UEAPME's main views on the REACH REFIT Review 2016

This position paper aims at giving a summary of UEAPME's views on the main issues/questions raised by the 2016 REACH Refit Review.

Does REACH achieve its objectives (=protection human health and environment, strengthening of the competitiveness and innovation, harmonisation of the internal market, reduction of animal-testing and development of alternative test-methods)? Are there any imbalances between the individual objectives?

Within its scope, REACH is improving the protection of health and the environment. However, other significant protection areas, such as climate protection, CO2 reduction, protection of drinking water remain mainly unaffected by REACH, although REACH would have the potential to contribute to these areas a lot with its huge amount of chemicals information.

The other main REACH objectives, namely the strengthening of competitiveness and innovation, are not on track. Too many resources are being reallocated for in-house bureaucratic activities instead for innovation like the development of new materials. Particularly small and medium-sized enterprises, both, registrants and downstream users, are highly affected. In particular, these companies are often in a sharp competition with larger competitors, what makes a direct and flexible access to resources even more difficult now.

REACH may promote the harmonisation of the internal market, however the actual degree of equal treatment within the EU depends highly on the factual enforcement. This especially applies to imports of substances, mixtures and articles from non-EU-countries.

The promotion of alternative test-methods and the reduction of animal-testing is well on track, although the mandatory data-sharing leads to a certain administrative burden. Especially the participation in consortia is no real advantage for SMEs, as these often transfer costs for e.g. staff and administration in a very generous way, what again raises the total costs of a registration. In general, the cost-sharing-requirement is still not optimally transparent, especially when it comes to predict future costs. However, this is a problem of the legislation itself, because in fact a dossier can be opened again at any time, and new data can be requested.

It is also important to note that the REACH-objectives are as well pursued by other legislation (e.g. environmental and worker protection legislation), although this may be with other legal instruments as REACH does. Confusion and incoherence are often the result.

Has REACH improved the data-situation for chemicals and the information in the supply chain (including information for consumers)? Are there positive and/or negative areas/examples?

The data-situation for chemicals and especially the access to data on chemicals has significantly improved due to the publication of information on ECHA's website. The impact of improved data affects primarily the quality of classification and labelling of chemicals. Less clearly, we observe this effect on the information in the supply chain, in particular safety data sheets. Due to the increasingly complex situation in the preparation of safety data sheets – and even more extended safety data sheets – we observe that often the essential aspects relevant for the safe use of chemicals and the needs of downstream users get lost in a pile of information. In this context and at the present moment we see the information value of the extended safety data sheets fundamentally threatened.

We have strong doubts that the private consumer makes efficient use of the newly available information on the proper and safe handling of chemicals, which is actually a waste of available knowledge delivered by EU-enterprises under very high costs.

In some sectors, we still observe that safety data sheets are not seen as a part of the delivered product. There is no understanding that downstream users are entitled to get a correct and useful safety data sheet. Unclear are also the language arrangements (e.g. translations) and the general rules about which uses are allowed and which are not or when and how uses/conditions of use are allowed, respectively covered by a supplier.

The bottom line is that REACH improved the data-situation. However, the communication in the supply chain is in urgent need of optimization. Furthermore, we observe that authorities very often mistrust data that are generated by companies. Also, a more intense use of REACH-data for other legislation, e.g. water-legislation, is highly desirable.

Do you have positive and negative experiences with ECHA? How do you see its work?

ECHA fulfils its tasks and - despite some initial difficulties – tries to solve problems and supports companies quickly. Nevertheless, some strict interpretations of REACH-provisions lead to an unnecessary level of bureaucracy. Access to data on ECHA's website has been improved significantly and serves as a major information source to many companies. However, the correct interpretation of the available information (info cards, brief-profiles and registration-information) is often not straightforward and requires a significant level of expertise or it ends up in erroneous conclusions.

Are the individual regulatory instruments successfully implemented and are REACH processes transparent? Have you observed any difficulties?

Regulatory processes became significantly more transparent and "early warning mechanisms" like the registry of intentions for substances, in particular of SVHCs, are well in place. The SVHC-roadmap has contributed very much to this improvement. Still we consider it as very important that especially the first step, namely the RMOA (risk management option analysis) is performed carefully and that also EU-legislation outside REACH (e.g. water preservation, protection of workers, legislation on operational plants) is considered as the possible best regulatory option. We see this as the best way forward to avoid double regulation.

We are so far lacking long-term experience with authorisation and, to a certain extent, with some newer elements of the restriction-process. Applications for authorisation like those for chromium VI show to be a huge challenge for our companies. In a nutshell, the registration is perceived positively although the costs are considered to be disproportionately high.

Room for improvement we see especially with the very high number of public consultations. The existing publication, which is focusing on the chemical name and other classic product identifiers, is not particularly user-friendly. An IT-notification system, that would allow the user to define a search-filter for specific uses, use-categories and use-sectors would be helpful to make this area more transparent.

We see the last registration deadline in 2018 as particularly problematic. We assume that many small businesses will be unable to administratively and financially cope with the registration process. For example, the Austrian impact assessment from 2005 ("Folgenabschätzung der neuen

EU-Chemikalienpolitik (REACH) für Österreich") expects that 3100 up to 4300 dossiers should be submitted during the three transitional periods. According to the last published statistics of ECHA, nearly 750 dossiers were submitted from Austria, what is les s than 25% of the dossiers projected.

What are positive aspects of REACH, what negative aspects? Does REACH lead to unintended (side) effects? Are they positive or negative? What is the cost-benefit of REACH for companies, public authorities, citizens, etc.?

A positive aspect is the increase of transparency about chemicals and the available information on ECHA's webpage. In contrast, there is a clear additional burden on companies due to registration- and authorisation costs, but also due to increasing demands from the communication in the supply chain. The increased administrative requirements led to the effect that resources are redirected from R&D and product innovation. They also promote the formation of monopolies or oligopolies and the creation of artificial raw material shortages. That is in particular an effect that is almost exclusively negatively effecting SMEs.

Apart from high bureaucratic burden for substances and mixtures we also observe this development for SVHC in articles. We consider that - especially due to the recent ECJ judgement - the effort is by far not in any relation to the corresponding benefits.

A further unintended side effect is that private end users have the subjective impression that everything is getting more "toxic". In particular, this happens because a proper assessment of hazardous and risks is practically not possible to them as laymen, although the necessary information would be available on ECHA's webpage.

We consider that a full and reliable cost-benefit-evaluation prior to the completion of the pending registration deadline and due to the high amount of pending authorisation applications is not possible at the time being.

One of the most prominent negative effects is the lack of proper enforcement related to imported goods, especially from areas, where the legal requirements are significantly lower than in the EU. This results not only in competitive disadvantages in the internal market and in the international competition (nor only up to relocation of production from the EU), but weakens confidence in REACH as a strategic approach 1) to strengthen the European competitiveness and 2) to improve the global environmental situation. Actually, the opposite is achieved when chemical production is moved from the EU to areas with lower protective standards.

Looking at the individual actors, we conclude that so far costs clearly exceed the benefits. Nevertheless, citizens have access to more information about chemicals. However, it is questionable whether this information is sufficiently understandable and the effort of data collection pays out. Therefore, in the future there should be a stronger focus on how such information can be better used by citizens. Furthermore, we expect that the private end user will have to pay higher prices for the products, the portfolio will shrink, but there will be more comprehensive information available on individual products that are still available.

Are there any areas where REACH could be simplified or burden could be reduced? Is REACH focused on the main relevant issues regarding the safe use of chemicals or is there need for improvement?

In the area of the information in the supply chain there is a considerable potential for reducing unnecessary burden. That could be especially achieved by standardization and a stronger focus on safe-use-aspects relevant in practice. In line with this, risk – in particular backed by chemical safety assessments and the development of exposure scenarios – should be given at least the same central role as inherent hazards already have. In that respect, probably the SVHC identification and inclusion in annex XIV are two of the most problematic areas, since risk is practically put aside in these two steps, although art. 55 clearly also talks about a proper control of risks.

Simplification of the legal text and guidelines are always desirable. The legal regime of REACH is altogether too complex and gives too much room for different interpretations. High costs for legal and technical consultants go along with this situation.

It would be helpful that substances with low/no critical properties - such as those which are subject to the simplifications based on the criteria listed in annex III - are subject to an even more simplified registration procedure. For example, ECHA could provide cost-free data – what would in fact be only data according to annex VII – for such substances. Furthermore it would be highly welcome that the authorisation application would be simplified significantly.

Does the enforcement work or/and what could be improved?

The activities of the Forum are a strong step for a harmonized enforcement within the EU. In particular, imported goods need a stronger attention, so that a true level playing field is established. There are individual cases, where companies reported the lack of REACH knowledge of enforcement-bodies. This is in particularly the case for more complex issues. Furthermore, and as already mentioned before, there is often a principal distrust in data provided by companies. Nevertheless, we observe and welcome the trend that enforcement authorities are progressively developing an approach that is not focused on fining, but rather on a collaborative problem-solving.

How is the situation for SME or/and what could be improved?

SME clearly report increased efforts and a substantial increase in bureaucracy because of REACH. Although the new IT tools are a good attempt to relieve the situation, further reductions are necessary. According to the feedback we got, more support from authorities would be highly desirable.

After many years with REACH it should be obvious to the legislator and the enforcement authorities that a legal system of such an extraordinary high grade of complexity can only be negatively discriminatory for SMEs. Apart from the already known problems with e.g. registration, now it also becomes more and more obvious that individual SME are overwhelmed by the elaboration of an application for authorisation. Establishing a level playing field between large and small actors clearly means that we need to find easier and more pragmatic ways to comply with REACH obligations.

The bottom line is that there is a great and urgent need to improve the situation for SME. This should be one of the most important priorities for future.

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