Annex to a news release ECHA/NR/20/09

Helsinki, 16 March 2020

ECHA's committees conclude on five restrictions

Siloxanes (D4, D5 and D6)

SEAC adopted its final opinion in support of the proposal by ECHA to restrict the placing on the market of D4, D5 and D6 as substances, as contituents of other substances, or in mixtures in a concentration equal or greater than 0.1% w/w of each substance. 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.

Cobalt salts

SEAC agreed on its draft opinion on the proposal by ECHA to restrict the placing on the market, manufacture and use of cobalt salts as substances on their own or in mixtures in a concentration equal or greater than 0.01 % by weight in industrial and professional applications. SEAC concluded that the restriction proposed by the dossier submitter is not the most appropriate EU-wide measure. The 60-day consultation on the SEAC draft opinion launches on 25 March 2020. RAC adopted its opinion on this dossier by written procedure in February 2020.

Skin sensitising substances

RAC adopted its opinion in support of the proposal by France and Sweden to restrict the skin sensitising substances in finished textile, leather, hide and fur articles, placed on the market for the first time. RAC concluded that the restriction proposed by the dossier submitter is the most appropriate EU-wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability. The agreement on the draft opinion on this dossier in SEAC is postponed until June 2020.

Perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances

RAC adopted its opinion, in support of the proposal by Norway, to restrict the manufacture or placing on the market of PFHxS (linear or branched), its salts or related substances[1] (abbreviated in this note to 'PFHxS'); and as a constituent of another substance, in a mixture or in articles. This follows the inclusion of PFHxS and its salts in the REACH Candidate List because of its very persistent and very bioaccumulative (vPvB) properties. Monitoring data indicates that PFHxS, along with PFOS and PFOA, is the most frequently detected perfluorinated substance in human blood samples worldwide. PFHxS is ubiquitously detected in environmental samples. PFHxS will leach from contaminated sites, such as airports and training areas for firefighters and can be a long-term source of contamination to underlying groundwater and drinking water.

SEAC agreed on its draft opinion in support of the proposal by Norway. 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. The 60-day consultation on the SEAC draft opinion launches on 25 March 2020.

[1] PFHxS-related substances are substances that based upon their structural formulae are considered to have the potential to degrade or be transformed to PFHxS – see Section 1.1.2 of the report.

Formaldehyde and formaldehyde releasers

RAC adopted its opinion on the proposed restriction on articles releasing formaldehyde. ECHA's proposal was to restrict the placing on the market of articles releasing formaldehyde at concentrations greater than 0.124 mg/m^3 (emission limit value) and that a formaldehyde concentration of 0.1 mg/m^3 must not be exceeded in the interiors of road vehicles and aircraft. The proposal was for articles where formaldehyde or formaldehyde releasing substances were used in their production process (either as such or in mixtures). Articles for outdoor use only, articles exclusively for industrial and professional use, second-hand articles, articles subject to other existing EU legislation (i.e. medical devices, personal protective equipment, toys, clothing and footwear), as well as the use of formaldehyde and formaldehyde releasers as biocides are intended to be exempted from the proposed restriction.

RAC's opinion supported the proposal but included several proposed modifications to its scope and conditions. RAC proposed an emission limit value of 0.05 mg/m^3 for articles and to limit the formaldehyde concentration in the interior of road vehicles to 0.05 mg/m^3. RAC recommended to include articles for outdoor use only within the scope of the restriction, but considered that aircraft should be excluded from the scope.

SEAC agreed on its draft opinion, concluding that ECHA's proposal is an appropriate EU-wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its costs. SEAC did not conclude definitively on the proportionality of RAC's proposed modification to the scope and conditions. The 60-day consultation on the SEAC draft opinion launches on 25 March 2020.

***

The Committees adopted and agreed on draft opinions, and discussed key issues in new applications for authorisation

RAC and SEAC adopted two opinions on applications for authorisation. The first adopted opinion concerns the use of chromium trioxide in surface treatment for the manufacture of grain-oriented electrical steel used in magnetic circuits of electric devices, in particular magnetic cores of high-performance transformers.

The second adopted opinion is on the use of octylphenol ethoxylates in a washing buffer to purify biological active pharmaceutical ingredients during the production of two medicinal products.

RAC agreed on 16 draft opinions on applications for authorisation of uses of octyl- and nonylphenol ethoxylates; pitch, coal tar, high temperature; anthracene oil and chromium trioxide, reaching provisional agreement on 21 further uses, which will now go to written procedure. SEAC agreed on 27 draft opinions on the uses of octyl- and nonylphenol ethoxylates; pitch, coal tar, high temperature; and anthracene oil.

RAC agreed on opinions on two applications for authorisation on the use of pitch, coal tar, high temperature as a binder in the manufacture of clay targets, as well as on opinions on two applications to use pitch, coal tar, high temperature and anthracene oil to manufacture formulations for various industrial uses. In addition, RAC agreed on 11 uses of octyl- and nonylphenol ethoxylates in the life sciences and pharmaceutical sectors. Further 21 uses from the same industrial sectors will go to written procedure. Another agreed draft opinion was on the use of chromium trioxide for the manufacture of electrolytic chromium/chromium oxide coated steel.

SEAC agreed on opinions on two applications for authorisation on the use of pitch, coal tar, high temperature as a binder in the manufacture of clay targets. In addition, SEAC agreed on 25 uses

of octyl- and nonylphenol ethoxylates in the life sciences, pharmaceutical and safety glass production sectors.

Furthermore, RAC discussed key issues in 10 applications for authorisation, which were received by ECHA in November 2019. Of these, roughly half are related to the formulation and use of *in vitro* diagnostic assays, the other half consists of the uses of octyl- and nonylphenol ethoylates in virus inactivation, and manufacturing of pharmaceuticals. The committees will continue their work on the opinion development on these applications for authorisation.

The opinions will be available on ECHA's website in the near future.
http://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment
http://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis

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

Background information

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