*Sweden, 15th of December 2014*

# ChemSec´s comments on the Commission proposal "Streamlining and simplifications of the authorisation process for some specific cases" (Doc. CA/81/2014)

ChemSec recognises the need for a streamlined, efficient and predictable authorisation process and welcomes the current discussion on how to improve this process. However, we fear that some of the Commissions suggestions will in fact jeopardise important intentions of REACH. Also it imposes additional burdens on both companies and authorities.

We find the following intentions being threatened by the proposal:

***Driving innovation and substitution***

Authorisation is about innovation and substitution, and many companies have acted accordingly in the REACH process by starting the process of searching for alternatives when a substance has been added to the candidate list so that when the substance eventually is added to the authorisation list they have already replaced the substance or could now easily shift to this alternative. Nevertheless, what the Commission now propose is to ease the burden on companies who wish to continue the use of recognised *Substances of Very High Concern* in processes and products. The proposal doesn't include any suggestions for how to encourage substitution and innovation, or how to reach companies that have already managed to find or develop alternatives. The proposal would therefore undermine the innovation potential in industry since the signal from regulators would be that SVHCs can be used until the market itself change to alternative substance/ techniques. Substitution would then only rely on voluntary action, without having regulation driving this change.

***Burden of proof***

While the authorisation process in its intent puts the burden of proof on industry to justify use of *Substances of Very High Concern*, the Commission propose to again increase the information requirements on ECHA and the member states, as in the suggestion to have ECHA providing "elements" for the authorisation dossiers and further assist applicants. We think ECHA should instead support companies in their substitution efforts.

***Protection of human health and the environment***

If the proposed simplifications in fact lead to more authorised uses of *Substances of Very High Concern,* or if several *Substances of Very High Concern* not even reaches Annex XIV, the level of protection of human health and the environment will decrease. Also the suggestion to base calculations of adequate control of "Occupational Exposure Limits" (OEL) instead of "Derived no Effect Levels" (DNEL) lowers the protection for the environment and for

sensitive groups of citizens. The increased focus on socioeconomic benefits, instead of the risks posed by these high concern chemicals, lowers the protection level.

***Transparency and predictability***
The candidate list is a recognised driver for innovation, the suggestion to take availability of alternatives and socioeconomic aspects into account before placing substances on the authorisation list will make the role of the candidate list unclear and confusing. Also, to gather such information on all potential uses, before having applications for authorisation, certainly makes the process more complex. In addition, the idea to without further scrutiny consider information on basis of being "manifestly known" certainly decreases the predictability. We fear that the suggestions given will not make the process easier but instead more complex and uncertain- the complete opposite to what was intended.

***Following the above, we do not agree that the proposed changes, as they are phrased, are within the scope of implementing acts. Rather they are an attempt to change the intention of REACH and such changes would require a co-decision process.***

Below, ChemSec concerns are given in more in detail and linked to the specific Commission proposals.

**2.1 Annex XIV amendment step:**
**"Extend ECHA public consultation (article 58(4)) on recommendations for Annex XIV to include socio-economic elements"**
*ChemSec concerns:*
SVHCs, with a priority for substances produced in high volumes, having PBT or vPvB properties or with wide dispersive use (§58(3)), should be added to annex XIV regardless of socio-economic implications like if alternatives or alternative techniques are available or not. The availability of alternatives as well as socio-economic implications for companies should be taken into account in the next step, when companies apply for authorisation. The proposal for adding socio-economic aspects into the early public consultation would therefore go against the intention of REACH.

If socio-economic elements will be included in the public consultation this will certainly influence both ECHA and MS in their work to suggest substances for Annex XIV which would mean a change in REACH since the intention of REACH is to add SVHCs to annex XIV regardless of socio-economic impacts on industry.

This proposal will also hamper the innovation potential within the EU and undermine companies producing the alternatives, making it more difficult for these producers make a profit.

To get a valid picture of the socio-economic considerations, socioeconomic aspects need to be given for *all possible uses* to be relevant at this stage. This would be an immense burden on companies producing the substance or any possible alternative. Moreover, these producers very seldom reply to public consultation leaving the Commission with a very fragmented picture of the socio-economic elements, inadequate as basis for decision-making. It is also a duplication of work since the same information is to be gathered when a

company has applied for authorisation.

This proposal would not only change the intention of REACH, it would additionally give the Commission extensive influence over what substances to add to Annex XIV and leave Member States with little to act upon.

**2.2 Application step. A: General solutions applicable for all applications:**
**" ECHA should provide elements that can be used to prove adequate control, lack or non-suitability of alternatives or fact that benefits outweigh the risks."**
*ChemSec concerns:*
We support and welcome the proposal for ECHA to, where appropriate, lighten the burden for companies, during the preparation of the applications. We also welcome the ECHA involvement in helping companies to define the use they apply for, to make sure that it is properly specified in order to allow accurate contributions to the public consultation regarding alternatives for that specific use. However, the current suggestion puts a strange task on ECHA, to find information arguing *against* substitution, instead of helping companies find alternatives. We are also very hesitant to what kind of "elements" the Commission has in mind when proposing ECHA to provide elements to prove lack or non-suitability of alternatives.

Many companies, especially SMEs, find the cost associated with applying for authorisation burdensome. The most efficient way to help SMEs not having to take this cost is to guide and help the companies to find substitutes to SVHCs in time to avoid the need of having to apply for authorisation in the first place. Even if the process to apply for authorisation is simplified it will still be a complex task for many of these small companies. Early guidance would also help these companies to replace SVHCs in their own time and shift to alternatives when economically most feasible. When a company is faced with the fact that a substance is on the authorisation list with a fixed sunset date they have very limited possibilities to start a cost-efficient process to find suitable alternatives.

**2.2 Application step. A: General solutions applicable for all applications:**
**" Communication activities should also aim to eliminate the misconception that authorisation means automatically a ban of a substance"**
*ChemSec concerns:*
The communication from ECHA and the Commission needs to be clear that it is possible to get authorisation for a substance on annex XIV *for a specific use and where no alternatives are available*. Otherwise companies will not look for alternatives early enough and will get caught red handed when substances they use are added to Annex XIV. The most efficient way to ease the economic burden for companies must be to help them to never have to apply for authorisation in the first place, if alternatives exist.

**2.2. Application step B: Specific cases:**
*ChemSec concerns:*
We find it important that these cases are well-defined, very limited and not exempt whole industries from REACH. We are concerned about the proposal "not to require authorisation for substances part of a process where the end products needs to be approved" since this could, for example, include car and airplane industry. End product approvals in these industries focus at safety and emissions and not at human health and environment.

**2.2. Application step B: Specific cases: 1. Application of article 58(2) exemption:**
*ChemSec concerns:*
Use of 58(2) could be applicable when it comes to very defined uses included in a restriction dossier but exempted in the restricted process, which would mean very few cases. It should **not** apply to the substance as such. The intention of REACH is that a substance can both be restricted and authorised under the regulation.

**2.2. Application step B: Specific cases: 2. Simplified, streamlined and fit-for-purpose authorisation application:**
*ChemSec concerns:*
The goal with this part of the proposal is to remove the uncertainty of industry. We support this initiative but do not agree with all the proposed changes. REACH requires all information in 62(4) to be part of an application for authorisation and we do not want this changed, it would change the intention of REACH. We agree however that the level of detail required could be limited and that the information required could be more efficiently presented by the applicant.

We also strongly question the following "…manifestly known that no alternative substances can be expected…" and "…which is manifestly known that the socio-economic benefits outweigh the risks." It's not clear to us in what kind of cases it is manifestly known that no alternatives are available or where socio-economic benefits outweigh the risks. We can't think of any cases. Also, including aspects of what is "manifestly known" decreases transparency and increase uncertainty.

**2.2. Application step B: Specific cases: 2. Simplified, streamlined and fit-for-purpose authorisation application:**
**"Using OELs (Occupational exposure limits) instead of calculating a DNEL (Dervived no effect level) for adequately controlled route"**
*ChemSec concerns:*
We find this proposal very worrisome. OELs are different in different countries. In many cases new scientific information is not taken into account and the OELs are not revised. Many of the used OELs are very old and sometimes the background documentation is missing. OELs take only inhalation into account and not dermal exposure. Moreover, OELs do not take the environment and sensitive groups like unborn babies or children into account. To use OELs as a baseline to claim that a substance is adequately controlled is not scientifically robust.

**Conclusion**
ChemSec recognises the need to simplify specific elements in the authorisation procedure, provided that it will not alter the intentions of REACH and not take market shares from companies producing alternatives to SVHCs. The system must promote innovation. We see the development of the authorisation procedure as a priority for the future success of REACH and we are hopeful that the Commission is willing to take stakeholders opinions into consideration also further on in the process.

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