REFIT Platform Opinion

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REFIT Platform Opinion on the submission by the Cross Industry Initiative on the interface between REACH and the EU Occupational Safety and Health (OSH) legislation

The REFIT Platform has considered the submission by the Cross Industry Initiative that the interface between certain REACH provisions and the EU occupational, safety and health (OSH) legislation is complex and clarification is needed.

The majority of the Platform acknowledges that REACH and OSH are mutually reinforcing and need to be maintained in their present form and support the recommendation that the Commission should raise awareness and issue guidance on their implementation.

Detailed Opinion

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1 Submission II.2.a 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.

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).

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’1 – 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’2. 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 Directive3 (CAD) and the Carcinogens and Mutagens Directive4 (CMD).

Recently, industry has expressed some concern about the interaction between OSH and REACH authorisation. The Commission services are working with stakeholders to find ways to manage the interface in order to avoid imposing a double burden on companies.

REACH5 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 controlled6. 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 the Commission. That case is now before the Court of Justice of the EU on appeal and the ruling 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 some aspects of the interface between the two systems, has been developed and published from different perspectives. Experience is developing of the implementation of REACH and the OSH directives have been subject to a major evaluation/fitness check and the outcome is expected in the course of 2016. REACH will be subject to a REFIT evaluation due to be concluded by the end of Q2 20177.

DG GROW, DG EMPL and DG ENV are working together to find possible solutions for those aspects of the two bodies of legislation, where conflicts have arisen, such as the

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2 Directive 89/391/EEC, Article 1(3).
5 Article 56(4) and 58(2)
divergences between 'derived no effect levels' (DNEL) and 'occupational exposure limit' (OEL) values, the methodologies used to derive them, and the application of appropriate risk management measures to control the risk of chemicals at the workplace. The Commission services mandated the respective scientific committees, i.e. the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) and the Scientific Committee on Occupational Exposure Limits (SCOEL) to create a Task Force to analyse the reasons for these divergences and to seek to converge their methodologies in order to bring about convergence of the numerical values.

Further activities are ongoing such as in the exchange network on exposure scenarios (ENES), an initiative of ECHA and industry stakeholders, working on guidance and best practice to ensure effective communication along the supply chain. ECHA’s FORUM of national enforcement authorities is working with the Senior Labour Inspectors Committee on the exchange of information among enforcement authorities. Lastly, the competent authorities in the Member States responsible for OSH and REACH are collaborating when assessing different regulatory options to manage chemicals at the workplace.

3 Opinion of the REFIT Platform

3.1 Considerations of the REFIT Platform Stakeholder group

- The majority of the Stakeholder group considers that: The two pieces of legislation REACH and OSH are complementary and work well together when correctly implemented (there are synergies rather than duplications). The REACH legal text is clear that REACH applies without prejudice to EU OSH legislations. Companies have therefore to comply with both the obligations of REACH and OSH legislation.

- The costs of accidents at work and occupational ill health range from 2.6% to 3.8% of GDP (EU-OSHA), and for every Euro invested in OSH, there is a return of 2.2 € (ISSA, 2013). Additionally, the Commission’s 2012 report on the Top 10 burdens for SMEs across the EU, alluded to in the section of this Opinion combining the "considerations of the Government group" is based on a poll with severe limitations. A truly in-depth study of the costs and benefits of REACH for SMEs has not been carried out. In addition, the term ‘burden’ is nowhere defined in the survey, leading to a worrying conflation of terms as disparate as information obligations (i.e. paperwork) and compliance costs (i.e. the costs associated with or resulting from the implementation of a piece of legislation). The fact that a piece of legislation has been designated as ‘burdensome’ in this report does therefore in no way entail that ‘administrative burden reduction’ is possible, and any attempt to do so may detract from the policy objectives of the legislation.

- The difference between DNEL and OEL is that DNEL establishes ‘a no-effect-level’ based on the scientific evidence available, whereas OELs effectively constitute a compromise among authorities, workers and employers, after reviewing scientific data, taking into account costs incurred by companies for implementing protection measures, etc. 13 new BOEL are considered. These include a proposed limit for the hazardous chemical Chromium VI of 25μg/m3, a level of exposure that is significantly and dangerously higher than many national requirements. This proposed level of exposure will have extremely harmful effects on workers and on the population living in the
vicinity of the facilities where it is used. According to ECHA, this proposed limit would result in fatal lung cancer in every tenth worker over a working-life exposure. When the health-based limit calculated by the businesses is higher (and therefore less protective) than that calculated by the SCOEL, protection of workers’ health is no longer assured. Exposure to the substance at levels lower than the DNEL but higher than the indicative OEL may be problematic. In this case, the role of ECHA, responsible for checking the compliance of the data provided by the companies with the obligations of the REACH regulation, is crucial assess the validity of the risk management measures proposed by these businesses.

- As an EU OSHA study has highlighted, confusion among SMEs often stems from their having insufficient understanding of chemical risk. Rather than compromising the policy outcomes of the legislation, efforts should be made by public authorities and industry sectoral associations to increase the knowledge and the capacity of SMEs to prevent chemical risks.

Concerning the second observation stated in the section "observations of the Government group" about the perceived length on the complexity of safety data sheets:

- We do not see the length and complexity of safety data sheets as a problem, but rather as an improvement for workers. Thanks to REACH, safety data sheets (SDS) are now providing safety information for all known uses of a substance. As a consequence, the Safety data sheets are indeed longer. The solution is certainly not to simplify SDS but rather to train workers on how to use them.

- It is however true that SMEs often have difficulties in understanding the SDS. The obligation under REACH to include exposure scenarios in the SDS is intended to help companies to apply the adequate risk management measures. However, what is needed is better information and training for SMEs and workers (for example informing workers that they only need to read the section of the SDS which is related to their specific use of the substance), not changing and thereby weakening the EU information requirements established by REACH to the basic/insufficient requirements from the Globally Harmonised System (GHS)

Concerning the third observation stated in the section of this Opinion combining the "observations of the Government group" about the perceived a lack of clarity on the issue of whether a substance with an OEL could be exempted from REACH authorisation under 58(2) of the REACH Regulation:

- We are of the opinion that the existence of a binding limit value for a carcinogen at EU level is not a reason to grant exemptions under REACH authorisation. This was confirmed in “Vecco case” (EU General Court judgment in case T-360/13). When workers are exposed to carcinogens (because substitution or use in closed system are not feasible), the best way to protect them is to have both a binding a limit value under OSH and an authorisation under REACH.

- Neither the existing indicative nor binding OELs are appropriate reasons to request authorisation exemptions under REACH Art 58(2).
Recommendation

The two pieces of legislation work on a complementary basis and there is no ground to assume that REACH authorisations are redundant. Efforts should be made by public authorities and industry sectoral associations to increase the knowledge and the capacity of SMEs to prevent chemical risks.

3.2 Considerations of the REFIT Platform Government group

All Member States accept the fact that REACH and the EU legislation on worker protection should complement each other and any proposals put forward here are not aimed at undermining the good existing levels of protection provided by both pieces of legislation. Some proposals to address the interface between REACH and OSH requirements are: (although these are not all supported by every Member State)

- more needs to be done so REACH and OSH legislation work together better and synergistically. DG Employment (responsible for the OSH Directives), DG Grow and DG Environment (jointly responsible for REACH) need to work more closely together in order to provide the clarity and changes necessary to attain the necessary regulatory efficiencies between REACH and OSH legislation, including reducing the double burden on companies particularly for SMEs. Such an alignment between REACH and EU Occupational Safety and Health (OSH) legislation is also in line with the objective of REACH to be aligned with workplace legislation (see Recitals 5, 12 and 111 of the REACH Regulation).

- there is only a limited set of options to control chemicals risks to workers – starting with substitution by a safer alternative, and then reducing exposure by means of shielding (e.g. using a closed system), reducing quantities used, duration of worker exposure, numbers of workers present, etc., and by using effective ventilation, protective equipment, and good workplace hygiene. The OSH Directives and REACH should align along these well-established risk control principles to help employers practice good occupational hygiene to control risks, and should not focus on ‘numbers’, which can seem confusing and daunting to employers – especially if they get different numbers for the same chemical. The numbers themselves may not be useful if they are calculated in a very abstract way, are based on too little or outdated information, or are not possible to achieve or measure.

- it may be the case that REACH authorisation may not be necessary where OSH legislation is shown to provide an appropriate, targeted, proportionate and mandatory regulatory control of risks. This should be decided on a case-by-case basis using defined criteria. On that basis, OSH legislation may be considered adequate where all of the following conditions are fulfilled:
  o the substance is used only in the workplace (the provisions of REACH may still continue to apply depending on the substance involved)
  o the substance is not hazardous to the environment (environmental risks are not addressed by OSH legislation)
  o the substance cannot be substituted wholesale by a less hazardous alternative (a driving force for REACH is removal of substances very hazardous to health from the market whereas OSH legislation approach that the employer is best placed to take decisions on substitution based on an assessment of the risks in
their own workplace rather than driving substitution via the supply chain in the same way as REACH). In cases where OSH legislation would apply, it should be ensured that the analysis of alternatives, regarding substances, techniques and technologies, is carried out in a thorough and robust manner.

- exposure to the substance can be demonstrated to be adequately controlled.

- more needs to be done to raise awareness of OSH legislation as an appropriate risk management measure. Appropriate risk management measures (RMMs) under REACH are considered case-by-case in the Risk Management Expert Group (RiME). Here experts from Member States routinely consider whether OSH or other controls are better able to manage risks than authorisation or restriction under REACH. This is done as part of a Risk Management Options Analysis (RMoA) which is undertaken for substances of concern, particularly those under consideration for REACH restriction or authorisation. Although OSH is now helpfully part of the discussions regarding the appropriate RMMs for substances, the awareness of OSH as a robustly enforced and rigorous control regime amongst those more acquainted with the requirements of REACH could be enhanced.

- more needs to be done to address the complexity of safety data sheets under REACH and make them more user friendly for SMEs (the basic headings of the safety data sheet is determined under UN Globally Harmonised System (GHS) requirements but the addition of further information such as extended exposure scenarios required by REACH makes them more lengthy and complex. The key question is about achieving the right balance between providing the required information to comply with REACH and tailoring the amount in a way proportionate to the needs of SMEs).

- more needs to be done to improve the way the EU sets and updates Indicative Occupational Exposure Limit Values (IOELVs) and especially Binding Occupational Exposure Limit values (BOELVs) – the current process for BOELVs takes years and this makes them difficult to see as credible equivalents to the much more modern and fast processes used under REACH. Also, it should be considered whether the usually time consuming concept of modifying health based limit values by socioeconomic impact assessments is justified from a political and scientific point of view. It may be preferable to accommodate relevant socioeconomic aspects by setting appropriate transitional periods.

To address the confusion, some definitive awareness raising and guidance from the Commission agreed between the relevant DGs (DG Grow, DG Environment and DG Employment) needs to be developed so that the interfaces between REACH and OSH legislation is clearly established in order that SMEs in particular have a better understanding of the purposes of both pieces of legislation and how they interact. Member States could also helpfully contribute to the issues raised in collaborating to share good practice of how the relevant authorities involved in REACH and worker protection have got together to agree a position on how to manage the interfaces between REACH and worker protection legislation and subsequent implementation and enforcement. Greater co-operation between the various EU enforcement platforms such the REACH FORUM and SLIC/CHEMEX would also be beneficial. The REFIT Platform will provide the right impetus to address the issues on REACH and OSH.
One Member State has the following observations:

Both the issues of the EU REACH Regulation (EU No. 1907/2006) and worker protection legislation featured in the Commission’s 2012 report on the Top 10 burdens for SMEs across the EU and subsequent follow up work. The issue of how business should comply with the requirements of REACH (a single market measure) and the relevant Directives dealing with protecting the health and safety of workers in the chemicals industry (a OSH acquis measure) was also raised by UK businesses during the development work of the report of the Prime Minister's EU Business Task Force on “Cutting EU Red Tape” in 2013. More recently, suggestions received via the Commission’s “Lighten the Load” website to inform the work of the REFIT Platform in 2015 also touched on the issue.

In response to these earlier concerns, the Commission has helpfully reduced the fees for SMEs under REACH by between 35-95% for medium-sized, small and micro companies (EU No. 254/2013) and an SME Ambassador has been appointed by the Commission’s European Chemicals Agency (ECHA). The Commission has also reviewed possible overlaps with other EU legislation affecting chemicals, as well as particular difficulties, for SMEs. Although further recommendations could result as a consequence of the planned REACH REFIT exercise, ECHA updated last year the ECHA website to provide greater support and guidance to assist SMEs


In spite of this, confusion still appears to exist in three areas.

Firstly, REACH uses a system called “Derived No Effect Levels” (DNELs) whereas the relevant OSH Directives – the Chemicals Agents Directive (98/24/EEC (CAD)) and the Carcinogens and Mutagens Directive (2004/37/EEC (CMD)) - use a system of worker exposure limits comprising both Indicative Occupational Exposure Limits (IOELVs) and Binding Occupational Exposure Limits (BOELVs). The methodology of setting DNELs and the worker protection limits is different and consequently different limits can appear for the same chemical substances or there may be a DNEL for a substance when there is no equivalent IOELV or BOELV under the OSH Directives. This leaves businesses, especially SMEs (and regulators) confused as to which chemicals management regime applies under which circumstances and what their purposes are, especially when one set of measures comes from a directly applicable EU Regulation – REACH – and the other set of requirements derive from Directives which have to be transposed into Member State law. It has also led to a perception that a DNEL is a different type of exposure limit. DNELs are mainly set by industry for use by their customers. ‘Reference’ or ‘harmonised’ DNELs under REACH have no legal status but have effectively become quasi-legal regulatory standards.

Secondly, REACH requires companies to produce safety data sheets in order to be able to circulate information on relevant chemicals to other businesses in the supply chain. These data sheets have, however, tended to become very technical and very long and it is confusing for SMEs to quickly access the information they need to effectively manage the risk for their workers and others who might be affected.

Finally, there is a lack of clarity on the issue of whether a substance with an OEL could it be exempted from REACH authorisation under 58(2) of the REACH Regulation. A recent case in the Court of Justice of the European Union in September last year (T-360/13, ‘Vecco’)

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may limit the situations where OSH legislation is considered sufficient to control carcinogens in the workplace as a derogation to authorisation under REACH. Put very simply, the case is essentially about whether chromium trioxide should be exempted from REACH authorisation because use is properly controlled under CAD and CMD as a carcinogen. The Court decided that, as chromium trioxide is not specifically listed in CMD [or CAD], these directives do not constitute ‘existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance’ within the meaning of Article 58(2) of REACH. However, the Court judgment is currently subject to appeal, so definitive conclusions cannot be drawn until that appeal has been heard.

Other Member States are opposed to the above assessment by one Member State.

Making EU legislation more simple and reducing the costs resulting from this legislation is praiseworthy. However, it must not be reached by weakening the level of environment or health protection, especially for workers, by introducing inconsistencies, confusions, distortions. All of that will result in shifting complexity and costs to other fields, especially to the sanitary and legal field.

As a matter of fact, the document put forward aims at unifying threshold limit values, whereas these values present very different objectives. Likewise, the simplification of safety data sheets will harm the quality of information that will be collected, without reflecting the reality of the diversity of risks for each substance.

The question of the exemption from REACH authorisation under 58(2) of the REACH Regulation is also mentioned inappropriately, given that a case is currently ongoing before the European Court of Justice on this question.

As far as the interface between REACH and OSH regulations are concerned, it is recalled that Commission plans a workshop next November on that topic, and that is not mentioned in the paper.

In substance, some Member States support a combined approach of the two legislative approaches that would tackle the issue of the protection of workers in a complementary way: that must concern the implementation deadline for the inactive to substitution and the prevention and inspections measures.

As a conclusion, it should be noted that the Commission has been working on the links between REACH and OSH for two years. This work has been shared with the Members-States, at the level of the relevant authorities on REACH and the Working Party on Chemicals (tripartite authority in charge of the OSH regulations).