Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Dimethylfumarate (DMFu)

Draft

9 March 2011

Annankatu 18 | P.O. Box 400 | 00121 Helsinki | Finland
www.echa.eu | Tel.: + 358 9 68.61.80

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Opinion of the Committee for Socio-economic Analysis
on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the Community

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation [and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation] on the proposal for restriction of

Chemical name(s):	***Dimethylfumarate***
EC No.:	***210-849-0***
CAS No.:	***624-49-7***

This document presents the draft opinion as agreed by SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

France has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The dossier conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at ***http://echa.europa.eu/consultations/restrictions/ongoing_consultations_en.asp*** on ***21/06/2010*** Interested parties were invited to submit comments and contributions by ***21/12/2010***.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***9 March 2011***

The draft opinion takes into account the comments of and contributions from the interested parties provided in accordance with Article 69(6) of the REACH Regulation

The draft opinion was published at *http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp* on ***18 March 2011*** Interested parties were invited to submit comments on the draft opinion by 17/05/2011.

OPINION

SEAC has formulated its opinion on the proposed restriction based on information related to the socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document SEAC considers that the proposed restriction on dimethylfumarate (DMFu) is the most appropriate Community wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs.

The conditions of the restriction proposed by SEAC are:

Dimethylfumarate (dimethyl (E)-butenedioate), CAS 624-49-7, EC 210-849-0

- Shall not be used in articles or any parts thereof in concentrations greater than 0.1 mg/kg
- Articles or any parts thereof containing DMFu in concentrations greater than 0.1 mg/kg shall not be placed on the market

JUSTIFICATION FOR THE OPINION OF SEAC

Based on considerations related to the impact on health of consumers and also to internal market, economic impacts and availability of alternatives *(see section "Justification that the suggested restriction is the most appropriate Community-wide measure)*, an action is required at the EU-level concerning the production and the placing on the market of articles containing DMFu.

Justification that the suggested restriction is the most appropriate Community-wide measure

As the use of DMFu as a biocide is not allowed in the EU, and imported articles seem to have caused many of the observed cases of DMFu-sensitisation, the regulatory action need to focus on DMFu in imported articles (DMFu being present either in the articles themselves or in sachets added to the articles). A restriction under REACH would result in this.

The Biocides Directive, which is in the process of revision, is supposed to ban the placing on the market of articles, treated with biocides containing active substances not included in Annex I of the Biocides Directive. However, the exact scope of the restriction of treated articles and the timing of the entry into force of the new regulation are still unclear. So consequently, at least for a period of several years, the baseline situation will depend on the outcome of the re-examination of decision 2009/251/EC, which will have to take place every year. Furthermore, this situation might continue indefinitely in case the extended scope of the Biocides Directive will not cover articles as restricted in this restriction proposal.

No other EU legislation which may have the potential to reduce the identified risks was identified.

Taking no action, and not renewing the current ban under the Product Safety Directive, is not effective in protecting human health. Voluntary action is not practical given the many actors, complex supply chains and variety of industry sectors involved (furniture, textile, etc). Continuously renewing the ban under the Product Safety Directive is contrary to the intentions of that directive, and incurs higher regulatory costs. The Biocides Directive does not cover the relevant articles and uses. Based on this it is concluded that a restriction is the most appropriate and least onerous of the available measures.

Effectiveness in reducing the identified risks, proportionality to the risks

Under REACH only a restriction will cover articles that are imported. The temporary ban entered into force in May 2009. No major problems of practicality or enforceability have been reported by stakeholders. A number of cases of DMFu in articles have been reported via the EU rapid alert system for dangerous consumer products, the RAPEX system, showing that enforcement authorities have been able to identify articles containing DMFu. Thus, experience from the current temporary ban shows that the proposed restriction, which is based on the temporary ban, is possible in practice, including that it can be enforced, and can be monitored through enforcement and gathering of information on reported cases. Although some cases of DMFu in articles are still reported, the current temporary ban seems to be generally effective. While there are no clear trends in the RAPEX notifications to date, the introduction of a restriction is likely to create an even greater international awareness. The proposed restriction is therefore likely to be effective in controlling the identified risks. Still it is acknowledged that further work on standardization and optimisation of sampling procedures and the analytical methods, as advised by the Forum for enforcement, would be helpful, both for enforcement authorities and the firms that need to comply with the restriction.

Some of the health effects from the use of DMFu in articles are irreversible and have in some cases led to the need for hospital care. The impacts of these health effects have not been monetised, but a number of recalls of furniture and shoes has been reported and insurers in the UK have agreed to compensation claims of between 1 400 to 11 200 EUR each (total of approximately 25 MEUR including legal costs) to more than 2000 persons for serious burns, eye problems and breathing difficulties caused by the use of DMFu in sofas. For a further 3 000 cases the liability is still reported to be in dispute. To this should be added the costs to health services and the cost for companies of recall or at least refund of articles. It should be noted that these numbers refers only to the UK, and only to sofas. Although compensation claims do not necessarily accurately measure welfare loss, they can in this case be seen as clear indication of such losses. Many other cases from at least eleven other Member States and involving other product-groups have been reported via RAPEX. It can be concluded that the benefits to both society and firms of not using DMFu in sofas outweigh the likely costs of using alternatives to DMFu. A similar overall conclusion is expected for other article types.

One of the main aims of REACH is to ensure a high level of protection of human health. Imposing restrictions under REACH is one measure for addressing risks to human health that are not adequately controlled. The proposed restriction aims to prevent adverse effects on

human health. The proposed restriction can therefore be justified, even with the existence of institutions for compensation for damage that has occurred.

Although the future use of DMFu in the baseline scenario (taking no action and no renewal of the current ban under the Product Safety Directive) cannot be predicted with any certainty, it is not unlikely that the use of DMFu would recur as the 'collective memory' of reported DMFu problems fades. That this may happen is supported by the facts that the relevant supply-chains are complex with new actors; that may not be familiar with the problem entering and other actors exiting the market. A Community-wide restriction would ensure that the use of DMFu remains regulated and would also mean an increased awareness of the problems with DMFu among all concerned parties, both outside and inside the EU.

No comments presenting any arguments for continued intentional use of DMFu in articles have been received during the stakeholder consultations when preparing the proposal or in the public consultation on the proposal as submitted by France. The practice of European exporters of shoes and sofas, who are not allowed to use DMFu because of the temporary restriction, clearly indicates that technically and economically feasible alternative methods of protection against mould formation are available.

Based on this, it is concluded that the restriction proposed is appropriate and necessary to achieve a high level of protection for human health and the disadvantages caused is not disproportionate to achieving this objective.

Practicality, incl. enforceability

Included in the text directly under heading "Effectiveness in reducing the identified risks, proportionality to the risks" above.

Monitorability

Included in the text directly under heading "Effectiveness in reducing the identified risks, proportionality to the risks"" above.

BASIS FOR THE OPINION OF SEAC

The Background Document, provided as a supportive document, gives the detailed grounds for the opinion.

The main changes introduced in the restriction as suggested in this opinion compared to the restrictions proposed in the Annex XV restriction dossier submitted by France are basically editorial by proposing in clear wording that the restriction applies to “any part” of the article. With this change, the footnote of the original French proposal (“The limit value should normally relate to individual articles, parts or materials that a complex article consists of”) is no longer needed. The basis for these changes is solely to make the text clearer. This reasoning is explained in more detail in the Background Document.

The opinion supports the restriction proposed in the Annex XV restriction dossier submitted by France.

Supportive documentation

Background Document