ECHA
EUROPEAN CHEMICALS AGENCY

Questions and Answers

Implementation of Annex XVII to REACH on the restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles

Questions and Answers on the implementation of Annex XVII to REACH on the restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles

Reference: ECHA-12-QA-05-EN
Publ.date: July 2012
Language: EN

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:
http://echa.europa.eu/about/contact_en.asp

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

Table of Contents

Introduction

This document gathers questions and agreed answers concerning the interpretation of the provisions in Annex XVII 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).

These replies were first developed for the purpose of implementing Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. These questions and answers will be complemented by further questions and answers, if and when they arise from the implementation of Annex XVII to REACH.

The answers are attempted to provide guidance to both Member States and economic operators.

This guidance document does not constitute any formal commitment on behalf of the Commission. Only the European Court of Justice can give an authoritative interpretation of Community legislation.

1. Mercury (Entry 18(a) of Annex XVII to REACH)

Repairing and maintenance activities

The question was raised as to whether the repairing and maintenance activities are covered by the restriction in Entry 18(a) of annex XVII to REACH.

Fever thermometers and other measuring devices for sale to the general public in use in the European Union before the 3 April 2009:

The prohibition concerns the placing on the market of fever thermometers and other measuring devices for sale to the general public after the 3 April 2009.

Pursuant to paragraph 2, thermometers as well as other measuring devices for sale to the general public in use in the European Union before the 3 April 2009 are exempted from the prohibition. These instruments containing mercury which were in use in the European Union before the 3 April 2009 can be placed on the second hand market except in the territories of Member States which decided to regulate theses existing instruments.

Repairing and maintenance activities for these existing instruments are excluded from the scope of the restriction.

Nevertheless, in the case of repairing and maintenance activities performed on these devices, new measuring devices containing mercury shall not be used as this would be considered making available new measuring devices to the general public.

Antique Barometers

Under 18(a) antiques measuring devices are defined as more than 50 years old on 3 October 2007.

Under paragraph 3 antique measuring devices are exempted from the restriction. Repairing and maintenance activities for these antique measuring devices are also exempted for the restriction.

The intention of the legislator in granting an exemption for antique measuring devices is that their trade should continue (Directive 2007/51/EC, Recital No 4) due to their cultural and/or historical value. Therefore these instruments should continue to be serviced in order to keep their cultural and/or historical value.

Antique measuring devices such as barometers containing two columns of mercury which one consists of a thermometer are considered falling within the derogation of paragraph 3 and therefore they should continue to be serviced. The columns can be repaired or replaced if these activities are part of the maintenance and repair services and preserve the cultural and/or historical value of the instrument.

Professionals may buy measuring devices containing mercury if they are destined for the repair and maintenance activities of antique measuring devices.

2. Arsenic Compounds (Entry 19 to Annex XVII)

2.1 Status of imported CCA treated wood

Are imports of CCA treated wood from outside the European Union banned under Entry 19 of Annex XVII?

Under Entry 19 of Annex XVII to REACH, CCA type C cannot be used to treat wood in the EU due to the fact that it has not been authorised under Directive 98/8/EC. A request for authorisation could, however, be made in the future in line with the requirements of Directive 98/8/EC.

Concerning wood newly treated with CCA type C and imported from third countries:

- paragraph 4 a) authorises only the treatment of wood with CCA type C if this biocidal product is authorised under Directive 98/8/EC.
- under paragraph 4 b) it is stated that "Wood treated with CCA solutions in accordance with point a) may …."

This implies that all wood that is placed on the market in the EU must conform to the requirements of paragraph 4 a).

Therefore wood newly treated with CCA type C may only be placed on the EU market if this biocidal product used for treatment is authorised under Directive 98/8/EC.

Whilst the Directive does not impose general obligations on wood treatment installations outside the EU, this requirement is valid for any manufacturer, distributor, or importer placing wood on the EU market whether this wood is manufactured in the EU or manufactured outside the EU and imported. Obviously the requirement does not apply to wood treatment installations outside the EU producing wood for marketing outside the EU.

In summary since 30 June 2007, it is prohibited to place on the market and to import wood newly treated with CCA type C, until such time as a biocidal product containing this active substance is authorised in line with all the requirements of Directive 98/8/EC.

2.2 Applications of wood treated with CCA Type C

Under Entry 19, paragraph 4b) of Annex XVII to REACH 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?

Paragraph 4b) of Annex XVII to REACH concerning arsenic compounds provides for a list of applications for which wood treated with CCA may be used. This is not a list of examples of possible uses but a limitative list of authorised applications.

Consequently, wood treated with CCA cannot be used for other applications than the ones listed in paragraph 4 b). Wood treated with CCA can, therefore, not be used for railway sleepers installed above ground.

3. Cadmium and its compounds (entry 23 of Annex XVII to REACH)

Paragraphs 10 and 11, clarification regarding the meaning of the placing on the market and the derogation

A question was raised in order to know whether the sale of jewellery 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 could continue to be placed on the market following the entry into force of the new restriction.

The prohibition of the placing on the market of jewellery and imitation jewellery articles containing cadmium includes sales from the manufacturers to distributors and from distributors to retailers, as well as imports.

However, Commission Regulation (EU) 494/2011 contains derogation for articles that were placed on the market before 10 December 2011 (for the date see corrigendum published in OJ L 136/105). This means that jewellery and imitation jewellery articles placed on the market for the first time before 10 December 2011 do not need to comply with the prohibition thus they can be sold following entry into force of the new restriction for example to a retailer or on the second-hand market.

4. Nickel and its compounds (Entry 27 of Annex XVII to REACH)

Mobile telephones

The question was raised whether mobile telephones are covered by the restriction set in entry 27 of annex XVII to REACH on nickel.

Entry 27 of Annex XVII to REACH states that nickel may not be used "in articles intended to come into direct and prolonged contact with the skin, if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0.5 µg/cm²/week".

The aim of this restriction to protect consumers against nickel allergy which may be caused by prolonged contact of the skin with nickel-releasing articles that come into direct and prolonged contact with the skin such as jewellery, buttons, tighteners, zips and rivets in items of clothing.

It has emerged that some mobile telephones contain nickel in surface material and that consumers are at risk of developing eczema through skin contact with the mobile telephone.

As mobile telephones are clearly intended to come into direct contact with the skin, and as they are used on a daily basis often for prolonged periods of time, it is considered that mobile telephones fulfil the condition of "direct and prolonged contact with the skin". Therefore mobile telephones are covered by the restriction and should comply with the conditions set in Entry 27 of Annex XVII to REACH.

5. CMR substances (Entries 28 to 30 of Annex XVII to REACH)

Concentration limits

Entries 28 to 30 of Annex XVII to REACH prohibit the placing on the market and use of mixtures when the concentration limit is greater than

- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,
- the relevant concentration specified in Directive 1999/45/EC.

The question was raised by operators on the interpretation of this provision in the case of a mixture for which a specific concentration limit is specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

Should this specific concentration limit be considered for the implementation of the restriction? Do operators have a choice between the specific concentration limit and the concentration specified in Directive 1999/45/EC?

Whenever a specific concentration limit is specified for a particular substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008, then the restriction in entries 28 to 30 of Annex XVII of REACH will apply to the mixtures which contain the substance at a concentration greater than that specific concentration.

Operators and Competent Authorities may not choose between the generic and the specific concentration limits but they should use the specific concentration limit as specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in order to implement the restriction.

In case no relevant specific concentration limit is specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, then, the relevant concentration specified in Directive 1999/45/EC should be used.

6. Flammable substances in aerosol generators for entertainment and decorative purposes (Entry 40 of Annex XVII to REACH)

Aerosol generators containing coloured hairsprays and glitter for the body

Entry 40 of Annex XVII to REACH 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".

A question was raised whether aerosol generators containing coloured hairsprays and glitter for the body and sold to the general public are restricted under this entry.

Entry 40 establishes a non-exhaustive list of examples of products that are covered by the restriction. These examples are all products to be used for decoration of venues of festivities/parties and for use during parties. None of these examples are cosmetic products.

Cosmetic products are covered under Directive 76/768/EEC1. Coloured hair sprays and body glitter enter in the definition of cosmetic products as they are intended "to be placed in contact with an external part of the human body" with a view to "changing its appearance". They have

---

1 OJ L 262, 27.9.1976, p.169

a similar use as the more classical cosmetic products, such as normal hair sprays and should not be considered as having an entertainment purpose.

For these reason it is considered that Entry 40 does not cover aerosols dispensers containing cosmetic products which are also covered by Directive 76/768/EEC.

Moreover Article 67 of REACH excludes cosmetics products from the scope of the restrictions when the restriction is targeting a risk for human health. This restriction on aerosol dispensers is entirely linked with human health.

Conclusion: The restriction in Entry 40 of Annex XVII to REACH, prohibiting 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" does not cover aerosol dispensers which contain cosmetic products.

7. Nonylphenol (Entry 46 of Annex XVII to REACH)

Traces in cosmetic products

Directive 76/768/EEC relating to cosmetic products, as amended by Commission Directive 2005/80/EC2, introduces a ban on the marketing of cosmetic products containing nonylphenol (CAS: 25154-52-3) and 4-nonylphenol, branched (CAS: 84852-15-3) (entry 1168 of Annex II).

Article 4 §2 of Directive 76/768/EEC allows the presence of traces in products provided that such presence is technically unavoidable in good manufacturing practice and that the product does not cause damage to human health.

Entry 46 of Annex XVII to REACH bans the placing on the market of nonylphenol and nonylphenol ethoxylates as a substance or in mixtures in a number of applications including cosmetic products, when the concentration is higher than 0.1% by weight.

Although the two texts pursue the same objective and impose the same restriction, they diverge concerning the tolerance of trace contamination.

8. Toluene (Entry 48 of Annex XVII to REACH)

Toluene in Adhesive Tapes

For adhesive tapes, does the concentration limit for toluene of 0.1% in adhesives apply to the whole mass of the tape or just to the mass of the adhesive layer on the tape?

Entry 48 prohibits the placing on the market for supply to the general public of toluene as a substance or in mixtures, in a concentration equal to or greater than 0.1% by weight, where the substance or the mixture is used in adhesives and spray paints.

Adhesive tapes consist of a layer of adhesive coated on a flexible substrate. As the restriction concerns the concentration of toluene in adhesives, the concentration of toluene must be calculated with reference to the amount of adhesive on the tape, and not with reference to the total weight of the adhesive and substrate.

---

[2] OJ L 303, 22.11.2005, p. 32

9. Azocolorants and Azodyes (Entry 43 OF ANNEX XVII to REACH)

Optical brightening agents

Are optical brightening agents (OBAs) azodyes within the meaning of the Entry 43?

Answer: Through a literature search and consultation with experts in this area it was not found any structural connection between optical brighteners (or better called fluorescent dyes) and azodyes since either the NH bonds in the fluorescent dyes are connected to heterocyclic N-C structures and therefore cannot form any of the 22 banned arylamines or they do not contain any azo bonds where reductive cleavage could take place to generate any of the aromatic amines covered by the azodyes ban.

Therefore at the present time, this information confirms that the restriction in Entry 43 to Annex XVII does not cover optical brightening agents (OBAs). Should the chemical structure of optical brightening agents be different from the definition as reported above, this answer may change accordingly.

10. PAH in extender oils and tyres (Entry 50 of Annex XVII to REACH)

10.1 Interpretation of the term "major operational change"

Questions have arisen concerning the requirement to control the calibration of the PAH/PCA ratio after each "major operational change" under Entry 50 to Annex XVII.

As stated in Recital 8 of the Directive 2005/69/EC3, there are at present no harmonized test methods for measuring PAHs in the extender oils, or for measuring PAHs in tyres that contain such oils. Until suitable harmonized methods are available, the only named method that is permitted for measuring the PAH content of extender oils is the IP346 analysis method. This method is permitted providing that certain additional conditions are met. These additional conditions are necessary because the IP346 method does not measure the PAH content directly.

In fact IP346 measures the total content of polycyclic aromatic compounds (PCA) rather than the PAH content. The PCAs are a group of substances to which PAHs belong, but in which PAHs are present in only very small amounts. The legal limit for PAHs in extender oils, which is 1 part per million (ppm) of BaP and 10ppm total PAH content, is considered to be met if the total PCA content is <3%. In other words, the PCA content of 3% is taken as a proxy measurement for a PAH content of 10ppm. The proxy measurements will be valid only if the ratio between the PAH and PCA content in the extender oil is known and does not change over time. The additional conditions therefore require an initial calibration of the technique (measurement of the PAH/PCA ratio) and recalibration at intervals of six months, or after "major operational change", in order to ensure that the measurements remain valid over time.

The term "major operational change" should therefore be taken to mean any change in materials or processes that could invalidate the results of the proxy measurement. The principle cause of invalid results would be a change in the PAH/PCA ratio in the extender oil. However, it should be remembered that not only is IP346 a proxy method for measuring PAH, but that the quantity that it does measure, namely PCA content, is measured in a rather indirect way, namely by a change in the refractive index of a solution, and that PCAs are not

[3] OJ L323, 9.12.2005, p.51

the only substances that affect the refractive index of a solution. The potential for obtaining invalid results is therefore quite high and the method should therefore be used with considerable caution. It would therefore be advisable to recalibrate in case of doubt.

The provision to control the calibration of the PAH/PCA ratio every six months is to safeguard the validity of the IP346 results against unintentional or unknown changes. This would apply for the case where the manufacturing process and materials used remain the same, and where there is no reason be expect a change in the PAH/PCA ratio. However, it is possible to imagine, for example, that a tyre manufacturer receives a reformulated extender oil from his supplier without being made aware of the change that has been made, and the results from the IP346 could be invalidated as a consequence. A six month recalibration interval was considered sufficient to cover such occurrences.

Conclusion: The provision to control the calibration of the PAH/PCA ratio after each "major operational change" is to safeguard the validity of the IP346 results. A major operational change is therefore a deliberate change to materials or processes that might be expected to significantly influence the PAH/PCA ratio, or otherwise affect the validity of the measurement. Examples of such a change would be where the source of supply for the extender oil is changed, or where the method of using the oil is changed.

Judgment of whether a particular change is sufficiently important to trigger the need for recalibration will necessarily be made case-by-case and will require expert opinion.

10.2 Tyres for mobile machinery

Does the restrictions provided in Entry 50 concerning on PAHs in tyres cover mobile machinery?

Entry 50 to Annex XVII as enacted by Commission Regulation 552/2009 restricts the use of PAH in tyres for "vehicles covered by Directive 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers".

Article 2 of Directive 2007/46 defines its scope. Paragraph 1 lists the vehicles designed for use on roads.

Article 2 of Directive 2007/46, Paragraph 3 lists the following vehicles:

a) vehicles designed and constructed for use principally on construction sites or in quarries, port or airport facilities;

b) vehicles designed and constructed for use by the armed services, civil defence, fire services and forces responsible for maintaining public order;

c) mobile machinery.

Article 2 of Directive 2007/46, paragraph 4 lists the following vehicles:

a) vehicles intended exclusively for racing on roads;

b) prototypes of vehicles used on the road under the responsibility of a manufacturer to perform a specific test programme provided they have been specifically.

In addition the definition of "motor vehicle" in point 11 of Article 3 requires that the vehicles covered should have a maximum design speed limit exceeding 25 km/h.

In conclusion the restriction in Entry 50 covers the tyres for vehicles listed in the Article 2 paragraph 1, 3 and 4 of Directive 2007/46/EC which have a maximum design speed limit

exceeding 25 km/h. Tyres of mobile machinery with a maximum design speed limit exceeding 25 km/h are therefore covered by the restriction and have to comply with the conditions set in the entry 50.

10.3 Standard reference tyres

Does the restrictions provided in Entry 50 concerning on PAHs in tyres cover "Standard reference tyres"?

Standard reference tyres are produced and imported solely for the purpose of providing a reference performance for other newly developed tyres. They are not placed on the market to be fitted on vehicles intended for final users.

For the purpose of entry 50, tyres are defined as tyres for vehicles covered by Directives 2007/46/EC on motor vehicles and their trailers, Directive 2003/37/EC on agricultural or forestry tractors, and Directive 2002/24/EC on two and three-wheeler motor vehicles.

It appears that Reference Tyres are not intended to be used on vehicles covered by the Directives 2007/46/EC, 2003/37/EC and 2002/24/EC.

In conclusion these tyres should not be considered as covered by the provisions of the restriction in Entry 50 of Annex XVII.

11. Phthalates in toys and childcare articles (Entries 51 and 52 of Annex XVII to REACH)

11.1 Traces of phthalates in toys and childcare articles

In Entries 51 and 52 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…".

The question has been asked whether that means that the 0.1% limit applies 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?

The threshold of 0.1% is the standard threshold used in Annex XVII. The value of 0.1% has been chosen because it represents a measurable quantity. It is being used to take into account impurities, not to allow the use of certain substances, e.g. phthalates in toys and childcare articles. One should be aware that in order to plasticise a toy or childcare article concentrations of phthalates of more than 10 per cent are needed.

Different restrictions are applied to each of the two groups of phthalates. The limit value of 0.1% should therefore be applied for each group of phthalates combined, i.e. the concentration of DEHP, DBP and BBP combined should not be higher than 0.1% and the concentration of DINP, DIDP and DNOP combined should also not be higher than 0.1%.

Conclusion: A toy or childcare article would not comply with the Entry 51 or Entry 52 respectively if it contained either more than 0.1% of DEHP, DBP and BBP combined or more than 0.1% of DINP, DIDP and DNOP combined. However, it would be considered compliant if it contained only 0.09% of DEHP, DBP and BBP combined and 0.09% of DINP, DIDP and DNOP combined.

11.2 Phthalates in articles used for the hygiene of children

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?

The entries 51 and 52 specify that "Childcare article" means "any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children."

As these articles are intended to facilitate the hygiene of children they should be considered as "childcare articles" as defined by the entries 51 and 52.

In conclusion, articles which are used for the hygienic care of children such as bathtubs, articles for the bath, bathtub mats, hairbrushes, bath thermometers, or nail cutters are therefore covered by the Entries 51 and 52 and use of phthalates and should conform to the prescriptions of the entries.

11.3 Mattress protectors

Do mattress protectors (covers, pads etc.) fall within the scope of entries 51 and 52 of Annex XVII?

The definition of childcare articles contained in Annex XVII to REACH is as follows:

"Childcare articles" are defined as "any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children".

Further explanation is provided by the Commission services' guidance document on the interpretation of the concept "which can be placed in the mouth". It gives the following examples: "The main purpose of pyjamas is to dress children when sleeping and not to facilitate sleep. Pyjamas should therefore be regarded as textiles and, like other textiles, do not fall under the scope of the Directive. Sleeping bags are designed to facilitate sleep, and should therefore fall under the Directive."

Taking this into account, and also taking into account that the guidance document explicitly contains a description and a photo of a mattress cover, it can be confirmed that mattress protectors are childcare articles as defined in Annex XVII.

This means that the three phthalates DEHP, BBP and DBP listed in entry 51 of Annex XVII may not be used in mattress protectors. The other three, DINP, DIDP and DNOP, listed in the entry 52, are only restricted in those articles that can be placed in the mouth by children.

Can mattress protectors (covers, pads etc.) be placed in the mouth by children?

The guidance document contains an example of a mattress cover that is not directly mouthable in normal and foreseeable use conditions. The edges and corner are not accessible for mouthing by the child – by design (the mattress should fit snugly in the cot to avoid entrapment risks), and the mattress is covered with a sheet in normal use and the surface is sufficiently taut (by design – to avoid suffocation risks) to prevent PVC from being mouthed through the sheet. This is based on the observation that inaccessible parts of articles can not be taken into the mouth. Articles or parts of articles should be considered inaccessible if, during proper use or reasonably foreseeable improper use by children, they can not be reached.

However, there will be other cases when parts of certain articles can be taken into the mouth under normal and foreseeable conditions, for example when the mattress protector is placed on the sheet or cannot be completely fixed.

In conclusion, mattress protectors that can be placed above sheets or that cannot be tightly fixed to the mattress have to comply with the restriction contained in entry 52 of Annex XVII to REACH. Authorities competent for market surveillance should assist manufacturers/importers in making a case-by-case assessment on the basis of the criteria described above and in the guidance document.

11.4 Di-2-propyl heptyl phthalate (DPHP), CAS No 53306-54-0

Is the substance Di-2-propyl heptyl phthalate (DPHP) 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?

The restriction in entry 52 concerns the substance "Di-isodecyl phthalate" (DIDP) which is listed with CAS Numbers 26761-40-0 and 68515-49-1. Di-2-propyl heptyl phthalate (DPHP) is an isomer of decyl phthalate and has the CAS No 53306-54-0.

According to the information at the Commission's disposal, DPHP (CAS # 53306-54-0) is different from DIDP and therefore not covered by entry 52 of Annex XVII.

In conclusion, the substance is not covered under the entry 52 of Annex XVII. The uses of the substance may be regulated in the future on a Community-wide basis, if it appears from the information which will become available that it causes unacceptable risks to human health or the environment. In addition DPHP is explicitly not promoted by its manufacturers for use in toys, food packaging or medical products.

12. Methylenediphenyl diisocyanate (MDI) (Entry 56 of Annex XVII to REACH)

Definition of the substance Methylenediphenyl diisocyanate (MDI)

A question was raised on whether the restriction in entry 56 of Annex XVII pertaining to the substance Methylenediphenyl diisocyanate (MDI) covers the substance defined by the EC number 247-714-0 and CAS number 26447-40-5 as well as other substances such as:

- 4,4'-Methylenediphenyl diisocyanate EC Number 202-966-0; CAS Number 101-68-8
- 2,4'-Methylenediphenyl diisocyanate EC Number 227-534-9; CAS Number 5873-54-1
- 2,2'-Methylenediphenyl diisocyanate EC Number 219-799-4; CAS Number 2536-05-2.

This question arose because the entry only makes reference in the column 1 solely to Methylenediphenyl diisocyanate with EC number 247-714-0 and CAS number 26447-40-5.

Answer: MDI refers to a number of isomeric compounds with the chemical formula $C_{15}H_{10}N_2O_2$. The substance defined by the EC number 247-714-0 and CAS number 26447-40-5, encompasses all isomeric mixtures and also all of the specific isomers even if those isomers have specific CAS or EC numbers.

These isomers are:

- 4,4'-Methylenediphenyl diisocyanate EC Number 202-966-0; CAS Number 101-68-8
- 2,4'-Methylenediphenyl diisocyanate EC Number 227-534-9; CAS Number 5873-54-1
- 2,2'-Methylenediphenyl diisocyanate EC Number 219-799-4; CAS Number 2536-05-2

This is confirmed in the Risk assessment report published in 2005 and the explanatory memorandum of the Commission published in October 2007 together with the proposal for a

Directive amending Directive 76/769/EC (COM(2007) 559 final).

Therefore it is confirmed that the restriction in Entry 56 of Annex XVII covers the substance defined by the EC number 247-714-0 and CAS number 26447-40-5 and also the following substances:

- 4,4'-Methylenediphenyl diisocyanate EC Number 202-966-0; CAS Number 101-68-8,
- 2,4'-Methylenediphenyl diisocyanate EC Number 227-534-9; CAS Number 5873-54-1,
- 2,2'-Methylenediphenyl diisocyanate EC Number 219-799-4; CAS Number 2536-05-2.

A second question was raised whether entry 56 of annex XVII covers, besides the MDI monomers, also the oligomers and polymers of MDI.

The polymeric MDI, with CAS number 9016-87-9, is not included in the definition of the substance with CAS 26447-40-5 and moreover is not classified as dangerous in Annex VI of Regulation (EC) No 1272/2008 (CLP). In the Risk assessment report and Risk reduction strategy performed by the Belgian Rapporteur, two main products were analyzed during the exposure assessment and throughout the decision making process: the one-component foams and hot melt adhesives, both containing respectively 10% and 2% of MDI. Other products with MDI content below 0.1% did not pose any risk and therefore were excluded by the final consideration on the risk reduction measures under Directive 76/769/EEC. However, polymeric MDI present in mixtures is covered by the restriction when such mixtures contain more than 0.1% of MDI (as defined in the RAR).

Therefore, dimers and polymeric forms of MDI are out of the scope of the current restriction except if they are part of mixtures containing more than 0.1% of MDI.

13. Amonium Nitrate (Entry 58 of Annex XVII to REACH)

Operators covered by the exemption in paragraph 2 of Entry 58

a) Operators and competent authorities have raised the question as to whether 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 to REACH covers only downstream users and distributors who have a licence under Council Directive 93/15/EEC on civil explosives4 or whether it covers all downstream users and distributors.

In entry 58, the terms "including natural or legal persons licensed or authorised in accordance with Council Directive 93/15/EEC" should be read as an example of operators that benefit from the exemption.

Therefore the derogation in paragraph 2(a) covers all downstream users and distributors as defined in Article 3(13) and 3(14) of REACH.

As a consequence, mixtures containing more than 16% of nitrogen in relation to ammonium nitrate may be placed on the market after 27 June 2010 for supply to downstream users and distributors as defined in REACH.

As consumers are not downstream users nor distributors, mixtures containing more than 16% of nitrogen in relation to ammonium nitrate may not be placed on the market for supply to consumers.

b) Operators have raised the question as to whether downstream users could acquire

[4] OJ L 010, 16.01.1993 p.19.

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.

If a downstream user uses ammonium nitrate to produce a mixture containing ammonium nitrate below the threshold, it may place this mixture on the market for supply the general public.

But downstream users should not use ammonium nitrate in order to produce a mixture containing ammonium nitrate above the threshold for supply to the general public.

The restriction is applicable to medical devices as well as to other mixtures containing more than 16% of nitrogen in relation to ammonium nitrate for supply to the general public. For example, instant cold packs which contain more than 16% of nitrogen in relation to ammonium nitrate may not be sold to the general public since 27 June 2010.

c) Operators have raised the question as to whether downstream users could 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.

The restriction is not applicable to downstream users who use ammonium nitrate for their industrial or professional activities in order to transform it into other substances for different purposes.

Therefore, for example the use of ammonium nitrate to produce nitrous oxide for use in the production of pressurised foods or for use as anaesthetics is not restricted.

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU