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REFIT Platform

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STAKEHOLDER SUGGESTIONS

- CHEMICALS -

DISCLAIMER

This document contains suggestions from stakeholders (for example citizens, NGOs, companies) or Member State authorities communicated to the Commission and submitted to the REFIT Platform in a particular policy area.

It is provided by the secretariat to the REFIT Platform members to support their deliberations on the relevant submissions by stakeholders and Member States authorities.

The Commission services have complemented relevant quotes from each suggestion with a short factual explanation of the state of play of any recent, relevant ongoing or planned work by the EU institutions.

The document does not contain any official positions of the European Commission unless expressly cited.

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1. SUMMARY

This briefing file includes two suggestions in two different areas:

Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH):

- The German Chambers of Commerce and Industry (DIHK) argue that more needs to be done to prepare SMEs prior to the 2018 registration deadline and make the authorisation process easier for firms. The REACH Regulation was adopted in 2006. A REFIT evaluation of REACH is due by 2017.

REACH – OSH:

- The Cross Industry Initiative suggests tackling the interface between the REACH Regulation's authorisation process and Occupational health and safety (OSH) legislation. The REACH regulation was adopted in 2006. The relevant pieces of OSH legislation are Chemical Agents Directive adopted in 1998 and the Carcinogens and Mutagens Directive from 2004. The latter two Directives are currently being evaluated by the Commission and conclusions are due in first quarter 2016.

2. REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTIONS OF CHEMICALS (REACH)

2.1. Submission by the German Chambers of Commerce and Industry (DIHK)

There is no current need to revise the REACH Regulation at the moment. The reason for this is that any such revision of the REACH Regulation would be associated with the risk that the measures which have already been taken by companies to deal with the very complex procedures for registering, evaluating and authorising substances would have to undergo fundamental changes.

Registration process

The European Commission, the European Chemicals Agency (ECHA), the Member States and the national chemical agencies must ensure the intensive preparation of companies in particular who will have to deal with the registration process for the first time for the 2018 registration deadline, as well as the transparent and SME-friendly implementation of the REACH registration.

The actions envisaged by ECHA and the Commission to support companies, especially SMEs, dealing with REACH are appreciated by DIHK. This specifically applies to a stronger emphasis on socio-economic aspects and a greater flexibility in finding the most appropriate Risk Management Measure. However, as we are mostly dealing with plans and not with adopted measures yet, a final appraisal is difficult.

In particular, when it comes to the 2018 registration deadline it will be decisive that the prepared actions will be implemented soon and will be communicated sufficiently and that they will generate significant positive effects.

Authorisation procedures

The authorisation procedures for substances listed in Annex XIV must also be manageable for SMEs and with respect to substances which are only used in special

applications.

2.2. Policy Context

REACH requires all companies manufacturing or placing a substance on the EU market in quantities at or greater than 1t/year to register that substance with the European Chemicals Agency (ECHA). The Regulation laid down three registration deadlines which depend on the tonnage band (quantity) of a substance manufactured or imported by each company and the classification of the substance. The last registration deadline of 31 May 2018 will concern substances produced or imported in the smallest bond of quantities between 1-100 tonnes.

ECHA's 2018 Roadmap expects up to 70.000 registrations under the 2018 deadline. This is three times more than for either of the previous deadlines. Significantly, many more of the registrants are expected to be from companies outside the chemical sector, and there will be more small and medium-sized enterprises (SMEs). It will constitute a major challenge in particular for SMEs, in view of their limited experience and resources.

Registration procedure

In the follow-up of the 2013 REACH Review, several actions aiming at providing support to SMEs to meet the 2018 registration deadline are being implemented. This is for example the case of the ECHA 2018 registration Roadmap which was published on 14 January 2015 and is available at the following address: http://echa.europa.eu/view-article/-/journal_content/title/reach-roadmap-published.

As part of its implementation, ECHA has developed specific webpages dedicated respectively to newcomers (http://echa.europa.eu/support/getting-started) and to 2018 registration (http://echa.europa.eu/reach-2018), as well as a simplified REACH Guide for SMEs:

(http://echa.europa.eu/documents/10162/21332507/guide_chemical_safety_sme_en.pdf).

ECHA has also dedicated a page to Substances of Very High Concern: http://www.echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan.

In addition an Implementing Regulation aiming to enhance the effectiveness of the data-sharing provisions in REACH by promoting good management practices and by ensuring that data-sharing agreements function in a manner that is fair, transparent and non-discriminatory was adopted in January 2016.

Other measures

A 'communicators' network' that brings together industry, national helpdesks, Enterprise Europe Network, ECHA and the Commission has been set up with the objective to coordinate awareness-raising activities and share best practices ahead of the 2018 deadline.

The Commission together with ECHA is also focusing on activities to assist specific sectors composed mainly of small enterprises to comply with the REACH registration. For example, a guidance document has been prepared by the essential oils sector and

endorsed by ECHA, providing concrete guidance on the issues of concern for that sector.

Background on authorisation procedure

The authorisation procedure aims to assure that the risks from Substances of Very High Concern (SVHC) are properly controlled and progressively replaced. Substances subject to authorisation cannot be used after a given date unless authorisation is granted.

The first step is identification of a substance as SVHC and then inclusion on the Candidate List. Finally the SVHC may be subject to authorisation if, through a Commission Regulation, it is included in Annex XIV of the REACH Regulation[1].

The Commission is considering reducing the frequency of amendments of Annex XIV and to simplify and streamline the application process; in particular in specific cases where risks to human health and the environment are clearly lower than the socio-economic benefits of continued use of the substances.

Current State of Play

A REFIT evaluation of REACH is due by 2017.

3. REACH – OCCUPATIONAL HEALTH AND SAFETY (OSH)

3.1. Summary of the Submission by the Cross Industry Initiative

In recent years there has been growing concern from Industry about the effectiveness of applying the EU chemical Regulation REACH's Authorisation scheme to substances that are exclusively handled in the workplace. In fact, the REACH Authorisation procedure has been considered for such substances despite the fact that there were no identified risks outside the workplace that would require further risk management measures. We believe that the authorisation should not be considered as the preferred option when potential risks can be more effectively addressed by workplace-specific legislation.

Such legislation, in our view, better addresses potential risks at the workplace as it also ensures the safety of employees working with intermediates (which fall outside the scope of REACH Authorisation). Opting for REACH Authorisation would not add any layer of protection where safety can already be established by applying occupational health and safety legislation, and by establishing a protective EU-wide occupational exposure limit (OEL). Furthermore, REACH Authorisation is significantly more costly than compliance with protective workplace legislation, given the costs for preparing the extremely complex application process and application fees. REACH Authorisation aims to increase the push towards substitution of substances. However, the replacement of carcinogens and mutagens and of hazardous substances is already foreseen, if feasible, under existing workplace legislation.

Furthermore, for many concerned uses neither suitable alternative substances nor technologies are expected to become economically and technically viable. In the cases described above, REACH Authorisation could have a severe impact on the economies of Member States and put jobs at risk.

[1] List of substances subjected to authorisation. These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use.

We would first like to stress that the proposed solution would not lead to less regulation, as some EU stakeholders could fear when hearing about a better regulation initiative. What we propose is a tailor-made and targeted regulation, which would avoid duplication, but without leaving gaps in regulation. The aim is a holistic consideration of applicable legislation, which allows selecting the most appropriate and efficient tool available in the legislation to address adequately the concerns raised by the use of a specific substance. In doing so, we systematically apply the principles outlined in the European Commission's Roadmap on Substances of Very High Concern (SVHC Roadmap).

While in other cases, REACH Authorisation may indeed be the best regulatory instrument to address the identified risks, in the specific situations that we describe, the workplace legislation with its comprehensive set of prevention and protection measures developed over the last decades, including but not limited to the setting of EU-wide Occupational Exposure Limits (OELs), be they indicative or binding OELs, is the appropriate, targeted and proportionate regulatory choice to address potential risks. The alignment between REACH and EU Occupational Safety and Health (OSH) legislation that we call for is also in line with the objective of REACH to be aligned with workplace legislation (see e.g. Recitals 5, 12 and 111 of the REACH Regulation).

3.2. Policy Context

EU OSH laws provide a comprehensive and long established framework to protect workers from chemical risks.

As horizontal harmonisation legislation, REACH generates information on chemicals whether used by consumers, professionals or workers and, when necessary, restricts or requires authorisation of chemicals for certain uses in order to ensure a high level of protection of human health and the environment as well as the free movement of substances, while enhancing competitiveness and innovation.

REACH and OSH legislation are complementary and both are necessary to protect workers from the risks from chemicals.

The EU acquis principles of worker protection are fundamentally laid out in the over-arching OSH 'Framework Directive'[2] – which applies without prejudice to 'existing or future national and EU provisions which are more favourable to protection of the safety and health of workers at work'[3]. REACH can be expected in some cases to fulfil this criterion. REACH in turn applies without prejudice to worker protection legislation, including the Framework Directive and those directives specifically dealing with chemicals risks, notably the Chemical Agents Directive[4] (CAD) and the Carcinogens and Mutagens Directive[5] (CMD).

Recently, industry has expressed some concern about the interaction between OSH and REACH authorisation. In general, REACH applies without prejudice to worker protection legislation and OSH legislation applies without prejudice to existing or future Union provisions that are more favourable to the protection of the safety and health of workers at work. The Commission services are working with stakeholders to find ways to manage

2 Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, OJ L183, 29.6.1989, p. 1.

3 Directive 89/391/EEC, Article 1(3).

4 Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, OJ L 131, 5.5.1998, p.11.

5 Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, OJ L 158, 30.4.2004, p.50.

the interface in order to avoid imposing a double burden on companies.

REACH[6] provides specific exemptions or derogations from the authorisation requirement for uses of substances in certain products (e.g., plant protection products, biocides, cosmetic products, food contact materials) and provides for a possibility to exempt specific uses or use categories where, on the basis of existing specific Union legislation imposing minimum requirements relating to the protection of human health or the environment for the use of a substance, the risk is properly controlled[7]. Possible exemptions must be considered on their individual merits.

Whether OSH legislation can justify exempting certain uses of substances from the REACH authorisation requirement was the subject of a recent judgment of the General Court in Case T-360/13 VECCO and Others v COM, which may be relevant for some of the points raised by the Cross-Industry Initiative and will also feed into further discussion between the different Commission services and Member States.

Current State of Play

Extensive guidance on the protection of workers from chemicals under both REACH and OSH, and on the interface between the two systems, has been developed and published from different perspectives while experience is developing of the implementation of REACH, the OSH directives have been subject to a major Fitness check due to be concluded in Q1 2016.

6 Article 56(4) and 58(2)

7 (EC) No 1907/2006, Article 58(2).