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ETAD communication on the dyes listed in REACH Annex III inventory January 2017

Background

As part of its activities aimed to identify substances of concern ECHA recently screened many chemical structures using various prediction tools. The results of this screening were summarized in an inventory of chemicals evaluated as potentially meeting the criteria of Annex III to the REACH Regulation. **Among the screened substances are several dyes**, considered as of possible concern as regards different CMR properties and environmental effects.

Is there an immediate effect on the classification of the dyes?

No. As clearly stated by ECHA on the inventory webpage *"the inventory is not a tool for classification, it only shows indications for concern. For instance, the fact that a substance is indicated as "Suspected mutagen" does not mean that ECHA considers it as a classified mutagen. All evidence should be taken into account before concluding on the need for classification."*

How are manufacturers of these dyes affected?

The substance screening had the practical aim to help identify whether a dossier could be submitted with the reduced minimum information requirements (data on physicochemical properties only) or when a full Annex VII information set is required. In fact, even when a substance is listed in the inventory a company will still be able to submit a dossier with reduced information requirements if the dossier provides a well-grounded justification of why the predicted concern can be disregarded. Alternatively, the substance will need a standard information set.

What are manufacturers doing as regards these dyes?

Many of the dyes listed in the inventory are relevant products on the market and their registration had already been planned according to the REACH deadlines. Corresponding dossiers have already been submitted or are being prepared for the 2018 registration phase. As required by REACH, the dyes are evaluated taking into account all information available by the registrant(s) and creating new data when necessary. Either in the case of a standard registration or in order to prove that the concern found in the Annex III inventory can be disregarded, this evaluation has to be performed.

What about the final classifications?

A proposed classification, based on the conclusion from all available data, will be part of the corresponding dossiers submitted to ECHA and will be reflected, if needed, in the (re-)classification of products by members of the corresponding dye consortia. This information will be immediately available to the customers of the dye industry.

In a nutshell

A dye listed in the Annex III Inventory does not represent a proven concern for human health and for the environment but needs to be evaluated in detail. However, the expected evaluation is already part of the standard dossier preparation for dyes; any new information on their classification will be communicated and updated following already known and well-established procedures.