

From: GROW D1
Sent: 27 October 2015 09:01
To:
Subject: FW: Question re Annex to Regulation (EU) No. 1272/2013

Dear

In response to your question whether "plastic bottles of the type that hold beverages" would be within the scope of the restrictions on PAHs in paragraphs 5 and 6 of entry 50 of Annex XVII to REACH, we consider that:

- This depends on the pattern of use of such bottles and whether there is "direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity". In that sense the description of the contact conditions refers to the use made of each individual article and therefore it is irrelevant if it is a single use (disposable) article or a multiple-use bottle.
- ECHA is currently working on a guideline, in support of the interpretation of the PAH restriction on articles. It will contain a number of illustrative examples of articles which according to ECHA and the Commission are included in or excluded from the scope of the restriction. A draft of this guideline will soon be submitted to public consultation.
- Although the guideline is not yet finalised, we cannot exclude that in normal use, dermal contact with a bottle, via both hands and lips, could be considered "short term repetitive contact".

It should be noted, though, that the considerations above are only applicable if there are indications that the material of which the bottle is made could actually contain PAH in concentrations that could exceed the content limits set out in paragraphs 5 and 6 of the entry, as applicable. It would be up to the manufacturer of the bottle to assess whether the raw materials used could contain PAH. In the event of having to demonstrate compliance with the restriction, relevant product declaration certificates from suppliers of the plastic material or, ultimately, analytical confirmation on a representative number of samples, should suffice.

Finally, plastic beverage bottles need to comply Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

Sincerely,
 REACH Unit



European Commission
 DG Internal Market, Industry, Entrepreneurship and SMEs

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From: [mailto:____]
Sent: Wednesday, September 23, 2015 11:15 AM
To: (ENV)
Cc:
Subject: Question re Annex to Regulation (EU) No. 1272/2013

Dear

We spoke some time ago in relation to a question that I had on the Annex to Regulation (EU) No. 1272/2013 amending Annex XVII of the REACH Regulation as regards polycyclic aromatic hydrocarbons ('PAHs').

Specifically, as you know, the Annex to this Regulation provides that

"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.

Such articles include amongst others:

- sport equipment such as bicycles, golf clubs, racquets
- household utensils, trolleys, walking frames
- tools for domestic use
- clothing, footwear, gloves and sportswear
- watch-straps, wrist-bands, masks, head-bands...."

Our specific question is whether the Commission would consider plastic bottles of the type that hold beverages "as articles 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", or whether the Commission's response would be dependent on whether the plastic bottles in question are repeated use or single use items? At the time you requested that I send this question to you in writing as you would like to consider it further. Hence, I am now doing this.

We also understand that the ECHA is working on a guidance document regarding the above Annex (I believe that you mentioned that you expect it to be published by early 2016). Hence, we simply wanted to check if the anticipated timing for publication remains the same, and if it would be possible to obtain further information regarding the draft guidance document that would be of relevance to our question.

We look forward to hearing from you, and thank you for your help.

Best regards,

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