

Restrictions Handbook

May 2023

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Table of Contents

1. Introduction	4
2. Restriction Procedure	5
a. Visual Overview	5
b. Phase 1: Preparation and submission of a restriction proposal	5
c. Phase 2A: Public Consultations	5
d. Phase 2B: Opinion Development	6
e. Phase 3: Decision and follow-up	6
i. Enforcement	6
3. Information on restricted substances.....	6
4. Guidelines.....	7
5. Q&As	7
a. General Q&As.....	7
b. Specific Entries	8
i. Entry 03 - Oil lamps.....	8
ii. Entry 08 – polybrominatedbiphenyls	8
iii. Entry 16-17 -lead compounds in paints	8
iv. Entry 18(a) – Mercury.....	8
v. Entry 19 - Arsenic Compounds	9
vi. Entry 20 - Organostannic compounds.....	9
vii. Entry 23 - Cadmium and its compounds	9
viii. Entry 27 - Nickel and its compounds	9
ix. Entry 28 to 30 - CMR substances.....	10
x. Entry 31 - Creosotes in wood	10
xi. Entry 40 - Flammable substances in aerosol generators for entertainment and decorative purposes	10
xii. Entry 43 - Azocolorants and Azodyes	10
xiii. Entry 46 - Nonylphenol.....	10
xiv. Entry 48 – Toluene	11
xv. Entry 50 - Polycyclic aromatic hydrocarbons (PAHs).....	11
xvi. Entry 51/52- Phthalates	11
xvii. Entry 56 - Methylenediphenyl diisocyanate (MDI)	12
xviii. Entry 58 - Ammonium Nitrate	12
xix. Entry 59 – Dichloromethane.....	12
xx. Entry 63 - Lead and lead compounds	12
xxi. Entry 65 - Inorganic ammonium salts.....	12
xxii. Entry 71- 1-methyl-2-pyrrolidone (NMP).....	12
xxiii. Entry 72 – CMR substances.....	12
xxiv. Entry 73 – TDFA and its derivatives	12
xxv. Entry 74 – Diisocyanates	13

xxvi. Entry 75 - Tattoo inks and permanent makeup 13

May 2023

LEGAL NOTICE

This document aims to assist national helpdesks and users with their obligations under the REACH/CLP Regulation. However, users are reminded that the text of the REACH/CLP 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 regards to the use that may be made of the information contained in this document.

Version	Changes	Date
Version 0	First edition	May 2022
Version 1	Revision of links and addition of new Q&As under "General Q&As" and "Specific entries" sections	May 2023

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1. Introduction

The restriction instrument has its roots in the pre-REACH era, it is a regulatory risk management tool meant to protect human health and the environment from unacceptable risks posed by

chemicals.

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.

Link: [Restriction - ECHA \(europa.eu\)](https://eucha.europa.eu)

2. Restriction Procedure

The restriction procedure is an articulate process composed by several steps described below.

Links: [Restriction procedure - ECHA \(europa.eu\)](https://eucha.europa.eu) and [Restriction process - ECHA \(europa.eu\)](https://eucha.europa.eu) and [ECHA's activities on restrictions - ECHA \(europa.eu\)](https://eucha.europa.eu)

a. Visual Overview



b. Phase 1: Preparation and submission of a restriction proposal

Who: A **Member State**, or **ECHA** at the request of the **European Commission**, can start the restriction procedure when they are concerned that a certain substance poses an unacceptable risk to human health or to the environment. ECHA can also propose a restriction on articles containing substances that are on the Authorisation List (Annex XIV).

What: The **intention** to prepare a restriction proposal is made public in the **registry of intentions** ([RoI](#)) before the **proposal file itself (dossier)** is prepared so as to give an advance notice for interested parties/ stakeholders.

The **restriction dossier** must **comply with Annex XV REACH** and to include information on hazards and risks, available information on **alternatives**, and a **justification** for restrictions at an EU-wide level.

Link: [Phase 1 Restriction process - ECHA \(europa.eu\)](https://eucha.europa.eu) and [Preparation of a restriction proposal - ECHA \(europa.eu\)](https://eucha.europa.eu) and [How to prepare an Annex XV report](https://eucha.europa.eu)

c. Phase 2A: Public Consultations

Who: ECHA's Committee for Risk Assessment (**RAC**) and Committee for Socio-economic Analysis (**SEAC**).

May 2023

What: The Committees **check** whether the submitted restriction dossier conforms with REACH **requirements**, then they consider the **appropriateness** and the **socio-economic impacts** of the suggested restrictions.

Third parties: interested parties may submit **comments** on committees' position or on any **supporting documents** within six months of the date of publication.

Links: [Phase 2 A Restrictions process - ECHA \(europa.eu\)](#) and [Consultations - ECHA \(europa.eu\)](#) and [current open consultations](#)

d. Phase 2B: Opinion Development

The **Forum for Exchange of Information on Enforcement** (Forum) may provide **advice** to RAC and SEAC on the **enforceability of the proposed restriction**. Then, within nine months of the publication of the conforming restriction report, RAC prepares and adopts an opinion based on the restriction dossier, the Forum's advice, and the comments received during the consultation on the report. SEAC does the same within 12 months of the publication of the conforming restriction report.

ECHA sends the compiled **opinions** of RAC and SEAC along with relevant background documents to the **European Commission**. These are also published on ECHA's website.

Link: [Phase 2 B](#)

e. Phase 3: Decision and follow-up

Who: The **European Commission**.

What: The European Commission will take a **balanced view** of the identified **risks** and of the benefits and costs of the proposed **restriction**. Then it will provide a **draft amendment** to the list of restrictions in Annex XVII to REACH.

The **final decision** is taken in a **comitology procedure** with scrutiny involving the Member States and the European Parliament.

i. Enforcement

Once the restriction has been adopted, industry **must comply**, including manufacturers, importers, distributors, downstream users and retailers.

The **Member States** are **responsible** for **enforcing** the restriction.

Link: [Phase 3 Restrictions process - ECHA \(europa.eu\)](#) and [National Inspectorates - ECHA \(europa.eu\)](#)

3. Information on restricted substances

Restrictions on substances, mixtures and/or articles are set out in **Annex XVII** to REACH. The opinions of the Committees for Risk Assessment and for Socio-economic Analysis provide scientific justifications on restriction proposals.

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.

May 2023

Links: [Substances restricted under REACH - table](#) and [Information on restricted substances - ECHA \(europa.eu\)](#)

4. Guidelines

A useful support is offered by the guideline documents available on specific entries.

Entry 27 Nickel: [Guideline on prolonged contact with skin](#)

Entry 50: [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: [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: [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: [How to comply with REACH Restriction 71, Guideline for users of NMP \(1-methyl-2-pyrrolidone\); Explanatory note: How to comply with REACH Restriction 71, guideline for users of NMP \(1-methyl-2-pyrrolidone\), Explanatory Note on Biological Monitoring](#)

Entry 72: [Explanatory guide on the restriction on CMRs 1a and 1b in textiles and clothing.](#)

5. Q&As

You can find a complete list of all available Q&As concerning restrictions at our section on [questions and answers on restrictions](#).

a. General Q&As

- Q&A 828 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?
- Q&A 944 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?
- Q&A 982 What is the definition of "toys", in the context of restrictions in Annex XVII to REACH?
- Q&A 983 What is the definition of "childcare articles", in the context of restrictions in Annex XVII to REACH?
- Q&A 1067 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?
- Q&A 1302 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?
- Q&A 1303 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?
- Q&A 1304 What is regarded as scientific research and development, which is exempted for restrictions? For example, does research by students at universities fall under this?
- Q&A 1305 Which restrictions under REACH concern textiles and leather articles?
- Q&A 1306 Which restrictions under REACH concern electrical and electronic equipment?

May 2023

- Q&A 1307 Which restrictions under REACH concern paints or paint strippers?
- Q&A 1520 In some cases a restriction entry (e.g. entries 32-38, 46) in Annex XVII refers to 'cleaning'. What does this mean?
- Q&A 1564 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?
- Q&A 1798 What is the meaning of the expression 'supply to the general public' in the context of restrictions in the Annex XVII to REACH?
- Q&A 1902 What happens to a substance included in Annex XVII of REACH (substances subject to restriction) if it is included in the list of POPs (Regulation (EU) No 2019/1021 on Persistent Organic Pollutants)?
- Q&A 1903 What requirements must be followed if a substance is included both in Annex XVII of REACH and in the list of POPs?
- Q&A 1904 What happened to PFOA substances previously included into restriction entry 68 and what substances are currently covered by this entry?
- Q&A 1905 What restriction entries in Annex XVII of REACH apply to plastic articles?
- Q&A 1906 What are the PFCA and PFCA-related substances in the scope of Entry 68 of Annex XVII to REACH? What substances are excluded?
- Q&A 1911 Which articles are under the scope of this restriction?
- Q&A 1920 Which are the analytical test methods recommended to check compliance of REACH restrictions?
- Q&A 1921 How frequently is the list of Restrictions under REACH (Annex XVII to REACH) updated?
- Q&A 1922 What are the phases of adopting a new restriction? What is the duration of this process?
- Q&A 1923 How can I participate/submit information regarding a prepared restriction based on an Annex XV dossier submitted in accordance with Art. 69?

b. Specific Entries

i. Entry 03 - Oil lamps

- Q&A 1068 Which type of oil lamps are considered as decorative within the context of Entry 3 of Annex XVII?
- Q&A 1521 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?
- Q&A 1799 What are the hazard classes for liquid substances or mixtures referred to in entry 3 of Annex XVII?

ii. Entry 08 – polybrominatedbiphenyls

- Q&A 1522 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?

iii. Entry 16-17 -lead compounds in paints

- Q&A 1178 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?

iv. Entry 18(a) – Mercury

- Q&A 658 Are the repairing and maintenance activities covered by the restriction in Entry 18(a) of Annex XVII?
- Q&A 659 How should derogation in entry 18(a) of Annex XVII related to Antique

May 2023

Barometers be interpreted?

- Q&A 1179 Is there any definition for measuring devices in the context of entry 18(a) of Annex XVII?

v. Entry 19 - Arsenic Compounds

- Q&A 660 Are imports of CCA treated wood from outside the European Union banned under Entry 19 of Annex XVII?
- Q&A 661 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?

vi. Entry 20 - Organostannic compounds

- Q&A 157 What types of organotin compounds are covered by entry 20 of Annex XVII of REACH "organostannic compounds"?
- Q&A 1069 What is the meaning of the expression "already in use" in the context of the entry 20 of Annex XVII to REACH?
- Q&A 1308 (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?
- Q&A 1309 Does the restriction in entry 20 (organostannic compounds) of Annex XVII to REACH apply to packaging?
- Q&A 1801 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?

vii. Entry 23 - Cadmium and its compounds

- Q&A 158 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?
- Q&A 662 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?
- Q&A 824 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)?
- Q&A 825 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)?
- Q&A 1180 What parts of plastic-coated copper beads (CCB) used in jewellery should comply with the cadmium restriction entry 23?
- Q&A 1310 Do paragraphs 5 and 6 of entry 23 (cadmium and its compounds) cover unplated metal parts?
- Q&A 1311 Is ink covered by entry 23 of Annex XVII to REACH, concerning cadmium and its compounds?

viii. Entry 27 - Nickel and its compounds

- Q&A 663 Are mobile telephones covered by the restriction set in Entry 27 of Annex XVII on nickel?

May 2023

- Q&A 935 How to clarify the "prolonged contact with the skin" in relation to the nickel restriction entry 27?

ix. Entry 28 to 30 - CMR substances

- Q&A 156 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?
- Q&A 1523 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?

x. Entry 31 - Creosotes in wood

- Q&A 1070 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?

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

- Q&A 665 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?
- Q&A 1181 Are there any definitions for aerosols, aerosol dispensers, in the context of Entry 40?
- Q&A 1182 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?
- Q&A 1800 Entry 40 provides hazard classes for which the restriction would apply. What are the hazard statements for these hazard classes?

xii. Entry 43 - Azocolorants and Azodyes

- Q&A 666 Are optical brightening agents (OBAs) azodyes within the meaning of the Entry 43 to Annex XVII?
- Q&A 1183 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?
- Q&A 1312 Is the list of restricted items in entry 43 of Annex XVII to REACH concerning azocolourants and azodyes exhaustive?
- Q&A 1313 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?

xiii. Entry 46 - Nonylphenol.

- Q&A 667 Does the entry 46 of Annex XVII cover traces in cosmetic products?
- Q&A 1113 Does the entry 46 of Annex XVII cover all nonylphenols?
- Q&A 1184 What are personal care products in entry 46?
- Q&A 1802 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?

May 2023

xiv. Entry 48 – Toluene

- Q&A 668 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?

xv. Entry 50 - Polycyclic aromatic hydrocarbons (PAHs)

- Q&A 669 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?
- Q&A 670 Does the restrictions provided in Entry 50 concerning on PAHs in tyres cover mobile machinery?
- Q&A 671 Does the restrictions provided in Entry 50 of Annex XVII concerning on PAHs in tyres cover "Standard reference tyres"?
- Q&A 1476 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?

xvi. Entry 51/52- Phthalates

- Q&A 672 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 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?
- Q&A 673 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?
- Q&A 674 Do mattress protectors (covers, pads etc.) fall within the scope of Entries 51 and 52 of Annex XVII?
- Q&A 675 Can mattress protectors (covers, pads etc.) be placed in the mouth by children within the meaning of Entries 51 and 52 of Annex XVII?
- Q&A 676 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?
- Q&A 748 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?
- Q&A 984 Do blankets and objects to facilitate the transport of children fall within the scope of Entries 51 and 52 of Annex XVII?
- Q&A 985 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?
- Q&A 1185 Does a baby monitor fall under the definition of childcare article in the context of entries 51-52 of Annex XVII to REACH?
- Q&A 1314 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)?
- Q&A 1524 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?

May 2023

xvii. Entry 56 - Methylenediphenyl diisocyanate (MDI)

- Q&A 677 Does the entry 56 of Annex XVII cover, besides the MDI monomers, also the oligomers and polymers of MDI?

xviii. Entry 58 - Ammonium Nitrate

- Q&A 678 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?
- Q&A 679 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?
- Q&A 680 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?

xix. Entry 59 – Dichloromethane

- Q&A 1133 Does the restriction of dichloromethane in REACH Annex XVII (entry 59) for paint strippers also cover ink strippers, adhesive removers and degreasing agents?

xx. Entry 63 - Lead and lead compounds

- Q&A 1190 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?

xxi. Entry 65 - Inorganic ammonium salts

- Q&A 1803 For which uses or applications of cellulose insulation material does entry 65 on inorganic ammonium salts apply?

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

- Q&A 1603 How can users of NMP ensure that they comply with the mandatory derived no-effect level (DNELs) established in the restriction Entry 71?
- Q&A 1828 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?

xxiii. Entry 72 – CMR substances

- Q&A 1805 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?
- Q&A 1806 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?

xxiv. Entry 73 – TDFA and its derivatives

- Q&A 1907 What are the substances in the scope of restriction entry 73?

May 2023

xxv. Entry 74 – Diisocyanates

- Q&A 1908 What are the diisocyanate substances in the scope of restriction entry 74?
- Q&A 1916 Which are the qualifications required for the experts conducting the training on safe handling of diisocyanates and how can it be provided?
- Q&A 1917 Who is responsible for preparation of training material and courses for safe use of diisocyanates?
- Q&A 1918 Does restriction entry 74 apply to adhesives, if they are part of articles?
- Q&A 1919 Who is responsible for labelling the products in the supply chain as specified in paragraph 2 (b) of restriction entry 74?

xxvi. Entry 75 - Tattoo inks and permanent makeup

- Q&A 1909 What are the substances in tattoo inks and permanent make up in the scope of restriction entry 75 and thus restricted for placing on the market for use for tattooing purposes?
- Q&A 1910 What substances can be used in tattoos and permanent make up?
- Q&A 1912 Who has to comply with the restriction on tattoos and who is responsible for enforcement?
- Q&A 1913 Which limit applies to a substance which has multiple harmonised classifications and is also included into Annex II or Annex IV of Regulation (EU) 1223/2009 (Cosmetic Products Regulation – CPR)?
- Q&A 1914 What happens if a substance is currently outside the scope of the restriction but it receives Harmonised Classification in the scope of the restriction or is included in the Regulation (EU) 1223/2009 Cosmetic Products Regulation (CPR) Annex II or Annex IV?
- Q&A 1915 Is there information on the analytical methods that can be used to verify compliance with the provision of Entry 75 of annex XVII to REACH on tattoo inks?