NEWSLETTER MARCH 2018

CHEMSAFE NEWS

Sodium Hypochlorite TASK FORCE Agreement signed on March 9 at Chemsafe offices

Chemsafe Business Unit Agro/Biocides, headed by Francesca Fasano with the help of Alice Basilio (Task Force Project Leader) and Paolo Rossi (BDM Chemical area) finalized the BPI Task Force regarding Sodium Hypochloride products. **On March 9, 2018 the TASK FORCE Agreement was signed at Chemsafe Offices with mutual satisfaction among TF new members**. The BPI Task Force has an international value as composed not only by Italian companies but by companies located in Southern Europe. Other companies has already expressed intention to join and will be welcome. The period to be considered Founding Members will expire on March 31, 2018; therefore we strongly invite those interested to contact us and start the membership procedure. From April 1, 2018 sweating activity additional membership fee will be introduced leading to increase of membership value. Later comers membership cost will be re-distributed amount founding members on the basis of a non-discriminatory principle similar to that applied in the REACH Consortia. The total amount of biocidal products represented in the Task Force is around 70 grouped following the family approach currently regulated by the specific guideline or kept as single biocidal product within the TF. Testing will started as soon as the pre-submission meeting with the suitable Competent Authorities will be arranged. Supporting testing laboratory will be selected within the Chemsafe testing laboratory network (well established since many years) on the basis of previous experience with the active substance particularly for stability testing and efficacy trials.
The BPI Task Force is organized into different internal bodies such as:

- The Technical and Steering Committees in charge of taking strategic and technical decision. They are composed by one delegate per member who votes with a weighted approach based on type of membership;
- The Technical Consultant in charge of discussion with Competent Authorities and preparing the common dossier (IUCLID 6 biocide version) as well as the customized dossier for each member;
- The Trustee in charge of keeping CBI (Confidential Business Information) and assuring the highest level of confidentiality during common discussion;
- The Secretariat in charge of managing financial issues and arrange meeting, phone conferences, exchange of information

Our model
As already said, our model is inspired by the ***data sharing principles*** and will allow each Task Force Member to have their own dossier property and decide where to submit the dossier selecting the most appropriate EU Member State. This way will assure to each Task Force Member a complete freedom to manage their biocidal product, to add mutual recognitions when they want, to change their formulation in future to improve the efficacy of the product, to decide to spend their money with an investment mind. All these features will not be covered and allowed by other task force models, i.e. those which imply the access to "same biocidal authorization" dossier (clones). In such cases the cost "may" be lower but companies are not free to manage their dossier as totally linked with the "father" dossier authorized by the Lead company within the Task Force. At the end they give money mostly to authorized the "father" dossier and not for their clones. We believe they are at risk in the future due to common saying "*spend less to spend more*".

Other Task Forces are going to be organized in 2018. We will keep you all update on this newsletter.

FROM ECHA

Message from the new Executive ECHA Director

"I am thrilled about my new role leading the European Chemicals Agency for the next five years. I am fortunate to have inherited a strong network of European associations with an interest in our work – our now 113 accredited stakeholders – and I will continue to foster and strengthen our engagement with you during my tenure.

It is good timing that, as I take up my new role, the Commission is due to publish its five-year review of REACH, summing up our strengths and highlighting areas of improvement. We are being asked to be more efficient in evaluation, restrictions and authorization. Besides looking closer at where we can do things better, for me it is also important that lessons learnt from one area, like REACH, are considered in other areas, like biocides and CLP, and viceversa.

We were set up in 2007 to implement REACH and CLP, but over the years we were entrusted with biocides and with PIC. It looks likely that we will be given certain chemical-related elements of the Waste Framework Directive when it is adopted. And later this year, the negotiations on the Persistent Organic Pollutants (POP) Regulation will start, probably resulting in further responsibilities for us. We will be relying on your expertise and networks to support us in implementing these new tasks.

I will undoubtedly meet many of you in the course of the coming months through various meetings and discussions, and I am especially looking forward to the annual accredited stakeholder workshop that will take place on 23 November in Brussels, so save the date.

I look forward to working with you in the years to come"

Bjorn Hansen, Executive Director of ECHA

Small Medium Enterprises (SMEs)

SMEs are always been the focal point of neverending discussions related to the huge impact of new EU regulations such as REACH, CLP, SDS regulations etc. on them. Many successful attempts have been carried on in order to facilitate the application of these complex regulation for SMEs. The fee regulation, for example, introduced reduced fees for three types of SMEs (medium, small, micro) based on two main principles: the annual turnover and the number of employees.

Small and Medium-sized Enterprises can benefit from reduced fees under the REACH, CLP and Biocidal Products Regulations. The reductions depend on the company size as defined by the ***Commission Recommendation 2003/361/EC*** and can be up to 95% from the standard fee for a REACH registration.

The European Commission is now reviewing the definition of an SME to ensure that it remains fit for purpose and meets its objectives in the current economic environment, and to evaluate the need for possible changes. The survey is available in all EU languages in the ECHA web site.

ECHA launches targeted consultation on the harmonized classification and labeling of zinc pyrithione

The proposal for the harmonized classification and labelling (CLH) of **pyrithione zinc**; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc (EC 236-671-3; CAS 13463-41-7), submitted by Sweden, was subject to a public consultation which ended on 7 July 2017.
On 8 December 2017, the zinc pyrithione industry consortium submitted new information, which included an amendment to a final study report. ECHA now invites all concerned parties to comment on the new information, available on ECHA's website, with regard to the dossier submitter's proposal to classify zinc pyrithione for developmental toxicity. The deadline for comments is **21 March 2018**

CLP

ECHA is looking for comments on the harmonized classification and labeling proposals for:

2-(4-tert-butylbenzyl)propionaldehyde (lysmeral) (EC n. 201-289-8; CAS n. 80-54-6). It is an industrial chemical used in consumer products including personal care, washing and cleaning products, as well as an active substance (e.g. in disinfectants, pest control products). It has no existing harmonized classification and labeling in Annex VI to CLP. Comments are invited on the reproductive toxicity hazard class.

dibenzo[def,p]chrysene; dibenzo[a,l]pyrene (EC n. 205-886-4; CAS n. 191-30-0). It is a chemical contaminant from the family of polycyclic aromatic hydrocarbons (PAHs). It is released into the environment during incomplete combustion or pyrolysis of organic matter, an important source for human exposure. It has been detected in consumer products and articles such as toys, tool handles, bicycle grips, shoes, and sports equipment. It has no existing harmonized classification and labeling in Annex VI to CLP. Comments are invited on germ cell mutagenicity and carcinogenicity hazard classes.

2,4-dinitrophenol (EC n. 200-087-7; CAS n. 51-28-5). It is an industrial chemical used as a monomer. It has also been misused as a weight control drug causing human poisonings. It has no existing harmonized classification and labeling in Annex VI to CLP. Comments are invited on acute toxicity specific and target organ toxicity - repeated exposure hazard classes.

4,5-dichloro-2-octyl-2H-isothiazol-3-one; [DCOIT] (EC n. 264-843-8; CAS n. 64359-81-5) is an active substance used in biocidal products as a preservative and anti-fouling agent. It has no existing harmonized classification and labeling in Annex VI to CLP. Comments are invited on all physical, human health and environment hazard classes except aspiration hazard and hazardous to the ozone layer.

phosphine (phosphane) (EC n. 232-260-8; CAS n. 7803-51-2). It is an active substance used in plant protection products and in biocidal products releasing phosphine. It is also an industrial chemical used in the manufacture of electrical, electronic and optical equipment. It has an existing harmonized classification and labeling in Annex VI to CLP. Comments are invited on the hazard class acute toxicity via inhalation route.

pirimiphos-methyl (ISO); O-[2-(diethylamino)-6-methylpyrimidin-4-yl] O,O-dimethyl phosphorothioate (EC n. 249-528-5; CAS n. 29232-93-7). It is an active substance used in plant protection products as a broad-spectrum insecticide. It has an existing harmonized classification and labeling in Annex VI to CLP. Comments are invited on the hazard classes acute toxicity via oral route, germ cell mutagenicity, carcinogenicity, specific target organ toxicity - repeated exposure and hazardous to the aquatic environment.
A synchronous public consultation on the assessment report for pirimiphos-methyl (ISO) as an active substance in plant protection products is ongoing on the website of the European Food Safety Authority (EFSA).

MIT

EU member states have voted to approve a harmonized classification of the preservative **methylisothiazolinone (MIT)** as an allergen in mixtures such as paint and detergents. The REACH committee vote means such mixtures must be labeled when they contain more than 0.0015% of MIT – a limit value lowered from 1%. The proposal will now undergo three months of scrutiny.

COSMETICS

Members of a European Parliament committee have approved a resolution that aims to establish a **global ban** on animal testing for cosmetics by **2023**. The resolution calls on the Commission, Council and Member States to push for such a ban when meeting with institutions from other countries, regions and the UN.

REACH

How to avoid unnecessary testing on animals

Under REACH, testing on vertebrate animals (e.g. rats, other mammals or fish) can only be used as a **last resort** to fulfill information requirements for registration. For companies manufacturing or importing between 1 to 100 tons per year, there are multiple ways to avoid unnecessary animal testing and to reduce the number of animal tests. For each individual information requirement you should consider the following:

1. Gather and share existing data. You may get access to published literature that is sufficient for fulfilling the information requirement. If a result of a valid animal test is available in the SIEF, it must be shared with co-registrants. The owner of the test must be compensated according to pre-agreed rules.
2. Data waiving or adaptations: rules for adaptations are part of the legal text. They can be either specific (under column 2 of each endpoint) or general (under Annex XI). To use the general rules, you can waive data or use an adaptation based on the following scientific arguments:
    - Weight of evidence. You have sufficient information from several independent sources that lead to the conclusion that your substance has (or does not have) a particular property.
    - QSAR models. Many properties of your substance can be predicted from structurally similar substances by using computer models. In of crucial importante to check the reliability of such models when used on a give molecular structure. The “consensus” method is also strictly suggest to make your evaluation as robust as possible;
3. “In vitro” methods. Tests performed with isolated tissues, organs or cells instead of a whole organism can be adequate to conclude on an information requirement. “in vitro” methods needs to be evaluated before their application to a give molecula structure in order to assure scientific and acceptable results:
4. Grouping and read-across. If you can show that the way your substance behaves for a certain property is similar to how another substance behaves, existing results for that property can be "read across" to your substance. Reach across approach is frequently (and better) associated with QSAR models.

If you decide to use one of the possibilities, you are **claiming an adaptation**.

The approach

a. Prepare a well-documented and valid scientific justification when adapting the standard information requirements and submit it in your registration dossier.
b. The chosen approach must deliver reliable information that is comparable to that from the standard test. If not, then you need to run the test as required.
c. The chosen approach must allow to classify the substance. When the substance is properly classified and labeled, additional testing may not be needed.

Note that it should carefully consider whether to rely on the worst-case classification just to avoid more testing. Over-classification may, for example, trigger risk management measures under occupational health and safety legislation or lead to prioritization for REACH regulatory risk management measures.

BIOCIDES

List of notifications updated

An updated list of those substance and product-type combinations for which a compliant notification for inclusion in the review program has been made is available. It also includes the names of the notifying companies to help you collaborate when submitting an application for approval of the active substance and to help avoid unnecessary testing on animals.

List of compliant notifications

Want to keep using copper in antifouling products?

The time is approaching to notify your interest in **seven** active substance and product-type combinations to get them approved in the biocides review programme. Check the substance-specific deadlines and notify your interest through the biocides IT tool R4BP 3.

Upcoming deadlines

Public consultation on derogation to the exclusion criteria for cholecalciferol

Substances that normally should not be approved as active substances may be used if they meet one or more of the following derogation criteria: exposure is negligible; the active substance is essential to prevent a serious danger to human or animal health or the environment; or, not approving the substance would have a disproportionate negative impact on society when compared to the risks.

Give comments on whether the conditions for derogation are met for **cholecalciferol** by **7 April 2018**.

ECHA has opened its first public consultation on a biocidal active substance with endocrine disrupting properties, the rodenticide cholecalciferol, since adoption last year of the criteria to identify EDCs under the BPR. The consultation is open until 7 April.

Latest events

Eco- toxicology and CLP/GHS – Substances and Mixture Classification
13 March 2018, Chemical Watch

"BPR Technical Equivalence – A Practical Guide"
20 March 2018, Chemical Watch

Toxicokinetics
27 March 2018, Chemical Watch

BREXIT and REACH – Q&A Webinar
27 March 2018, REACHLaw, Online Webinar

Chemistry for the Non-Chemist - Now coming to London
28 March 2018, Chemical Watch, Etc. Venues (Marble Arch)

Paper Packaging Law Seminar
11-12 April 2018 * Keller and Heckman LLP * Atlanta, USA

TSCA, Food-Contact Substances, and FDA Seminar
8-10 May 2018, Keller and Heckman LLP, Omni Chicago Hotel, USA

SETAC Europe 28th Annual Meeting
13-17 May 2018, SETAC Europe, Rome, Italy

CHCS Training "Advanced Preparation of Safety Data Sheets" (Module 15)
23 May 2018, Chemical Hazards Communication Society (CHCS), Malmaison Hotel, 1-3 Piccadilly, Manchester, M1 1LZ

AFI Symposiun 2018, Rimini 6-8 June
Chemsafe workshop on Medical device, June 6, morning
Chemsafe workshop on ERA, June 6, morning

OECD QSAR Toolbox V 4.2 training: Basic (June 11-12) and Advanced Practical (June 13-15)
11-15 June 2018, Reach Monitor SL and LMC OASIS, World Trade Center, Barcelona, Spain

Chemspec Europe 2018
20-21 June 2018, Mack Brooks Exhibitions , Cologne, Germany

TSGE Prague Biocide Conference 2018, Prague
Focus on SMEs - Keeping up with the progress on active substance approvals
Date: 21 - 22 June 2018
Two Chemsafe lectures

ITALY

How do companies use safety data sheet information?

The Italian National Institute for Insurance against Accidents at Work (**INAIL**) has launched a survey on hazardous chemicals for Italian companies working in the rubber, textiles, leather, paper and wood sectors. The aim is to better understand how companies use the information provided in safety data sheets to ensure they handle hazardous chemicals safely, and identify potential areas for improvement in the information communicated.
The survey, developed in collaboration with ECHA, was launched on 19 February 2018 and will run until the end of March 2018. Please find herewith the Italian test from INAIL.

Sostanze chimiche pericolose, al via l'indagine pilota INAIL-ECHA

Partirà il 19 febbraio l'indagine progettata dall'Istituto e rivolta a un campione qualificato di imprese dei settori gomma plastica, tessile e cuoio, carta e legno, che le impiegano nei loro processi di produzione. L'obiettivo è raccogliere informazioni sulla fruibilità delle schede di sicurezza usate in azienda e sulle criticità legate al loro utilizzo nella valutazione del rischio chimico

ROMA - Identificare le eventuali cause che impediscono un uso efficace delle informazioni contenute nelle schede di sicurezza (Sds) per la valutazione del rischio chimico in azienda e proporre le modifiche più idonee per migliorarle. Questo il contributo richiesto a un ampio panel mirato di imprese, attraverso la compilazione di un questionario che sarà online a partire dal 19 febbraio. Il questionario, predisposto da un gruppo di lavoro multidisciplinare Inail, coordinato dalla Direzione centrale prevenzione, è stato condiviso con Echa (European chemicals agency) e Federchimica. I destinatari sono i soggetti, interni o esterni all'azienda, chiamati a occuparsi della valutazione del rischio chimico e del rispetto degli obblighi previsti dal Regolamento Europeo Reach.

Dalle schede di sicurezza le informazioni necessarie contro i rischi chimici. *Le schede dati di sicurezza rappresentano il principale documento informativo che accompagna le sostanze chimiche e le loro miscele. Contengono dati fondamentali per una corretta e sicura manipolazione di sostanze e miscele e consentono al datore di lavoro di identificare le sostanze pericolose e di conoscere i rischi per la salute e la sicurezza dei lavoratori e dell'ambiente, consentendo di adottare le necessarie misure di prevenzione e protezione.*

È la prima indagine europea sul tema. *L'obiettivo della collaborazione fra Inail ed Echa, con il supporto di Federchimica, è quello di realizzare un'indagine per misurare l'impatto delle schede dati di sicurezza delle sostanze pericolose e delle miscele sugli utilizzatori a valle. Con questa denominazione, secondo i regolamenti tecnici Reach e Clp (Classification, labelling and packaging), sono indicati lavoratori individuali o imprese per i quali l'utilizzo di sostanze chimiche non rappresenta l'elemento principale dell'attività ma entra pienamente nel ciclo produttivo aziendale. È il caso, per esempio, delle aziende operanti nei settori prescelti per l'indagine, della gomma plastica, del tessile e del cuoio, della carta e del legno. Tra i prodotti chimici impiegati ci sono solitamente vernici, metalli, adesivi, solventi e detergenti. Lo studio costituisce la prima indagine pilota attivata in uno Stato dell'Unione europea e potrà rappresentare un modello trasferibile anche ad altri Paesi membri.*

Il questionario si articola in 24 domande. *Il questionario, che sarà compilabile online fino al 20 aprile, è strutturato in 24 domande, suddivise in quattro ambiti tematici: organizzazione, conoscenza, aspetti tecnici e gradimento/criticità. Rispondendo a un primo invito, le imprese coinvolte potranno partecipare all'indagine attraverso un link personalizzato che ne consentirà l'attivazione.*

CHEMSAFE: PARTICIPATION TO EVENTS

In the frame of our pharmaceutical/medical health activity, we are now engaged in organizing two workshop during the Italian ***AFI*** (Associazione Farmaceutici Industria) Symposium in Rimini on 6-8 June 2018.
The first workshop will be focused on Medical Devices and the second one on ERA (Environmental Risk Assessment) of medicines. 8 Chemsafe experts will be directly involved as speakers; we expect also to have external guests from companies. Both workshop will be held on Wednesday June 6, 29018 in the morning session. The participation is free; you are all welcome!!

Chemsafe will sponsor and participate as speaket at the **TSGE Prague Biocide Conference 2018**: *Focus on SMEs - Keeping up with the progress on active substance approvals*
Date: 21 - 22 June 2018
Venue: Hotel Occidental Praha (formerly known as Barceló Praha Hotel), Prague
TSGE Forum's annual biocide conference will be returning to the Occidental Praga Hotel, Prague for the fourth consecutive year. Suitable for those involved in the biocides industry, the conference is ideal for meeting a wide range of EU regulators, experts and industry participants from across Europe. The 2018 program will focus on the experience and challenges of SMEs in respect to Mutual Recognition procedures and further progress made in active substance approvals. In addition latest developments in data protection issues, BPR enforcement, borderline cases with other EU legislations and EU guidances will be discussed.
As with previous conferences, the event will offer plenty of networking opportunities, including a drinks reception.

Confirmed speakers include:
Dr Mandy Osterloh - Dow Microbial Control
Product Authorization: Industry Experience with Union Authorization
Thomas Raas - Redebel Regulatory Affairs
Dr. Antonio Conto - Chemsafe Srl
BPR Dossier Project Management, regulatory and management challenges
Dr. Francesca Fasano - Chemsafe Srl
Risk Assessment of Disinfection By-Products
Tatjana Röder - aquagroup AG