

8 February 2023 Final

**OPINION OF THE MEMBER STATE COMMITTEE
ON THE DRAFT 11TH RECOMMENDATION OF THE PRIORITY
SUBSTANCES TO BE INCLUDED IN ANNEX XIV OF THE REACH
REGULATION AND THE ASSOCIATED ANNEX XIV ENTRIES**

Adopted on 8 February 2023

OPINION

This opinion of the Member State Committee (MSC) is on the draft 11th recommendation of European Chemicals Agency (ECHA) concerning priority substances to be included in Annex XIV. The opinion was adopted on 8 February 2023 in accordance with Article 58(3) of the REACH Regulation (EC) No 1907/2006¹.

THE DRAFT 11TH RECOMMENDATION OF ECHA

The draft 11th recommendation for priority substances to be included in Annex XIV of REACH (hereafter referred to as the “draft 11th recommendation”) prepared by ECHA included 8 substances and specified the following information for priority substances:

- The identity of the substance as specified in section 2 of Annex VI
- The intrinsic property(-ies) of the substance referred to in Article 57
- Transitional arrangements
 - The sunset date
 - The application date

No review periods, uses or categories of uses exempted from the authorisation requirement or PPORD exemptions were specified in the draft 11th recommendation.

The draft 11th recommendation as updated by ECHA Secretariat after the stakeholder consultation is attached to this opinion (Annex II).

FOCUS OF THE OPINION OF MSC

The opinion of MSC focuses on the draft 11th recommendation and the comments received during the consultation. Further details of the information taken into account by MSC in the preparation of its opinion and further justification for MSC views are presented in the support document (see Annex I).

¹ Regulation (EC) No 1907/2006 of the European Parliament and 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

Emphasis in the support document is given to comments received and issues raised during the consultation that are not specifically addressed in 'ECHA's general responses on issues commonly raised in consultations on draft recommendations'² document.

OPINION OF MSC ON THE 11TH DRAFT RECOMMENDATION FOR PRIORITISATION OF SUBSTANCES TO BE INCLUDED IN ANNEX XIV

PRIORITISED SUBSTANCES

MSC is of the opinion that no information has been received that would justify not including all 8 substances in the final recommendation. MSC is of the opinion that all substances listed in ECHA's draft 11th recommendation and as indicated in the table below, fulfil the prioritisation criteria and should be prioritised for inclusion into Annex XIV in accordance with Article 58(3) of REACH.

#	Substance	EC number	CAS number
1	Ethylenediamine	203-468-6	107-15-3
2	2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers	-	-
3	Lead	231-100-4	7439-92-1
4	Glutaral	203-856-5	111-30-8
5	2-methyl-1-(4-methyl thiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5
6	2-benzyl-2-dimethyl amino-4'-morpholino butyrophenone	404-360-3	119313-12-1
7	Diisohexyl phthalate	276-090-2	71850-09-4
8	Orthoboric acid, sodium salt	237-560-2	13840-56-7

TRANSITIONAL ARRANGEMENTS

MSC notes that the draft 11th recommendation of ECHA proposed to allocate the substances to latest application date (LAD) slots, 18, 21 or 24 months after the date of inclusion in Annex XIV. ECHA indicated that the final LAD allocation for each substance/substance group would be done taking into account all available information including feedback from the consultation and registration updates. Sunset dates for all substances were proposed as LAD plus 18 months.

Following the consultation, ECHA proposed LADs for each substance/substance group which are presented in the table below.

Substance/Group	No. of substances in Group	Proposed LAD
Ethylenediamine	1	18 months

² https://echa.europa.eu/documents/10162/13640/recom_general_responses_doc_en.pdf/44e192e5-ac72-4458-b4f5-c016754a1d4c (version 5 March 2020)

Substance/Group	No. of substances in Group	Proposed LAD
2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers	1	18 months
Diisohexyl phthalate	1	18 months
Orthoboric acid, sodium salt	1	18 months
Glutaral	1	21 months
2-methyl-1-(4-methyl thiophenyl)-2-morpho linopropan-1-one ¹	2	24 months
2-benzyl-2-dimethyl amino-4'-morpholino butyrophenone ¹	2	24 months
Lead	1	At least 36 months

¹ Substances belonging to the same group

Taking into account all available information, the MSC is of the opinion that the LAD allocation proposed by ECHA is appropriate.

MSC is also of the opinion that the sunset date for all substances should be assigned as the LAD plus 18 months.

REVIEW PERIODS FOR CERTAIN USES

In its draft 11th recommendation, ECHA did not recommend any review period.

As the review period is closely connected to the use(s) for which the authorisation is requested and is set on a case-by-case basis when granting the authorisation, MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for inclusion of substances in Annex XIV.

USES OR CATEGORIES OF USES EXEMPTED FROM THE AUTHORISATION REQUIREMENT

In its draft 11th recommendation, ECHA did not recommend any uses or categories of uses that should be exempted from authorisation pursuant to Article 58(2) of REACH.

MSC is of the opinion that there is currently not a clearly sufficient basis for recommending exemptions in Annex XIV for the prioritised substances under Article 58(2) of REACH.

MSC notes ECHA's view that uses of lead exempted/authorised and subject to regular review under the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS), End-of-Life Vehicles (ELV) and Drinking Water Directive (DWD) legislations may have a stronger case for an Article 58(2) exemption than other uses. When considered with other legislation such as occupational safety and health (OSH) and product legislation, MSC acknowledges that these pieces of environmental legislation may contribute to a basis for an exemption under Article 58(2). However, MSC is of the opinion that it cannot be concluded that these environmental legislations offer a similar level of protection for the human health as could be achieved under REACH authorisation and agrees with ECHA that it is not clear as to whether the Article 58(2) conditions are met for any of the uses that fall within the scope of authorisation. MSC therefore

invites the European Commission to examine the possibility for exemptions for uses of lead that are exempted or authorised and subject to regular review under the RoHS, ELV and DWD legislation.

MSC also notes a request for exemption based on the future Batteries Regulation. MSC is in agreement with ECHA's response to the comments, namely that this proposal was not taken into account by ECHA since it is not existing community legislation. MSC also invites the European Commission to consider this upcoming regulation before including the substance in Annex XIV.

EXEMPTIONS FOR THE USE IN PRODUCT AND PROCESS ORIENTED RESEARCH AND DEVELOPMENT

ECHA in its draft 11th recommendation did not recommend any exemptions from the authorisation requirements for uses in product and process oriented research and development (PPORD), as provided for in Article 56(3) of REACH. No requests for exemptions for PPORD were received during the consultation.

MSC is of the opinion that PPORD exemptions in Annex XIV are not required.

OTHER ISSUES

MSC is of the opinion that no additional issues were raised in the consultation which would lead to a different opinion on the draft 11th recommendation.

- Annex I: Support document for the opinion of MSC
- Annex II: ECHA's draft 11th recommendation for Annex XIV, updated on 31 October 2022

8 February 2023

**ANNEX TO THE MEMBER STATE COMMITTEE'S OPINION ON
ECHA'S DRAFT 11TH RECOMMENDATION (ADOPTED ON 8 FEBRUARY 2023)**

**ANNEX I SUPPORT DOCUMENT FOR THE OPINION OF MSC
ANNEX II DRAFT RECOMMENDATION OF PRIORITY SUBSTANCES TO
BE INCLUDED IN ANNEX XIV OF THE REACH REGULATION
UPDATED BY ECHA AFTER THE CONSULTATION ON ECHA WEBSITE**

SUPPORT DOCUMENT FOR THE OPINION OF THE MEMBER STATE COMMITTEE ON ECHA'S DRAFT 11TH RECOMMENDATION OF PRIORITY SUBSTANCES TO BE INCLUDED IN ANNEX XIV OF THE REACH REGULATION (ADOPTED ON 8 FEBRUARY 2023)

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1. INTRODUCTION

In accordance with Article 58(3) of REACH, the Member State Committee (MSC) must provide an opinion on ECHA's draft recommendation for priority substances to be included in Annex XIV of REACH (hereafter referred to as the "draft recommendation"). ECHA takes into account the opinion of the MSC, as well as comments received during the consultation, when finalising its recommendation for priority substances to be included in Annex XIV of REACH to be sent to the European Commission for decision making.

This support document aims at providing background information on the process for adoption of the MSC opinion on the draft recommendation, the information taken into account by MSC in forming its opinion and further details on the grounds for MSC's views on the draft 11th recommendation.

The aim of this document is not to reproduce the full information justifying the prioritisation of the substances or to summarise all the comments received during the consultation. Rather, emphasis is given to comments received and issues raised that are not addressed in '*ECHA's general responses on issues commonly raised in consultations on draft recommendations*'¹ document.

2. PROCESS FOR ADOPTION OF THE OPINION

ECHA published its draft 11th recommendation on 2 February 2022 on its website for consultation. The draft 11th recommendation addressed in the consultation is included in Annex II of the MSC Opinion.

MSC was requested to provide an opinion to ECHA on the draft 11th recommendation. The opinion of MSC considers whether the substances that ECHA has prioritised meet the criteria of Article 58(3) of REACH for prioritisation of substances from the candidate list for inclusion in Annex XIV, using the agreed approach presented in the document on prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)² and the document on general approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV³.

MSC appointed a Rapporteur and a Co-Rapporteur for preparing its opinion on ECHA's draft 11th recommendation and a Working Group to support the Rapporteur and the Co-Rapporteur at its 78th meeting (15-16 June 2022).

For the preparation of its opinion the MSC took into account:

- ECHA's priority setting approach and its application to all substances on the candidate list not already included or recommended for inclusion in Annex XIV of REACH
- General approach for defining the REACH Annex XIV entries³
- ECHA's draft 11th recommendation of priority substances for inclusion in the list of substances subject to authorisation (available for consultation on ECHA website on 2 February 2022)⁴

¹ https://echa.europa.eu/documents/10162/13640/recom_general_responses_doc_en.pdf/44e192e5-ac72-4458-b4f5-c016754a1d4c (version 5 March 2020)

² https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930

³ https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_2020_en.pdf/

⁴ <https://echa.europa.eu/draft-recommendation-for-inclusion-in-the-authorisation-list-consultation>

- (Draft) Background documents for each substance summarising the available information used for priority setting at the start of the consultation and specification of draft REACH Annex XIV entries prepared by ECHA (published 2 February 2022 on the ECHA website in the context of the consultation)
- Comments of the interested parties provided during the consultation period that started on 2 February 2022 and closed on 2 May 2022. In its review of the comments received, MSC also took into account 'ECHA's general responses on issues commonly raised in consultations on draft recommendations'
- Preliminary assessment by the ECHA Secretariat of the information received during the consultation and its potential impact on the Annex XIV entries, including
 - Updated prioritisation table (with a summary of changes)
 - Table with proposed latest applications dates (slots) after closure of the consultation
- Draft responses to comments as provided by the ECHA Secretariat to MSC as supportive material during the process (by 31 October 2022).

The Rapporteur and the Co-Rapporteur, supported by a Working Group, assessed the above information, together with input from MSC, for drafting the opinion of MSC on the draft 11th recommendation.

The draft opinion provided to the MSC by the Rapporteur was finalised and adopted on 8 February 2023 after discussion at the 81st meeting of MSC.

3. MSC VIEWS ON THE RECOMMENDATION

3.1 PRIORITISED SUBSTANCES LISTED IN THE DRAFT 11TH RECOMMENDATION

In its draft 11th recommendation, ECHA proposed eight substances for possible inclusion in Annex XIV. The substances are listed in the following table:

#	Substance	EC number	CAS number
1	Ethylenediamine	203-468-6	107-15-3
2	2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers	-	-
3	Lead	231-100-4	7439-92-1
4	Glutaral	203-856-5	111-30-8
5	2-methyl-1-(4-methyl thiophenyl)-2-morpho linopropan-1-one	400-600-6	71868-10-5
6	2-benzyl-2-dimethyl amino-4'-morpholino butyrophenone	404-360-3	119313-12-1
7	Diisohexyl phthalate	276-090-2	71850-09-4
8	Orthoboric acid, sodium salt	237-560-2	13840-56-7

MSC is of the opinion that no information was received during the consultation that would justify not including all eight substances, as indicated in the table above, in the final recommendation. MSC is of the opinion that prioritisation is justified for all substances/substance groups due to the intrinsic properties, the volume used in the scope of authorisation and the wide dispersiveness of use or based on grouping considerations.

3.1.1 COMMENTS RECEIVED ON PRIORITISATION DURING CONSULTATION

During the consultation, comments were received on ethylenediamine, glutaral and lead that challenged the prioritisation of those substances. MSC considered all the comments in preparing its opinion. MSC notes that the comments were similar across the three substances and these are addressed in section 3.1.1.1 below. In addition to the comments that were similar across several substances, some comments were received which related to individual substances only. These were noted by MSC and are addressed in section 3.1.1.2 below, where deemed relevant.

3.1.1.1 COMMON ELEMENTS FOR ALL SUBSTANCES/SUBSTANCE GROUPS

As indicated above, comments were received from industry that were similar across ethylenediamine, glutaral and lead. These addressed such issues as authorisation not being the most appropriate risk management measure to control risk, that other regulatory processes would be more appropriate and that there are already measures in place to control risks or the uses have low risk and so there is no need to prioritise these substances.

For some substances, the comments indicated that a targeted restriction would be more appropriate. For others, it was indicated that there are other regulatory measures that already exist for the substance and that these should be taken into account when considering prioritisation. Some comments also made the point that any risks could be controlled by means of appropriate safety and risk management measures already in place.

On the above aspects, MSC notes ECHA's view expressed in '*ECHA's general responses on issues commonly raised in consultations on draft recommendations*' document and is of the opinion that such arguments do not justify not prioritising the substances.

3.1.1.2 SUBSTANCE SPECIFIC ISSUES ON PRIORITISATION

Ethylenediamine

During the consultation, comments were received from industry indicating that ethylenediamine acts as an intermediate and is used as monomer.

ECHA notes that not all uses described in the registration dossiers can be considered intermediate use. Therefore, ECHA, in applying a reasonable worst-case approach, has assumed that some uses and related volumes are relevant for prioritisation. The MSC is in agreement with the approach taken by ECHA.

MSC notes that following the consultation, ECHA adjusted the volume and wide dispersive use (WDU) scores of ethylenediamine, based on additional information provided during the consultation and registration updates. This adjustment resulted in a decrease in the prioritisation score from 28-31 to 25. MSC agrees with the revised score and notes that it does not affect the overall prioritisation of ethylenediamine.

Lead

During the consultation, comments were received from industry indicating that lead is an essential material for several industries.

Comments were received proposing not to include lead in the Recommendation due to the excessive number of expected Applications for Authorisation (AfA). MSC acknowledges the high workload and invites the Commission to take this into account.

Comments were also received proposing to postpone the recommendation for lead due to several ongoing legislative updates, including REACH, Batteries Regulation, Restriction of Hazardous

Substances in Electrical and Electronic Equipment (RoHS), End-of-Life Vehicles (ELV) in addition to the revision of the binding Occupational exposure limits (OEL) and the Biological limit values (BLV) for lead. Postponement was also suggested due to the European Commission's decision to postpone the inclusion of other recommended lead compounds into Annex XIV. ECHA notes that the European Commission is responsible for the various regulatory activities and the decision on the inclusion of lead in Annex XIV. Therefore the Commission can ensure best timing and that all necessary actions are complementary. MSC is in agreement with ECHA's response to the comments, such as the Commission being best placed to ensure timely and complementary implementation of these legislations. MSC is also in agreement with the point that the recommendation of lead metal now would ensure that lead compounds recommended for inclusion in Annex XIV so far are at the same regulatory stage, thus facilitating a more holistic regulatory approach for the lead compounds with similar uses (e.g. batteries).

Additionally, the volume and WDU scores and the quantification method were questioned. MSC notes that following the consultation, ECHA considered the registration updates and comments received during the consultation but no changes occurred in the prioritisation score for lead. The MSC is in agreement with the approach taken by ECHA.

Glutaral

During the consultation, comments were received from industry claiming that uses of glutaral in leather tanning and as cross-linking agent are intermediate uses. MSC opinion is in line with ECHA's assessment that one of the three cumulative conditions to qualify as intermediates are not met for the uses of glutaral in leather tanning and as cross-linking agent. The second condition implies that another substance must be obtained from the intermediate via a chemical process (i.e. synthesis) and dedicated equipment must be used for that. When a substance is used to produce an article or in the treatment process of an article, no synthesis takes place even though the substance reacts chemically. In the use of glutaral in leather tanning and as cross-linking agent the other substance is only obtained on the surface (or in the body) of an article during the treatment process (i.e. the starting and ending element of the process is always an article and not a substance).

MSC notes that based on additional information provided during the consultation and registration updates, ECHA revised the volume score from 15 to 12. Specifically, the volume of glutaral manufactured and/or imported decreased since the previous assessment to range of 1,000 - <10.000 t/y. The part exported after manufacture is not taken into account for prioritisation purposes. MSC agrees with the revised score and notes that it does not affect the overall prioritisation.

During the consultation, comments were received from industry questioning the WDU assessment and claiming that presence of the substance in articles is negligible. MSC opinion is in line with ECHA's assessment that the industrial and professional uses in the scope of authorisation in tonnage > 10t/y have been confirmed, justifying an initial WDU score of 10. Furthermore, MSC supports ECHA's approach to further refine the WDU score to 11, reflecting the information available concerning the presence of the substance in articles based on the notifications in the SCIP database, although no uses in articles have been reported in the registration dossier.

2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers

Although no comments were received challenging the prioritisation, MSC notes that following the consultation, ECHA adjusted the volume score of 2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers based on the registration updates. The volume in the scope for authorisation increased and resulted in an increase in the prioritisation score from 28 to 28-31. MSC agrees with

the revised score and notes that it does not affect the overall prioritisation of 2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers.

2-benzyl-2-dimethyl amino-4'-morpholino butyrophenone and 2-methyl-1-(4-methyl thiophenyl)-2-morpho linopropan-1-one

For 2-benzyl-2-dimethyl amino-4'-morpholino butyrophenone and 2-methyl-1-(4-methyl thiophenyl)-2-morpho linopropan-1-one, no comments on prioritisation were received during the consultation.

MSC notes that following the consultation, ECHA considered the registration updates for both substances, although there were no changes on the prioritisation of 2-benzyl-2-dimethyl amino-4'-morpholino butyrophenone nor of 2-methyl-1-(4-methyl thiophenyl)-2-morpho linopropan-1-one. MSC agrees that the substances are recommended for inclusion in Annex XIV based on prioritisation criteria and on grouping considerations.

Diisoheptyl phthalate

MSC notes that there were no changes on the prioritisation of diisoheptyl phthalate. Diisoheptyl phthalate is recommended for inclusion in Annex XIV based on grouping with other phthalates already recommended and included in Annex XIV. MSC agrees that diisoheptyl phthalate is recommended for inclusion in Annex XIV.

Orthoboric acid, sodium salt

MSC notes that there were no changes on the prioritisation of orthoboric acid, sodium salt. Orthoboric acid, sodium salt is recommended for inclusion in Annex XIV based on grouping with other borates recommended in the 6th and 10th ECHA recommendation of priority substances. MSC agrees that orthoboric acid, sodium salt is recommended for inclusion in Annex XIV.

3.2. TRANSITIONAL ARRANGEMENTS: LATEST APPLICATION DATE AND SUNSET DATE

In its draft 11th recommendation, ECHA proposed to set the latest application date (LAD) to one of three slots: 18, 21 or 24 months after the date of inclusion in Annex XIV. ECHA indicated the final allocation of the substances into those slots would be made after the consultation, taking all new information available into account. Sunset date for all substances was proposed as the LAD plus 18 months.

MSC notes ECHA's general principles to setting LADs:

- Substances with no registration requirement or those which are not registered should be assigned a longer LAD
- Substances with complex supply chains and high number of uses should be assigned a longer LAD
- Substances considered as a group should preferably be included together in same LAD slot
- Assignment of substances to slots should support balanced workload for the ECHA Committees/ European Commission

Following the consultation, ECHA analysed information available on the complexity of the supply chain for each prioritised substance/substance group and used that information to derive a 'complexity of supply chain score'. Using that score, ECHA then proposed LADs for each substance/substance group which are presented in the table below.

Substance/Group	No. of substances in Group	Proposed LAD
Ethylenediamine	1	18 months
2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers	1	18 months
Diisohexyl phthalate	1	18 months
Orthoboric acid, sodium salt	1	18 months
Glutaral	1	21 months
2-methyl-1-(4-methyl thiophenyl)-2-morpholinopropan-1-one ¹	2	24 months
2-benzyl-2-dimethyl amino-4'-morpholino butyrophenone ¹	2	24 months
Lead	1	At least 36 months

¹ Substances belonging to the same group

A longer LAD (at least 36 months) was proposed for lead considering that more time would be needed to prepare applications for authorisation (AfA), including a high number of companies would be involved. MSC supports the proposal for a longer LAD for lead.

During the consultation a request for a LAD of 24 months for glutaral was received. MSC supports the latest application date of 21 months proposed by ECHA based on the assessment indicating that the supply chain of glutaral being of medium complexity compared to other substances included in the recommendation.

MSC also notes a request for a latest application date of 24 months for 2-benzyl-2-dimethyl amino-4'-morpholino butyrophenone. ECHA considers that this LAD of 24 months is justified due to the higher complexity of the substance supply chain in comparison to the other substances included in the final recommendation. MSC is of the opinion that LAD proposed by ECHA is appropriate.

Comments were received for ethylenediamine requesting a LAD of 24 months due to complexity of the supply chain. ECHA proposes a LAD of 18 months considering that the supply chain is less complex compared to other substances included in the final recommendation. MSC is of the opinion that LAD of 18 months is appropriate.

For lead, a longer time between the LAD and sunset date was requested during the consultation. MSC is in agreement with ECHA's response to the comments.

MSC is of the opinion that the sunset date for all substances should be set as the LAD plus 18 months.

3.3. REVIEW PERIODS FOR CERTAIN USES

In its draft 11th recommendation, ECHA did not recommend any review period.

As the review period is closely connected to the use(s) for which the authorisation is requested and is set on a case-by-case basis when granting the authorisation, MSC is of the opinion that upfront specified review periods are not warranted in the recommendation.

3.4 USES OR CATEGORIES OF USES EXEMPTED FROM THE AUTHORISATION REQUIREMENT

ECHA did not propose any specific exemption of uses or categories of uses in its draft 11th recommendation.

Requests for exemption of uses or categories of uses were received on ethylenediamine, glutaral and lead. These requests, and MSC consideration on them, are detailed below.

3.4.1 EXEMPTION REQUESTS FOR USES THAT APPEAR TO FALL UNDER THE GENERIC EXEMPTIONS FROM THE AUTHORISATION REQUIREMENT

There were exemption requests regarding uses that appear to fall under the generic exemptions from authorisation, such as use as an intermediate (Article 2(8)(b) of REACH), use in the production of a medical device (Articles 60(2) and 62(6) of REACH) or use in research and development (Articles 3(23) and 56(3) of REACH). MSC is of the view that industry has to examine whether the specific uses of a substance can be regarded as uses where the generic exemptions from authorisation can be applied. MSC notes that for such uses that fall under the generic exemptions from the authorisation requirement, there is no need to propose any additional specific exemptions.

3.4.2 EXEMPTION REQUESTS SUBSTANTIATED BY REFERENCE TO SPECIFIC EU LEGISLATION

3.4.2.1 LEAD

MSC notes that specific requests were received from industry during the consultation on lead referring to existing legislation, including restriction under REACH, RoHS, ELV, Chemicals Agents Directive, Carcinogens and Mutagens Directive, Industrial Emissions Directive, Drinking Water Directive (DWD) and the existence of a binding OEL. The comments noted that existing legislation would cover any risk related to exposure covered by these different pieces of legislation and that the impacted uses should be exempted.

MSC notes that according to Article 58(2) of REACH, it is possible to exempt from the authorisation requirement uses or categories of uses 'provided that on the basis of the existing community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substances, the risk is properly controlled'.

MSC notes ECHA's view that uses of lead exempted/authorised and subject to regular review under the RoHS, ELV, and DWD legislations may have a stronger case for Article 58(2) exemption than other uses. When considered with other legislation such as occupational safety and health (OSH) and product legislation, MSC acknowledges that these pieces of environmental legislation may contribute to a basis for an exemption under Article 58(2). However, MSC is of the opinion that it cannot be concluded that these environmental legislations offer a similar level of protection for the human health as could be achieved under REACH authorisation and agrees with ECHA that it is not clear as to whether the Article 58(2) conditions are met for any of the uses that fall within the scope of authorisation. MSC therefore invites the European Commission to examine the possibility for exemptions for uses of lead that are exempted or authorised and subject to regular review under the RoHS, ELV and DWD legislation.

MSC also notes a request for exemption based on the future Batteries Regulation. MSC is in agreement with ECHA's response to the comments, namely that this proposal was not taken into account by ECHA since it is not existing community legislation. MSC also invites the European Commission to consider this upcoming regulation before including the substance in Annex XIV.

3.4.2.2 Glutaral

During the consultation an exemption for uses of glutaral in tanning was requested by the industry with a reference to the generic exemptions for intermediate use and with a reference to the restriction proposal on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances. As explained above, MSC, in line with ECHA's recommendation, does not consider the use of glutaral in tanning as an intermediate use and therefore this generic exemption does not apply. MSC, in agreement with ECHA, considers that the restriction proposal on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances is not a sufficient basis for granting an exemption for the use of glutaral in tanning under Article 58(2). MSC notes that the restriction: i) is not yet in force and therefore does not constitute an 'existing' community legislation, ii) does not address the risks from the use of the substance arising from the intrinsic properties of the substance specified in Annex XIV. Glutaral is included in the Candidate list based on its respiratory sensitising properties. The proposed restriction addresses skin sensitising properties, iii) the proposed restriction does not cover all the life cycle stages that are exerting the risks. The restriction is targeted to the presence of the substance in articles and does not cover risks from upstream uses. MSC is of the opinion that exemptions under Article 58(2) are not warranted for glutaral.

3.4.3 EXEMPTION REQUESTS NOT SUBSTANTIATED BY REFERENCE TO SPECIFIC EU LEGISLATION

There were exemption requests for ethylenediamine, glutaral and lead which were not substantiated by reference to specific EU legislation.

Across the different substances, these requests were based on issues such as no/controlled exposure, critical uses in defence, uses in protecting workers against ionising radiation. Many comments also requested exemptions for uses for which currently no alternatives exist, or for uses where it would take a very long time to find alternatives.

MSC considered all of these requests and is of the opinion that, while noting the points already made above, such exemptions are not warranted. MSC particularly referred to the information provided in '*ECHA's general responses on issues commonly raised in consultations on draft recommendations*' in forming its opinion in that regard.

3.5 EXEMPTIONS FOR THE USE IN PRODUCT AND PROCESS ORIENTED RESEARCH AND DEVELOPMENT

No exemptions for PPORD were proposed by ECHA. No requests for exemptions for PPORD were received during the consultation.

MSC is of the opinion that PPORD exemptions in Annex XIV are not required.

3.6 OTHER ISSUES

For some of the prioritised substances, comments were raised during the consultation expressing concern that inclusion of the substances in Annex XIV would lead to socio-economic impacts in general, including a loss of competitiveness for certain European industries and negative effects on manufacturing processes in Europe.

Further comments stated that currently, no alternatives exist for certain uses.

MSC took note of these comments and is of the view that while these are valid issues, they do not affect the prioritisation of the substances for authorisation. MSC notes that these issues have been addressed previously in '*ECHA's general responses on issues commonly raised in consultations on draft recommendations*' and refers to the responses accordingly.

MSC concludes that these other issues do not affect the prioritisation of the substances in the draft 11th recommendation.

DRAFT 11TH RECOMMENDATION UPDATED AFTER THE CONSULTATION ON ECHA WEBSITE (31.10.2022)

Draft 11th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation
(List of Substances Subject to Authorisation)

* Draft Annex XIV entries									
#	Substance	EC number	CAS number	SVHC-relevant intrinsic properties*	Latest application date pursuant to REACH Art. 58 (1) (c) (ii)**	Sunset date	Review periods	Exempted uses or categories of uses	Exemptions for PPORD
1	Ethylenediamine	203-468-6	107-15-3	Respiratory sensitising properties (Article 57f – human health)	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None
2	2-(4-tert-butylbenzyl) propionaldehyde and its individual stereoisomers	-	-	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None
3	Lead	231-100-4	7439-92-1	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus at least 36 months (¹)	Latest application date plus 18 months	None	None	None
4	Glutaral	203-856-5	111-30-8	Respiratory sensitising properties (Article 57f – human health)	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None
5	2-methyl-1-(4-methyl thiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 21 months	Latest application date plus 18 months	None	None	None
6	2-benzyl-2-dimethyl amino-4'-morpholino butyrophenone	404-360-3	119313-12-1	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 24 months	Latest application date plus 18 months	None	None	None

* Draft Annex XIV entries									
#	Substance	EC number	CAS number	SVHC-relevant intrinsic properties*	Latest application date pursuant to REACH Art. 58 (1) (c) (ii)**	Sunset date	Review periods	Exempted uses or categories of uses	Exemptions for PPORD
7	Diisohexyl phthalate	276-090-2	71850-09-4	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None
8	Orthoboric acid, sodium salt	237-560-2	13840-56-7	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None

* Reference is made to the identified SVHC properties in accordance with Article 57 of the REACH Regulation and to the corresponding classification in accordance with Annex VI, Table 3.1 (*List of harmonised classification and labelling of hazardous substances*) of 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.

** ECHA proposes to set the LADs within the range of 18, 21 or 24 months after the date of inclusion in Annex XIV. The specific LAD allocation will be done when finalising the recommendation. For this, ECHA will use all available relevant information including that received in the consultation. ECHA's recommendation for specific LAD slots will be based on the *General approach for the preparation of draft Annex XIV entries for substances to be included in Annex XIV*⁵ and as further specified in the *practical implementation document*⁶. Substances considered as a group will be allocated to the same slot.

1) As outlined in Art. 58(3) of REACH, when setting LADs, ECHA also needs to consider the Agency's capacity to handle applications in the time provided for. In case uses that are within the scope of the RoHS Directive, ELV Directive, and Drinking Water Directive, (including upstream uses)) would not be exempt from the Authorisation requirement under Art 58(2), the Commission may contemplate the possibility/added value of defining additional longer LAD(s) and Sunset dates(s) for such uses, with the aim to spread the workload for ECHA, its Committees and Commission when dealing with AfAs, and to facilitate regulatory coherence of decisions taken under those specific legislative frameworks and REACH.

⁵ General approach can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_2020_en.pdf/

⁶ Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf