DIMETHYLFUMARATE

France proposes a restriction on dimethylfumarate

Dimethylfumarate (DMFu) has been used in furniture, clothing, shoes, etc. to prevent moulds that may deteriorate the product during transport and storage. Consumer articles containing DMFu can cause severe skin problems (dermatitis). Currently, there is a temporary ban that requires Member States to ensure that articles containing DMFu are not placed on the market. France proposed a restriction process under the REACH Regulation to make this temporary ban permanent.

PROPOSED RESTRICTION

The Commission Decision of 17 March 2009 requires Member States to ensure that products containing dimethylfumarate are not placed or made available on the market. This Decision is currently valid until 15 March 2011 by Commission Decision 2010/153/EU. France has prepared a proposal (so called Annex XV restriction report) with the aim to make this restriction permanent by introducing a restriction on DMFu in Annex XVII of the REACH Regulation.

The conditions of the proposed restriction are the following: Articles containing DMFu in concentration greater than 0.1 mg/kg are prohibited from being produced and placed on the market.

The restriction would apply to all types of articles which contain DMFu. The concentration of 0.1 mg/kg should be considered for each individual part of the article. If a part has a DMFu concentration which exceeds this limit, it should be considered that the article is not allowed to be produced or placed on the EU market. Manufacturing and import of the substance DMFu itself are not included in the restriction proposal.

According to the report no derogations are needed. The restriction shall apply as soon as the amendment of Annex XVII of the REACH Regulation enters into force.

The biocidal use of DMFu is already prohibited under the Biocides Directive (98/8/EC). However, as treated articles fall outside the scope of the Biocides Directive it has been possible to import DMFu containing articles in the EU. Therefore, the aforementioned temporary ban was introduced to control the import of such articles.

THE USE OF DMFu

DMFu is used to protect articles such as furniture, shoes and clothes from mould during storage and transport.

The report suggests that the presence of DMFu in articles may result from at least two processes:

- DMFu can be incorporated in little sachets that are in contact with the article and the substance can thus migrate to the article from these sachets, or/and
- a DMFu preparation can be sprayed either on the articles themselves or inside the containers which are used for transport and storage.

In either case, residues of DMFu may remain in the articles afterwards. This can cause skin problems in consumers.

REASONS FOR ACTION

Recently, articles containing DMFu have been identified as causing dermatitis in several Member States. According to the report, the patients have been diagnosed with a severe dermatitis and a few cases even required hospitalization. The dermatitis affected the part of the body in contact with the article, e.g. the feet, trunk, limbs, buttocks and even the face. The severity of the risk is significant - skin lesions can be severe and sensitisation is an irreversible effect.

Without a restriction all potential consumers including vulnerable sub-groups throughout the EU could be exposed.

CONSEQUENCES OF THE ACTION

The restriction proposal aims to make the existing temporary ban permanent. According to the report, making the ban permanent will have no additional economic impacts. Technically and economically feasible alternatives to DMFu exist and are used in the EU.

The positive health impacts are the same as of the current temporary ban.

COMMENTS PREFERABLY BY 21 SEPTEMBER

The ECHA Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) received the restriction report from France on 3 May 2010. The opinion forming of the committees starts with a public consultation in June 2010. In October 2010 the Rapporteurs of RAC and SEAC will discuss in detail the restriction report. Therefore they would appreciate receiving comments by 21 September 2010. The public consultation is however open until 21 December 2010. Thus, there is a possibility to submit comments till then.

The RAC is scheduled to give its final opinion on the proposed restriction by 21 March 2011. SEAC will give its draft opinion at the same time. This draft opinion will be placed on the internet for public consultation. SEAC is scheduled to give its final opinion on the proposed restriction by 21 June 2011. ECHA will send these two opinions to the European Commission which will take the decision as whether to introduce the suggested restriction in Annex XVII of the REACH Regulation.

Submit comments on the restriction report

FURTHER INFORMATION

- Annex XV restriction report
- Restriction process - Description of the whole restriction process including information on different steps and statuses mentioned in the table.
- Press release: ECHA calls for information on the first two proposals for restriction under REACH