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Sent by email only

Ms Véronique Willems, Secretary General
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UEAPME – the European craft and SME employers' organisation
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Subject: Response to UEAPME's position paper on "Making REACH better workable for SME: A collection of suggestions and observations by UEAPME"

Dear Ms Willems,
Dear Mr Lena,

Thank you for sending to the European Chemicals Agency (ECHA) the UEAPME's position paper on "Making REACH better workable for SME: A collection of suggestions and observations by UEAPME" and for sharing the UEAPME's thoughts and suggestions from the perspective of small and medium-sized enterprises (SMEs).

ECHA understands the significance of SMEs for the European economy and society, and acknowledges the importance to address the challenges REACH may have brought to them. As the Commission's REACH Review has recently stated, SMEs need to remain a focus of attention.

Evidently, SMEs are subject to the same regulatory requirements as other actors on the market to handle their chemical safely. The only differentiator on information requirements is provided by the tonnage bands. In this light, ECHA has focused on making its support to companies increasingly SME-friendly, accessible and understandable.

During recent years, ECHA undertook an SME visits programme to introduce young regulatory scientific officers to "real life" small and medium-sized companies. You will have seen from our REACH 2018 Roadmap, which we published in early 2016 that it took many findings contained in publications on the burden of REACH on SMEs into account. More particularly, when we rolled out our REACH 2018 information, providing guidance to companies in seven steps and three layers of complexity, taking readers through these steps by links to webpages, guidance documents, webinars, animated presentations etc., our main intention was to help SMEs prepare for the May 2018 REACH registration deadline. The same was the case when proposing the recommendations that the Directors' Contact Group (DCG) issued to duty holders. In the last three years running up to the deadline, our network of national helpdesks (HelpNet) also focused on sharing the most appropriate approaches to supporting SMEs, making information available to companies in their own languages.

Furthermore, the Agency undertook a number of measures to simplify the registration for SMEs. The IT tools have been largely simplified during these past years, e.g. building a simple way to create and submit your registration dossier online, with the help of a guided workflow. Numerous training initiatives have been held throughout Europe, often in collaboration with national or regional entities to ensure that SMEs can have access to hands-on training and practical information sessions. Our intention is to continue these actions as appropriate.

In this respect, in the role of ECHA SME Ambassador, I would like to address below the specific suggestions and observations made in UEAPME's position paper and the Agency's position with regard to them.

Registration

One of the aims of the REACH Regulation is to encourage innovation. To help achieve this aim and to encourage innovating companies, chemicals intended for 'product and process orientated research and development (PPORD)' can be exempted from the obligation to register for five years. However, these chemicals must not reach the general public at any time.

Companies that want to benefit from the exemption must submit a PPORD notification to ECHA. This notification is very easy to prepare, with only little information required. By submitting a notification, companies can get a five-year exemption from registration, which can be extended, on request, for another five years and in special cases for an additional 10 years. However, while doing the research and development work, the notifier may develop sufficient knowledge of the substance and its market, leading him to decide to follow up with a REACH registration. When the exemption expires, it is expected that the cost for access to the joint submission will have significantly decreased.

ECHA has also clarified in the PPORD guidance that a PPORD notifier may combine a registration for lower tonnage with a PPORD notification covering the tonnages used to explore new developments, alone or in cooperation with selected customers.

Therefore, the PPORD exemption is certainly a relevant business opportunity and shall be promoted among SMEs, as it may effectively make the registration process become more workable for them, especially in a professional context when new production processes are implemented and when customers of the notifier need to implement new options and prospects for their markets.

Now that the phase-in scheme has ended and companies can no longer make use of their pre-registrations to cover the PPORD uses of their existing substances, ECHA will increase its awareness-raising of this option, and look to better integrate it in the advice on how to inquire and register. We also take note of your suggestion for a PPORD navigator, and will investigate its feasibility.

With regard to your proposal for a staged approach to the data requirements for the lower tonnage bands, ECHA understands your concerns on the impact of the testing costs on the growth of small companies, and it is proposed that you also share them with the European Commission. The Agency is considering initiating discussions about these concerns in the context of the Action 1 of the REACH Review on Dossier updates, where clarification of the timelines for updating dossiers, including updates needed for tonnage band increases will also be sought.

Finally, concerning enforcement, you have suggested three characteristics of pragmatic enforcement approach, addressed in turn below:

1. *Uniformity*: ECHA Secretariat understands the call for uniform enforcement and fully supports the Member States in continuous drive towards closer coordination of the enforcement efforts. ECHA's Enforcement Forum has prepared a "REF-7" enforcement project that will focus on the registration obligation after the third registration deadline. Inspectors will also control that strictly controlled conditions are applied for registrations of intermediates, where they are required and when controlling imports will work closely with customs authorities. 30 countries will take part in the REF-7 project. The Forum's enforcement projects are designed to promote uniformity in enforcement – inspectors check the same duties, look for the same

issues while using the same inspection questionnaire. Forum also strongly promotes that inspectors interpret similar situations in a similar way. REF-7 project was preceded by a Forum training for enforcement trainers related to enforcement of registration, where inspectors were given a common set of training materials and worked on the same case studies.

Please be aware that there is a limit to uniformity and harmonisation of enforcement – this is possible up to the point where the compliance of a company is determined. Inspectors in different countries will assess in the same way whether or not a company is compliant. Once the non-compliance is established, the inspectors have to follow their national legislations when applying enforcement measures (e.g. advices, fees, orders or prohibitions). Thus the enforcement measures applied to non-compliant companies may be different in different countries as they depend on the national legislations.

2. Supporting enterprises who failed to register for reasons such as overload by legal complexity or misunderstanding of obligations: This is an issue in the sole competence of the EU Member States.

As enforcement is fully within the remit of the Member States, ECHA Secretariat can make no commitments on how enforcement authorities apply measures in cases of non-compliance. However, in the last Forum project focusing on Registration¹ 69% of all corrective measures applied by inspectors were written or verbal advices. Based on this result ECHA Secretariat deems that enforcement authorities are quite supportive in bringing about compliance in the companies who failed their registration duty.

3. Taking into account the Directors' Contact Group (DCG) solutions: The enforcement authorities are aware of the DCG solutions and ECHA has provided them with a list of companies who benefitted from them. Therefore, in ECHA Secretariat's understanding, inspectors will take these solutions into account when controlling these companies.

On the topic of substance information exchange forum (SIEF), ECHA acknowledges the need to keep a structure in place to continue ensuring swift data and cost sharing, and the on-boarding of new registrants. Also the updates of dossiers will need to be organised together in the joint submission.

The Implementing Regulation on joint submission of data and data-sharing clearly states that fair and non-discriminatory data-sharing agreements are needed, which include cost itemisation and a reimbursement mechanism, also in the absence of SIEFs. Following the end of the phase-in scheme the formal operation of the substance information exchange platforms (SIEFs) is no longer obligatory after 1 June 2018 in accordance with Article 29(3) of REACH; however, the data sharing and joint submission obligations continue to apply. ECHA through the inquiry process ensures that new potential registrants are put in contact with previous registrants. In addition, the existence of the discussion platforms agreed between registrants under the SIEF concept is still strongly recommended to facilitate the exertion of these obligations. In the data-sharing disputes, the Agency continues to look for these elements of transparency, fairness and non-discrimination, to reinforce the message that swift data and cost sharing are needed. It is important to ECHA that the data-sharing negotiations are not used to hamper new or small businesses to access the market. The European Commission is also considering how to clarify further the data-sharing (and other) obligations on substances that benefitted from the phase-in scheme. In this respect, an Implementing Regulation is planned to be published in the first half of 2019.

¹ REF-3 final report: https://echa.europa.eu/documents/10162/13577/ref_3_report_en.pdf

Authorisation

It should be noted that according to REACH, the legal requirements for getting the authorisation for the use of substances of very high concern are the same for all economic operators in the EU, irrespective the size. Thus far, about a fifth of the applicants have been SMEs. Sometimes they have applied alone, sometimes together with larger companies. Recognising that SMEs do not necessarily have the same expertise as larger companies, ECHA has provided specific attention to them, e.g. as part of Pre-submission Information Sessions. In these meetings ECHA staff have emphasised the need for the applications to be “fit-for-purpose” and thus avoid gathering and providing unnecessary information.

Concerning your suggestion on “data sharing rules” ECHA has made an important clarification for downstream users (DU), including SMEs, that needs to be highlighted. DUs need to submit only the exposure scenario relating to their use. Thus, there is no need to enter into any “SIEF” type data sharing arrangement with the holder of the hazard data of the Chemical Safety Report. This has simplified already a lot the application work of SMEs. Concerning highly sensitive business information, ECHA has set up a system where the applicants black out such information from the public version of the applications. This has proven to be a workable solution to balance business sensitive information and transparency of the process.

ECHA has also worked with the European Commission in the task force that has addressed the workability of the applications for authorisation and made suggestions to simplify the authorisation process. As the simplifications need to be adopted in implementing legislation, the Commission is currently working on this.

One way of addressing the specific needs for authorisation of SMEs is that their uses would be covered “upstream” by the manufacturers, importers or Only Representatives (OR) of substances of very high concern (SVHCs). In such cases the application still needs to cover all the requirements placed on the SME, but by having one application efficiencies can be gained by bundling similar situations. This has indeed also been taken place, for instance for chromates. Another way is that SMEs team up with larger companies and apply together for the same use. Given the recent change in the Fee Regulation, an SME would not need to pay an additional fee in joint applications.

Regarding your suggestion for “regionally limited authorisations” we understand that this would require a change in the REACH Regulation. Thus, we propose that you make this suggestion to the Commission.

In terms of your suggestion that SMEs would be granted longer review periods than other applicants, please note that each application is evaluated and decided upon on a “case-by-case” basis. Thus, a SME can make such an argument in its application. However, the REACH Regulation does not provide for an overall preferential treatment in this regard to all SMEs.

According to Article 58(2) of REACH, it is indeed possible to exempt from the authorisation requirement uses or categories of uses “provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled”.

As you know, the decision to grant an exemption from the authorisation requirement under Article 58(2) is taken by the Commission, taking into consideration ECHA’s recommendation.

In preparing its recommendation, ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;
- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;
- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

It should be noted that any Art. 58(2) request is assessed case-by-case. Please also note that obtaining an exemption is a possibility, not an entitlement.

Substances included on the Candidate List have been identified as substances of very high concern based on their hazardous properties. There is a societal interest to substitute these substances in order to protect humans and/or the environment from risks potentially arising from the uses of these substances. At the same time, aspects such as the availability and suitability of alternatives, socio-economic, human health or environmental benefits of continuing a particular use or the (adverse) impacts of ceasing it are important. The authorisation process as a whole (inclusion in the Candidate List, inclusion in Annex XIV and application and granting the authorisations) takes into account and aims to balance these interests and aspects.

The Member State Committee (MSC) plays an important role within the authorisation process by resolving divergences among Member States during SVHC identification and by providing an opinion on ECHA's draft Annex XIV recommendation. However, only in the next step of the authorisation process, the application for authorisation, socio-economic aspects can be considered because only then the respective information needed to be able to do such an assessment is provided by the applicant within his application. This assessment is the task of the Committee for Socio-Economic Analysis (SEAC).

Communication in supply chain

It is positive to learn from you that awareness on and quality aspects of the safety data sheet have improved with the REACH Regulation. Your observations on the challenges faced by downstream users in handling the amount of information now available and identifying what's important in the extended safety sheet are known to us and some efforts to tackle these points are being taken within the activities of the Exchange Network on Exposure Scenarios (ENES); UEAPME's participation in the Network's coordination group is therefore appreciated. ECHA acknowledges that digitalisation, or improving the harmonisation/standardisation of the data format of the extended safety data sheet to facilitate the transfer of information in a way that IT systems could directly process, is worth further consideration.

We note your concerns about the workability of the substances in articles information obligations which have been extensively discussed during the updating of the related guidance document. In addition, the practical aspects of these obligations will be further discussed during the development of the notification tools for the SVHC in articles database that needs to be set up under the Waste Framework Directive (WFD). We would not necessarily agree with your comment that analytical methods are a prerequisite for adding substances to the Candidate List for the mere reason that in addition to performing analytical test there can be other ways to obtain information on which substances are present in articles, notably through better communication between the actors involved in the production of the articles. It is expected that during the discussions on the WFD further opportunities will come up to clarify the 'articles in articles' principle and how different actors should handle these situations.

Brexit

Undoubtedly, the UK withdrawal from the EU will have a significant impact on the obligations of companies maintaining supply chains of chemical substances across the English Channel or the border within the island of Ireland. It is with this in mind that ECHA, already in September 2017, published Q&As to provide advice to affected companies. We appreciate that you deem this information on ECHA's webpages to constitute a very useful information source.

With regard to the three proposals that you make in your letter, we would like to encourage you to share what ideas for a simple relocation of Only Representatives to EU-27 member states you have in mind. As things now stand, the change of OR merely requires a contractual agreement and notification to ECHA.

As an EU Agency, ECHA is not a party to the withdrawal negotiations between the EU and the UK. It will fall upon ECHA to implement any arrangement that will be the outcome of these negotiations. It is therefore not in the hands of ECHA to grant transitional periods to companies that will remain subject to the EU chemicals legislation beyond the date of the UK withdrawal. Should the parties conclude and ratify a Withdrawal Agreement with the already drafted potential arrangement of a transition period until 31 December 2020, this would provide companies with a "grace period", during which current EU-27-located downstream users would have time to register UK-sourced substances or apply for authorisations on their own. For the reason mentioned above, as a matter of principle, ECHA abstains from speculating on any future scenario that may need to be taken into account, such as contingency measures for the eventuality of no withdrawal agreement being found or measures that may result from an EU-UK agreement on their future relations.

Intermediates

ECHA and the Commission recognise the importance of the court judgement in case C-650/15 P and are in the process of analysing its contents to see how it might affect the way intermediate use of substances would be regulated under the REACH Regulation. Further discussions with the Member States Competent Authorities are likely to take place in one of the upcoming Competent Authorities for REACH and CLP (CARACAL) meetings after which ECHA will see whether any modifications will need to be made to the guidance on Intermediates to reflect the Court's considerations.

Nanomaterials

We take note of your concerns relating to nanomaterials, the amendments of the REACH annexes and the impact it may have on downstream users and the considerations on the Commission Recommendation of a definition. We recommend that you also share these concerns with the Commission (DG ENV and DG Grow) who has the responsibility for amending REACH and the Recommendation for a Definition of a Nanomaterial. In doing so, the Commission assesses the potential impact both in terms of burden on industry as well as predicted benefits to human health and the environment. Consequently, this has also been done for the amendments in the REACH Annexes and therefore, there may be aspects in their assessment that could be of interest.

ECHA will initiate our guidance developments to provide further support to registrants on how to comply with the amendments of the REACH annexes for nanomaterials. In this process, we encourage you to raise your concerns and views on the practical implementation to ensure that the final guidance provides the support it is intended for. For more information on how to engage in our guidance process, kindly visit our website: <https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach>.

Interaction with OSH

We in general agree with you that there's an important interaction between REACH/CLP and the Occupational Safety and Health (OSH) legislation that needs to be handled carefully. Throughout the years various aspects of such interactions have surfaced in different processes. This has been as well recognised by the European Commission which has included a specific action as a follow-up to the REACH review in which ECHA participates. Your specific point on the need to maintain the high expertise gathered by Scientific Committee on Occupational Exposure Limits (SCOEL) is being addressed by ECHA, for instance through the nomination of several co-opted members on Committee for Risk Assessment (RAC) that have served as well in SCOEL.

Setting an Occupational Exposure Limits (OEL) as an alternative risk management option is a consideration that quite a number of Member States have made when developing their Risk Management Option Analysis (RMOA). As for the comment that the existence of an OEL should be a basis for an exemption based on art 58(2) we would like to refer to our responses given above under authorisation.

Balancing Financial and Administrative Burden

Thank you very much for your further ideas on how to improve the public consultations in order to achieve a higher participation by SMEs. ECHA is continuously trying to improve its approaches on public consultations, recognising though that some of the ideas put forward by stakeholders would introduce an extensive amount of extra work that is not sustainable.

ECHA is pleased to hear that once the European Chemical Legislation Finder (EUCLEF) is established it will be a useful navigator tool, in particular for SMEs to ensure better compliance and at the same time serve authorities to observe the potential overlaps and to thus promote better regulation. EUCLEF will easily be accessible on ECHA's webpage and free of charge.

Finally, we must advise you to direct your suggestion regarding an SME Compliance Fund to the services of the European Commission or to national authorities. In the past, ECHA has undertaken numerous attempts to persuade such public actors to establish mechanisms for making EU funds available to help SMEs² bear the financial burden related to the safe handling of chemicals in accordance with the EU regulatory regime as well as to investments into R&D linked to innovation and substitution. In our experience, it appears legally problematic to use public funding to support compliance.

We hope that the above addresses your suggestions and concerns satisfactorily. Should you have any further questions, please do not hesitate to contact us.

Yours sincerely,

SIGNED

Christel Schilliger-Musset
SME Ambassador - ECHA

² Some indirect SME funding opportunities are available: https://europa.eu/youreurope/business/finance-funding/getting-funding/access-finance/index_en.htm. The DCG also published a Fact Sheet on the issue: https://echa.europa.eu/documents/10162/23556156/171128_dcg_smes_access_to_finance_en.pdf.