NEWSLETTER DECEMBER 2017

GLYPHOSATE'APPROVAL

Glyphosate is an active substance (heribicide) used in plant protection products to control plants.
Glyphosate is the most frequently used herbicide both worldwide and in the EU; it has been used for several decades and has been thoroughly assessed by Member States and the European Food Safety Authority (EFSA) in recent years.
Glyphosate-based pesticides are used as herbicides in agriculture, horticulture and in some non-cultivated areas and they are used primarily to combat weeds that compete with cultivated crops or present problems for other reasons (e.g. on railway tracks). They are typically applied before crops are sown to control weeds and therefore facilitate better growth of crops by eliminating competing plants. This approach eliminates or minimizes the need to use ploughing machines ("zero tillage" farming), thereby reducing soil erosion and carbon emissions. Glyphosate is also used to a lesser extent as a pre-harvest treatment to facilitate better harvesting by regulating plant growth and ripening
On 15 March 2017, the Risk Assessment Committee (**RAC**) of the European Chemicals Agency concluded by consensus that:

- *There is no evidence to link glyphosate to cancer in humans, based on the available information*
- *Glyphosate should not be classified as a substance that causes genetic damage (mutagen) or disrupts reproduction.*

The same conclusion was also reached by the other important organizations such as:

- *European Food Safety Authority (EFSA), supported by experts from 27 EU Member State Competent Authorities*
- *National Authorities outside the EU (e.g. Canada, Japan, Australia, New Zealand)*
- *Joint Food and Agriculture Organization of the United Nations – World Health Organization Meeting on Pesticide Residues (JMPR)*

The International Agency for Research on Cancer (IARC) remains, therefore, the only Agency with a different view on glyphosate.
On November 27, 2017 the EU Member States agreed by a qualified majority to renew the approval of the glyphosate for five years. The Member States' representatives voted in the appeal committee on the Commission's proposal. The vote was distributed as follows:

- **18** Member States voted in favour (representing 65.71% of the EU population)
- **9** Member States voted against (representing 32.26 % of the EU population)
    - two Member States voted against as they wanted a renewal or extension of approval for a maximum period of 3 years.
    - one Member State voted against as it could only support a 3-year extension of the current approval, followed by a phase-out period of two years.
    - three Member States voted against due to political and societal sensitivity and environmental concerns.
    - one Member State voted against without any explicit reason.
    - one Member State voted against as it considered a 5-year renewal period as too long.
    - one Member State voted against as its National Parliament had adopted a formal position against any period of renewal or extension of approval.
- **1** Member State abstained (representing 2.02 % of the EU population)

NEW SUBSTANCE EVALUATION CONCLUSIONS PUBLISHED

Acetone oxime (EC 204-820-1; CAS 127-06-0), added to the CoRAP list in 2016 and evaluated by Austria;
Chloromethane (EC 200-817-4; CAS 74-87-3), added to the CoRAP list in 2012 and evaluated by Italy;
Resorcinol (EC 203-585-2; CAS 108-46-3), added to the CoRAP list in 2016 and evaluated by Finland;
Cyclohexylamine (EC 203-629-0; CAS 108-91-8), added to the CoRAP list in 2016 and evaluated by Belgium;
Tetrahydrofuran (EC 203-726-8; CAS 109-99-9), added to the CoRAP list in 2013 and evaluated by Germany;
Hydroquinone (EC 204-617-8; CAS 123-31-9), added to the CoRAP list in 2012 and evaluated by Italy.

REACH AUTHORISATION

On December 12, 2017 Commission publishes study on the impacts of REACH Authorization

The EU Commission published a study report carried out by an external team of consultants whose aim is to assess the performance of the REACH authorization system and to provide evidence of its effects.
The study on the impacts of REACH authorization indicates that the system is achieving its objectives. The authorization system is progressively promoting substitution of substances of very high concern (SVHCs) by available alternatives and reducing risks associated with the use of SVHCs.
The main benefits of authorization:
- *REACH is one of the main drivers for substitution of SVHCs, from as early as the candidate listing stage*
- *Companies are improving Risk Management Measures (RMM) and Operating Conditions (OC) when substitution of SVHCs is not possible*

The study faced the changes in the market for SVHCs and the markets for their alternatives but found no clear indications of changes. Furthermore, the study could not fully quantify the costs of the overall authorization process. However, it did provide an estimation of costs related to the process of application for authorization, both for Authorities and for Companies.

The following two pictures show some results of the study:

Costs of authorisation	
Costs to EU public authorities	~€8.4million per year
Costs to EU applicants	~€9million per year
Costs of additional RMMs associated with these applications	~€7million per year
Costs of substitution	Not possible to estimate the total costs without knowing how many firms in the EU have substituted. One off costs estimated at <€1million per company (mean ~€1.5million per company) and €768k annual operating costs per company.
Costs of compliance	Not possible to estimate the total costs without knowing how many firms are affected. The costs of compliance are likely to run into thousands (possibly tens of thousands) of euros per company, which could make them significant at an aggregate level.
Costs to third parties	Not possible to estimate a total cost due to limited responses. The average time spent per submission varies from up to 1 day to 40 days depending on the type of public consultation and stakeholder.

Benefits of authorisation	
Human Health benefits	Clear evidence of improved RMM and reduced exposure
Benefits of substitution	Mainly reduction in exposure and emissions
Benefits from closure and relocation	Few case of relocation or closure identified
Benefits to alternative suppliers	Authorisation process helps to create a market for alternatives in a controlled way
Benefits of better information	Improved transparency and communication with authorities.
Other benefits	Communication between applicants leading to exchange in experience. Driver for innovation. Collection of structured information on the use of SVHC

FROM ECHA

The Directors' Contact Group (DCG) recommends four actions to ease the cost burden on first-time registrants for accessing data and the joint submission for their REACH 2018 registration.
The DCG recommends four actions for companies and ECHA to allow small-volume or SME registrants that have not registered substances before to access data and the joint submission with reasonable effort.

These actions are:

1. **Reducing the costs of data for 1-10 tons registrants by exploring data waiving arguments**: Companies should check whether they are exempted from providing toxicological data with their small-volume registration and could register only with physicochemical data. These exemptions relate to Articles 12(1)(a) and (b) and Annex III of REACH. Those who can register with physicochemical data only, should get access to the data and joint submission at reduced or no costs.
2. **Addressing situations caused by late data-sharing negotiations or pending dispute decisions**: The DCG recommends that first-time registrants file a data-sharing dispute with ECHA if the negotiations for access to data have come to a standstill and all means to reach an agreement have been exhausted. Companies will be able to submit their registration dossier while the negotiations or the dispute process are ongoing. ECHA will clarify how it will deal with these dossiers by the end of January 2018.
3. **Reducing the cost burden on SMEs by allowing payment in instalments**: If a one-time payment of the letter of access (LoA) is unaffordable for the first-time registrant – and they can justify why – lead registrants and the managers of the substance information exchange fora (SIEF) should consider granting the registrant the opportunity to pay in instalments.
4. **Offering a low-cost affordable lump sum payment option for 1-10 tons registrants**: Lead registrants and SIEF managers can reduce the administrative burden of joining an existing joint submission and the risk of a data-sharing dispute by offering first-time registrants the opportunity to make an affordable lump sum payment. The recommendation also provides circumstances and conditions that facilitate lump sum charging.

The DCG recommendation only concerns access to existing data for registering substances by the May 2018 deadline. It will not apply to sharing the costs of creating new data or providing information, for example, in response to ECHA's substance evaluation decision.

On 31 January 2018, ECHA holds its REACH 2018 Stakeholders' Day where first-time registrants get advice from ECHA and industry experts and can ask questions from ECHA staff.

BIOCIDES

ECHA and EFSA published a draft ED guidance for public consultation on December 7th, 2017

ECHA and the European Food Safety Authority (EFSA) have published their draft Endocrine Disruptors (EDs) Guidance for public consultation. The European Commission asked the agencies to produce guidance on the identification of EDs according to the new EU criteria, which will have a direct impact on regulatory risk assessment of pesticides and biocides. The guidance, like the criteria, is largely based on the 2002 definition of an ED, published by the WHO and the International Program for Chemical Safety and it describes how to:

- *gather, evaluate and consider all relevant information for the assessment;*
- *conduct a mode-of-action (MoA) analysis;*
- *apply a Weight-Of-Evidence (WoE) approach, in order to establish whether the ED criteria are met.*

Chapter 3 of the guidance gives the assessment strategy for determining whether a substance meets the criteria. It includes a proposed approach to study the information provided in a dossier, submitted for approval in the context of the plant protection products (PPP) or Biocides Regulation (BPR).
Chapter 4 provides an overview of sources that may provide suitable information. It also describes how to use the scientific data from standard test methods to evaluate adverse effects and endocrine activity. Effects can be grouped via an approach, based on those published previously by the OECD and the Commission's Joint Research Centre. The document only addresses endocrine disruption caused by oestrogen, androgen, thyroid and steroidogenic (EATS) 'mode of action'. It says these are the best characterized pathways for which there is "relatively good mechanistic understanding". And they are standardized test methods with broad scientific agreement on interpretation of data.
In general, the document bases the suitability of test methods on the OECD "*conceptual framework for testing and assessment of endocrine disruptors*", which is still under development but available as a draft.
The ED criteria state that scientific data generated without standard test methods should be gathered via systematic review but does not endorsed a specific conceptual framework, of which there are now many.
The document says that users should follow EFSA guidance on:

- *application of systematic review methodology to food and feed safety assessments to support decision making, published in 2010*
- *submission of scientific peer-reviewed open literature for the approval of pesticide active substances, published in 2011.*

The public consultation follows two targeted consultations involving experts from member state competent authorities, industry and NGOs. The most recent generated 1,800 comments.

Interested parties have until 31 January 2018 to submit comments. The final guidance is slated for publication in June 2018, when the criteria enter into force.

ECHA Events for December 2017 – February 2018

Committee for Risk Assessment
4-5 December

Member State Committee
11-15 December

Biocidal Products Committee
11-15 December

Management Board meeting
14-15 December

REACH 2018 Stakeholders' Day
29-31 January 2018

Member State Committee
5-9 February 2018

WORLWIDE

Restrictions on methylene chloride, NMP, TCE apparently shelved by US EPA

The US EPA has informed it is shelving proposals to restrict the use of the solvents ***methylene chloride*** (dichloromethane), ***n-methylpyrrolidone*** (NMP) and ***trichloroethylene*** (TCE).
Section 6 of TSCA, which predates the 2016 amendments, gives the EPA power to ban or restrict a chemical if it concludes that it presents an unreasonable risk to human health or the environment. The agency issued three proposed section 6 rules in the Obama administration's final days in January 2017.
One would restrict the use of methylene chloride and NMP for all consumers and most commercial paint removal. Two separate proposals would prohibit the use of TCE in vapour degreasing and as an aerosol degreaser and spot cleaner. On 14 December, the EPA, along with all federal agencies, published a semi-annual regulatory agenda that lists the status of pending proposals.
The methylene chloride/NMP rule, as well as the TCE proposal regarding vapour degreasing, were moved to the "long-term action" list of items the EPA does not plan to act on within a year, with no projected date for further action. When an agency does this, it often means it is abandoning the issue.
The second TCE rule had already been moved to "long-term action" when the regulatory agenda was last updated on 24 August.
The August version of the agenda indicated that the EPA intended to propose an amended proposal on methylene chloride and NMP and some observers held out hope that the agency might proceed. The EPA held a 12 September workshop on the use of methylene chloride in furniture refinishing, which it had explicitly excluded from its initial rule.
"All three chemicals have been extensively studied and associated with both illness and death," Daniel Rosenberg, senior attorney at the National Resource Defence Council (NRDC), wrote in his blog. "The next

death(s) due to inhalation of methylene chloride will truly be on the hands of Scott Pruitt, Nancy Beck and President Trump."
Environmental groups characterized the new agenda as solid evidence that under the Trump administration, the EPA agency will not take any action on toxic chemicals that is not mandated.
TCE, NMP and methylene chloride are still among the first ten substances undergoing risk evaluation under the new TSCA, and industry has argued that the EPA should defer to that process. Industry groups have attacked the section 6 proposals on procedural grounds and argued that the agency improperly relied on old risk assessments.

CHEMSAFE NEWS

Every year, we celebrate the incoming Christmas and New Year Eve with a social lunch all together in a selected restaurant close to our location. This year we went to the *Canavese Golf and Country Club*, a wonderful golf facility in the green forest close to San Giovanni village. Before the event, our Managing Director, Antonio Conto, briefly talk about the 2017 results and future expectation. 2017 was a very good year in terms of revenue, number of services/dossier carried out and new opportunities. The next 2018 will be a transitional year as all of the REACH dossiers will be submitted by end of May (around 250); new opportunities and ideas are already in place. In such a year Chemsafe will attend to 9-10 events presenting talks, posters or simply exhibiting in order to increase its visibility at international level. Antonio underlined that all persons in Chemsafe represent a high level of professionals, top skilled, working with a team approach and giving to customer quick and precise answers. He counted the number of customers that have been working with Chemsafe since its foundation. The number is close to **500**; an amazing reality! Only in 2017 Chemsafe got **42** new customers! ***2018 will be a challenge.. we are ready to face it!!***

PARTICIPATION TO EVENTS

On December 18 and 19, the Xth National Conference on Medical Devices took place in Rome. Chemsafe attended with 4 people of its dedicated service group. The conference was mainly focused on the Italian Competent Authority activity rather than giving regulatory/technical details on technical dossier, risk assessment, biological and clinical studies which are the relevant news in the Reg. EU 745/2017. A huge participation of attendees (around 1.000) demonstrate the high interest of the industrial community to this piece of new regulation deeply impacting such sector. Chemsafe will focus such argument in a workshop during the 58° AFI Symposium in Rimini on June 6-8, 2018. Further information will be given in the next newsletters.