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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies

Directorate-General for Environment
Green Economy

Directors

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NOTE FOR THE ATTENTION OF MR G. DANCET, EXECUTIVE DIRECTOR ECHA

Subject: Request to the European Chemicals Agency to prepare restriction proposals conforming to the requirements of Annex XV to REACH

In accordance with Article 69 (1) of the REACH Regulation, we would like to request ECHA to prepare Annex XV dossiers in view of three possible restrictions on lead (metal) in shot, lead compounds as stabilisers in PVC, and tattoo inks, as set out below.

We also take this opportunity to draw your attention to further possible restrictions on formaldehyde for which ECHA should conduct preliminary work.

Lead (metal) in shot

As lead in shot may pose a risk to human health and the environment, and particularly to aquatic bird species, which is currently not adequately controlled and may need to be addressed on a Union-wide basis, the Commission hereby requests ECHA to assess this risk and the need for European Union-wide action beyond any national measures already in place.

The need for harmonisation of the use of lead in shot in wetlands is a priority as national legislation has already been enacted by some Member States (or regions in some Member States) further to international action through the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) under the auspices of the UN Environment Programme (UNEP) to which the EU is a Party. Therefore we would like to ask ECHA to prepare immediately an Annex XV dossier for a potential restriction in order to properly control the risk to the environment and human health in the Union. Any aspect related to the contamination of food and related exposure to consumers should be discussed with the specific service of the Commission, i.e. DG SANTE.

For any other uses of lead ammunition, including hunting in other terrains than wetlands and target shooting, as well as, for the use of lead weights for fishing, we would like to ask ECHA to start collecting information for the assessment of the risk and the socio-



economic impact with a view, except if no risk can be demonstrated, to preparing another Annex XV dossier for restriction.

When collecting such information ECHA should assess aspects of animal welfare such as avoided suffering of animals in the context of hunting and aspects related to potential accidents to hunters and sport shooters of lead ammunition and its alternatives. Particular attention should be paid to the differences of different types of ammunition (e.g. bullets, pellets, shot, etc.). Military use of ammunition should be excluded. The details of this second Annex XV dossier will be further discussed with DG GROW and DG ENV.

Timing

ECHA should prepare a short RMOA justifying that a restriction is the most appropriate regulatory measure. This conclusion will be published in the Public Activities Coordination Tool (PACT). Following this, ECHA shall enter the relevant intention into the Registry of Intentions (RoI) for lead in shot in wetlands. We expect this work to be done within two months of receipt of this note.

Within 12 months after the entry in the RoI, ECHA should communicate its conclusion to the Commission and initiate the restriction process, should the Annex XV dossier demonstrate that action on the use of lead in shot in wetlands beyond any measures already in place is necessary on a Union-wide basis.

In parallel with the preparation of the Annex XV dossier for the use in wetlands, ECHA will start collecting information for all the other uses of lead ammunition and of weights for fishing with a view to possibly prepare another Annex XV dossier for restriction in the future. The timing should then be further discussed with DG GROW and DG ENV.

Lead compounds as stabilisers in PVC

Under the voluntary commitment VinylPlus, the European industry has committed to eliminating as of 2015 the use of lead compounds as stabilisers in new PVC materials and articles. However, not all producers of PVC are participating in VinylPlus and imports of articles containing lead from outside of the EU may still occur. In addition, under the same voluntary commitment, significant amounts of post-consumer PVC containing lead stabilisers from the past are being recycled.

Lead released from articles produced from recycled PVC or from new PVC materials containing lead compounds as stabilisers may pose a risk to human health or the environment. The Commission hereby requests ECHA to assess this risk and the need for European Union-wide action beyond any measures already in place, and to prepare an Annex XV dossier for a potential restriction. During the preparation of the Annex XV dossier specific attention should be given to the risks associated with the presence of lead in recycled PVC and to the socio-economic impact of a potential restriction in order to have a robust assessment on recycled PVC which should consider all the specific technicalities such as the concentration limit of lead in recycled PVC, the availability of analytical methods and the potential impact on operators working in the recycling sector.

Timing

ECHA should enter the relevant intention into the RoI as soon as the precise scope of the work is agreed in consultation with DG GROW and DG ENV and an RMOA conclusion has been published in PACT. We expect this work to be done within two months of receipt of this note.

Within 12 months after the entry in the RoI, ECHA should communicate its conclusion to the Commission and initiate the restriction process, should the Annex XV dossier demonstrate that action on a Union-wide basis is necessary to limit the use of lead compounds as stabilisers in PVC beyond any measures already in place.

Tattoo inks

The composition of tattoo inks raises numerous concerns for public health (e.g. allergies caused by substances used in inks and possible carcinogenicity).

Several Member States already have national legislation in place that regulates, among others, the chemical composition of tattoo inks, while other Member States recently notified national measures under Directive 98/34/EC. These were blocked by the Commission to the extent that they concerned the chemical composition of tattoo inks, because such national measures are incompatible with the harmonising effect of the REACH restrictions title. The Commission will provide this information to ECHA as well as any other relevant information in its possession.

As the chemicals classified as CMR or skin sensitisers contained in tattoo inks pose a risk to human health that is currently not adequately controlled and needs to be addressed, the Commission asks ECHA to assess this risk and assess relevant socio-economic impacts and the need for European Union-wide action beyond any national measures already in place by preparing an Annex XV dossier for restriction. A recent report from the Commission's JRC provides a comprehensive overview of the regulatory situation in the Member States and in some 3rd countries, as well as of analytical measures that can be used to detect substances in tattoo inks¹.

The Annex XV dossier should address all substances listed in the Council of Europe resolution ResAP(2008)1² and potentially any additional substances with a harmonised classification as CMR Cat. 1(a) and 1(b) or as skin sensitiser. Due to the complexity and high number of substances concerned, we would like to discuss with ECHA the best way to prepare the Annex XV dossier, potentially with the involvement of some Member States (e.g. by grouping substances on the basis of their hazard classes (skin sensitisers, CMRs)), and the possibility to use Article 68(2) for CMRs in order to reduce the workload.

Timing

ECHA and possibly Member States acting as Dossier Submitters should enter the relevant intention into the RoI as soon as the precise scope of the work is agreed in consultation with DG GROW and DG ENV. We expect this work to be done after the workshop in January 2016 on the application of the recommendations of the task force on restriction.

That workshop will be an occasion to present the best way to prepare restriction proposals for all substances concerned. This will be a good opportunity to apply the recommendations of the task force and can become a model for a more streamlined restriction process.

¹ http://publications.jrc.ec.europa.eu/repository/bitstream/JRC94760/wp1_tr_pubsy.pdf

² http://www.coe.int/t/e/social_cohesion/soc-sp/resap_2008_1%20e.pdf

Formaldehyde and formaldehyde releasers on their own, in mixtures or in articles used by workers, professionals or consumers

Formaldehyde is included in the Community Rolling Action Plan (CoRAP) for evaluation of consumer emission/exposure which has already led to a decision by ECHA requiring registrants to provide data. We would like to ask ECHA to inform the Commission on the current situation in CoRAP.

Based on a request by the Commission³ the Scientific Committee on Exposure Limits (SCOEL) has recently started to review their scientific opinion and the 2008 recommendation on occupational exposure limit values for formaldehyde. The reply to the Commission is expected for 20 December 2015.

We are also aware that France has made public in PACT its intention to prepare a RMOA on formaldehyde for industrial and professional use and, if agreed, ECHA would cooperate with France in their preparation of the RMOA. DG GROW and DG ENV will contact the French Authorities to clarify their intention and foreseen timing.

In addition, the Commission would like to ask ECHA to collect information on formaldehyde releasers, such as a list of known formaldehyde releasers, uses of such releasers other than for biocidal purposes etc. in order to assess if they should be part of a possible Annex XV dossier on formaldehyde.

As some releasers used as preservatives are listed in the Cosmetic Products Regulation 1223/2009, we would like to ask ECHA to start with the list provided in Annex V of that Regulation. This investigation will not be part of the preparation of an RMOA by France.

Once the situation becomes clearer, the Commission will consider whether to request ECHA to prepare an Annex XV dossier for restriction on formaldehyde.

Yours sincerely,

(e-signed)

Carlo Pettinelli
DG Internal market, Industry,
Entrepreneurship and SMEs

(e-signed)

Kestutis Sadauskas
DG Environment

³ <https://circabc.europa.eu/d/a/workspace/SpacesStore/b72e6fc9-98c7-4379-a173-f090ce783d89/2015-05-04v03%20Mandate%20COM%20to%20SCOEL%20on%20Formaldehyde%2020DEC2015.pdf>