex XV dossier as well as the RAC and SEAC opinions, considers that there is an unacceptable risk to human health arising from formaldehyde released from articles, and that a restriction establishing an emission limit for articles emitting formaldehyde to decrease exposure of the general public to formaldehyde via inhalation is the most appropriate Union-wide measure to address the risk.

(22) The Commission agrees with the Dossier Submitter that the proposed limit value of 0,124 mg/m^3 prevents articles that emit high amounts of formaldehyde from being placed on the market in the Union and that it is appropriate to limit exposure to formaldehyde in indoor environments. However, the Commission considers that the risk reduction realised by achieving the WHO Guideline value is modest because of existing voluntary and national emission limits and the fact that the majority of articles placed on the market today are already expected to be compliant with the limit value

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[7] Compiled version prepared by the ECHA secretariat of RAC's opinion (adopted 12 March 2020) and SEAC opinion (adopted 17 September 2020)
https://echa.europa.eu/documents/10162/f10b57af-6075-bb34-2b30-4e0651d0b52f

of 0,124 mg/m^3. Achieving the WHO guideline value would also be insufficient to address the risk identified, taking into account RAC's opinion. Likewise, current interior concentrations in road vehicles mostly comply with the proposed limit value of 0,1 mg/m^3.

(23) The Commission also acknowledges, based on SEAC's conclusions on the socio-economic assessment, that the limit value of 0,05 mg/m^3 , as proposed by RAC, would entail major socio-economic impacts for the Union; and that such a limit value requires, in specific cases, shifting to less sustainable alternatives with negative effects on the circular economy and recycling, in particular in view of the absence of an assessment of the additional health benefits of such a limit compared to the limit proposed by the Dossier Submitter.

(24) The Commission therefore examined the appropriateness of the intermediate limit values of 0,080 mg/m^3 and 0,062 mg/m^3 that had been partly assessed by SEAC based on input received from stakeholders in the consultations. The Commission concluded that the adoption of such intermediate values would entail a higher protection of human health, in particular that of vulnerable populations, compared to the limit proposed by the Dossier Submitter, while entailing a lower socio-economic burden and fewer technological challenges than the limit proposed by RAC, particularly if taken in combination with adequate transitional periods and specific derogations.

(25) The Commission recognises the exponential increase in costs when lowering the limit value, and that the estimated combined costs for industry would be at minimum in the range of hundreds of millions of euros for the limit value of 0,080 mg/m^3, compared with billions of euros for the limit value of 0,062 mg/m^3. The Commission has further analysed the break-even analysis by SEAC, which calculates that, for the limit value of 0,062 mg/m^3 to break even, the incidence of nasopharyngeal cancer among the population in the Union living in new dwellings would have to be 70 times higher than the actual observed incidence, and 30 times higher for the limit value of 0,080 mg/m^3. However, the Commission also considers that formaldehyde is a carcinogenic substance, for which the limit value of 0,062 mg/m^3 would provide higher health benefits to the population in the Union. The Commission, although recognising that the differences in costs between the two values are significant, considers, in view of the potential additional health benefits, in particular to vulnerable groups such as children, that the higher costs for the lower limit value are justified for articles contributing the most to indoor air quality.

(26) In its consideration, the Commission takes into account that wood-based panels and articles made of wood-based panels or other wood-based articles, as well as furniture that contains wood or other materials, in which formaldehyde is used during their production to confer a sought-after function, are the main emission sources of formaldehyde in indoor air, in particular in newly built homes. Therefore, the Commission considers that a lower emission limit for such articles and such products composed of more than one article ('complex products') that are the biggest sources of formaldehyde in indoor air is appropriate and provides for increased protection of the general public, while limiting the socio-economic costs for those sectors that do not contribute to the same extent to the emissions.

(27) Likewise, it is appropriate to establish a lower limit for the presence of formaldehyde in the interior of road vehicles where the general public is present to ensure adequate protection in particular of vulnerable populations also in the worst-case scenarios.

(28) The Commission therefore concludes that the most appropriate Union-wide measure to address the risk of formaldehyde in indoor air and in the interior of road vehicles is a restriction setting the limit value of 0,062 mg/m^3 for wood-based articles and furniture, applied to the whole complex product, as well as in the interior of road vehicles; and of the limit value of 0,080 mg/m^3 for all other articles. The concentration of formaldehyde emitted from articles into indoor air is to be measured under specific reference conditions. Other test conditions can also be used provided that a scientifically valid correlation of test results is applied. The Agency should support the implementation of this restriction by developing specific guidance.

(29) In order to mitigate the negative impacts and to lower the costs for the affected sectors, as well as to provide sufficient time for stakeholders to implement the restriction, the Commission considers appropriate a deferral of 36 months for all sectors as regards the application of the restriction. For road vehicles, however, a deferral of 48 months is deemed appropriate due to the long development and marketing time for vehicles, the high material requirements in the automotive industry, the complex supply chains including original equipment manufacturers, as well as the time needed to implement the standard analytical method for measuring emissions for trucks and buses[8].

(30) Articles that are exclusively used in outdoor environments under foreseeable conditions for which it could be expected that consumer exposure takes place outside the exterior wall of buildings and articles in constructions, that are exclusively used outside the building shell and the vapour barrier and that do not emit formaldehyde into indoor air, should not be included in the scope of the restriction, as they do not contribute to exposure to formaldehyde in indoor air.

(31) Articles that are exclusively for industrial or professional use should not be included in the scope of the restriction, as long as these uses do not lead to exposure of the general public. Furthermore, exposure of industrial and professional workers to formaldehyde is already regulated by Council Directive 98/24/EC[9], and Directive 2004/37/EC of the European Parliament and of the Council[10].

(32) Formaldehyde emissions from articles are expected to decrease over time due to 'off-gassing' of residual formaldehyde. Therefore, second-hand articles should not be included in the scope of the restriction. Moreover, the Forum for Exchange of Information on Enforcement also recommended a derogation for second-hand articles, as enforcing the restriction with regard to second-hand articles may be difficult.

(33) The following products are already subject to Union rules on limit values to formaldehyde and should therefore not be included in the scope of the restriction: articles within the scope of entry 72 of Annex XVII to Regulation (EC) No 1907/2006, articles that are biocidal products within the scope of Regulation (EU) 528/2012 of the European Parliament and of the Council[11], devices within the scope of Regulation

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[8] 12219-10: Interior air of road vehicles — Part 10: Whole vehicle test chamber — Specification and methods for the determination of volatile organic compounds in cabin interiors — Trucks and buses.

[9] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

[10] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

[11] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

(EU) 2017/745 of the European Parliament and of the Council[12], and personal protective equipment within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council[13].

(34) Commission Regulation (EU) No 10/2011[14] establishes a limit value for formaldehyde for plastic materials and articles intended to come into contact with food. Although Union law does not set a specific formaldehyde limit for other materials and articles in contact with food, producers must be able to demonstrate their safety to the competent authorities. The requirements of food contact materials aim to protect human health by addressing the potential migration of substances into food. As due to those requirements significant release of formaldehyde from articles intended to come into contact with food, within the meaning of Regulation (EU) 1935/2004 of the European Parliament and the Council[15], into the surrounding atmosphere is highly unlikely, the Commission considers that those articles should not be included in the scope of the restriction.

(35) The Dossier Submitter, RAC and SEAC proposed a derogation for toys covered by Directive 2009/48/EC of the European Parliament and of the Council[16] which sets a limit of 0,1 mg/m^3 for formaldehyde emissions in resin-bonded wooden toys for children younger than 3 years. However, the Commission considers such a derogation not appropriate because children should not be protected less strictly than any other part of the population. The limit value for formaldehyde emissions into indoor air should therefore apply to toys for children of all ages.

(36) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(37) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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12 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

13 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

14 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

15 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

16 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

Done at Brussels,

For the Commission
The President
Ursula von der Leyen

EUROPEAN
COMMISSION

Brussels, XXX
D084710/01
[...](2022) XXX draft

ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) .../... of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

(1) the following entry is added:

'xx. Formaldehyde CAS No 50-00-0 EC No 200-001-8 and formaldehyde releasing substances	1. Shall not be placed on the market in articles, after [*OP, please insert the date: 36 months after the date of entry into force of this amending Regulation*] where formaldehyde or formaldehyde releasing substances are used during their production to confer a sought-after function, if, under the test conditions specified in Appendix [X], the concentration of formaldehyde released from those articles exceeds: (a) 0,062 mg/m^3 for wood-based articles and furniture; (b) 0,080 mg/m^3 for articles other than wood-based articles and furniture. The first subparagraph shall not apply to: (a) articles that are exclusively for outdoor use under foreseeable conditions; (b) articles in constructions, that are exclusively used outside the building shell and vapour barrier and that do not emit formaldehyde into indoor air; (c) articles exclusively for industrial or professional use unless formaldehyde released from them leads to exposure of the general public under foreseeable conditions of use; (d) articles within the scope of entry 72 of this Annex; (e) articles that are biocidal products within the scope of Regulation (EU) 528/2012 of the European Parliament and of the Council*; (f) devices within the scope of Regulation (EU) 2017/745; (g) personal protective equipment within the scope of Regulation (EU) 2016/425; (h) articles intended to come into contact directly or indirectly with food within the scope of Regulation (EC) No 1935/2004;

	(i) second-hand articles. 2. Shall not be placed on the market in road vehicles after [*OP, please insert the date: 48 months after the date of entry into force of this amending Regulation*] where formaldehyde or formaldehyde releasing substances are used during their production to confer a sought-after function, if, under the test conditions specified in Appendix [X], the concentration of formaldehyde in the interior of those vehicles exceeds 0,062 mg/m^3. The first subparagraph shall not apply to: (a) road vehicles exclusively for industrial or professional use unless the concentration of formaldehyde in the interior of those vehicles leads to exposure of the general public under foreseeable conditions of use; (b) second-hand vehicles.'

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* Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).';

(2) the following Appendix [X] is added:

'Appendix [X]

1. Measurement of formaldehyde released to indoor air from articles referred to in paragraph 1, first subparagraph, of entry [xx]

The formaldehyde released from articles referred to in paragraph 1, first subparagraph of entry [xx] shall be measured in the air of a test chamber under the following reference conditions:

(a) the temperature in the test chamber shall be (23 ± 0,5) °C;

(b) the relative humidity in the test chamber shall be (45 ± 3) %;

(c) 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; this loading factor corresponds to the testing of wood-based panels; for other material or products, if such a loading factor is clearly not realistic under foreseeable conditions of use, loading factors in accordance with Section 4.2.2 of EN 16516[1] may be used;

(d) the air exchange rate in the test chamber shall be (1 ± 0,05) h^{-1};

(e) an appropriate analytical procedure for measuring the formaldehyde concentration in the test chamber shall be used;

(f) an appropriate method for sampling of the test pieces shall be used;

(g) the formaldehyde concentration in the air of the test chamber shall be measured at least twice per day throughout the test with a time interval between two consecutive samplings of 3 hours at a minimum; the measurement shall be repeated until sufficient data are available to determine the steady state concentration;

(h) the duration of the test shall be sufficiently long to allow the determination of the steady state concentration and shall not exceed 28 days;

(i) the steady state concentration of formaldehyde measured in the test chamber shall be used to verify the compliance with the limit value of formaldehyde released from articles referred to in paragraph 1, first subparagraph, of entry [xx].

If data from a test method using the reference conditions are not available or suitable for the measurement of the formaldehyde released from a specific article, data obtained from a test method using non-reference conditions may be used, where there is a scientifically valid correlation between the results of the test method used and the reference conditions.

2. Measurement of formaldehyde concentration in the interior of vehicles referred to in paragraph 2, first subparagraph, of entry [xx]

For road vehicles, including trucks and buses, the formaldehyde concentration shall be measured in ambient mode in accordance with the conditions specified in ISO 12219-1[2] or, ISO 12219-10[3] , and the concentration measured shall be used to verify the compliance with the limit value referred to in paragraph 2, first subparagraph, of entry [xx].'.

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[1] EN 16516: Construction products – Assessment of release of dangerous substances – Determination of emissions into indoor air.

[2] ISO 12219-1: Interior air of road vehicles – Part 1: Whole vehicle test chamber – Specification and method for the determination of volatile organic compounds in cabin interiors.

[3] ISO 12219-10: Interior air of road vehicles — Part 10: Whole vehicle test chamber — Specification and methods for the determination of volatile organic compounds in cabin interiors — Trucks and buses.

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COMMISSION

Brussels, XXX
D084710/02
[...](2022) XXX draft

COMMISSION REGULATION (EU) .../...

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 68(1) thereof,

Whereas:

(1) Formaldehyde is a highly reactive gas at ambient temperature and atmospheric pressure conditions. It is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2] as carcinogen category 1B, mutagen category 2, acute toxicant category 3, skin corrosive category 1B and skin sensitiser category 1.

(2) Formaldehyde is a high-production volume chemical with a wide array of uses. It is also produced endogenously in humans and animals, and it is an essential metabolic intermediate in all cells. Furthermore, 98 % of the formaldehyde manufactured or imported in the Union is used as a chemical intermediate in the production of formaldehyde-based resins, thermoplastics and other chemicals, which are further used in a broad range of applications. Formaldehyde-based resins are used in the production of a wide variety of articles, which, as a result, may release formaldehyde. 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 like furniture and flooring, and for wallpapers, foams, parts for road vehicles and aircraft, textile and leather products.

(3) On 20 December 2017[3], pursuant to Article 69(1) of Regulation (EC) No 1907/2006, the Commission asked the European Chemicals Agency ('the Agency') to prepare a dossier which conforms to the requirements of Annex XV to that Regulation

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1 OJ L 396, 30.12.2006, p. 1.

2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

3 https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e

(hereinafter 'the Annex XV dossier'), in order to assess the risk to human health from formaldehyde and formaldehyde-releasing substances in mixtures and articles for consumer uses.

(4) On 11 March 2019, the Agency (to be known as 'the Dossier Submitter' in the context of submission of a dossier) submitted the Annex XV dossier[4], which demonstrated that the risk to human health from formaldehyde released from consumer articles in indoor environments is not adequately controlled under all scenarios, and that action on a Union-wide basis is necessary to address that risk.

(5) The Dossier Submitter assessed the hazard of formaldehyde by considering the effects of the substance on several endpoints, concluding that the risk from inhalation leading to sensory irritation is the most sensitive effect in humans. The Annex XV dossier assessed the risks from inhalation of formaldehyde associated with consumer exposure against the World Health Organization (WHO) Guideline for Indoor Air Quality for formaldehyde (30-minute average concentration based on sensory irritation in humans)[5]. The Guideline provides for a short-term value (0,1 mg/m^3) with a view to preventing detrimental effects on lung function, as well as long-term health effects, including nasopharyngeal cancer. The Dossier Submitter used that value as the level above which humans should not be exposed (derived no-effect level ('DNEL')) and to calculate the proposed emission limit of 0,124 mg/m^3.

(6) Based on available literature and the outcome of the exposure estimation, the Dossier Submitter concluded that human health risks from formaldehyde release from mixtures for consumer use are adequately controlled.

(7) The Dossier Submitter, therefore, proposed to prohibit the placing on the market of formaldehyde and formaldehyde-releasing substances in articles generating consumer exposure where the formaldehyde releases lead to concentrations exceeding 0,124 mg/m^3 in the air of a test chamber. Moreover, the Dossier Submitter specified that, where formaldehyde or formaldehyde-releasing substances were intentionally added during their production, road vehicles and aircraft should not be placed on the market if the formaldehyde measured in their interior exceeds a concentration of 0,1 mg/m^3 and if exposure of formaldehyde to consumers can occur in such vehicles and aircraft[6].

(8) The Dossier Submitter's original proposal established EN 717-1 as the standard method to measure in a test chamber the emissions for formaldehyde released from wood-based panels. To clarify that other suitable test methods can also be used and to cover articles other than wood-based panels, the Dossier Submitter replaced the reference to standard EN 717-1 in its proposal by a wider description of conditions and methods. Ambient conditions may have an influence on formaldehyde emissions from articles and, therefore, relevant testing parameters were also listed in the Annex XV dossier.

(9) On 13 March 2020, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion. In its opinion, RAC considered that the WHO guideline value was not sufficiently protective for the general population and concluded in particular that short-term sensory irritation effects in humans cannot be used to predict long-term

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4 https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182439477

5 WHO 2010-WHO Guidelines for Indoor Air quality: Selected Pollutants. Geneva. World Health Organization, p. 103.

6 ECHA (2020). Background Document to the Opinion on the Annex XV report proposing restrictions on formaldehyde and formaldehyde releasers

effects such as cancer. RAC instead set a DNEL of 0,05 mg/m^3 derived from data on chronic effects in animals for the inhalation route and concluded that a limit value of 0,05 mg/m^3 for formaldehyde released from articles and for formaldehyde in the interior of road vehicles was needed to control the risk.

(10) RAC concluded that the risk to passengers from formaldehyde in aircraft is adequately controlled.

(11) RAC recommended a transitional period of 24 months from the entry into force until the application of the proposed restriction, compared to the 12-month period suggested by the Dossier Submitter, as a longer time was considered necessary to allow for the development of standard analytical methods in all affected sectors. RAC concluded that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks to human health arising from consumer exposure to formaldehyde, in terms of its effectiveness in reducing the risk, its practicality, and the manner in which it can be monitored.

(12) On 17 September 2020, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion, concluding on the Dossier Submitter's proposed restriction and the modifications proposed by RAC.

(13) In its opinion, SEAC acknowledged that the Dossier Submitter's proposal entails costs in terms of production, sampling, testing and enforcement in the order of tens of millions of euros. However, SEAC concluded that those costs are expected to be limited for the concerned sectors, as most of the articles, including road vehicles, placed on the market in the Union today are already compliant with the proposed limit value. SEAC also concluded that benefits from the Dossier Submitter's proposed restriction would result from restricting the placing on the market of articles emitting high concentrations of formaldehyde, including imports. The restriction would result in reduced adverse health effects related to the irritation of the eyes, upper airways and nasopharyngeal cancer, mainly for individuals living in new dwellings.

(14) SEAC considered that the benefits deriving from limiting formaldehyde emission from consumer articles indoors and in the interior of road vehicles, as proposed, could be achieved at limited costs for society. Therefore, SEAC concluded that the Dossier Submitter's proposal is the most appropriate Union-wide measure to address the identified risk to human health, in terms of its socio-economic benefits and its socio-economic costs, if certain derogations are included and if proposed testing conditions are accepted.

(15) To provide sufficient time for stakeholders to implement the restriction, SEAC recommended a deferral of 24 months for all sectors as regards the application of the restriction. For trucks and buses, however, SEAC recommended 36 months due to the need to develop standard analytical methods for measuring formaldehyde concentrations in the interior of such vehicles.

(16) SEAC concluded further that the proposed restriction, as modified by RAC, entails major socio-economic costs, in the order of tens of billions of euros, in terms of investment in research and development, new technologies, higher production costs, sampling and testing costs, as well as job losses. Furthermore, it potentially has negative effects on recycling sectors and the circular economy. SEAC recognised that, to achieve the limit proposed by RAC, technically feasible alternatives exist for certain applications; however, they require far-reaching technological changes and, in specific cases, the use of less sustainable alternatives.

(17) SEAC acknowledged that RAC's proposal has potential additional benefits in terms of reduced exposure that may lead to a greater reduction in eye and upper airway irritation and nasopharyngeal cancers compared to the Dossier Submitter's proposal. However, RAC did not quantify the risk reduction associated with lowering the limit value; hence, the magnitude of the additional health benefits remains unknown. Furthermore, as part of its assessment, SEAC carried out an analysis by which it calculated that, given the high socio-economic costs, the incidence of nasopharyngeal cancer among the population in the Union living in new dwellings would have to be 200 times higher than the actual observed incidence, for the RAC proposal to break even. Taking into account this break-even analysis, the information received from industry during the consultations, and the absence of data or information that would allow the quantification of additional health benefits, SEAC concluded that the restriction based on the limit value proposed by RAC does not appear to be an appropriate measure to address the identified risk in terms of socio-economic benefits and socio-economic costs.

(18) The Forum for Exchange of Information on Enforcement was consulted on the Dossier Submitter's proposal and its recommendations on its implementability and enforceability have been taken into account; it is to be noted that the Forum did not consider the modifications recommended by RAC, as they were presented after the consultation of the Forum.

(19) On 23 February 2021, the Agency submitted the opinions of RAC and SEAC to the Commission[7]. The opinions of RAC and SEAC concluded that there is a risk to the health of consumers that is not adequately controlled and that needs to be addressed on a Union-wide basis due to the emissions of formaldehyde from articles into indoor air and from road vehicles into their interior.

(20) The Commission notes that, while the proposed restriction by the Dossier Submitter as well as the opinions by RAC and SEAC refer to consumers, the assessment underpinning the proposal addresses the risk to the population that could be exposed to formaldehyde in indoor air other than workers, and including persons that are not direct consumers. For the sake of legal clarity, it is, therefore, appropriate to refer to the general public as the population targeted by the restriction.

(21) The Commission, taking into account the Annex XV dossier as well as the RAC and SEAC opinions, considers that there is an unacceptable risk to human health arising from formaldehyde released from articles, and that a restriction establishing an emission limit for articles emitting formaldehyde to decrease exposure of the general public to formaldehyde via inhalation is the most appropriate Union-wide measure to address the risk.

(22) Formaldehyde is a substance naturally occurring in living organisms. Moreover, formaldehyde can be released by decomposition of substances naturally present in the materials used to produce an article such as from lignin degradation in solid wood. The Commission agrees with the Dossier Submitter that articles in which formaldehyde is exclusively emitted due to its natural occurrence, or due to the natural occurrence of formaldehyde-releasing substances, in the materials from which the articles are produced, should be exempted from the scope of this restriction.

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[7] Compiled version prepared by the ECHA secretariat of RAC's opinion (adopted 12 March 2020) and SEAC's opinion (adopted 17 September 2020) https://echa.europa.eu/documents/10162/f10b57af-6075-bb34-2b30-4e0651d0b52f

(23) The Commission agrees with the Dossier Submitter that the proposed limit value of 0,124 mg/m3 prevents articles that emit high amounts of formaldehyde from being placed on the market in the Union and that it is appropriate to limit exposure to formaldehyde in indoor environments. However, the Commission considers that the risk reduction realised by achieving the WHO Guideline value is modest because of existing voluntary and national emission limits and the fact that the majority of articles placed on the market today are already expected to be compliant with the limit value of 0,124 mg/m3. Furthermore, achieving the WHO guideline value would be insufficient to address the identified risk, taking into account RAC's opinion. Likewise, current interior concentrations in road vehicles mostly comply with the proposed limit value of 0,1 mg/m3.

(24) The Commission also acknowledges, based on SEAC's conclusions on the socio-economic assessment, that the limit value of 0,05 mg/m^3, as proposed by RAC, would entail major socio-economic impacts for the Union; and that such a limit value requires, in specific cases, shifting to less sustainable alternatives with negative effects on recycling sectors and the circular economy, in particular in view of the absence of an assessment of the additional health benefits of such a limit compared to the limit proposed by the Dossier Submitter.

(25) The Commission, therefore, examined the appropriateness of the intermediate limit values of 0,080 mg/m^3 and 0,062 mg/m^3 that had been partly assessed by SEAC based on input received from stakeholders in the consultations. The Commission concluded that the adoption of such intermediate values would entail a higher protection of human health, in particular that of vulnerable populations, compared to the limit proposed by the Dossier Submitter, while entailing a lower socio-economic burden and fewer technological challenges than the limit proposed by RAC, particularly if taken in combination with adequate transitional periods and specific derogations.

(26) The Commission recognises the exponential increase in costs when lowering the limit value, and that the estimated combined costs for industry would be at minimum in the range of hundreds of millions of euros for the limit value of 0,080 mg/m^3, compared with billions of euros for the limit value of 0,062 mg/m^3. The Commission has further analysed the break-even analysis by SEAC, which calculates that, for the limit value of 0,062 mg/m^3 to break even, the incidence of nasopharyngeal cancer among the population in the Union living in new dwellings would have to be 70 times higher than the actual observed incidence, and 30 times higher for the limit value of 0,080 mg/m^3. However, the Commission also considers that formaldehyde is a carcinogenic substance, for which the limit value of 0,062 mg/m^3 would provide higher health benefits to the population in the Union. The Commission, although recognising that the differences in costs between the two values are significant, considers, in view of the potential additional health benefits, in particular to vulnerable groups such as children, that the higher costs for the lower limit value are justified for articles contributing the most to indoor air quality.

(27) In its consideration, the Commission takes into account that wood-based panels and articles made of wood-based panels or other wood-based articles, as well as furniture that contains wood or other materials, in which formaldehyde other than naturally occurring formaldehyde is used during their production, are the main emission sources of formaldehyde in indoor air, in particular in newly built homes. Therefore, the Commission considers that a lower emission limit for such articles and such products composed of more than one article ('complex products') that are the largest sources of formaldehyde in indoor air is appropriate and provides for increased protection of the

general public, while limiting the socio-economic costs for those sectors that do not contribute to the same extent to the emissions.

(28) Likewise, it is appropriate to establish a lower limit for the presence of formaldehyde in the interior of road vehicles where the general public is present to ensure adequate protection in particular of vulnerable populations also in the worst-case scenarios.

(29) The Commission, therefore, concludes that the most appropriate Union-wide measure to address the risk of formaldehyde in indoor air, and in the interior of road vehicles, is a restriction setting the limit value of 0,062 mg/m^3 for wood-based articles and furniture, applied to the whole complex product, as well as in the interior of road vehicles; and of the limit value of 0,080 mg/m^3 for all other articles. Moreover, the Commission considers that the concentration of formaldehyde emitted from articles into indoor air should be measured under specific reference conditions to ensure harmonised implementation of this restriction. In certain cases it should also be possible to use other test conditions provided that a scientifically valid correlation of test results is applied.

(30) In order to mitigate the negative impacts and to lower the costs for the affected sectors, as well as to provide sufficient time for stakeholders to implement the restriction, the Commission considers appropriate a deferral of 36 months for all sectors as regards the application of the restriction. For road vehicles, however, a deferral of 48 months is deemed appropriate due to the long development and marketing time for such vehicles, the high material requirements in the automotive industry, the complex supply chains including original equipment manufacturers, as well as the time needed to implement the standard analytical method for measuring emissions for trucks and buses[8].

(31) As for articles that are exclusively for outdoor use under foreseeable conditions it is expected that consumer exposure takes place outside the exterior wall of buildings, such articles should be excluded from the scope of the restriction. Articles in constructions, that are exclusively used outside the building shell and the vapour barrier and that do not emit formaldehyde into indoor air, should also be excluded from the scope of the restriction, as they do not contribute to exposure to formaldehyde in indoor air.

(32) Articles that are exclusively for industrial or professional use should not be included in the scope of the restriction, as long as these uses do not lead to exposure of the general public. Furthermore, exposure of industrial and professional workers to formaldehyde is already regulated by Council Directive 98/24/EC[9], and Directive 2004/37/EC of the European Parliament and of the Council[10].

(33) Formaldehyde emissions from articles are expected to decrease over time due to 'off-gassing' of residual formaldehyde. Therefore, second-hand articles should not be included in the scope of the restriction. Moreover, the Forum for Exchange of

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8 12219-10: Interior air of road vehicles — Part 10: Whole vehicle test chamber — Specification and methods for the determination of volatile organic compounds in cabin interiors — Trucks and buses.

9 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

10 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004,p. 50).

Information on Enforcement also recommended a derogation for second-hand articles, as enforcing the restriction with regard to second-hand articles may be difficult.

(34) The following products are already subject to Union rules on limit values on formaldehyde and should, therefore, not be included in the scope of the restriction: articles within the scope of entry 72 of Annex XVII to Regulation (EC) No 1907/2006, articles that are biocidal products within the scope of Regulation (EU) 528/2012 of the European Parliament and of the Council[11], devices within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council[12], and personal protective equipment within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council[13].

(35) Commission Regulation (EU) No 10/2011[14] establishes a limit value for formaldehyde for plastic materials and articles intended to come into contact with food. Although Union law does not set a specific formaldehyde limit for other materials and articles in contact with food, producers must be able to demonstrate their safety to the competent authorities. The requirements of food contact materials aim to protect human health by addressing the potential migration of substances into food. As, due to those requirements, a significant release of formaldehyde from articles intended to come into contact with food, within the meaning of Regulation (EU) 1935/2004 of the European Parliament and the Council[15], into the surrounding atmosphere is highly unlikely, the Commission considers that those articles should not be included in the scope of the restriction.

(36) The Dossier Submitter, RAC and SEAC proposed a derogation for toys covered by Directive 2009/48/EC of the European Parliament and of the Council[16] which sets a limit of 0,1 mg/m^3 for formaldehyde emissions in resin-bonded wooden toys for children younger than 3 years. However, the Commission considers such a derogation not appropriate because children should not be protected less strictly than any other part of the population. The limit value for formaldehyde emissions into indoor air should therefore apply to toys for children of all ages.

(37) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(38) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

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11 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

12 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

13 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

14 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

15 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

16 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen

EUROPEAN
COMMISSION

Brussels, XXX
D084710/02
[…](2022) XXX draft

ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) .../...

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

(1) the following entry is added:

'xx. Formaldehyde CAS No 50-00-0 EC No 200-001-8 and formaldehyde-releasing substances	1. Shall not be placed on the market in articles, after [*OP, please insert the date: 36 months after the date of entry into force of this amending Regulation*], if, under the test conditions specified in Appendix [X], the concentration of formaldehyde released from those articles exceeds: (a) 0,062 mg/m^3 for wood-based articles and furniture; (b) 0,080 mg/m^3 for articles other than wood-based articles and furniture. The first subparagraph shall not apply to: (a) articles in which formaldehyde or formaldehyde releasing substances are exclusively naturally present in the materials from which the articles are produced; (b) articles that are exclusively for outdoor use under foreseeable conditions; (c) articles in constructions, that are exclusively used outside the building shell and vapour barrier and that do not emit formaldehyde into indoor air; (d) articles exclusively for industrial or professional use unless formaldehyde released from them leads to exposure of the general public under foreseeable conditions of use; (e) articles within the scope of entry 72 of this Annex; (f) articles that are biocidal products within the scope of Regulation (EU) 528/2012 of the European Parliament and of the Council*; (g) devices within the scope of Regulation (EU) 2017/745; (h) personal protective equipment within the scope of Regulation (EU) 2016/425;

	(i) articles intended to come into contact directly or indirectly with food within the scope of Regulation (EC) No 1935/2004; (j) second-hand articles. 2. Shall not be placed on the market in road vehicles after [*OP, please insert the date: 48 months after the date of entry into force of this amending Regulation*] if, under the test conditions specified in Appendix [X], the concentration of formaldehyde in the interior of those vehicles exceeds 0,062 mg/m^3. The first subparagraph shall not apply to: (a) road vehicles exclusively for industrial or professional use unless the concentration of formaldehyde in the interior of those vehicles leads to exposure of the general public under foreseeable conditions of use; (b) second-hand vehicles.

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* Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).';

(2) the following Appendix [X] is added:

'Appendix [X]

1. Measurement of formaldehyde released to indoor air from articles referred to in paragraph 1, first subparagraph, of entry [xx]

The formaldehyde released from articles referred to in paragraph 1, first subparagraph of entry [xx] shall be measured in the air of a test chamber under the following cumulative reference conditions:

(a) the temperature in the test chamber shall be (23 ± 0,5) °C;

(b) the relative humidity in the test chamber shall be (45 ± 3) %;

(c) 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. This loading factor corresponds to the testing of wood-based panels; for other material or products, if such a loading factor is clearly not realistic under foreseeable conditions of use, loading factors in accordance with Section 4.2.2 of EN 16516[1] may be used;

(d) the air exchange rate in the test chamber shall be (1 ± 0,05) h^{-1};

(e) an appropriate analytical procedure for measuring the formaldehyde concentration in the test chamber shall be used;

(f) an appropriate method for sampling of the test pieces shall be used;

(g) the formaldehyde concentration in the air of the test chamber shall be measured at least twice per day throughout the test with a time interval between two consecutive samplings of 3 hours at a minimum; the measurement shall be repeated until sufficient data are available to determine the steady state concentration;

(h) the duration of the test shall be sufficiently long to allow the determination of the steady state concentration and shall not exceed 28 days;

(i) the steady state concentration of formaldehyde measured in the test chamber shall be used to verify the compliance with the limit value of formaldehyde released from articles referred to in paragraph 1, first subparagraph, of entry [xx].

If data from a test method using the reference conditions specified above are not available or suitable for the measurement of the formaldehyde released from a specific article, data obtained from a test method using non-reference conditions may be used, where there is a scientifically valid correlation between the results of the test method used and the reference conditions.

2. Measurement of formaldehyde concentration in the interior of vehicles referred to in paragraph 2, first subparagraph, of entry [xx]

For road vehicles, including trucks and buses, the formaldehyde concentration shall be measured in ambient mode in accordance with the conditions specified in ISO 12219-1[2] or ISO 12219-10[3], and the concentration measured shall be used to verify the compliance with the limit value referred to in paragraph 2, first subparagraph, of entry [xx].'.

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[1] EN 16516: Construction products – Assessment of release of dangerous substances – Determination of emissions into indoor air.

[2] ISO 12219-1: Interior air of road vehicles – Part 1: Whole vehicle test chamber – Specification and method for the determination of volatile organic compounds in cabin interiors.

[3] ISO 12219-10: Interior air of road vehicles — Part 10: Whole vehicle test chamber — Specification and methods for the determination of volatile organic compounds in cabin interiors — Trucks and buses.

EUROPEAN
COMMISSION

Brussels, XXX
D084710/03
[…](2023) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 68(1) thereof,

Whereas:

(1) Formaldehyde is a highly reactive gas at ambient temperature and atmospheric pressure conditions. It is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2] as carcinogen category 1B, mutagen category 2, acute toxicant category 3, skin corrosive category 1B and skin sensitiser category 1.

(2) Formaldehyde is a high-production volume chemical with a wide array of uses. It is also produced endogenously in humans and animals, and it is an essential metabolic intermediate in all cells. Furthermore, 98 % of the formaldehyde manufactured or imported in the Union is used as a chemical intermediate in the production of formaldehyde-based resins, thermoplastics and other chemicals, which are further used in a broad range of applications. Formaldehyde-based resins are used in the production of a wide variety of articles, which, as a result, may release formaldehyde. 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 like furniture and flooring, and for wallpapers, foams, parts for road vehicles and aircraft, textile and leather products.

(3) On 20 December 2017[3], pursuant to Article 69(1) of Regulation (EC) No 1907/2006, the Commission asked the European Chemicals Agency ('the Agency') to prepare a dossier which conforms to the requirements of Annex XV to that Regulation

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1 OJ L 396, 30.12.2006, p. 1.

2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

3 https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e

(hereinafter 'the Annex XV dossier'), in order to assess the risk to human health from formaldehyde and formaldehyde-releasing substances in mixtures and articles for consumer uses.

(4) On 11 March 2019, the Agency (to be known as 'the Dossier Submitter' in the context of submission of a dossier) submitted the Annex XV dossier[4], which demonstrated that the risk to human health from formaldehyde released from consumer articles in indoor environments is not adequately controlled under all scenarios, and that action on a Union-wide basis is necessary to address that risk.

(5) The Dossier Submitter assessed the hazard of formaldehyde by considering the effects of the substance on several endpoints, concluding that the risk from inhalation leading to sensory irritation is the most sensitive effect in humans. The Annex XV dossier assessed the risks from inhalation of formaldehyde associated with consumer exposure against the World Health Organization (WHO) Guideline for Indoor Air Quality for formaldehyde (30-minute average concentration based on sensory irritation in humans)[5]. The Guideline provides for a short-term value (0,1 mg/m^3) with a view to preventing detrimental effects on lung function, as well as long-term health effects, including nasopharyngeal cancer. The Dossier Submitter used that value as the level above which humans should not be exposed (derived no-effect level ('DNEL')) and to calculate the proposed emission limit of 0,124 mg/m^3.

(6) Based on available literature and the outcome of the exposure estimation, the Dossier Submitter concluded that human health risks from formaldehyde release from mixtures for consumer use are adequately controlled.

(7) The Dossier Submitter, therefore, proposed to prohibit the placing on the market of formaldehyde and formaldehyde-releasing substances in articles generating consumer exposure where the formaldehyde releases lead to concentrations exceeding 0,124 mg/m^3 in the air of a test chamber. Moreover, the Dossier Submitter specified that, where formaldehyde or formaldehyde-releasing substances were intentionally added during their production, road vehicles and aircraft should not be placed on the market if the formaldehyde measured in their interior exceeds a concentration of 0,1 mg/m^3 and if exposure of formaldehyde to consumers can occur in such vehicles and aircraft[6].

(8) The Dossier Submitter's original proposal established EN 717-1 as the standard method to measure in a test chamber the emissions for formaldehyde released from wood-based panels. To clarify that other suitable test methods can also be used and to cover articles other than wood-based panels, the Dossier Submitter replaced the reference to standard EN 717-1 in its proposal by a wider description of conditions and methods. Ambient conditions may have an influence on formaldehyde emissions from articles and, therefore, relevant testing parameters were also listed in the Annex XV dossier.

(9) On 13 March 2020, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion. In its opinion, RAC considered that the WHO guideline value was not sufficiently protective for the general population and concluded in particular that short-term sensory irritation effects in humans cannot be used to predict long-term

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4 https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182439477

5 WHO 2010-WHO Guidelines for Indoor Air quality: Selected Pollutants. Geneva. World Health Organization, p. 103.

6 ECHA (2020). Background Document to the Opinion on the Annex XV report proposing restrictions on formaldehyde and formaldehyde releasers

effects such as cancer. RAC instead set a DNEL of 0,05 mg/m^3 derived from data on chronic effects in animals for the inhalation route and concluded that a limit value of 0,05 mg/m^3 for formaldehyde released from articles and for formaldehyde in the interior of road vehicles was needed to control the risk.

(10) RAC concluded that the risk to passengers from formaldehyde in aircraft is adequately controlled.

(11) RAC recommended a transitional period of 24 months from the entry into force until the application of the proposed restriction, compared to the 12-month period suggested by the Dossier Submitter, as a longer time was considered necessary to allow for the development of standard analytical methods in all affected sectors. RAC concluded that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks to human health arising from consumer exposure to formaldehyde, in terms of its effectiveness in reducing the risk, its practicality, and the manner in which it can be monitored.

(12) On 17 September 2020, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion, concluding on the Dossier Submitter's proposed restriction and the modifications proposed by RAC.

(13) In its opinion, SEAC acknowledged that the Dossier Submitter's proposal entails costs in terms of production, sampling, testing and enforcement in the order of tens of millions of euros. However, SEAC concluded that those costs are expected to be limited for the concerned sectors, as most of the articles, including road vehicles, placed on the market in the Union today are already compliant with the proposed limit value. SEAC also concluded that benefits from the Dossier Submitter's proposed restriction would result from restricting the placing on the market of articles emitting high concentrations of formaldehyde, including imports. The restriction would result in reduced adverse health effects related to the irritation of the eyes, upper airways and nasopharyngeal cancer, mainly for individuals living in new dwellings.

(14) SEAC considered that the benefits deriving from limiting formaldehyde emission from consumer articles indoors and in the interior of road vehicles, as proposed, could be achieved at limited costs for society. Therefore, SEAC concluded that the Dossier Submitter's proposal is the most appropriate Union-wide measure to address the identified risk to human health, in terms of its socio-economic benefits and its socio-economic costs, if certain derogations are included and if proposed testing conditions are accepted.

(15) To provide sufficient time for stakeholders to implement the restriction, SEAC recommended a deferral of 24 months for all sectors as regards the application of the restriction. For trucks and buses, however, SEAC recommended 36 months due to the need to develop standard analytical methods for measuring formaldehyde concentrations in the interior of such vehicles.

(16) SEAC concluded further that the proposed restriction, as modified by RAC, entails major socio-economic costs, in the order of tens of billions of euros, in terms of investment in research and development, new technologies, higher production costs, sampling and testing costs, as well as job losses. Furthermore, it potentially has negative effects on recycling sectors and the circular economy. SEAC recognised that, to achieve the limit proposed by RAC, technically feasible alternatives exist for certain applications; however, they require far-reaching technological changes and, in specific cases, the use of less sustainable alternatives.

(17) SEAC acknowledged that RAC's proposal has potential additional benefits in terms of reduced exposure that may lead to a greater reduction in eye and upper airway irritation and nasopharyngeal cancers compared to the Dossier Submitter's proposal. However, RAC did not quantify the risk reduction associated with lowering the limit value; hence, the magnitude of the additional health benefits remains unknown. Furthermore, as part of its assessment, SEAC carried out an analysis by which it calculated that, given the high socio-economic costs, the incidence of nasopharyngeal cancer among the population in the Union living in new dwellings would have to be 200 times higher than the actual observed incidence, for the RAC proposal to break even. Taking into account this break-even analysis, the information received from industry during the consultations, and the absence of data or information that would allow the quantification of additional health benefits, SEAC concluded that the restriction based on the limit value proposed by RAC does not appear to be an appropriate measure to address the identified risk in terms of socio-economic benefits and socio-economic costs.

(18) The Forum for Exchange of Information on Enforcement was consulted on the Dossier Submitter's proposal and its recommendations on its implementability and enforceability have been taken into account; it is to be noted that the Forum did not consider the modifications recommended by RAC, as they were presented after the consultation of the Forum.

(19) On 23 February 2021, the Agency submitted the opinions of RAC and SEAC to the Commission[7]. The opinions of RAC and SEAC concluded that there is a risk to the health of consumers that is not adequately controlled and that needs to be addressed on a Union-wide basis due to the emissions of formaldehyde from articles into indoor air and from road vehicles into their interior.

(20) The Commission notes that, while the proposed restriction by the Dossier Submitter as well as the opinions by RAC and SEAC refer to consumers, the assessment underpinning the proposal addresses the risk to the population that could be exposed to formaldehyde in indoor air other than workers, and including persons that are not direct consumers. For the sake of legal clarity, it is, therefore, appropriate to refer to the general public as the population targeted by the restriction.

(21) The Commission, taking into account the Annex XV dossier as well as the RAC and SEAC opinions, considers that there is an unacceptable risk to human health arising from formaldehyde released from articles, and that a restriction establishing an emission limit for articles emitting formaldehyde to decrease exposure of the general public to formaldehyde via inhalation is the most appropriate Union-wide measure to address the risk.

(22) Formaldehyde is a substance naturally occurring in living organisms. Moreover, formaldehyde can be released by decomposition of substances naturally present in the materials used to produce an article such as from lignin degradation in solid wood. The Commission agrees with the Dossier Submitter that articles in which formaldehyde is exclusively emitted due to its natural occurrence, or due to the natural occurrence of formaldehyde-releasing substances, in the materials from which the articles are produced, should be exempted from the scope of this restriction.

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7 Compiled version prepared by the ECHA secretariat of RAC's opinion (adopted 12 March 2020) and SEAC's opinion (adopted 17 September 2020)
https://echa.europa.eu/documents/10162/f10b57af-6075-bb34-2b30-4e0651d0b52f

(23) The Commission agrees with the Dossier Submitter that the proposed limit value of 0,124 mg/m3 prevents articles that emit high amounts of formaldehyde from being placed on the market in the Union and that it is appropriate to limit exposure to formaldehyde in indoor environments. However, the Commission considers that the risk reduction realised by achieving the WHO Guideline value is modest because of existing voluntary and national emission limits and the fact that the majority of articles placed on the market today are already expected to be compliant with the limit value of 0,124 mg/m3. Furthermore, achieving the WHO guideline value would be insufficient to address the identified risk, taking into account RAC's opinion. Likewise, current interior concentrations in road vehicles mostly comply with the proposed limit value of 0,1 mg/m3.

(24) The Commission also acknowledges, based on SEAC's conclusions on the socio-economic assessment, that the limit value of 0,05 mg/m^3, as proposed by RAC, would entail major socio-economic impacts for the Union; and that such a limit value requires, in specific cases, shifting to less sustainable alternatives with negative effects on recycling sectors and the circular economy, in particular in view of the absence of an assessment of the additional health benefits of such a limit compared to the limit proposed by the Dossier Submitter.

(25) The Commission, therefore, examined the appropriateness of the intermediate limit values of 0,080 mg/m^3 and 0,062 mg/m^3 that had been partly assessed by SEAC based on input received from stakeholders in the consultations. The Commission concluded that the adoption of such intermediate values would entail a higher protection of human health, in particular that of vulnerable populations, compared to the limit proposed by the Dossier Submitter, while entailing a lower socio-economic burden and fewer technological challenges than the limit proposed by RAC, particularly if taken in combination with adequate transitional periods and specific derogations.

(26) The Commission recognises the exponential increase in costs when lowering the limit value, and that the estimated combined costs for industry would be at minimum in the range of hundreds of millions of euros for the limit value of 0,080 mg/m^3, compared with billions of euros for the limit value of 0,062 mg/m^3. The Commission has further analysed the break-even analysis by SEAC, which calculates that, for the limit value of 0,062 mg/m^3 to break even, the incidence of nasopharyngeal cancer among the population in the Union living in new dwellings would have to be 70 times higher than the actual observed incidence, and 30 times higher for the limit value of 0,080 mg/m^3. However, the Commission also considers that formaldehyde is a carcinogenic substance, for which the limit value of 0,062 mg/m^3 would provide higher health benefits to the population in the Union. The Commission, although recognising that the differences in costs between the two values are significant, considers, in view of the potential additional health benefits, in particular to vulnerable groups such as children, that the higher costs for the lower limit value are justified for articles contributing the most to indoor air quality.

(27) In its consideration, the Commission takes into account that wood-based panels and articles made of wood-based panels or other wood-based articles, as well as furniture that contains wood or other materials, in which formaldehyde other than naturally occurring formaldehyde is used during their production, are the main emission sources of formaldehyde in indoor air, in particular in newly built homes. Therefore, the Commission considers that a lower emission limit for such articles and such products composed of more than one article ('complex products') that are the largest sources of formaldehyde in indoor air is appropriate and provides for increased protection of the

general public, while limiting the socio-economic costs for those sectors that do not contribute to the same extent to the emissions.

(28) Likewise, it is appropriate to establish a lower limit for the presence of formaldehyde in the interior of road vehicles where the general public is present to ensure adequate protection in particular of vulnerable populations also in the worst-case scenarios.

(29) The Commission, therefore, concludes that the most appropriate Union-wide measure to address the risk of formaldehyde in indoor air, and in the interior of road vehicles, is a restriction setting the limit value of 0,062 mg/m^3 for furniture and wood-based articles, applied to the whole complex product, as well as in the interior of road vehicles; and of the limit value of 0,080 mg/m^3 for all other articles. Moreover, the Commission considers that the concentration of formaldehyde emitted from articles into indoor air should be measured under specific reference conditions to ensure harmonised implementation of this restriction. In certain cases it should also be possible to use other test conditions provided that a scientifically valid correlation of test results is applied.

(30) In order to mitigate the negative impacts and to lower the costs for the affected sectors, as well as to provide sufficient time for stakeholders to implement the restriction, the Commission considers appropriate a deferral of 36 months for all sectors as regards the application of the restriction. For road vehicles, however, a deferral of 48 months is deemed appropriate due to the long development and marketing time for such vehicles, the high material requirements in the automotive industry, the complex supply chains including original equipment manufacturers, as well as the time needed to implement the standard analytical method for measuring emissions for trucks and buses[8].

(31) As for articles that are exclusively for outdoor use under foreseeable conditions it is expected that consumer exposure takes place outside the exterior wall of buildings, such articles should be excluded from the scope of the restriction. Articles in constructions, that are exclusively used outside the building shell and the vapour barrier and that do not emit formaldehyde into indoor air, should also be excluded from the scope of the restriction, as they do not contribute to exposure to formaldehyde in indoor air.

(32) Articles that are exclusively for industrial or professional use should not be included in the scope of the restriction, as long as these uses do not lead to exposure of the general public. Furthermore, exposure of industrial and professional workers to formaldehyde is already regulated by Council Directive 98/24/EC[9], and Directive 2004/37/EC of the European Parliament and of the Council[10].

(33) Formaldehyde emissions from articles are expected to decrease over time due to 'off-gassing' of residual formaldehyde. Therefore, second-hand articles should not be included in the scope of the restriction. Moreover, the Forum for Exchange of

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8 12219-10: Interior air of road vehicles — Part 10: Whole vehicle test chamber — Specification and methods for the determination of volatile organic compounds in cabin interiors — Trucks and buses.

9 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

10 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004,p. 50).

Information on Enforcement also recommended a derogation for second-hand articles, as enforcing the restriction with regard to second-hand articles may be difficult.

(34) The following products are already subject to Union rules on limit values on formaldehyde and should, therefore, not be included in the scope of the restriction: articles within the scope of entry 72 of Annex XVII to Regulation (EC) No 1907/2006, articles that are biocidal products within the scope of Regulation (EU) 528/2012 of the European Parliament and of the Council[11], devices within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council[12], and personal protective equipment within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council[13].

(35) Commission Regulation (EU) No 10/2011[14] establishes a limit value for formaldehyde for plastic materials and articles intended to come into contact with food. Although Union law does not set a specific formaldehyde limit for other materials and articles in contact with food, producers must be able to demonstrate their safety to the competent authorities. The requirements of food contact materials aim to protect human health by addressing the potential migration of substances into food. As, due to those requirements, a significant release of formaldehyde from articles intended to come into contact with food, within the meaning of Regulation (EU) 1935/2004 of the European Parliament and the Council[15], into the surrounding atmosphere is highly unlikely, the Commission considers that those articles should not be included in the scope of the restriction.

(36) The Dossier Submitter, RAC and SEAC proposed a derogation for toys covered by Directive 2009/48/EC of the European Parliament and of the Council[16] which sets a limit of 0,1 mg/m^3 for formaldehyde emissions in resin-bonded wooden toys for children younger than 3 years. However, the Commission considers such a derogation not appropriate because children should not be protected less strictly than any other part of the population. The limit value for formaldehyde emissions into indoor air should therefore apply to toys for children of all ages.

(37) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(38) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

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11 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

12 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

13 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

14 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

15 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

16 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen

EUROPEAN
COMMISSION

Brussels, XXX
D084710/03
[...](2023) XXX draft

ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) .../... of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

(1) the following entry is added:

'xx. Formaldehyde CAS No 50-00-0 EC No 200-001-8 and formaldehyde-releasing substances	1. Shall not be placed on the market in articles, after [*OP, please insert the date: 36 months after the date of entry into force of this amending Regulation*], if, under the test conditions specified in Appendix [X], the concentration of formaldehyde released from those articles exceeds: (a) 0,062 mg/m^3 for furniture and wood-based articles; (b) 0,080 mg/m^3 for articles other than furniture and wood-based articles. The first subparagraph shall not apply to: (a) articles in which formaldehyde or formaldehyde releasing substances are exclusively naturally present in the materials from which the articles are produced; (b) articles that are exclusively for outdoor use under foreseeable conditions; (c) articles in constructions, that are exclusively used outside the building shell and vapour barrier and that do not emit formaldehyde into indoor air; (d) articles exclusively for industrial or professional use unless formaldehyde released from them leads to exposure of the general public under foreseeable conditions of use; (e) articles for which the restriction laid down in entry 72 applies; (f) articles that are biocidal products within the scope of Regulation (EU) 528/2012 of the European Parliament and of the Council*; (g) devices within the scope of Regulation (EU) 2017/745; (h) personal protective equipment within the scope of Regulation (EU) 2016/425;

	(i) articles intended to come into contact directly or indirectly with food within the scope of Regulation (EC) No 1935/2004; (j) second-hand articles. 2. Shall not be placed on the market in road vehicles after [*OP, please insert the date: 48 months after the date of entry into force of this amending Regulation*] if, under the test conditions specified in Appendix [X], the concentration of formaldehyde in the interior of those vehicles exceeds 0,062 mg/m^3. The first subparagraph shall not apply to: (a) road vehicles exclusively for industrial or professional use unless the concentration of formaldehyde in the interior of those vehicles leads to exposure of the general public under foreseeable conditions of use; (b) second-hand vehicles.

* Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).';

(2) the following Appendix [X] is added:

'Appendix [X]

1. Measurement of formaldehyde released to indoor air from articles referred to in paragraph 1, first subparagraph, of entry [xx]

The formaldehyde released from articles referred to in paragraph 1, first subparagraph of entry [xx] shall be measured in the air of a test chamber under the following cumulative reference conditions:

(a) the temperature in the test chamber shall be (23 ± 0,5) °C;

(b) the relative humidity in the test chamber shall be (45 ± 3) %;

(c) 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. This loading factor corresponds to the testing of wood-based panels; for other material or products, if such a loading factor is clearly not realistic under foreseeable conditions of use, loading factors in accordance with Section 4.2.2 of EN 16516[1] may be used;

(d) the air exchange rate in the test chamber shall be (1 ± 0,05) h^{-1};

(e) an appropriate analytical procedure for measuring the formaldehyde concentration in the test chamber shall be used;

(f) an appropriate method for sampling of the test pieces shall be used;

(g) the formaldehyde concentration in the air of the test chamber shall be measured at least twice per day throughout the test with a time interval between two consecutive samplings of 3 hours at a minimum; the measurement shall be repeated until sufficient data are available to determine the steady state concentration;

(h) the duration of the test shall be sufficiently long to allow the determination of the steady state concentration and shall not exceed 28 days;

(i) the steady state concentration of formaldehyde measured in the test chamber shall be used to verify the compliance with the limit value of formaldehyde released from articles referred to in paragraph 1, first subparagraph, of entry [xx].

If data from a test method using the reference conditions specified above are not available or suitable for the measurement of the formaldehyde released from a specific article, data obtained from a test method using non-reference conditions may be used, where there is a scientifically valid correlation between the results of the test method used and the reference conditions.

2. Measurement of formaldehyde concentration in the interior of vehicles referred to in paragraph 2, first subparagraph, of entry [xx]

For road vehicles, including trucks and buses, the formaldehyde concentration shall be measured in ambient mode in accordance with the conditions specified in ISO 12219-1[2] or ISO 12219-10[3], and the concentration measured shall be used to verify the compliance with the limit value referred to in paragraph 2, first subparagraph, of entry [xx].'.

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[1] EN 16516: Construction products – Assessment of release of dangerous substances – Determination of emissions into indoor air.

[2] ISO 12219-1: Interior air of road vehicles – Part 1: Whole vehicle test chamber – Specification and method for the determination of volatile organic compounds in cabin interiors.

[3] ISO 12219-10: Interior air of road vehicles — Part 10: Whole vehicle test chamber — Specification and methods for the determination of volatile organic compounds in cabin interiors — Trucks and buses.