# REACH E-NEWSLETTER





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SGS

# WELCOME

Dear Reader,

The UK REACH e-bulletin brings you key issues relating to the EU REACH (Registration Evaluation and Restriction of Chemicals) regulation.

We bring information on proposed changes, confirmed changes and the possible effects of these changes from a manufacturing, retail and consumer perspective. Opinions from all concerned parties are reported so a full picture of the workings and effects of the regulation are shared.

Some of the information in the following pages is sourced from European Chemicals Agency (ECHA) and Chemical Watch. Each of our articles are linked back to source for further reading.

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# 10 NEW SUBSTANCES ADDED TO THE CANDIDATE LIST

ECHA has added eight new SVHCs to the Candidate List following the SVHC identification process with the involvement of the Member State Committee (MSC).

Two further substances, TMA and DCHP, have also been added to the list, having been identified as SVHCs by the European Commission due to their respiratory sensitising properties and toxic for reproduction and endocrine-disrupting properties, respectively. The Commission's decision follows the referral of the MSC opinions on these SVHC proposals in 2016.

The Candidate List of substances of very high concern (SVHCs) for authorisation now contains 191 substances.

Substances included in the Candidate List for authorisation on 27 June 2018 and their SVHC properties:

| # | SUBSTANCE NAME | EC NUMBER | CAS NUMBER | REASON FOR INCLUSION | EXAMPLES OF USE(S) |
|---|---|---|---|---|---|
| 1 | Octamethylcyclotetra-siloxane (D4) | 209-136-7 | 556-67-2 | PBT (Article 57d)<br>vPvB (Article 57e) | Used in washing and cleaning products, polishes and waxes and cosmetics and personal care products. |
| 2 | Decamethylcyclopen-tasiloxane (D5) | 208-764-9 | 541-02-6 | PBT (Article 57d)<br>vPvB (Article 57e) | Used in washing and cleaning products, polishes and waxes, cosmetics and personal care products, textile treatment products and dyes. |
| 3 | Dodecamethylcyclohex-asiloxane (D6) | 208-762-8 | 540-97-6 | PBT (Article 57d)<br>vPvB (Article 57e) | Used in washing and cleaning products, polishes and waxes, cosmetics and personal care products. |
| 4 | Lead | 231-100-4 | 7439-92-1 | Toxic for reproduction (Article 57c) | Used in metals, welding and soldering products, metal surface treatment products, and polymers. |
| 5 | Disodium octaborate | 234-541-0 | 12008-41-2 | Toxic for reproduction (Article 57c) | Used in anti-freeze products, heat transfer fluids, lubricants and greases, and washing and cleaning products. |
| 6 | Benzo[ghi]perylene | 205-883-8 | 191-24-2 | PBT (Article 57d)<br>vPvB (Article 57e) | Not registered under REACH. Normally not produced intentionally but rather occurs as a constituent or impurity in other substances. |
| 7 | Terphenyl hydrogenated | 262-967-7 | 61788-32-7 | vPvB (Article 57e) | Used as a plastic additive, solvent, in coatings/inks, in adhesives and sealants, and heat transfer fluids. |
| 8 | Ethylenediamine (EDA) | 203-468-6 | 107-15-3 | Respiratory sensitising properties (Article 57(f) – human health) | Used in adhesives and sealants, coating products, fillers, putties, plasters, modelling clay, pH regulators and water treatment products. |
| 9 | Benzene-1,2,4-tricarbo-xylic acid 1,2 anhydride (trimellitic anhydride) (TMA) | 209-008-0 | 552-30-7 | Respiratory sensitising properties (Article 57(f) – human health) | Used in the manufacture of esters and polymers. |
| 10 | Dicyclohexyl phthalate (DCHP) | 201-545-9 | 84-61-7 | Toxic for reproduction (Article 57c)<br>Endocrine disrupting properties (Article 57(f) – human health) | Used in plastisol, PVC, rubber and plastic articles. A further use is also as a phlegmatiser and dispersing agent for formulations of organic peroxides. |

### BACKGROUND

The Candidate List is a list of substances that may have serious effects on human health or the environment. Substances on the Candidate List are also known as Substances of Very High Concern and are candidates for eventual inclusion in the Authorisation List. Once they are on the Authorisation 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 (27 June 2018) to notify ECHA.

*Article source: ECHA.europa.eu*

# FRANCE URGES ROBUST REACH AUTHORISATION AND SVHC ACTIONS IN ECHA PLAN

The French competent authority is calling on ECHA to include measures to strengthen the REACH authorisation process in its strategic plan for the next five years.

France's comments – along with those of member states, NGOs and industry – were submitted to the agency's recent consultation on the draft plan for 2019-23.

ECHA has set three priorities for that period:

- identification and risk management of substances of concern;
- safe and sustainable use of chemicals by industry; and
- sustainable management of chemicals by applying EU legislation.

The member states also want the process to be accelerated and said that inclusion of a substance in Annex XIV – the Authorisation List – is a "cumbersome process" and that all chemicals that "should be" on the list are not.

Furthermore, France wants ECHA to work to "strengthen the coupled use of authorisation and restriction procedures" to create a "simplified procedure to obtain bans on (imported) articles containing Annex XIV substances". This, it said, will protect European industry while ensuring its security of supply.

The agency should also create initiatives for producers and importers to provide data on the SVHC content of products, it said. "Attention should be given to the control of online sales for the period 2019-23, taking into account, as part of these controls, the REACH obligations relating to substances in the articles (restrictions in particular)."

ECHA's Management Board is expected to endorse the strategy in December.

*Article source: ChemicalWatch.com*

# IRELAND HSA LAUNCHES BREXIT WEBPAGES

The Irish Health and Safety Authority has created webpages to keep businesses informed, including those in the chemicals industry, of the potential impacts of Brexit.

The HSA says that "potentially significant implications for Ireland and Irish companies are anticipated due to our shared market with the UK".

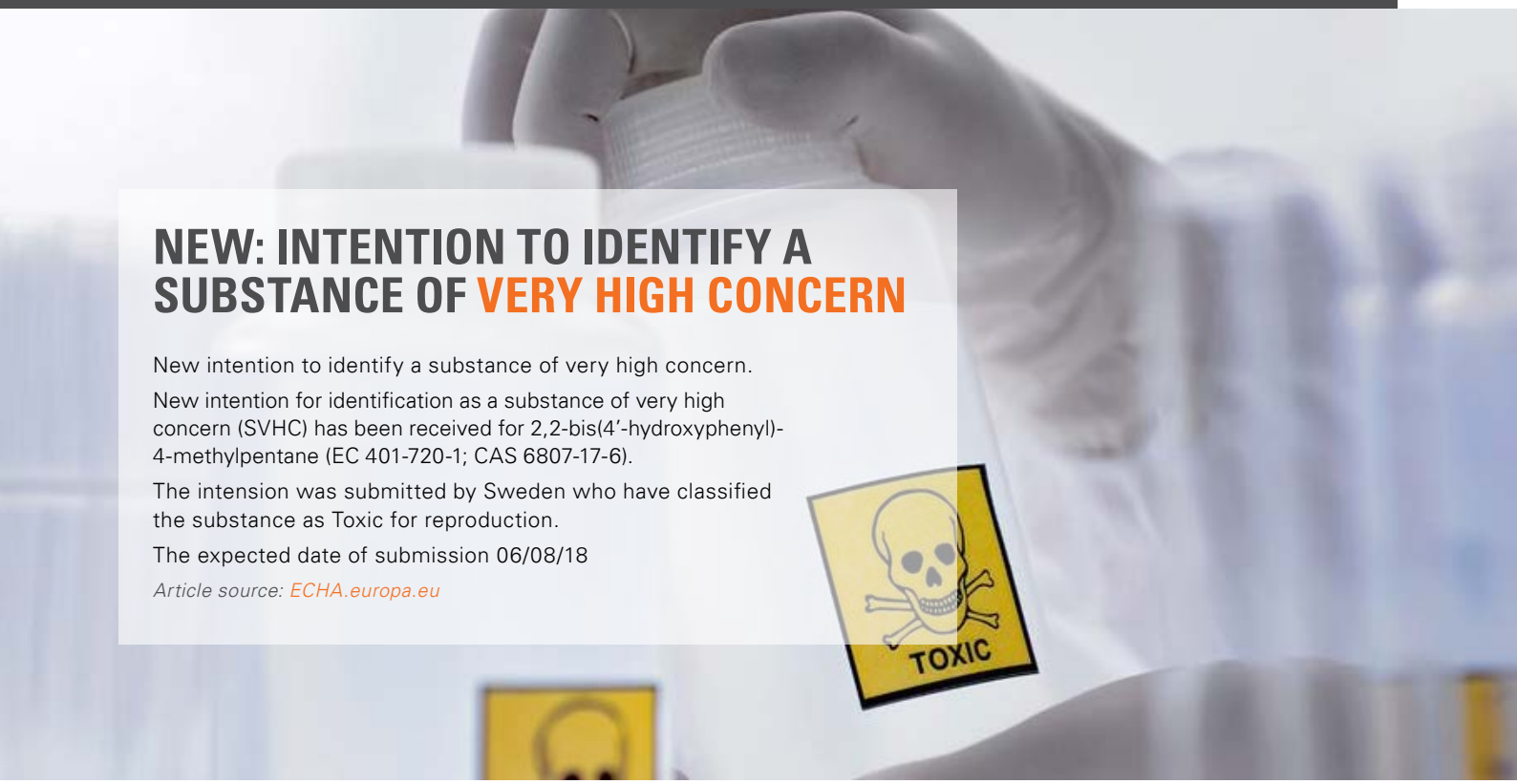
It has established an internal committee to prepare for Britain's withdrawal and has urged companies in Ireland to start considering the potential effects of Brexit to their business immediately.

They may face new and different UK rules on the import and use of chemical substances, it says, and they may also need to review their supply chains involving UK-based business partners.

The webpage dedicated to REACH and CLP includes information about:

- registrations and any role change concerning them;
- joint submissions with a UK-based lead registrant;
- only representatives; and
- impact on authorisations.

*Article source: ChemicalWatch.com*




# NEW: INTENTION TO IDENTIFY A SUBSTANCE OF VERY HIGH CONCERN

New intention to identify a substance of very high concern.

New intention for identification as a substance of very high concern (SVHC) has been received for 2,2-bis(4'-hydroxyphenyl)-4-methylpentane (EC 401-720-1; CAS 6807-17-6).

The intension was submitted by Sweden who have classified the substance as Toxic for reproduction.

The expected date of submission 06/08/18

*Article source: ECHA.europa.eu*

# REACH DIRECTORS' CONTACT GROUP PUBLISHES POST – 2018 SIEF RECOMMENDATIONS

The REACH Directors' Contact Group has published recommendations urging members of substance information exchange fora (Siefs) to continue to cooperate after the 31 May final registration deadline.

From 1 June Siefs will cease to exist in a legal context. Decisions are still pending on the format and name of new fora, in which registrants will discuss post-deadline activities such as dossier updates, joint submissions, new information requests by ECHA and cost sharing.

But in a statement issued hours before the deadline, the DCG – an informal group of directors from the European Commission, ECHA and industry associations – made the following recommendations for future collaboration platforms:

- co-registrants of phase-in (or existing) substances should continue to cooperate after 31 May;
- the cooperation should cover, among other things, the process for managing dossier updates, coordinated responses to regulatory requests related to dossier and substance evaluation, and processes related to changes in the composition or status of co-registrants;
- co-registrants are free to agree on the form of their cooperation and should put in place adequate, jointly agreed contractual measures for managing the work;
- the cooperation contract should take into account the special nature of the work as 'cooperation among competitors', and ensure that only information that is necessary to complete the regulatory task is shared among the co-registrants;
- the Sief agreements should form a good basis for designing the cooperation contracts; and
- co-registrants of non-phase-in substances and of NONs (substances notified under Directive 67/548/EEC which preceded REACH) may also consider establishing a form of cooperation as outlined for phase-in substances.

The DCG also urged Sief members to "make every effort" to reach mutual agreement in their discussion. It added that the new framework, as well as any decisions taken within such cooperation, should aim to be "fair, non-discriminatory and transparent to all involved actors".

Administrative costs for managing the platform must be fairly distributed among the co-registrants, the group said.

ECHA has said it supports a new "collaboration platform" and told registrants to "continue their current structures as they will be crucial for newcomers as well as for the work on updates".

But the European industry council Cefic has warned about potential antitrust issues arising from new platforms. It said members should share only information specific to certain agreed tasks.

Cefic has stated recently that its members have agreed to maintain the Siefs platform "as is" after the deadline.

*Article source: ChemicalWatch.com*

# INTENTION TO RESTRICT ARTICLES THAT CONTAIN LEAD CHROMATE

A notice of intention to restrict the following substances in imported articles was submitted by ECHA on 22 May:

- lead chromate
- lead sulfochromate yellow (C.I. Pigment Yellow 34)
- lead chromate molybdate sulphate red (C.I. Pigment Red 104)

Stakeholders are requested to provide any information relevant to the Dossier Submitter during the Annex XV Restriction Dossier process, either in any call for evidence or separately during the process. This information will be used, among other issues, to determine if any derogations are required for the potential restriction as these cannot be proposed without adequate risk and socio-economic information. If a derogation is not proposed by the Dossier Submitter then it will be incumbent on the relevant stakeholders to do so during any public consultation process with a full risk and socio-economic justification accompanying it.

The planned dossier submission date is 12 April 2019.

*Article source: ECHA.europa.eu*


# AUSTRIAN EU PRESIDENCY TO 'FINALISE' POPs RECAST

Austria said it aims to finalise the recast of the persistent organic pollutants (POPs) Regulation during its presidency of the Council of the EU, which starts on 1 July for 6 months.

This recast was to update the repealed regulatory procedures and align with the Lisbon Treaty; introduce the European Chemicals Agency (ECHA) to handle technical matters related to POPs Regulation as well as an adaptation of the monitoring system. Most importantly, the Annexes of POPs is proposed to include new POPs from the Stockholm Convention.

In May, NGO the Health and Environment Alliance (HEAL) sent a letter to Austrian chancellor Sebastian Kurz urging the country to seize "significant opportunities" to improve chemicals regulations and push for better controls of hazardous substances during its presidency. The letter was also sent to European Council president Donald Tusk and other ministers and commissioners, including Commissioner of environment, maritime affairs and fisheries Karmenu Vella.

*Article source: ChemicalWatch.com*

# DID YOU MISS THE REGISTRATION DEADLINE? MAKE YOURSELF REACH COMPLIANT AS SOON AS POSSIBLE

31 May was the last chance to submit a registration for existing (phase-in) substances manufactured or imported in amounts more than one tonne per year. If the registration obligation applied to you but you did not submit your dossier then, as of 1 June you can no longer manufacture or import your substance legally in the EU/EEA.

If you missed the deadline, you should make yourself compliant without delay:

- If you have pre-registered or inquired about your phase-in substance, you can register it directly (until further notice, you can still use the pre-registration number).
- If you have not pre-registered or inquired about your phase-in substance, you need to submit an inquiry before registering it.

If you submit your dossier after 31 May, you will need to wait until you receive your registration number before resuming or starting manufacture or import of your substance.

*Article source: ECHA.europa.eu*

# ECHA OPENS CONSULTATION ON DEROGATION REQUEST FOR PFOA RESTRICTION

ECHA is inviting comments on a proposal for an additional derogation to the restriction of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (entry 68 of Annex XVII to REACH).

The agency's Committees for Risk Assessment and for Socio-economic Analysis (Rac and Seac) have been requested to prepare an opinion.

ECHA says this assessment is not being carried out under the normal restriction procedure as it is a specific request from the European Commission for a derogation on an existing restriction. The opinions will be sent to the Commission by 1 December 2018.

The restriction entered into force in June 2017 and includes several derogations for different industrial sectors and uses.

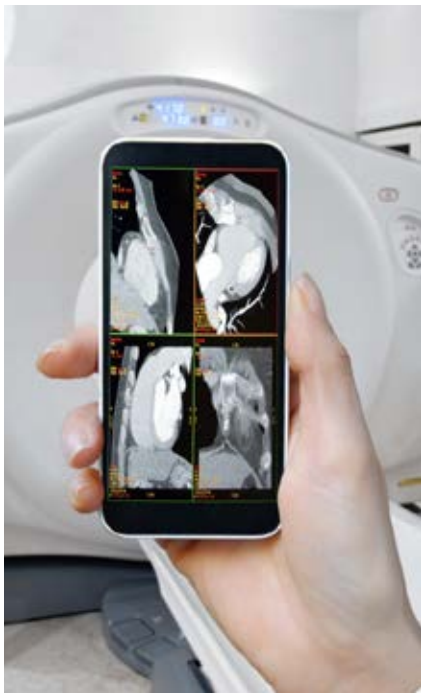
The derogation review request came from pharmaceutical company AstraZeneca, which uses perfluorooctane bromide (PFOB) for the manufacturing of pharmaceutical products for the treatment of pulmonary diseases.

PFOB is excluded from the scope of the PFOA restriction, but it contains perfluorooctane iodide (PFOI) as an impurity in concentrations above the threshold in the PFOA restriction. PFOI is a PFOA-related substance that is covered by the restriction.

The public consultation ends on 20 August.

*Article source: ChemicalWatch.com*


# EU COMMISSION: EXEMPTED USES OF PHTHALATES 'MAY REQUIRE AUTHORISATION'



The European Commission is preparing to amend the REACH Authorisation List entries of four phthalates, following their identification as SVHCs due to endocrine disrupting effects on humans and the environment.

The four phthlates are:

- bis(2-ethylhexyl) phthalate (DEHP);
- benzyl butyl phthalate (BBP);
- diisobutyl phthalate (DIBP); and
- dibutyl phthalate (DBP).

The Commission has also said that some uses that were previously exempted "may require authorisation".

On its behalf, ECHA is launching a public consultation targeting affected sectors that will seek information on the uses "that might no longer be covered by generic exemptions from the authorisation requirement". These include those in food contact materials, medical devices, as well as transitional arrangements, exemptions and review periods.

It will examine uses that are already subject to authorisation separately. The deadline for comments is 6 August.

The phthalates have been on the Authorisation List since 2012 due to their reprotoxic qualities.

Their endocrine disrupting effects on human health – and in the case of DEHP also on the environment – were added to their SVHC classification in 2014 and 2017.

The phthalates' addition to the Candidate List of SVHCs for their endocrine disrupting properties followed a proposal from Denmark. Many member states backed the proposal last year, although the vote was delayed due to opposition from some countries.

*Article source: ChemicalWatch.com*

# EU COMMISSIONERS URGE GREATER ACTION FROM SVHCs IN IMPORTED ARTICLES

The EU Commissioner for environment, maritime affairs and fisheries has urged ECHA to assess the need for a restriction of SVHCs in imported articles earlier in the regulatory process.

Action 11(1) of the REACH Review calls upon ECHA to consider developing systematically a restriction dossier before the sunset date for substances listed on Annex XIV – the Authorisation List.

Speaking to delegates at a recent conference on the second Review of the Regulation, Karmenu Vella said that when companies point out that articles imported into the EU can still contain substances for which they have had to obtain authorisation "they do have a point".

It is an "understandable concern" for domestic companies which want a level playing field for EU and non-EU companies, he added. It is also "a very obvious concern" to citizens because of the potential impact on the environment and human health.

He said he would be following the outcome of ECHA's assessment "very, very closely".

Mr Vella's calls are related to the requirement in REACH Article 69(2), which states that ECHA must assess the need for a restriction on substances included in Annex XIV for their use in articles (EU produced and imported) and propose such a measure – if the risks are not adequately controlled – once the sunset date for the substance has passed.

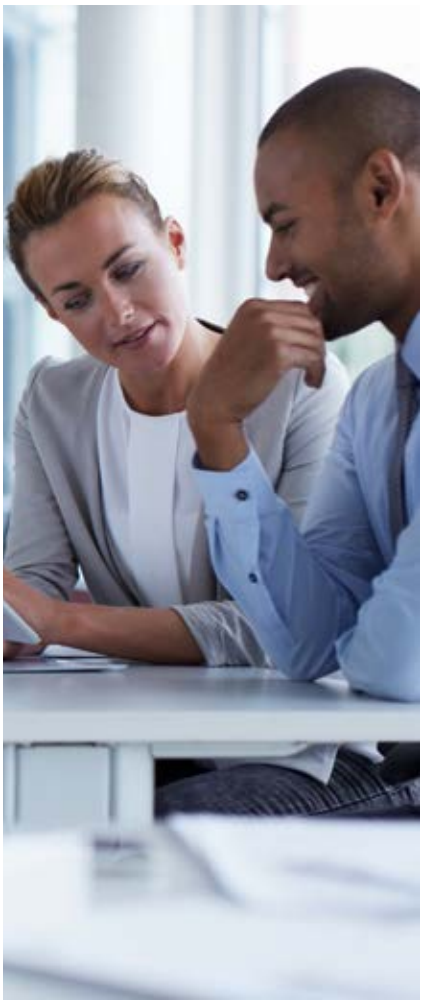
The agency stated it has already assessed five substances and concluded that no restriction is required. For another four substances – the phthalates DEHP, DBP, DIBP and BBP – ECHA proposed a restriction, which was supported by the Committees for Risk Assessment and Socio-economic Analysis (Rac and Seac) and is currently being discussed in the REACH Committee.

Meanwhile, restriction dossiers are being prepared for TCEP and lead chromates. For the remaining substances, ECHA said it will carry out screening reports to assess if a restriction is required over the next six to 12 months.

The agency added that it is also assessing what can be done to speed up the process in the future, "such as gathering information on the use of Annex IV substances in articles whilst the application for authorisation process is ongoing".

However, it said, the outcome of the application for authorisation process and whether an authorisation is granted "is an important issue to be clarified before any restriction is proposed".

*Article source: ChemicalWatch.com*



# EU EXPANDS CMR LIST UNDER ANNEX XVII OF REACH

The list of CMRs under Annex XVII of REACH has been expanded. The new provisions are implemented in two phases, starting 24 May, 2018 for formaldehyde.

Under entries 28 to 30 of Annex XVII of REACH, the use of carcinogenic, mutagenic or reprotoxic category 1A or 1B substances (CMR category 1A or 1B substances) is prohibited as substances, constituents of other substances or in mixtures, for the general public if their concentrations are greater than prescribed limits.

On 4 May, 2018, the EU published Regulation (EU) 2018/675 to expand the list of CMR category 1B substances in each of the three CMR categories. This latest addition aligns the CMRs from two pieces of legislation:

- Formaldehyde, classified as a carcinogenic category 1B substance by Regulation (EU) 605/2014
- CMR substances in Regulation (EU) 2017/776, amending Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation)

There are two effective dates in the new Regulation. These are:

- 24 May, 2018 for formaldehyde
- 1 December, 2018 for CMRs other than formaldehyde

Highlights of Regulation (EU) 2018/675 are summarised in Table 1.

*Article source: SGS.com*

| Regulation (EU) 2018/675 amending Annex XVII to Regulation (EC) 1907/2006 (REACH) | | | |
|---|---|---|---|
| Entry Number under Annex XVII of REACH | CMR Classification | Appendix | Number of Substances Added |
| 28 | Carcinogenic category 1B | 2 | 10, including formaldehyde |
| 29 | Mutagenic category 1B | 4 | 3 |
| 30 | Reprotoxic category 1B | 6 | 9 |

# EU MEMBER STATES CONSIDER CENTRAL HAZARDOUS MIXTURES DATABASE

EU member states are considering whether ECHA should develop a searchable database for information captured by the forthcoming central notification portal for Annex VIII of CLP (the Classification Labelling and Packaging Regulation).

Under this annex, importers and downstream users are obliged to submit information on hazardous chemical mixtures to "appointed bodies" in each of the member's states where the products are marketed. This information is made available to poison centres for use in emergencies involving those mixtures.

The idea of a central EU notification portal is to make the process less onerous for industry, by reducing the total number of submissions that must be made.

The portal could have various functionalities, according to a European Commission document prepared for the next meeting of Competent Authorities for REACH and CLP (Caracal).

In particular, it could dispatch captured information to the relevant appointed bodies, or it could store the information, and make it available to those bodies using a searchable database.

The dispatch functionality would be enough to achieve the primary goal of alleviating some administrative burden for industry, the document says. But the database could create efficiency gains for member states by shifting responsibility to ECHA for the management of submitted data.

The agency started work on the portal, including the dispatch functionality, in January.

On the database, the Caracal document says that the Commission has verified the possibilities for additional financing through EU subsidy or ECHA fee income. The latter would come from "regulatory processes other than the notification obligation under Article 45 of CLP" because fees cannot be levied at EU level for such notification.

The Commission's REACH Committee will view a draft implementing Decision at their meeting on 13 June. A vote is expected at the following meeting in July. The document says that work on the database could start this summer, with the aim of making it available by November 2019 to coincide with release of version two of the portal.

Earlier this year, ECHA published its draft guidance on the data submission process. The final version is expected before the end of the year. The agency also released the harmonised "poison centre notification" (PCN) format, which must be used for submissions.

*Article source: ChemicalWatch.com*

# EU MEMBER STATES VOTE TO BAN THREE PESTICIDES

EU member states have voted in favour of a near total ban on the use of three neonicotinoid pesticides that was proposed by the European Commission.

The three are:

- Clothianidin
- Imidacloprid
- Thiamethoxam

They have been restricted to non-flowering crops since 2013 over concerns they were harming bees and other insect pollinators. The new ban goes much further, completely prohibiting there use outdoors although farmers will still be able to use them in glasshouses.

In November last year the UK government said it would change its stance on pesticides and support a ban in Europe following the results of its own research on the effects of exposure in honeybees.

The near total ban will come into force by the end of this year the European Commission says.

Adapted from Chemistry World
www.chemistryworld.com

# FINLAND WARNS AGAINST ONLINE PURCHASES OF BORAX FOR 'SLIME' TOYS

The Finnish Safety and Chemicals Agency (Tukes) has warned parents about children purchasing the hazardous chemical borax, or mixtures containing it, from non-EU online stores for use as an ingredient for creating toy slime.

Borax is classified as reprotoxic category 2 and as such is banned for sale to consumers in the EU.

The agency said that substances sold on non-EU online stores often do not carry warning labels to indicate the hazardous properties of the chemical.

National enforcement authorities in the EEA have been actively investigating hazardous chemicals in slime products. In April, the Norwegian Environmental Directorate removed some slime-like toy products from the market, after it found they contained high levels of lead and arsenic.

And a month later the French Agency for Food, Environmental and Occupational Health and Safety, Anses, warned that homemade toy slime can pose health risks to children because they may contain hazardous substances.

Article source: ChemicalWatch.com

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