NEWSLETTER JANUARY 2018

BPA IN FOOD CONTACT MATERIAL (FCM)

The EU Commission's draft amending Regulation proposes a tighter limit on the amount of BPA (Bisphenol A) allowed to migrate from plastic FCMs. For varnishes and coatings used for non-plastic groups it would reduce the limit to 0.05mg of BPA/kg of food; it currently stands at 0.6mg.

MEPs have voted to reject a motion calling for a total ban on BPA in food contact materials. The motion had also demanded a draft EU Commission proposal to lower migration limits be dismissed.

The defeated motion was tabled by four MEPs at the European Parliament's Environment Committee (ENVI) meeting with 42 members voting against, 17 for and one abstention.

NGOs have heavily criticized the draft Regulation, saying it does not go far enough to protect consumers.
Health and Environment Alliance (HEAL), by the voice of one of its officer, claims that the result of the vote means "*European politicians are failing in their responsibility to protect people's health and to act on their earlier commitments*". Safer alternatives are available and some governments, such as France, and industry retailers are "already on the path" to substitution.
The adverse health effects of BPA, even at low doses, are so well documented that it should already have been banned from all consumer products a long time ago, they added.

Meanwhile, CHEM Trust's also says that the Commission's proposed controls "*are not strong enough*" and, unfortunately the European Parliament is not able to directly amend this measure, "*which would have been the best way to strengthen it*".

Many green institutions, hence, were very disappointing that the resolution was not passed by the ENVI, but it is expected that DG Health should now address the concerns raised in the resolution and develop further controls on BPA

On the other end, the polycarbonate/BPA group of trade association *PlasticsEurope*, claims that the Commission's proposed Regulation will cover all major food contact applications and additionally comprises precautionary elements for the protection of young children. "*In essence it will ensure a higher level of consumer protection, and also help to regain consumer trust in EU regulation and restore the internal marke*t."

The European Council has already evaluate the draft Regulation, paving the way for its adoption, which is expected in the next few months. The Regulation should then, according to the draft text, apply six months after entry into force.

In December, ECHA's Member State Committee (MSC) agreed with Germany's proposal to identify BPA as an SVHC due to its endocrine-disrupting properties causing probable serious effects in the environment.
The substance is already on the REACH candidate list of SVHCs on two counts; it is considered toxic to reproduction and it also has endocrine-disrupting properties which cause probable serious effects to human health.

CANDIDATE LIST

Seven new substances have been added to the Candidate List and entry for bisphenol-A has been updated. The BPA was updated to reflect an additional reason for inclusion due to its endocrine disrupting properties causing adverse effects to the environment. The candidate list now contains up to ***181*** total substances. Last added substances are shown in the next figure.

Substance name	EC number	CAS number	Reason for inclusion	Examples of use
4,4′-isopropylidenediphenol (bisphenol A; BPA)	201-245-8	80-05-7	Endocrine disrupting properties (Article 57(f) - environment)	Manufacture of polycarbonate, as a hardener for epoxy resins, as an anti-oxidant for processing PVC and in thermal paper production.
Chrysene	205-923-4	218-01-9	Carcinogenic (Article 57a) PBT (Article 57d)vPvB (Article 57e)	Normally not produced intentionally but rather occurs as a constituent or impurity in other substances.
Benz[a]anthracene	200-280-6	56-55-3	Carcinogenic (Article 57a) PBT (Article 57d)vPvB (Article 57e)	Normally not produced intentionally but rather occurs as a constituent or impurity in other substances.
Cadmium nitrate	233-710-6	10325-94-7	Carcinogenic (Article 57a)Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)	Used for the manufacture of glass, porcelain and ceramic products and in laboratory chemicals
Cadmium hydroxide	244-168-5	21041-95-2	Carcinogenic (Article 57a)Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)	Used for the manufacture of electrical, electronic and optical equipment and in laboratory chemicals.
Cadmium carbonate	208-168-9	513-78-0	Carcinogenic (Article 57a)Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)	Used as a pH regulator and in water treatment products, laboratory chemicals, cosmetics and personal care products.
1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene ("Dechlorane Plus"^{TM}) [covering any of its individual anti- and syn-isomers or any combinationthereof]	-	-	vPvB (Article 57e)	Used as a non-plasticising flame retardant, used in adhesives and sealants and in binding agents.
Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]	-	-	Endocrine disrupting properties (Article 57(f) – environment)	Used as a lubricant additive in lubricants and greases.

Substances on the Candidate List are also known as ***SVHC*** "*substances of very high concern*" and are candidates for possible inclusion in the Authorization List. Once they are on the Authorization List, industry will need to apply for permission to continue using the substance after the Sunset Date. Companies may have legal obligations resulting from the inclusion of the substance in the Candidate List. These obligations may apply to the listed substance on its own, in mixtures or in articles. In particular, any supplier of articles containing a Candidate List substance above a concentration of 0.1% (weight by weight) has communication obligations towards customers down the supply chain and consumers. In addition, importers and producers of articles containing the substance have six months from the date of its inclusion in the Candidate List (15 January 2018) to notify ECHA. Information on these obligations and related tools are available on ECHA's website.

FROM ECHA

236 substances shortlisted for possible regulatory action

ECHA has selected 236 substances for further scrutiny by the Member State Competent Authorities (MSCA) in its annual screening exercise. The competent authorities will carry out a manual examination of dossiers they prioritize to decide whether regulatory action is needed.

ECHA and the Member State Competent Authorities (MSCA) annually conduct IT-based and manual screenings of registered substances as part of a common screening approach. The aim is to identify substances that pose a risk for human health or the environment and take them forward to the most appropriate REACH and CLP processes to ensure their safe use. The common screening approach is part of ECHA's integrated regulatory strategy.

The previous four rounds of IT screening have identified altogether **1.084 substances** for further scrutiny. Of those, Member States have examined **714 substances** and three-quarters of them required follow-up activities.

The selection for short-listing is mostly based on an approach where groups are created around substances with suspected or known concerns, such as those on the Community Rolling Action Plan (CoRAP) for substance evaluation or on the Candidate List of substances of very high concern (SVHCs). Substances are selected to the groups based on read-across arguments and categories available in registration dossiers or categories used in other regulatory programs (e.g. OECD), as well as structural similarity.

Addressing substances in groups will make sure similar substances are treated consistently. The grouping extends beyond the REACH registered substances and the current shortlist includes **40** substances notified to the C&L Inventory, as well as the **39** group seeds (substances with suspected or know concerns) included on the CoRAP or Candidate List, and therefore already being looked at.

A company which has registered one of the substances now shortlisted, can receive a letter from ECHA informing of the potential examination of your registration. ECHA encourages companies to update your dossiers to address any shortcomings as soon as possible. Up-to-date information will help the Member State authorities better assess if regulatory action – either further data generation or regulatory risk management measures - is needed.

A webinar will take place on **1 February.** In this webinar, details about the screening process and the next steps will be given. with opportunity to ask ECHA staff questions.

If the Member States or ECHA take actions on a substance, this information will be published on the Agency's website in the list of substances potentially subject to compliance checks, the Registry of Intentions (ROI) or the draft CoRAP for substance evaluation or the Public Activities Coordination Tool (PACT). The status of your substance can be checked by the search for chemicals functionality available on ECHA's homepage. ECHA does not make the list of shortlisted substances public as it is based on automated selection and manual verification is needed to confirm a potential concern.

BIOCIDES

Draft ED guidance for public consultation issued on December 7th, 2017

This draft guidance, requested by the European Commission, has been developed by the two agencies with the support of the Commission's Joint Research Centre (JRC). Earlier this year EFSA and ECHA conducted two targeted consultations on the draft of the guidance with experts representing Member States Competent Authorities and with stakeholders from industry and NGOs. Numerous comments were received and taken into account in the revision of the guidance.ECHA and EFSA now invite all interested parties to comment on the updated draft guidance by using the dedicated web form below. The deadline for providing comments is **31 January 2018**. All received comments will be taken into consideration in finalizing the guidance, which is scheduled to be available by June 2018.

ECHA Events for January- February 2018

REACH 2018 Stakeholders
Day: 29-31 January 2018

Member State Committee
5-9 February 2018

CHEMSAFE NEWS

On February 1, 2018, we will celebrate all together the 10th anniversary of ***Lara De Luca*** as our colleague.
Lara, owning a Degree in Chemistry got at University of Turin, joint Chemsafe on 1th February 2008 and after a training time of few months started taking care of risk assessment and REACH consultancy for our customers as well as to follow SDS preparation of mixture in special cases. With the income of REACH registrations in 2010, she took care of CSA/CSR preparation, exposure scenarios setting and e-SDS preparation. She has been continuously improving her expertise in the chemical regulation all along the years with a main focus on REACH.
From 2016, She is the Head of our Business Unit CHEMICAL which offer all the services related to REACH, CLP and SDS and represents the core business of our company.
Lastly, she started offering her technical support to downstream users (important Italian companies) concerning the assessment and application of exposure scenario given by the manufacturers in their CSA/CSR with a specific attention to substances under authorization/restriction.
We really thank Lara for her contribution to the success of our company and for her utmost professionalism.

PARTICIPATION TO EVENTS

On March 11-15, Chemsafe will attend the ***US SOT*** (Society of Toxicology) ***57th Annual Meeting*** in San Antonio Texas (USA). Colleagues of the PHARMA Business Unit have prepared two posters regarding the PDE (Permissible Daily Exposure) assessment on specific pharma API (Active Principle Ingredient):

Prostaglandin analogs: PDE assessment and relationship to the therapeutic dose
Acebrophylline: a PDE case study

Chemsafe has also rent ***Booth number 1266*** where we will welcome all visitors. We will present our services to pharmaceutical companies with a special focus on "*in silico*" prediction, genotoxicity evaluation of impurities, toxicological evaluation of impurities as for ICH guidances and Risk Assessment (ERA) for medicinal products as for EMA guidance. All other services will be shown too. A warm invitation to visit us!