

Handbook on restrictions

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Disclaimer

This document aims to assist National Helpdesks in their role to support companies and stakeholders in understanding the restriction procedure and complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

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1. Introduction

Restrictions are regulatory measures to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market or use of a substance. A restriction under REACH Annex XVII can apply to any substance on its own, in a mixture or in an article, including those that do not require registration. Restrictions setting out conditions for the placing on the market of substances apply to both domestic production and imports.

Restrictions are normally used to limit or ban the manufacture, placing on the market (including imports) or use of a substance, but can impose any relevant condition, such as requiring technical measures or specific labels. Some of the restrictions originate from the previous chemicals legislation, before REACH (Directive 76/769/EEC). Individual entries of Annex XVII apply simultaneously and independently, and all of them should be complied with.

Link: [Commission \(DG GROW\) website](#)

2. Restriction Procedure

Articles 69 – 73 of REACH set out the procedure for adopting restrictions. Restrictions of substances under REACH may be initiated by Member States, the Commission or ECHA when it is assessed that a substance is not adequately controlled and needs to be addressed on a Union-wide basis. The Commission together with the Member States then decides if the risk is unacceptable.

The process starts when:

- a Member State sends a notification of intention to ECHA to prepare a dossier for a restriction proposal;
- the Commission requests ECHA to prepare a dossier for a restriction proposal;
- ECHA decides to prepare a dossier on its own initiative, for substances listed on Annex XIV where it considers the use in articles not to be adequately controlled; or
- a Member State starts preparing an Annex XV restriction proposal if an urgent action is necessary under REACH (Safeguard clause).

In addition, the Commission can also propose a restriction for substances classified as carcinogenic, germ cell mutagenic and toxic to the reproduction (CMR) categories 1A and 1B without the involvement of ECHA's Committees.

The ECHA Committees for risk assessment (RAC) and socio-economic analysis (SEAC) provide opinions on restriction proposals, taking into account the comments received from the public consultations. These opinions are transmitted to the European Commission, who together with the EU countries, take the final decision. Restrictions are enacted via amendments of Annex XVII to REACH.

Once the restriction has been adopted, industry **must comply**, including manufacturers, importers (including importers of articles), distributors, downstream users and retailers. The **Member States** are **responsible** for **enforcing** the restriction.

Links: [Restriction - ECHA \(europa.eu\)](#) [Restriction procedure - ECHA \(europa.eu\)](#)

3. Information on restricted substances

ECHA has published the restriction entries and supporting information in the Substances restricted under REACH -table. The history of each entry provides links to the relevant directives and regulations, of which preambles give background to the restriction in question. In addition, the Commission website provides information on restrictions. The opinions of the Committees for Risk Assessment (RAC) and for Socio-economic Analysis (SEAC) provide scientific justifications on restriction proposals submitted to ECHA and these are available at the dedicated website.

The table at the link below includes all the restrictions adopted in the framework of REACH and the previous legislation, Directive 76/769/EEC. Each entry shows a substance or a group of substances or a substance in a mixture, and the consequent restriction conditions, including other relevant information.

Links: [Substances restricted under REACH - table](#), [Information on restricted substances - ECHA \(europa.eu\)](#), and [Registry of restriction intentions until outcome](#)

4. How to approach a question

In this paragraph the reader will find a short guide on how to approach a question concerning restrictions.

1. The first step implies reading the **conditions of the restriction** in order to get a clearer overview of the matter. The wording of each restriction entry defines its scope.
2. The second useful step is carefully considering the **Q&As** (links provided in Chapter 6), since these questions cover a wide range of themes about restrictions and can provide the reader with an answer.
3. If the Q&As were not helpful, the third suggested step consists in reading **the legislative background** so as to search whether in the legal texts there is some sort of advice (see History in the Substances restricted under REACH -table).
4. While looking through the legislative content, it could be opportune to establish whether there are specified specific **analytical methods** (Forum Compendium of methods, link provided below).
5. Entry specific **guidelines** can provide specific advice on the scope of the restriction (links provided in Chapter 5).
6. Finally, it is crucial to consider the potential presence of **exemptions**. Exemptions are very specific and need to be appreciated with a case-by-case approach. In fact, the nature of the case and the existence of derogations could play an important role in assessing the question.

Links: [Substances restricted under REACH - table](#) [Compendium of analytical methods to enforce restrictions](#) and [Methodology for recommending analytical methods to check compliance with REACH Annex XVII restrictions](#) and [Enforcement Forum](#)

5. Guidelines

A useful support is offered by the guideline documents available on specific entries. These guidelines with their respective entries are listed as follows (also referred by a specific Q&A).

- **Entry 27 Nickel:** [Guideline on prolonged contact with skin.](#)
- **Entry 50 PAH:** [Guideline on the scope of restriction entry 50 of Annex XVII to REACH: Polycyclic aromatic hydrocarbons in articles supplied to the general public.](#)
- **Entry 52 Phthalates:** [Guideline on the interpretation of the concept "which can be placed in the mouth" as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006](#)
- **Entry 63 Lead:** [Guideline on the scope of the Entry 63 \(paragraphs 7 to 10\) of Annex XVII to REACH on: Lead and its compounds in articles supplied to the general public that can be mouthed by children.](#)
- **Entry 71 NMP:** [How to comply with REACH Restriction 71, Guideline for users of NMP \(1-methyl-2-pyrrolidone\)](#)
- **Entry 72 CMR:** [Explanatory guide on the restriction on CMRs 1a and 1b in textiles and clothing.](#)
- COM page with translations: <https://ec.europa.eu/docsroom/documents/32006>

6. Q&As

All available Q&As on ECHA website concerning restrictions are listed below. The link to all restriction Q&As is [here](#).

6.1. General Q&As

- Does the importer of a mixture have any obligations concerning potential impurities present in the mixture, where the impurity is a substance listed in Annex XVII? [Answer](#)
- When a specific Annex XVII entry (e.g. entry 56 MDI) specifies the requirement for the package to contain protective gloves in order for the mixture to be placed on the market, is it possible to attach the protective gloves to the package, if it cannot contain them? [Answer](#)
- What is the definition of "toys", in the context of restrictions in Annex XVII to REACH? [Answer](#)
- What is the definition of "childcare articles", in the context of restrictions in Annex XVII to REACH? [Answer](#)
- What is the meaning of the expression "placing/placed on the market for the first time" in the context of entries 3(7), 31(2)(b), 58(1) and 59(1)(b) of Annex XVII to REACH? [Answer](#)
- In some cases a restriction entry in Annex XVII refers to specific Directives/Regulations when describing the inclusion or exception of some substances or product categories from the entry. If this Directive/Regulation is repealed or modified, is the new/amended legislation applicable to the restriction? [Answer](#)
- What information on restrictions is needed on the safety data sheet and when does the safety data sheet need to be updated due to restrictions? [Answer](#)
- What is regarded as scientific research and development, which is exempted for

restrictions? For example, does research by students at universities fall under this?

[Answer](#)

- Which restrictions under REACH concern textiles and leather articles? [Answer](#)
- Which restrictions under REACH concern electrical and electronic equipment? [Answer](#)
- Which restrictions under REACH concern paints or paint strippers? [Answer](#)
- In some cases a restriction entry (e.g. entries 32-38, 46) in Annex XVII refers to 'cleaning'. What does this mean? [Answer](#)
- What is understood by an 'article' in the restrictions in Annex XVII to the REACH Regulation, following the judgement of the European Court of Justice (ECJ) on substances (SVHCs) in articles? [Answer](#)
- What is the meaning of the expression 'supply to the general public' in the context of restrictions in the Annex XVII to REACH? [Answer](#)

6.2. Specific Entries

6.2.1. Entry 03 - Oil lamps

- Which type of oil lamps are considered as decorative within the context of Entry 3 of Annex XVII? [Answer](#)
- In entry 3(1) what is included within the scope of 'ornamental articles', in addition to the examples of ornamental lamps and ashtrays in the legal text? [Answer](#)
- What are the hazard classes for liquid substances or mixtures referred to in entry 3 of Annex XVII? [Answer](#)

6.2.2. Entry 08 – polybrominatedbiphenyls

- What is the scope of entry 8 which concerns polybromobiphenyls and polybrominatedbiphenyls? A specific CAS number (59536-65-1) is referred to in the entry, but are other polybrominated biphenyls also included in the scope of this restriction? [Answer](#)

6.2.3. Entry 16-17 -lead compounds in paints

- What is the definition of paints in the context of entries 16 and 17 of Annex XVII? In particular, are children's paint sets, and also other stationery-type paints such as artist paints and do-it-yourself (DIY) decorations for t-shirts also covered? [Answer](#)

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6.2.4. Entry 18(a) – Mercury

- Are the repairing and maintenance activities covered by the restriction in Entry 18(a) of Annex XVII? [Answer](#)
- How should derogation in entry 18(a) of Annex XVII related to Antique Barometers be interpreted? [Answer](#)
- Is there any definition for measuring devices in the context of entry 18(a) of Annex XVII? [Answer](#)

6.2.5. Entry 19 - Arsenic Compounds

- Are imports of CCA treated wood from outside the European Union banned under Entry 19 of Annex XVII? [Answer](#)

- Under Entry 19, paragraph 4b) of Annex XVII there is a list of applications for which wood treated with CCA type C can be used. May treated wood be used for other applications, such as railway sleepers other than underground railway sleepers? [Answer](#)

6.2.6. Entry 20 - Organostannic compounds

- What types of organotin compounds are covered by entry 20 of Annex XVII of REACH "organostannic compounds"? [Answer](#)
- What is the meaning of the expression "already in use" in the context of the entry 20 of Annex XVII to REACH? [Answer](#)
- (a) Do toys fall within the scope of the dioctyltin (DOT) compounds restrictions of entry 20 (paragraph 6)? (b) Can toys benefit from the derogations for organotins in entry 20 of the Restriction List (Annex XVII)? (c) Would a paint coating on a toy that contains dibutyltin (DBT) as a biocide and not as a catalyst fall within the derogation? [Answer](#)
- Does the restriction in entry 20 (organostannic compounds) of Annex XVII to REACH apply to packaging? [Answer](#)
- Entry 20(5) on dibutyltin compounds, paragraph (a) imposes a concentration limit for tin in mixtures and articles for supply to the general public. If a paint layer with dibutyltin compound is applied to the article, how should the concentration of tin be calculated: in the dry paint layer alone, or across the weight of the painted article? [Answer](#)

6.2.7. Entry 23 - Cadmium and its compounds

- According to paragraph 10 of entry 23 of Annex XVII to REACH cadmium shall not be used or placed on the market if the concentration is equal to or greater than 0,01% by weight of the metal in metal parts of jewellery. Does this concentration threshold apply to each metal component of an item of jewellery or to the jewellery item as a whole? [Answer](#)
- Is it allowed to continue the sale/placing on the market of jewelry articles containing more than 0.01% of Cadmium, manufactured and already placed on the market (e.g. sold by the manufacturer to the distributor) before the 10 December 2011 following the entry into force of the new restriction according to Entry 23 of Annex XVII, paragraphs 10 and 11? [Answer](#)
- Which uses of brazing fillers containing cadmium can be regarded as uses for safety reasons (derogation in paragraph 9 of entry 23 of Annex XVII to REACH)? [Answer](#)
- Which types of articles coloured with mixtures containing cadmium can be regarded as using cadmium for safety reasons (derogation in paragraph 3 of entry 23 of Annex XVII to REACH)? [Answer](#)
- What parts of plastic coated copper beads (CCB) used in jewellery should comply with the cadmium restriction entry 23? [Answer](#)
- Do paragraphs 5 and 6 of entry 23 (cadmium and its compounds) cover unplated metal parts? [Answer](#)
- Is ink covered by entry 23 of Annex XVII to REACH, concerning cadmium and its compounds? [Answer](#)

6.2.8. Entry 27 - Nickel and its compounds

- Are mobile telephones covered by the restriction set in Entry 27 of Annex XVII on nickel? [Answer](#)
- How to clarify the "prolonged contact with the skin" in relation to the nickel restriction entry 27? [Answer](#)

6.2.9. Entry 28 to 30 - CMR substances

- Are substances classified as CMRs, and included in Annex VI to CLP but not yet included in the Appendices 1-6 of Annex XVII to REACH, covered by the restrictions in entries 28-30 of Annex XVII to REACH? [Answer](#)
- Entries 28-30 of Annex XVII restrict substances that are carcinogenic, mutagenic and toxic to reproduction (CMR). Do these restrictions apply to these substances when they are present in articles? [Answer](#)

6.2.10. Entry 31 - Creosotes in wood

- What is the meaning of the expression "second hand market for re-use" in paragraph 2(c) of entry 31 of Annex XVII to REACH? [Answer](#)

6.2.11. Entry 40 - Flammable substances in aerosol generators for entertainment and decorative purposes

- Entry 40 of Annex XVII prohibits the use of flammable, highly flammable or extremely flammable substances in "aerosol generators placed on the market for the general public for entertainment and decorative purposes". Are aerosol generators containing coloured hairsprays and glitter for the body and sold to the general public restricted under this entry? [Answer](#)
- Are there any definitions for aerosols, aerosol dispensers, in the context of Entry 40? [Answer](#)
- What is the meaning of products for entertainment and decorative purposes in the context of entry 40 of Annex XVII? Are aerosol dispensers containing coloured hairsprays and glitter for the body and sold to the general public restricted under this entry? [Answer](#)
- Entry 40 provides hazard classes for which the restriction would apply. What are the hazard statements for these hazard classes? [Answer](#)

6.2.12. Entry 43 - Azocolorants and Azodyes

- Are optical brightening agents (OBAs) azodyes within the meaning of the Entry 43 to Annex XVII? [Answer](#)
- The restriction indicated in entry 43(3) applies only to the placing on the EU market of substances or mixtures containing the azodyes listed in Appendix 9 at a concentration exceeding 0.1% by weight, and to the use of such substances/mixtures within the EU. Does the restriction therefore not apply to imported articles which have been dyed with the azodyes listed in Appendix 9? [Answer](#)
- Is the list of restricted items in entry 43 of Annex XVII to REACH concerning azocolourants and azodyes exhaustive? [Answer](#)
- Do sofas and chairs (e.g. garden chairs/sun loungers' type) fall under the scope of the restriction entry 43 of Annex XVII to REACH? [Answer](#)

6.2.13. Entry 46 - Nonylphenol.

- Does the entry 46 of Annex XVII cover traces in cosmetic products? [Answer](#)
- Does the entry 46 of Annex XVII cover all nonylphenols? [Answer](#)
- What are personal care products in entry 46? [Answer](#)
- What is the meaning of the expressions 'textile articles which can reasonably be expected

to be washed in water' (paragraph 1) and 'new textile articles produced exclusively from recycled materials' (paragraph 2) in the context of the entry 46a on nonylphenol ethoxylates? [Answer](#)

6.2.14. Entry 48 – Toluene

- For adhesive tapes, does the concentration limit for toluene of 0.1% in adhesives as specified in Entry 48 of Annex XVII apply to the whole mass of the tape or just to the mass of the adhesive layer on the tape? [Answer](#)

6.2.15. Entry 50 - Polycyclic aromatic hydrocarbons (PAHs)

- What is an interpretation of the "major operational change" concerning the requirement to control the calibration of the PAH/PCA ratio after each "major operational change" under Entry 50 to Annex XVII? [Answer](#)
- Does the restrictions provided in Entry 50 concerning on PAHs in tyres cover mobile machinery? [Answer](#)
- Does the restrictions provided in Entry 50 of Annex XVII concerning on PAHs in tyres cover "Standard reference tyres"? [Answer](#)
- Can you give examples of articles that are covered by or excluded from Entry 50 (paragraphs 5 and 6) of Annex XVII to REACH: Polycyclic aromatic hydrocarbons in articles supplied to the general public? [Answer](#)

6.2.16. Entry 51/52- Phthalates

- In Entries 51 and 52 of Annex XVII respectively it is stated that the substances DEHP, DBP and BBP on the one side and the substances DINP, DIDP and DNOP on the other side "shall not be used as substances or in mixtures, in concentrations of greater than 0.1% by weight of the plasticised material...". Does the 0.1% limit apply to each phthalate listed individually, or whether it applies to the 3 or 6 phthalates combined? How should this limit of 0.1% be applied when a product contains traces of more than one these substances? [Answer](#)
- Are the articles destined to be used for the hygiene of children such as bathtubs, articles for the bath, bathtub mats, hairbrushes, bath thermometers, or nail cutters covered under Entries 51 and 52 of Annex XVII? [Answer](#)
- Do mattress protectors (covers, pads etc.) fall within the scope of Entries 51 and 52 of Annex XVII? [Answer](#)
- Can mattress protectors (covers, pads etc.) be placed in the mouth by children within the meaning of Entries 51 and 52 of Annex XVII? [Answer](#)
- Is the substance Di-2-propyl heptyl phthalate (DPHP), CAS No 53306-54-0 restricted under Entry 52 of Annex XVII or is DPHP as a new compound different from DIDP and therefore not covered by the restrictions in Entries 51 and 52? [Answer](#)
- What is the interpretation of the concept "which can be placed on the mouth" as laid down in the entry 52, concerning toys and childcare articles? [Answer](#)
- Do blankets and objects to facilitate the transport of children fall within the scope of Entries 51 and 52 of Annex XVII? [Answer](#)
- In entry 51 of Annex XVII to REACH, does the concentration limit "0,1 % by weight of the plasticised material in toys and childcare articles" relate to the whole article or only part of it?". For instance, if only the head of a doll contains more than 0.1 % w/w phthalates, should the concentration be calculated on the total weight of the plasticised

material of the whole toy or only for the weight of the plasticised material of the head?

[Answer](#)

- Does a baby monitor fall under the definition of childcare article in the context of entries 51-52 of Annex XVII to REACH? [Answer](#)
- Do entries 51 and 52 of Annex XVII of REACH cover certain articles often used by children (e.g. school supplies, clothing or hair accessories)? [Answer](#)
- Entries 51 and 52 restrict the placing on the market and use of phthalates in toys and childcare articles. Does this restriction apply to medical devices, such as nebulisers? [Answer](#)

6.2.17. Entry 56 - Methylenediphenyl diisocyanate (MDI)

- Does the entry 56 of Annex XVII cover, besides the MDI monomers, also the oligomers and polymers of MDI? [Answer](#)

6.2.18. Entry 58 - Ammonium Nitrate

- Does the derogation to the prohibition of supply of mixtures containing more than 16% of ammonium nitrate in paragraph 2(a) of Entry 58 of Annex XVII cover only downstream users and distributors who have a licence under Council Directive 93/15/EEC on civil explosives (OJ L 010, 16.01.1993 p.19) or whether it covers all downstream users and distributors? [Answer](#)
- Can the downstream users acquire ammonium nitrate in order to produce mixtures containing more than 16% of nitrogen in relation to ammonium nitrate for supply to the general public, for example, in cold packs according to Entry 58 of Annex XVII? [Answer](#)
- Can the downstream users acquire ammonium nitrate in order to produce mixtures containing more than 16% of nitrogen in relation to ammonium nitrate for their industrial or professional activities according to paragraph 2 of Entry 58 of Annex XVII? [Answer](#)

6.2.19. Entry 59 – Dichloromethane

- Does the restriction of dichloromethane in REACH Annex XVII (entry 59) for paint strippers also cover ink strippers, adhesive removers and degreasing agents? [Answer](#)

6.2.20. Entry 63 - Lead and lead compounds

- Can you give examples of lead-containing articles intended for the general public that are covered by or excluded from Entry 63 (paragraphs 7 to 10) of Annex XVII to REACH? [Answer](#)

6.2.21. Entry 65 - Inorganic ammonium salts

- For which uses or applications of cellulose insulation material does entry 65 on inorganic ammonium salts apply? [Answer](#)

6.2.22. Entry 71- 1-methyl-2-pyrrolidone (NMP)

- How can users of NMP ensure that they comply with the mandatory derived no-effect level (DNELs) established in the restriction Entry 71? [Answer](#)
- I manufacture and place on the market articles that contain 1-methyl-2-pyrrolidone (NMP). How does the restriction on the placing on the market, manufacture and use of NMP (entry 71, Annex XVII to REACH) impact my business? [Answer](#)

6.2.23. Entry 72 – CMR substances

- Does the restriction in entry 72 on specific substances which are carcinogenic, mutagenic and toxic to reproduction apply to clothing or related accessories such as rainwear, accessories or footwear mainly made of plastic material or synthetic leather? [Answer](#)
- To which phthalates does entry 72 apply and what concentration limits of phthalates are applicable to clothing and related accessories, other textiles and footwear placed on the market? [Answer](#)