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Concerns: Interpretation of entry 50 of Annex XVII to REACH

Agenda Point: 6.3

Action Requested: The REACH and CLP Competent Authorities are invited to take note of this document for discussion

Interpretation of entry 50 of Annex XVII to REACH

As a consequence of on-going work by ECHA on the development of guidelines for the application of the restriction on PAHs in consumer articles, contained in paragraph 5 of entry 50 of Annex XVII to REACH, two possible interpretations of "placing on the market for supply to the general public" have emerged.

This paper describes the two interpretations and Member States are asked to indicate which they consider best describes the intention of the text that they voted on. Clarification of the meaning of this phrase is urgent both because the new PAH restriction applies from 27 December 2015 and because the phrase is used in other restrictions, which might be affected by the interpretation given to this terminology in this entry.

In addition, the Netherlands and the European Tyre and Rubber Manufacturers Association (ETRMA) have expressed concerns as to whether synthetic turf, and rubber mats and tiles produced from synthetic rubber, fall within the scope of the restriction. These concerns raise the question whether these products are articles or integral parts of structures, or indeed mixtures. This paper also addresses these issues.

A. Interpretations of paragraph 5 of entry 50 of Annex XVII

Paragraph 5 of entry 50 of Annex XVII states:

*“Articles shall not be **placed on the market for supply to the general public** if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0,0001% by weight of this component) of any of the listed PAHs.” (emphasis added)*

INTERPRETATION 1

The restriction on placing on the market for supply to the general public does not cover cases where tiles/mats used in public playgrounds and synthetic turf used on artificial sports fields, both made from recycled tyres, are merely made accessible (and not sold) to the public.

The legal basis of Commission Regulation (EU) No 1272/2013 amending Annex XVII as regards PAHs is Article 68(2) of REACH. Therefore the overall aim of the amendment, which adds paragraphs 5 to 8 to entry 50, is to restrict the presence of PAHs in articles that could be used by consumers. This is reflected in Recital (6). As it would be impossible to enforce a restriction on the use by consumers of articles containing PAHs above a certain concentration, Regulation (EU) No 1272/2013 restricts the placing on the market of such articles.

“Placing on the market” is defined in Article 2(12) of REACH as “supplying or making available, whether in return for payment or free of charge, to a third party”. The addition of the words “for supply to the general public” in paragraph 5 of entry 50 is intended to describe more precisely the activity that is intended to be caught by this particular restriction. Thus,

for the purposes of this restriction, the activity restricted is the supply of articles containing PAHs to the general public or, put simply, the sale of articles containing PAHs to consumers.

Regulation (EU) No 1272/2013 could have restricted another activity – the placing on the market of articles likely to be used by the general public. This would have prevented sales by one actor in the supply chain to another of articles containing more than the permitted concentration of PAHs where it is reasonably foreseeable that the article would be used by members of the general public. Indeed, this approach was initially proposed by DE (see below the wording suggested in the Annex XV dossier) but was subsequently changed to the current text of paragraph 5.

“Articles which could be used by consumers (including articles in contact with the oral mucosa, toys, and childcare articles) shall not be placed on the market, if they contain any of the PAHs listed in column 1 at levels above the limit of quantitation (LOQ)”.

In support of this interpretation, Recital (3) of Regulation (EU) No 1272/2013 states that entry 28 of Annex XVII **bans the sale** of PAHs on their own or in mixtures to the general public. Entry 28 also uses the phrase “placed on the market . . . for supply to the general public”. It is, therefore, clear from the Recitals of Regulation (EU) No 1272/2013 that the intention of the Regulation is to provide the same protection for the public from risks posed by articles as entry 28 already provides in relation to substances and mixtures.

The wording of paragraph 5 of entry 50 was extensively discussed in several meetings of the REACH Committee, as reflected in the respective minutes, and the intention is particularly clear in the approved minutes of the meeting of 22-23 February 2013, where it is stated that *“SE proposed to replace the whole term by ‘foreseen to be used by general public’. COM indicated that changing the wording would entail the risk to include many professional and even industrial products, which would not be proportionate in the context of a measure the main target of which are consumers (general public).”*

Interpretation 2 set out below would introduce uncertainty in many sectors of manufacturing and the integration of articles in industrial or professional contexts, even where such articles were ultimately used by consumers only occasionally or incidentally. Examples of this include:

- Rubber elements in the handrails of escalators, lifts and other parts of public buildings etc. These elements are manufactured industrially and are installed by professionals. However incidental exposure of consumers using these facilities and premises is possible.
- Plastic or rubber elements in the seats and other parts of trains, aircraft, ships, etc. used by the public. Manufacture and assembly is industrial but occasional use by consumers may lead to exposure to PAHs.

None of these examples seem to have been the objective of the restriction voted on in the REACH Committee. It is recognised that under interpretation 1, articles sold to professionals and intended for subsequent use by consumers would be excluded from the restriction, for example bed linen, furniture and appliances supplied to hotels, restaurants, schools and so on.

However, in practice, any risk to consumer health would be limited because manufacturers of such articles generally use the same production lines and processes for the manufacture of articles that will be supplied to professionals (and could then be used by consumers) and articles intended for sale to consumers.

Of course, any case that is not covered by the restriction as construed in accordance with interpretation 1 which might realistically lead to consumer exposure equivalent to that from articles sold directly to consumers can be addressed by new restrictions. In that event, Member States considering that there are risks that need to be addressed are encouraged to come forward with proposals.

INTERPRETATION 2

The restriction on placing on the market for supply to the general public covers the supply of tiles/mats used on public playgrounds and synthetic turf used on artificial sports fields, both made from recycled tyres.

Arguments supporting this option are the following:

1.- Purpose of the restriction: protection of the general public

The purpose of a restriction is to avoid exposure to a substance of the people (or the environment) by following the conditions specified in the restriction. Therefore its terms should be analysed within that purpose.

A restriction "for placing on the market for supplying to the general public" intends to avoid that the 'general public' is exposed to a particular substance by means of banning the 'placing on the market' of an item to be supplied to them. Therefore the terms of the restriction should be interpreted in a way ensuring that the placing on the market for supply to the general public which leads to an exposure of the substance to that general public is precluded.

2. Analysis of the terms of the restriction: "placing on the market for supplying to the general public"

Article 3(12) REACH defines 'placing on the market' as "*supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market*".

Where a definition is not given in the legislation, it should be attended to the general meaning of the terms. In this sense:

- '*To Supply*' is defined as "*Make (something needed or wanted) available to someone; provide*"¹.

- '*available*' means "*Able to be used or obtained; at someone's disposal*"². Therefore 'making something available' to someone means to put it at his disposal, to make it able to be used by that person.

¹ Oxford dictionary, <http://www.oxforddictionaries.com/definition/english/supply>

Therefore the meaning of "supplying" covers also the one of 'making available'. . This is confirmed by the definition of 'supplier' in Article 3(32) ("*Supplier of a substance or a mixture means any manufacturer, importer, downstream user or distributor **placing on the market** a substance, on its own or in a mixture, or a mixture*").

'Making available' is seen as the passive form of providing, while 'supply' is the active form of providing. In this sense 'making available' would mean that a third party has access to the item that has been put at his disposal, while 'supply' would include any action by which the supplier provides the item to that third party.

It should be highlighted that the definition in REACH of '*placing on the market*' does not limit the means by which an item can be supplied or made available. Therefore it covers all ways, direct or indirect, including in the context of the provision of a service for use by someone else. Moreover, as regards the 'supply' as active form of providing an item, the means by which it can be supplied depends also on the item itself, on its purpose, and on the recipient.

For example: soft playground tiles are placed in a public garden or communal playground, being the product provided by both, the operator installing the tiles (service to the town hall) and by the municipality (making it available to the citizens).³ The act of installing the tiles would cover the supply to the town hall and to the general public, at the same time. Since the communal playground is for all the citizens the town hall supplies it to them by ensuring they are placed physically in the city's property and putting them at the disposal of the citizens. Therefore by that action, the town hall has supplied the citizens with the playground and all its components (swings, slides, tiles, etc).

It should be noted that REACH does not subject placing on the market (supply or making available) to payment in return, therefore not constraining the concept of supply or making available into that of a sale (which is by definition in return of payment).

As regards the supply/making available within the provision of a service it is relevant who, by the provision of that service, would be exposed to the relevant substance: the professional providing the service, the recipient of the service or both?

The fact that REACH does not specify in the definition of placing on the market that it also covers the 'supply' or 'making available' through the provision of a service does not mean that it is excluded, since the definition is worded in general terms and making available or supplied through the provision of a service is just one way to comply with the definition. Moreover, a "supplier" can be a downstream user, not just a distributor (Article 3(32) REACH). This confirms that 'supply' or 'making available' can also happen within the development of a professional/industrial activity, such as being tattooed in a tattoo parlor by a professional tattoo artist.

² Oxford dictionary, <http://www.oxforddictionaries.com/definition/english/available>

³ Both of these supplies even involve a financial component within the supply, as the products provided by the town hall are actually paid by public funds (taxpayer's money) and therefore the general public.

Consequently, a restriction for placing on the market for supply to a third party precludes that an item is supplied or made available to that third party, including through the provision of a service.⁴

'General public':

There is no definition in REACH of what 'general public' means. From recitals (4) to (7) in Regulation (EU) No 1272/2013⁵ it follows that the intention of the restriction is to protect consumers, for which there is not a definition in REACH either, albeit being mentioned in some definitions (Article 3(13) and (35) and in other provisions (Article 33(2)). The use of 'general public' instead of 'consumer' indicates that the scope of the restriction is wide.⁶

Article 3(13) defines 'downstream user' as "*any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. (...)*". Equally, Article 3(35) defines 'recipient of an article' as "*an industrial or professional user, or a distributor, being supplied with an article but does not include consumers*". Although these definitions refer to the use of a substance or

⁴ For some similarities it is worth to refer to the Products Safety Directive (Directive 2001/95/EC), which in recital (9) states: "*This Directive does not cover services, but in order to secure the attainment of the protection objectives in question, its provisions should also apply to products that are supplied or made available to consumers in the context of service provision for use by them. The safety of the equipment used by service providers themselves to supply a service to consumers does not come within the scope of this Directive since it has to be dealt with in conjunction with the safety of the service provided(...)*" and to attain that purpose Article 2(a) specifies that 'product' means "*any product -including in the context of providing a service- which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new used or reconditioned*". Also within the framework of product liability (directive 85/374/EEC concerning liability for defective products products) products are put into circulation, if they are used within a service.

It may also be worth to refer to the ECJ judgment in case C-203/99 where, in the context of Directive 85/374/EEC the ECJ ruled that "*a defective product is put into circulation when it is used during the provision of a specific medical service, consisting in preparing a human organ for transplantation, and the damage caused to the organ results from that preparatory treatment*"

⁵ (4) Information submitted by Germany to the Commission indicates that *articles containing PAHs may pose a risk to consumers' health by ingestion, dermal adsorption and, in some cases, by inhalation.*
(...)

(6) The Commission evaluated the information provided by Germany and concluded on the existence of a risk to consumers posed by articles containing PAHs, indicating that a restriction would limit the risk. The Commission also consulted industry and other stakeholders on the impact of restricting the presence of PAHs in articles that could be used by consumers.

(7) In order to *protect the health of consumers* from the risk arising from exposure to PAHs in articles, limits on the PAH content *in the accessible plastic or rubber parts of articles* should be set, *and the placing on the market of articles* containing any of the PAHs in concentrations greater than 1 mg/kg in those parts *should be prohibited*.

⁶ Other restrictions (Benzene, Creosote, Azocolourants and Azodyes) use the term 'consumers'.

the receipt of an article, they may be used to support that in REACH the context in which an item is used is relevant for the definition of a consumer under REACH. (i.e. for other purposes than carrying out industrial or professional activities).

Following the above, the target of this restriction is to protect the general public (beyond the concept of consumer) as opposed to industrial or professional users. This means that articles placed on the market for supply to industrial or professional users are not covered by the restriction. The exclusion of supply for industrial or professional use was intended in the negotiation of the restriction, as reflected in the minutes of the REACH Committee.

However, since the target in this restriction is the general public (and therefore the driver of the interpretation), the fact that an article is placed on the market for supply to both, the general public and a professional, does not exclude it from the restriction, but only the placing on the market for the general public will be subject to the restriction. Only when the item is placed on the market for supply for professionals only (e.g. over the counter) the item is excluded from the scope of entry 50(5).

3. Restriction for 'placing on the market for supply to the general public':

Taking into account the previous points, a restriction for placing on the market for supply to the general public limits the access by the general public to a particular item. **The target is the general public**, regardless of the means by which the item may be put at its disposal (i.e. regardless of the means by which it is supplied).

In the case that the item is supplied or made available in the context of a professional activity, the fact that the supply to a professional (first step) may not be covered by the wording "*placing on the market for supplying to the general public*" does not imply that the supply or availability made to the general public (second step) is not covered either. The supply or availability made to the general public is covered by the restriction in any case, whoever or by whatever means is supplied or made available to the general public.

For example:

1) mat/tiles placed on public playgrounds: A professional installs the tiles in the playground. There is a restriction to place on the market for supply to the general public such an article due to the substances it contains.

There are two "supply steps" here:

- The 'tiles' company supplying the tiles to the town hall which may also provide its installation. The professionals installing the furniture may not be covered by the restriction.
- The town hall, which puts the playground at the disposition of the general public. The citizens, in particular children, who are in contact with these articles, are not using them in order to develop their particular professional activity. These articles are not a tool for their professional activity. Therefore the supply of the playgrounds to the citizens would be covered by the restriction.

For the case that the playground were in a kindergarten or school or in a private playground/amusement park, the same logic would apply. It may be argued that the

supply/installation to the legal entity (school, kindergarten, amusement park) is carried out in the context of a professional activity and it is not covered by the restriction. The teachers are also professionals. However the children supplied with the playground are not professionals and therefore are not using them in the context of their professional activity.

2) Synthetic turf used on artificial sports fields owned by a professional private company (e.g. a football club):

As in the previous examples there are two different supply steps: one by the "turf company" to the football club, which would be excluded from the restriction, and another one from the football club as legal entity to the third parties of whom it puts the football field at their disposal.

When those third parties are professionals (e.g. professional football players), the supply by the football club is not covered by the restriction. However, the football club would not be allowed to put the football field at the disposal of non-professionals, since in that case, it would be covered by the restriction (e.g. juvenile teams, to be used for concerts or open to the general public for non-professional activities).

4. Final remarks

It can be concluded that supply, making available and placing on the market are all interrelated and their definitions are circular, in that they are all used to define each other. Therefore, supplying is understood to mean actively providing something and passively making it available, and includes for example provision of a product/article within a service.

There is however no limitation in terms of payment being needed in return, and therefore the concept of sale is far too narrow in this context.

Furthermore, interpretation 1 as set above would introduce huge problems for enforcement as it will be almost impossible for authorities to distinguish the articles sold to professionals and intended for subsequent use by consumers (that interpretation 1 excludes from the restriction) with the (very same) articles placed on the market to be sold to the general public (that interpretation 1 finds are within the scope of the restriction).

B. Are synthetic turf and rubber mats/tiles installed in public places ‘articles’?

In relation to entry 50 of Annex XVII to REACH, this question is only relevant if interpretation 2 is considered to be the correct one and “for supply to the general public” means that the restriction covers articles that were supplied to professionals and are accessible to and capable of being used by the general public. If interpretation 1 is correct, the mere use of these products by members of the public in premises accessible to them (but in the absence of any actual sale of those articles to them) is not within the scope of the restriction.

So far, the Commission's legal interpretation in relation to buildings, which was required in discussions about the interpretation of the restriction in entry 6 of Annex XVII has been:

“buildings do not constitute “articles” for the purposes of Article 3(3) - so long as they remain fixed to the land on which they stand. The same applies to other large structures such as bridges. Smaller objects affixed to land such as garden swings or garden statuary are probably to be treated in the same way. However, once again, if the objects are removed, then they constitute “articles”.”

Therefore, according to this interpretation and insofar as synthetic turf and rubber tiles/mats that are permanently fixed are considered part of the facility or premises where they have been laid, arguably they will not be “articles” for the purposes of entry 50 of Annex XVII.

It must be noted that the Commission's interpretation in relation to buildings took as a starting point the definition of ‘article’ and its further interpretation as reflected in the guidance on substances in articles, which is currently being revised on the basis of the Court judgement in case C-106/14. This interpretation may, therefore, be subject to change.

Furthermore, as regards the rubber crumb infill used in synthetic turf, the rubber is present in the form of loose small granules which are comparable to pellets for plastic materials. As in the case of such pellets, these granules are not articles but mixtures. To the extent that a product containing PAHs is considered a mixture rather than an article, it will fall within the scope of entry 28 of Annex XVII which imposes a limit of 0.01% for benzo(a)pyrene and of 0.1 % for other PAHs classified as Carc 1B. If Member States or the Commission consider these limits too high they are free to propose modifications through an Annex XV dossier.

Action Requested: The REACH Competent Authorities are invited to express their opinions in relation to the two interpretations in Part A and their views on Part B.