Position Paper

Making REACH better workable for SME: *A collection of suggestions and observations by UEAPME*

I. Introduction

During the 11 years of REACH we have followed the developments of this legal giant intensively. Now with the end of the phase-in-period and the publication of the second REACH-review, we would like to share some thoughts and suggestions from the perspective of SME. While REACH has to a certain extend improved the management of chemicals in the EU, it has also brought huge challenges for small and medium-sized enterprises. Some of these challenges have been addressed in the past. However, some will need to be addressed in the future.

In general, there is no homogenous perception of REACH in SME. Some see more the benefits, others see more the burden. No one is applauding to have REACH, but most understand the benefit of having good information about the properties of chemicals to ensure their safe use. The major problem for SME are the widespread activities related to REACH. It is hard – sometimes impossible – to follow all the changes and ongoing work. This again leads to an exclusion of the far largest type of enterprises in the EU. We recognize that authorities do not want this exclusion and they also made valuable efforts to steer against this in the past.

Efficient inclusion of SME in regulatory processes can work. The development of the data sharing regulation (EU) Nr. 2016/9 is a very good example for this. This example also shows that the interests between large enterprises and SME can be quite different. A good solution for one, is just the opposite for the other. Because of this, it is even more important to listen to both sides carefully to be able to estimate possible impacts better. With the following chapters we would like to contribute to this dialogue and the building of a strong European economy that is based on many small and only a few large enterprises. Finally, this model brought us through the roughest years of the past economic-crisis.

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II. Registration

Briefly

- ***Promote PPORD-notification***
- ***Reduce discrimination of lower tonnage bands***
- ***Pragmatic and supportive enforcement***
- ***Future of SIEF***

An important element to make the registration process more workable for SME and also for lower tonnage bands is the **PPORD notification**. In this respect we see the need for an even stronger promotion of this instrument. Within its limitations, it is a very useful tool and could be much better exploited, especially when using a substance in a professional context. Apart from usual awareness-raising that we – stakeholders and authorities – have done so far, we should implement an even more efficient way to do so.

In our view this could be done in the context of an inquiry. Now that the last registration transitional deadline has past, practically every registration needs a previous inquiry. When an enterprise starts an inquiry, this process should include a short PPORD navigator at the beginning. With this tool future registrants could pre-assess the relevance of a PPORD notification for their specific case and they could at the same time learn more about PPORD, what eventually opens additional business opportunities.

However, a more fundamental problem of the registration process is that it is highly negative discriminating low tonnage substances between 1 to 100 t/a. This inherent property of the current information requirements design makes extension of production capacities in this tonnage band less profitable than in other tonnage bands. The following example reflects this:

Scenario 1:
An enterprise manufactures 6 t/a. The usual costs for a testing data package (annex VII) in this tonnage band per substance are € 30.000 to € 70.000. The same enterprise doubles the production volume to 12 t/a. The usual costs for a testing data package (annexes VII and VIII) in this tonnage band per substance are € 300.000 to € 500.000.

- *Doubling of the production volume causes a non-proportional multiplication of the testing costs.*

Scenario 2:
An enterprise manufactures 2.000 t/a and extends the production volume to 20.000 t/a. Both production volumes require the same testing data package (annexes VII, VIII, IX and X).

- *The new significantly higher production volume does not cause any increase of the testing costs.*

This effect has a high potential to hamper growth and to keep small enterprises small. This effect could however be moderated by a hybrid approach between a PPORD notification and the current registration regime. Based on this, the **testing costs should be distributed over several years**

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and also market response to a substance could be taken into account. A possible concretisation of this approach could be:

- For 1-10 t/a and 10-100 t/a tonnage bands:
  - First 3 years: Half of the data required by annex VII and all available data
  - Next 3 years: Full annex VII
- For 10-100 t/a tonnage band:
  - Next 3 years: Half of the data required by annex VIII and all available data
  - Next 3 years: Full annex VIII

During every 3 years block the concerned enterprise could re-evaluate the profitability of the substance and decide to stop. In the case of stopping, the next information package does not need to be submitted.

Finally, we need to agree on a pragmatic strategy how to face the recent results of the 3rd registration deadline. There may be arguments, why the number of newly registered phase-in substances is so low, but there are also arguments why the number should be higher. Considering the potential gap of 10.000 to 15.000 phase-in substances, we should not rely on the most positive assumptions, but rather take into account that a significant gap exists. In the light of this, we are of the opinion that we need a **very pragmatic enforcement** approach that:

- is uniform throughout the EU;
- pursues the objective to support enterprises, who failed a registration due to reasons like overload by the legal complexity, misunderstanding of legal obligations and similar;
- takes into account solutions of the Directors' Contact Group and tries to solve as many problems based on them.

With the 1st June 2018 not only the last registration deadline expired, but also **substance information exchange fora (SIEF)** are not obligatory anymore. To ensure the continuity of swift data-/cost-sharing processes and other regulatory cooperation, we see the need to continue with this type of cooperation platform. Existing infrastructure could be used for this purpose. The Directors' Contact Group has given a recommendation on this topic and we advocate for a swift implementation of such "neo-SIEF" by all necessary means to make them function in a fair, transparent and non-discriminatory way.

III. Authorisation

Briefly

- ***Simplification of the application***
- ***Regional limitation of application***
- ***Data-sharing***
- ***Longer Review-periods***
- ***Application of art. 58 (2)***
- ***Role of MSC***

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The authorisation process is a considerable challenge for SME and it is becoming more important every day. While an authorisation is already highly challenging for large industry, it can be existence threatening for an SME. After some years, we have observed potential fields for improvement. The most obvious is a quick implementation of **a simplified application for authorisation** for specific cases. Such cases are in particular:

- Use of a substance in low quantities.
- Use of a substance for spare parts of no longer produced articles.
- Use of a substance for maintenance of no longer produced articles.
- Use of a substance in a closed environment as a process chemical.
- Use of a substance with an OEL in an industrial environment.
- Use of a substance that is of high relevance for the society.

Such a simplification could – eventually depending on the specific use scenario - concretely include:

- Lighter requirements for or waiving of the socio-economic assessment.
- Lighter requirements for or waiving of the analysis of alternatives.
- Lighter requirements for the chemical safety assessment.
- Lower fees.

An even more significant simplification would be the option for a authorisation-scheme that takes into account that most activities of SME – also such with annex XIV substances - are usually geographically very limited. Consequently, the full potential of an EU-wide valid authorisation is significantly flawed. Many small users usually stay within their Member State or a specific region, what is finally not only due to limited language skills. An optional **regionally limited authorisation**, which should be simpler and more cost-efficient could balance this situation. Further benefits of this approach are:

- With the support of the competent authority, such an application could be designed very specifically for the individual circumstances.
- Relevant national legislation could be considered.
- The difficulties related to the translation of non-English documents and the interpretation of meetings with the dossier submitter could be avoided.
- Due to the regionally restricted scope, the distribution of SVHC would be stronger limited, while the substance could be used exactly there, where it is needed.

Based on the experience with Chromiumtrioxide we have observed that the preparation of an application is not only costly, but also very time consuming. One important factor for this is that SME lack of in-house expertise and general regulatory experience. This was also confirmed by the 2nd REACH-Review by attesting that the consultancy-sector has benefited by REACH outmost. Furthermore, as we have learned from the registration process, SME are rarely preparing a larger number of dossiers. Therefore, the regulatory experience, which is mainly acquired when the first dossier is prepared, cannot be used as efficiently as an enterprise preparing a very large number of dossiers can do. When setting the review periods for such dossiers developed by SME, this effect should be taken into account by **granting longer review periods**. This would lower the investment barrier caused by authorisation drastically. At the same

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time the necessary investment would be still very high and a sufficient motivation to search for alternatives, if those are available.

Furthermore, we consider that the **data sharing rules** as known from registration could be a useful element also for the authorisation application process. These rules have proven to be a major element to relieve SME from prohibitively high testing costs and to reduce testing intensity in the EU. However, in this context confidentiality plays a very important role, because the application for authorisation contains highly sensitive business information like R&D plans, socio-economic analysis and similar. Such data needs to be reliably protected. Furthermore, collection and disclosure of personal data (e.g. monitoring data on employees-exposure) needs to respect the rights of individuals of privacy.

Another instrument that has potential to make authorisation more SME compatible is the **application of art. 58 (2)**, which allows to exempt certain uses of a substance from authorisation. So far this article has not been used very frequently. In our view, this is a missed opportunity to avoid unnecessary burden and double regulation. A first step to a more intensive use of this instrument should be a clear and realistic catalogue of criteria.

The **Member State Committee (MSC)** plays a very important role during the first phase of the authorisation process, the SVHC identification. An SVHC identification already can have significant economic and other impacts. This effect is even stronger for the prioritisation process, also a process the MSC is involved in. Although we consider that the MSC's mandate is much wider, the committee has restricted itself to discuss only about very specific aspects of a substance. For example, economic considerations are ignored out of principle, although such arguments are highly relevant for a sound formulation of a prioritisation recommendation in relation to adequate transitional arrangements or the understanding of production cycles as required by art. 58 (1c). We consider that for a more proportional regulation of substances the MSC will need to extend its scope of evaluation or it should hand over critical dossiers to the regulatory committee to allow such discussions there.

IV. Communication in the Supply Chain

Briefly

- ***Simplify Safety Data Sheet Rules***
- ***Substances in Articles***

As far as we can see, the awareness of the role of **safety data sheets (SDS)** has increased significantly over the past years. The same goes for their quality. The extended SDS, however, is still not easy to handle. The main problem is the amount of information that is often of limited use for a specific downstream user. This makes it difficult to recognize and identify the important bits. In particular, SME struggle with the time-consuming regular review of the voluminous documents. To a certain extend this is also true for the "normal" SDS, which became much more

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voluminous due to the formal requirement to include all chapters and subchapters. In our view, the digitalisation offers opportunities to improve this situation and could be exploited much better. Here we see the following key points:

- We need to come to a joint understanding of when an SDS is "made available" electronically. Clear criteria would be very useful to answer questions like: "Is it sufficient to send a direct link leading to an SDS by mail?" etc.
- Disentangling of the current SDS and eSDS by introducing a "basic SDS" (bSDS). This SDS of 2 pages should include the most essential information and hyperlinks to more detailed information. The most essential information could be for example an emergency number, emergency measures, allowed uses, classification and labelling.

The **information obligations for substances in articles** (art. 33) are a huge bureaucratic exercise with a very limited value and in particular for SME often impossible to comply with. In particular, for start-ups with usually low resources such opaque obligations are a considerable burden. With the new rule in the waste directive, art. 9, many more actors in the supply chain will be concerned by this obligation. In our opinion, such a system has only a chance to function, if we start a systematic development of testing methods. Furthermore, a substance should be only included in the candidate list, once there is an adequate testing method available. Additionally, a regulatory accepted collection of examples that explains the "articles in articles" principle would be highly appreciated and useful for SME to understand what is relevant to assess. Such a collection should cover all types of articles relevant for the EU.

V. Brexit

Briefly

- ***Secure Supply of Resources***

There is no doubt that the United Kingdom has an important role in the **supply with chemical resources** for the EU. Many SME depend on suppliers and only representatives (OR) based in the UK. The webpage offered by ECHA is a very useful information source to keep informed about the most important facts related to chemicals legislation. In parallel we think we should start developing options, guidance and tools that allow the following:

- Simple relocation of ORs to other Member States.
- 3 years transitional period for downstream users (DU), who now receive a substance from an UK supplier and due to the Brexit decide to register this substance on their own.
- 5 years transitional period for DU, who now receive a substance from an UK supplier and due to the Brexit decide to apply for authorisation for this substance on their own.

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VI. Intermediates

Briefly

- ***Clarity on Intermediates***

Case C-650/15 P could fundamentally change the current understanding of the **definition of an intermediate**. In particular, we refer to this quote:
"Accordingly, by failing to classify acrylamide, in the context of the process of transformation into polyacrylamide for grouting purposes, as an 'intermediate', the General Court, by adding a condition that is not laid down in Article 3(15) of the REACH regulation, misinterpreted that provision."
This additional view may have an important impact on a number of registration dossiers and authorisation applications. Furthermore, it will have consequences on some areas we are right now struggling with to solve efficiently, e.g. substances solely used at the workplace. For this reason, it should find its way into the relevant guidelines swiftly.

VII. Nanomaterials

Briefly

- ***Workability for Downstream Users (DU)***
- ***Workable Definition***

The recently adopted rules for nano-forms seem to be a workable compromise. However, we need to highlight a potential problem that in our opinion needs careful monitoring and an eventual adaptation. This aspect relates to **annex XII and the DU-obligations**. Consider the following scenario:
A DU transforms bulk material to a nano-form. This DU wants to (confidentiality) or needs to (supplier refuses to) cover his own uses based on art. 37 (4). Based on the new rules this DU needs to cover all relevant data requirements for the specific form, because it is not covered by the data of the registrant of the bulk form or the DU has not access to this data. Consequently, the DU would have to perform all the tests on his own, without any previous knowledge from the bulk registration data to reuse data or to establish a more efficient testing strategy. The DU also could not start an obligatory data sharing.

Based on this scenario we see several effects, which are very much unfavourable:

- Duplication of testing data is favoured due to the lack of an obligatory data sharing process.
- The costs for covering a new "nano-use" would be disproportionally high.
- A DU could be pressured to disclose confidential information up the supply chain, if the costs are too high.
- A higher investment barrier would hamper the development of new "nano-uses" and consequently innovation.

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- Practically a DU, who wants to cover a new "nano-use", will have comparable information requirements to a registrant, what in our view is not justified looking at the systematic obligations of these two roles in the regulation.

Furthermore, we consider that the practical application of the current **definition for nanomaterials** is very limited. In our view, the following elements would make it more workable and appropriate for SME:

- Agglomerates should not be included. It is not possible or very difficult to define what the primary particles from an agglomerate are. In our opinion, it is also not necessary to understand what the primary particle was, because such particles are ultimately integrated in a larger matrix.
- Availability of an affordable standard testing method.
- Nanomaterials/nanoforms occurring in nature should be excluded.
- Considering the omnipresence of natural materials containing nanoparticles current share of nanoparticles in particle size distribution of 50% should be higher (not less than 90%).

VIII. Interaction with OSH-legislation

Briefly

- ***Role of SCOEL***
- ***Setting BOEL***

There is no doubt that REACH contributes significantly to the objective of the OSH legislation to protect workers. This may be for example through better substance data or more refined risk management measures. On the other hand, also OSH complements REACH by for example setting occupational exposure limits (OELs) or by functionalising SDS to ensure safety of workers. In our view, it is only consistent that these two legal areas are increasingly overlapping. However, the high expertise that was gathered in **Scientific Committee on Occupational Exposure Limits (SCOEL)** and the efficient way to set practical limits needs to be maintained. Furthermore, the involvement of the social partners proved to be very meaningful in the past years. This needs to be further ensured without any limitations.

Setting of occupational exposure limits (OEL) as an alternative and equivalent risk management option (RMO) to REACH and CLP is crucial for a more proportional chemicals regulation. In particular, we see this as a valuable alternative to restriction and authorisation. OEL should also be a generally excepted pre-requisite for an exemption based on art. 58 (2) of REACH, which can make regulatory actions even more balanced and able to address a problem more targeted. On this route also intermediates could be addressed efficiently.

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IX. Balancing Financial and Administrative Burden

Briefly

- ***Improving Public Consultations***
- ***Develop EUCLEF***
- ***Financial Support***

Participation at **public consultations** may be a standard procedure for large industry. However, for the majority of SME the opposite is the case. There are a few reasons for this:

- Consulted dossiers are voluminous and technical.
- Consulted dossiers are in English.
- SME have the perception their opinion does not matter.
- SME are overwhelmed by the large number of public consultations.
- Questionnaires are often noticed to forestall certain results.

We see two main areas, how the participation of SME in public consultations could be improved:

- Every consultation dossier should be accompanied by a short fact sheet (max. 2-3 pages). The fact sheet should include (in order of relevance):
  - Uses (described in an understandable way, no codes)
  - Sectors of use (described in an understandable way, no codes)
  - An (qualitative) estimation to which extend uses and sectors are covered and potentially relevant uses and sectors which are missing in the dossier
  - The RMO proposed
  - Chemical identifiers
- The fact sheet should be translated into all official languages.
- The fact sheet should be available in an online database with a filter option for parameters like use or sector. The database should also include an e-mail notification for specific filter options.
- Highlight in every final regulatory action, where and how the input from SME was taken into account.

The EU's legislation regulating chemical substances is very widespread. Finding all relevant pieces of legislation for one specific substance is sometimes an enormous challenge. We acknowledge that the European Commission and ECHA have started the **European Chemicals Legislation Finder (EUCLEF)** project. When implemented, this one-stop-shop for chemicals legislation could be a very useful tool for SME, lowering administrative burden significantly and ensuring their compliance even more efficiently. However, this should not be seen as an alternative to the general need to reduce regulatory overlaps and inefficiencies. In this regard, we would like to highlight the finding from the Staff Working Document of the 2nd REACH-Review that REACH is causing costs of about € 86.000 per substance, the US approach is only in the range of € 6.500 per substance. It would be worthwhile to look into this in more detail, if there is potential to reduce regulatory-costs also for EU-enterprises.

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We have highlighted many elements in REACH that in particular - and sometimes exclusively – have negative effects on SME. Such elements are preventing us from having an EU wide level playing field. A straightforward solution to establish such a level playing field would be direct financial support to the concerned enterprises. An **SME Compliance Fund** could be established for this purpose. The attribution of financial resources could be based on the monetarisation of the negative and/or disproportional effects. The so financed support could be more general like for example making available testing data for significantly reduced prices or direct support for individual enterprises based on established criteria.

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