EUROALLIAGES

COMITÉ DE LIAISON DES INDUSTRIES DE FERRO-ALLIAGES

CASI institute

EUROALLIAGES AND THE CASI INSTITUTE POSITION PAPER ON THE PUBLIC CONSULTATION ON REACH REFIT - JANUARY 2017

EUROALLIAGES is the European association of Ferro-Alloys and Silicon producers, representing about 95% of the sector in Europe. The sector is composed of a majority of SMEs. The total membership includes 21 companies, regrouping 45 plants established in 12 different countries. These companies produce Ferro-manganese, Ferro-silico-manganese, Ferro-chromium, Ferro-molybdenum, Ferro-silicon, Silicon metal, Calcium-silicon alloys and Ferro-nickel.

The European Ferro-Alloys and Silicon industry is the iron, steel, aluminium and chemicals industries' first supplier. It also provides the electronic and solar industries with elements essential to their manufacturing process, offering the highest qualities of products. The importance of the interdependence along this supply chain is worth mentioning.

THE CASI INSTITUTE is a Global Association of CaSi producers mainly in Europe and South America. CaSi ferro-alloys are mainly used in steel.

EUROALLIAGES and the CaSi Institute fully agrees with the objectives of REACH to protect the human health and the environment, as well as with the aim to harmonize chemical legislations in the European Union to ensure a free circulation of substances on the internal market, rather than having various chemical management systems across Member States.

REACH is a very complex regulation, and the quality of its enforcement is questionable as well as its impact to promote competition and innovation of the European Industry. The lack of level playing field between EEA and non-EEA operators in terms of social and environmental standards can induce distortion of competition.

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1. Data sharing

In January 2016, the Commission Implementation Regulation on Data Sharing was published, aiming at putting the provisions of REACH "efficiently into effect" (REACH, Art 132). The positive aspect is that this Implementing Act is seeking to enforce the "one substance one registration" (OSOR) principle of Article 11 of REACH and better empowers ECHA to fight against free riders and companies filing "Wikipedia" separate submissions. However, there are other provisions which can – and are -negatively impact(ing) consortia and letter of access agreements implemented since the advent of REACH.

The Data Sharing Regulation grants a series of individual rights not only to existing registrants, but also to "potential registrants," a term that is not defined. Such an undefined potential registrant has a right to impose demands on existing registrants, and require itemisation of data and cost, as well as a reimbursement mechanism; even though the existing registrants may not want these features and the potential registrant may decide not to join the agreement after all. The burden imposed is becoming disproportional and some players are already abusing the system. We are experiencing such a situation with a case launched at the Board of Appeal that has entered a negotiation phase whereby those having created parallel dossiers - by simply copy-pasting our dossier - are now requesting detailed information without providing answers to our questions. Free-riders are thus auditing yet compliant companies. The national enforcement authority in our case has recognized that the companies at stake are breaching the law but they won't act without a Sonc letter which is not issued by ECHA (see enforcement chapter).

In addition, there is an inherent confusion in REACH between the process to creating a joint submission and becoming member of an existing joint submission, in particular for the enquiry of studies which does not make sense for the latter. Instead of trying to clarify the issue, the guidance on data sharing seems to amplify the problem, hence creating more confusion. The right to refer, the right to use or the co-ownership of a single study or a full dossier are mixed up. The concept of the right to refer is contradicted with the supposed right suggested by the guidance to have access to <u>all</u> information, regardless the provisions of the contracts between the involved parties (and the related costs). Other elements of the guidance go beyond Art. 11 3 of REACH, like the concept of fully opting-out.

2. Enforcement

<u>Controls at the customs boarders</u>

We have concerns about the current lack of proper controls at the EEA customs boarders related to REACH. The growing number of legal requirements and harmonized classifications like restrictions, authorizations etc., make controls even more difficult. This can trigger a growing number of infringements in particular from non-EU producers. The consequence will be a more acute lack of level playing field between EU and non EU producers and therefore unfair competition.

This will result in a lack of relevant protection of the human health and the environment due to a lack of traceability of goods put on the European market, which will be hence counterproductive for the objective of REACH and also other legislations or objectives like the Circular Economy and non-toxic environment goals. To be efficient, controls have to be made at the earliest stages possible, e.g. at the customs boarders and when delivering registration numbers.

Member States' Customs must play a key role in support of the national Enforcement Authorities in the fair enforcement of REACH. Harmonized regime for controls at EU borders is an absolute necessity to avoid distortion of completion of the internal market. The same market must have the same rules. This not necessarily calls for stricter rules but for strictly the same rules for all. At the last stakeholder meeting of ECHA, firm and fair enforcement of REACH was ranked at the top by the stakeholders for the 2018-2020 ECHA planning. DG TAXUD has started conducting an evaluation and a fitness check of the European Customs Inventory of Chemical Substances (ECICS), and its coherence vis-à-vis other existing databases, and in particular REACH/CLP. This is an important issue as the customs officers need relevant, efficient and use-friendly tool/data bases to perform their controls in a context of a growing number of legal requirements.

Respect of the OSOR Principle

Another aspect of enforcement is the respecting the OSOR principle. Despite OSOR being one of the pillar of REACH, it has however not prevented some 'free-riding', with companies deliberately abusing the system by opening a second/parallel submission for their full REACH dossiers. This issue is leading to unfair competition. The solution shall come from both Member States and ECHA via the setting up and the implementation of efficient and pragmatic guidance and procedures. We welcome the fact that ECHA has started to check around 700 parallel registration dossiers and is working on IT solutions: e.g. the joint submission object for the same substance is no longer possible for new joint submission but what about existing parallel dossiers (more than 6000) ? Member States seem to be reluctant utilizing their enforcement power but in fact one of the hurdle is the so-called "Sonc" letter (statement of non-compliance). Indeed, the national enforcement authorities do not proceed with infringements procedures without this Sonc letter that has to be issued by ECHA. In the General Report on REACH, ECHA notes that penalising breaches of data sharing obligations is difficult due to the different organisation of enforcement authorities in the Member States. There is some kind a vicious circle in the procedure as implemented today, blocking the efficiency of enforcement.

Setting priorities – targeting defrauders

We are concerned about the fact that more and more requirements are imposed on yet compliant companies with sometimes additional heavy testing on the one hand, and a current very permissive system for free-riders/defrauders on the other hand, in particular in the light of the Commission report of April 2016 where

Member States indicate "insufficient financial and human resources are impeding the successful operation of REACH and CLP in their countries"[1].

Indeed, it shall be noted that free-riding becomes an issue in the context of updates and mandatory maintenance of registration dossiers: it appears that many co-registrants (and subsequently free-riders, too) become inaccessible once the first version of the joint registration dossier is submitted and the registration number granted after payment. In addition, we have been told that letters of Access and IP rights are not part of the enforcement. Defrauders can therefore put dangerous substances on the market without being prosecuted. Costs tend to be prohibitive for taking legal action with regards to both, violation of IP rights at national courts and appealing to the European Court of Justice.

One of the solution to the issue of updates would be to generate a new token and remove from the ECHA public website the name of the co-registrants having not confirmed the update.

3. Administrative and costs burden

Dossier maintenance and update

Despite the huge burden on Industry that REACH has already imposed, there are in addition significant unexpected costs related to keep the REACH registration dossiers up to date. This is not only due to both new available scientific (studies/publications) and technical information (volumes, technologies…) but also on evolving interpretation of the legal text, changes in guidance and procedures. The current version of IUCLID 6 is affecting the content of the information provided in the registration dossier and can create a huge workload when updates are envisaged. This is particularly demotivating for the registrants of an existing joint submission. There are no incentive for industry to update the joint registration dossiers as and where relevant or to conduct further studies. In addition, consortia set up already 10 years ago for mainly higher tonnages band registrations are running out of money and the companies are more and more reluctant to pay any additional fees for maintenance or non-scientific updates. Finally, some lead registrants are now even expressing their wish to step out of this status of "lead" requiring responsibilities and resources.

We have also serious concerns about the fact that ECHA in its Review Report intends to suggest an Implementing Act to make dossier updates mandatory. We wonder what is the proportionality of such proposal and the legal basis of it, considering the provisions of Article 22 of REACH which stated that "a registrant shall be responsible on his own initiative for updating his registration". In this respect, it is worth to remind that adopting an Implementing Act requires also to first start with an Impact Assessment.

[1] http://ec.europa.eu/environment/chemicals/reach/pdf/final_report_2016.pdf

Working methods

We acknowledge that ECHA needs to develop IT algorithms to screen and assess a huge number of registrations dossiers, depending on the objective sought. However, some aspects of the working methods are questionable and may lead to waste of resources not only for the consortia but also for ECHA and the Member States:

- For the shortlisting of substances based on some effect like endocrine disruptor, joint submission dossiers are put on equal footing with lists circulating on the web which are not providing any evidence supporting the declared classification/statements
- the top-down approach, starting from reviews and risk assessment documents that may be based on outdated evidence and potentially bypass the use of more recent REACH work/data. This leads sometimes to unexpected selection of substances requiring additional duties despite the scientific evidence of irrelevance, like requirement of annex XI studies of some slags from the smelting industry despite their inert characteristics.
- bulk work instead of qualitative selection. The ECHA's ambition that by end of 2018, they want to know for all the substances above 100 tonnes whether they are of potential concern and how to address them, is probably far too ambitious.

We acknowledge ECHA's challenge in the assessment of thousands of different chemical substances that exhibit countless phys-chem and tox properties. However, also ECHA should acknowledge that organic and inorganic substances require different approaches. Instead of trying to cover the assessment of most of the substances, solid state chemistry and basics concept should be better understood and integrated in the way of working, e.g. essentiality and homeostasis, speciation and valence. Using "Wikipedia" lists/untrustable lists in terms of scientific validity should be avoided. Finally, more emphasis should be given to evidence from epidemiological studies.

Guidance: stability, relevance

If changes in guidance are supposed to bring more clarity or resolve some pending problems, others are creating new problems with, sometimes, snowball effect requiring further workload from the registrant's side. One example is the "soft letter campaign". We received such a letter from ECHA for one of our compounds for a supposed endocrine disrupting effect without any scientific background to be able to further investigate the issue. In addition, this letter was triggered by potential significant exposure to humans and/or the environment.

We have in fact discovered that the changes of the Guidance on Uses descriptor has transformed initial ERC3 "Formulation in materials" into "Formulation into solid matrix" and initial ERC 5 "Industrial use resulting in inclusion into or onto a matrix" into "Use at industrial site leading to inclusion into/onto article". This revised guidance is changing the meaning of this codes with an interference with the initial choice made by the registrants in the registration dossiers. Indeed, the word "Article" is triggering automatically a supposed consumer use and hence related exposure with wide dispersive use which does not correspond to the reality.

4. Authorisation

Currently Authorisation is exclusively focused on hazard whilst a risk-based approach can be far more effective and efficient. When there is a risk to be tackled in an industrial workplace, REACH authorization does not necessarily bring any added value compared with the level of protection that can be achieved with well implemented workplace legislation (by e.g. applying an EU-wide Occupational Exposure Limit).

This should be consistently addressed via a RMOA process that should consider OSH and the prioritisation of setting an EU-wide OEL as most targeted and proportionate measure. In this respect, we are fully supporting the Cross-Industry Initiative on this issue, and in particular its position paper related to this REACH REFIT. Indeed, according to recital (5) of REACH, the Regulation should apply without prejudice to Community workplace and environment legislation. This RMOA should be further harmonised and formalized. At the beginning on 2017, the European Commission launched a communication on the modernisation of OSH legislation and policy. Awareness raised on the need to issue guidance on the interfaces between REACH and OSH legislation. With regards to the scientific basis of any occupational safety and health action, the communication mentions that the EC will seek advice from the Scientific Committee on Occupational Exposure Limits (SCOEL) **or** from the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). In this respect, we would like to stress that SCOEL (and not RAC) is the expert committee for the derivation of inhalable exposure limit values at the workplace.

The possibility of substitution and alternatives should be further carefully assessed, keeping in mind the feasibility aspects including cross media effect (e.g. use of energy, CO_2 emission, use of raw materials) to avoid regrettable or not applicable substitution, as well as investment and innovation leakages. Energy intensive industries like the ferro-alloys Industry is already exposed to high risk of carbon leakage.

It is also very important to streamline authorization to ensure allocating properly resources of all players involved. In this respect, we welcome the experience acquired last year with the holding of workshops with ECHA to discuss and raise awareness about the intermediate issue of high temperature coal tar pitch.

5. Use of REACH Registration datasets in the EEA and abroad

Despite being an exhaustive hazard and risks assessment without real precedence, the REACH dataset remains to be disregarded in Member States and EU policies such as the Water Framework Directive, the Waste Directives, or the IED, under which it is not yet fully recognised as a reliable reference. We have concerns on the fact that at some national level old data/quality thresholds (i.e. from the landfill directive) are used, ignoring the state-of-the art information generated under REACH.

For example, since the advent of the current Landfill Directive in 2008/2009, industry has generated a robust scientific dataset (for REACH) that strongly demonstrates the low environmental toxicity of molybdate. The

current leaching limit value for molybdenum applied to inert waste in the Waste Acceptance Criteria for landfills (Council Decision of 2002 pursuant to Article 16 of and Annex II to Landfill Directive) are outdated (too low) and need revising (higher limit values) in line with the currently available scientific dataset generated under REACH. This outdated data is jeopardizing valuable uses of ferro-molybdenum slags in road construction applications and hence the objectives of the circular economy.

We support to a certain degree the publication of the content of the registration dossier and the optimization of the REACH Registration process so that REACH hazard and exposure datasets become reference datasets used in other legislations and initiatives, including at global level. But issue like confidentiality, legitimate possession and copyright should be better addressed. In particular, a warning box[2] on legitimate possession or permission to refer should appear in key places on the ECHA website, like on the front page of the registered substances.

6. Competition & Innovation

It is unclear whether REACH has added value in stimulating industry to more innovate and e.g. replace harmful substances with less harmful alternatives. Substance substitution is inherent to the industry. Unnecessary burden imposed by some REACH processes like authorization might reallocate resources away from R&D towards compliance. The 2011 Innovation Survey conducted by CSES showed already that resources have been diverted from R&D to compliance management and regulatory affairs.

An unintended key impact on competitiveness is the legal uncertainty around which substances will be targeted, and under which procedures they will fall (Candidate Lists, restrictions, etc.). Implementing Act so far are seen as a source of instability should they go beyond the provisions of the law. REACH may be causing companies to consider relocating their factories outside of the EU where chemical legislation is less rigid, producing there and re-importing the final product back into the EU, particularly when they are exposed to a very intensive international competition. Improvement of the predictability and efficiency of the various REACH regimes is needed for Industry as well as avoidance of duplication of rules.

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[2] See box on p 67 in data sharing guidance of January 2017:
https://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf