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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 assess whether the presence of certain substances in recycled rubber granules used as infill in synthetic turf could pose a risk to human health;
- to assess whether the presence of bisphenol S in thermal paper could pose a risk to human health;
- to review the derogation for cadmium and its compounds in mixtures and articles containing recovered PVC.

Recently, concerns have been raised that the placing on the market and use of recycled rubber granules for use as infill in synthetic turf, and of bisphenol S (BPS) in thermal paper, may pose risks to human health that are not adequately controlled. Accordingly, to enable the Commission to consider whether, for the purposes of Article 69(1) of REACH, there are such risks that need to be addressed, the Agency is hereby asked to conduct preliminary evaluations.

In addition, pursuant to paragraph 4 of entry 23 of Annex XVII to REACH, the Commission must review the derogation contained therein, in particular with a view to reducing the maximum cadmium content permitted in mixtures and articles containing recovered PVC in specified rigid PVC applications and to reassess the derogation for applications listed in points (a) to (e) of paragraph 4 of entry 23. In order to enable the Commission to carry out this review, the Agency is requested to carry out an assessment of the current situation and future trends regarding the cadmium content of post-consumer rigid PVC recyclate and, if appropriate, to prepare an Annex XV restriction dossier, pursuant to article 69(1) of REACH.

Rubber granules used in synthetic turf

In the light of the discussion during the 20th CARACAL meeting on 8 March 2016 and the input received subsequently from Member States, there is a need to evaluate the risks potentially posed to human health by the presence of certain substances in rubber

granules, obtained from end-of-life tyres, which form part of the synthetic turf used in sports grounds. To assist with this evaluation, the Commission will forward to the Agency all relevant studies already in its possession that were conducted by Member States¹. Furthermore, ECHA should take into account relevant international and regional activities in this area, such as recent research actions on recycled tyre crumb used on playing fields, launched by the US-EPA².

The investigation by the Agency should aim to identify any relevant hazardous substances (including in particular carcinogenic polycyclic aromatic hydrocarbons (PAHs)) contained in recycled rubber granules that may pose a risk to human health in relation to the use of the granulate as infill in synthetic turf. Risks to be evaluated should cover those resulting from dermal, oral (including from ingestion of rubber granules), and inhalation exposure to the relevant substances arising from the reasonably foreseeable use of synthetic turf in both, open air and indoor installations, by the general population (including children) and professionals.

Timing

ECHA should finalise its preliminary evaluation by January 2017. The ECHA evaluation should be structured in the format of a RMOA and the conclusion should be made public in PACT in February 2017.

On the basis of the conclusions, the Commission will consider whether there is a risk to human health that is not adequately controlled and needs to be addressed and, if so, will ask the Agency to prepare an Annex XV dossier for restriction. The precise scope of a possible Annex XV dossier in terms of substances to be addressed, uses of rubber granulate infill, and activities (e.g. sports and recreation) to be covered will be discussed with the Agency on the basis of the results of this preliminary evaluation.

Bisphenol S

During the restriction process for bisphenol A (BPA) in thermal paper, the Risk Assessment Committee (RAC) noted in its opinion that, according to the submitter of the Annex XV dossier (France), the most likely substitute for BPA, BPS, may have a toxicological profile similar to BPA and may cause similar adverse health effects. A recent substance evaluation decision on BPS requested to the registrant to provide data on hazard and exposure. Therefore, in order to avoid the adverse effects of BPA being merely superseded by equivalent adverse effects of BPS, the trend towards substitution of BPA with BPS should be carefully monitored.

Consequently, ECHA should launch a survey in the course of 2017, in order to:

- verify if BPS is used in thermal paper and what are the volumes;
- verify if thermal paper manufacturers are substituting BPA with BPS.

¹ At the 20th CARACAL the Commission asked Member States to forward available studies on the safety of recycled rubber infill material to the Commission or to ECHA.

² https://www.epa.gov/chemical-research/federal-research-recycled-tire-crumbs-used-playing-fields

Timing

The results of the survey should be delivered by end of 2017 and be structured in the format of a RMOA. The conclusion should be made public in PACT in early January 2018. If the survey shows the substitution of BPA with BPS and depending also on the availability of hazard and exposure data from the substance evaluation of BPS, the Commission will evaluate whether there is a risk to human health that is not adequately controlled and needs to be addressed and, if so, will ask the Agency to prepare an Annex XV dossier for restriction.

Cadmium and its compounds in recovered rigid PVC

In order to review the existing derogation for cadmium and its compounds, as required by paragraph 4 of entry 23 of Annex XVII to REACH, the Commission requests ECHA to:

(i) determine, based on the most up-to-date data available, the current quantities and average cadmium content of post-consumer rigid PVC waste and of recovered PVC obtained from it, related to the applications referred to in points (a) to (e) of that paragraph ["profiles and rigid sheets for building applications; doors, windows, shutters, walls, blinds, fences and roof gutters; decks and terraces; cable ducts; pipes for non-drinking water if the recovered PVC is used in the middle layer of a multi-layer pipe and is entirely covered by a layer of newly produced PVC in compliance with paragraph 1 above"].

Estimations of cadmium content and projections of cadmium content in recovered rigid PVC which served as a basis for the existing derogation [VITO report 2009/TEM/R/189] should be reviewed and updated, together with a targeted impact assessment which should address different lower maximum cadmium limit values in recovered PVC down to the full elimination of the derogation.

(ii) review the hazards associated to cadmium as well as the risks associated to the use of recovered PVC containing cadmium. The review should be based on the available information from studies conducted in the EU or abroad, including reports from industry.

Timing

ECHA should finalise its evaluation report no later than 1 September 2017. Based on this evaluation, the Commission will consider whether to request ECHA to prepare an Annex XV dossier in accordance with Article 69(1) to launch the procedure to amend the derogation granted in paragraph 4 of entry 23, in particular with a view to reducing the limit value for cadmium and/or to revoke the derogation for one or all of the applications listed in points (a) to (e) of that paragraph.

Yours sincerely,

(e-signed)

Carlo Pettinelli DG Internal Market, Industry, Entrepreneurship and SMEs (e-signed)

Kestutis Sadauskas DG Environment