

## **Annex to a news alert ECHA/NA/17/05**

Helsinki, 21 March 2017

### **The Committee for Risk Assessment (RAC) adopted two opinions on the restriction proposal on the four phthalates (DEHP, DBP, DIBP and BBP) in articles and on TDFAs . The Socio-economic Analysis Committee (SEAC) agreed its draft opinions on the same proposals:**

#### **Four phthalates**

RAC adopted its opinion, in support of the proposal by ECHA and Denmark to restrict the four phthalates (DEHP, DBP, DIBP and BBP) in articles. The four phthalates are all classified as toxic to reproduction in category 1B and have a similar anti-androgenic mode of action.

RAC concluded that there is a need to address the risks from combined exposure to the four phthalates in articles. The recommendation is to ban phthalates in articles that cause exposure through the skin or by inhalation, such as flooring, coated fabrics and paper, recreational gear and equipment, mattresses, footwear, office supplies and equipment, and other articles moulded or coated with plastic.

SEAC agreed its draft opinion, in support of the proposal by ECHA and Denmark to restrict the four phthalates (DEHP, DBP, DIBP and BBP) in articles. SEAC concluded that the proposed restriction is the most appropriate EU-wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its costs.

#### **TDFAs**

##### **Restriction proposal of TDFAs (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives.**

RAC adopted its opinion in support of the proposal by Denmark to restrict the placing on the market of sprays used for the general public containing TDFAs (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives.

SEAC agreed its draft opinion in support of the proposal. SEAC concluded that the proposed restriction is the most appropriate EU-wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs.

The products should not be placed on the market if they contain TDFAs in a concentration equal to or greater than 2 parts per billion by weight in a mixture with organic solvents. Spray products comprise aerosol dispensers, pump and trigger sprays and mixtures marketed for spray applications.

The proposed restriction will apply 18 months after the amendment of the REACH Annex XVII comes into force. There are no uses that are proposed to be derogated (excluded) from the scope of the restriction.

## **Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) agreed on 19 draft opinions and adopted 3 final opinions on applications for authorisation:**

RAC and SEAC continued their work on 26 applications for authorisation. The committees agreed in total on 19 draft opinions on the specific uses of chromium (VI) substances, 1,2-dichloroethane (EDC) and bis(2-methoxyethyl) ether (diglyme).

According to the REACH Regulation, the agreed draft opinions will be sent to the applicants for comments before final adoption.

The committees also finalised their work on the three applications for authorisation by adopting the opinions on the industrial use of arsenic acid and chromium trioxide for the treatment of copper foil used in the manufacture of printed circuit board (applications submitted by Circuit Foil Luxembourg), and on the use of chromium trioxide in plating on plastics for automotive applications (submitted by Gerhardi Kunststofftechnik GmbH).

In between the December 2016 and March 2017 plenary meetings, the committees adopted 21 opinions on 15 applications for authorisation on the uses of chromium (VI) substances, EDC and diglyme. In these cases, the applicants did not wish to comment on the draft opinions of the committees, which were agreed earlier in 2016.

## **The Committee for Risk Assessment (RAC) adopted 5 opinions on harmonised classification and labelling:**

### **Glyphosate (ISO); N-(phosphonomethyl)glycine**

Glyphosate (ISO) is a herbicide used in plant protection products in agriculture and horticulture to destroy annual and perennial weeds and other unwanted plants. The substance already has an entry in Annex VI to CLP where it is classified as Eye Dam. 1 (H318) and Aquatic Chronic 2 (H411).

RAC concurred with Germany's proposal not to classify Glyphosate (ISO) for carcinogenicity, mutagenicity, reproductive toxicity, specific target organ toxicity after single exposure, acute toxicity for all routes of exposure, skin corrosion/irritation and skin sensitisation.

In addition, RAC agreed with the dossier submitter to retain the current harmonised classifications of Glyphosate (ISO) as causing serious eye damage (Eye Dam. 1; H318) and as toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411).

RAC did not follow the dossier submitter's proposals to classify Glyphosate (ISO) as a substance which may cause damage to organs through prolonged or repeated exposure (STOT RE 2; H373), and therefore decided on no classification for this hazard class.

For further information on RAC's opinion for Glyphosate (ISO), please see <https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa>

### **2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone**

2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone ("BDMBP") is used as a photosensitive agent in printing inks, pigmented coatings and photopolymers for imaging applications. BDMBP has an existing entry in Annex VI to the CLP Regulation where it is classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with no M-factors set.

RAC previously adopted an opinion for BDMBP, which concluded to add a harmonised classification as a presumed human reproductive toxicant in relation to developmental effects (Repr. 1B; H360D) to Annex VI.

In relation to the ongoing CLH proposal from Germany to remove the aquatic classifications from Annex VI, RAC did not agree and decided to retain the current classification.

### **Mandestrobin (ISO); (RS)-2-methoxy-N-methyl-2-[ $\alpha$ -(2,5-xylyloxy)-*o*-tolyl] acetamide**

Mandestrobin (ISO) is a fungicide used as an active substance in plant protection products. The substance does not currently have an entry in Annex VI to CLP. This means that all hazard classes had to be evaluated.

RAC agreed to Austria's proposal to classify the substance as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) and to assign an M-factor of 1 to the acute and an M-factor of 10 to the chronic aquatic classification.

### **Thiabendazole (ISO); 2-(1,3-thiazol-4-yl)-1H-benzimidazole**

Thiabendazole (ISO) is an active substance used in plant protection products as a systemic benzimidazole fungicide. It has an existing entry in Annex VI to the CLP Regulation where it is classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with no M-factors set.

RAC agreed to Spain's proposal to assign an M-factor of 1 to both the acute and the chronic aquatic classification.

### **Methylmercuric chloride**

Methylmercuric chloride is used as a laboratory chemical. The substance has an existing entry in Annex VI to the CLP Regulation where it is classified as part of the group of organic mercury compounds as Acute Tox. 2\* (H330; minimum classification), Acute Tox. 1 (H310), Acute Tox. 2\* (H300; minimum classification), STOT RE 2\* (H373\*\*) with SCL  $\geq$  0.1%, Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with no M-factors set.

RAC agreed to France's proposal to convert the minimum classifications for acute oral and inhalation toxicity into category 2 for both routes of exposure and concluded that category 2 would be appropriate for the dermal route as well while the dossier submitter had proposed to retain category 1.

RAC also decided to add harmonised classifications as a substance which is suspected of causing cancer (Carc. 2; H351), which may damage fertility and the unborn child (Repr. 1A; H360Df) and which may cause harm to breast-fed children (H362).

In relation to repeated dose toxicity, RAC agreed to assign a more severe classification, namely as a substance which causes damage to the central nervous system and kidneys through prolonged or repeated exposure (STOT RE 1; H372) with these target organs mentioned in the Annex VI entry (nervous system, kidneys).

Methylmercuric chloride, which is currently part of a group entry of organic mercury compounds, will receive a separate entry in Annex VI. The existing classification and labelling for the aquatic hazards will be transferred across to the new entry without further review as these hazards were not part of the current assessment.

## **Background Information**

### **The role of RAC in EU regulatory processes**

The committee is responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions and proposals for harmonised classification and labelling. RAC also prepares opinions on specific questions relating to risks of chemicals to human health or the environment and on any other aspects concerning the safety of substances at the Executive Director's request. The final decision for proposals for harmonised classification and labelling, for proposals for restrictions as well as on applications for authorisation will be taken by the European Commission through a committee procedure.

Further information about RAC is available on ECHA's website at the link below:

<http://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment>

### **Role of SEAC in EU regulatory processes**

The committee is responsible for preparing the opinion of the Agency on applications for authorisation and proposals for restrictions. SEAC also prepares opinions on specific questions relating to socio-economic issues and on any other aspects concerning the safety of substances on their own, in preparations or in articles at the Executive Director's request. The final decision for proposals for restrictions as well as on applications for authorisation will be taken by the European Commission through a committee procedure.

Further information about SEAC is available on ECHA's website at the link below:

<https://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis>