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Anne-Sofie Andersson
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Subject: Your letter of 3 July 2018

Dear Ms Andersson,

Thank you for sharing ChemSec's view on the progress made in implementing the Commission's Roadmap on Substances of Very High Concern (SVHCs). Thank you as well for the wishes regarding my new job. After six months, I indeed feel settled. I was warmly welcomed, received very solid support from the colleagues to help me learn and have been treated with the utmost patience!

You raise a number of points, reiterating concerns expressed in publications or your contribution to the public consultation on ECHA's future strategy. I value this, as I do discussing these issues regularly with you. To reply to your points, I will first explain how I, in my new position, see the SVHC Roadmap implementation, and how this is linked to the REACH and CLP regulations. I will then answer your five specific questions.

As stipulated in Article 1 of REACH and articulated in the Commission's REACH General Report, I will, within the mandate of ECHA, focus on protecting human health and the environment and preserving the internal market. In doing so, innovation and competitiveness will be enhanced. I will also promote non-animal test methods, for example, through the OECD QSAR Toolbox. Whether this focus is greater than before is best left to you and others to judge.

I agree with the findings of the Commission's REACH General Report, in particular that implementation of REACH has to become more efficient and needs to deliver quicker. This does not contradict the finding that the implementation of the SVHC Roadmap is "progressing beyond expectations" nor that this part of REACH has promoted innovation and substitution. Much of REACH needs to improve, but the SVHC Roadmap is doing well.

The Commission's SVHC Roadmap was endorsed in 2013 by the EU Member States. ECHA coordinates the implementation in cooperation with partners from European and national authorities, industry and civil society. The SVHC Roadmap aims to have all relevant currently known SVHCs added to the REACH Candidate List by 2020, but also to continue adding substances after 2020. As you mention, in the aim there are three key terms: 'relevant', 'known' and implicitly 'unknown'.

Regarding your five specific questions:

First question (related to 'relevant'): The definition of 'relevant' was set jointly by the Commission and Member States. ECHA implements it. Up to 2020, non-registered substances should not have priority for Candidate Listing, unless they form part of a group. In fact, ECHA itself listed several of such substances.

Second question (related to 'known'): CMRs are not necessarily adequately regulated through the requirements that apply following classification. The purpose of risk assessment, by industry

or authorities, is to assess if this is the case for each CMR. As part of the SVHC Roadmap, authorities have assessed (not risk assessed) all substances with a CMR classification to see whether they need further regulation. Once this assessment is done we say the substance has been 'addressed'. They concluded for a number of them that, at the moment, there is no need for further action at the EU level. This relates, for example, to the fact that these substances have often had a harmonised classification as CMRs for many years, and hence are highly regulated under REACH and other legislation, or they are not registered. These conclusions are reviewed regularly to observe any changes in use patterns or other information that would change this conclusion.

Third question: Except for CMRs, the identification as an SVHC can facilitate the discussions of a restriction proposal. Conversely, existing restrictions are taken into account when considering the need for further measures, including inclusion in the Candidate List. However, apart from those for which a full ban is in place, no substances are excluded from the screening based exclusively on an existing restriction.

Fourth question (related to 'unknown'): We are generating data for or assessing 750 substances, many of which have so far not been on the radar screen of the authorities. As you state, information generation is time-consuming when it concerns long-term effects. We are continuously working with national authorities to keep the timelines as short as possible, including effective use of the expert groups and we have started implementing the REACH General Report actions to significantly speed up the evaluation processes. However, as a science-driven agency we need scientifically valid information to identify substances as SVHCs.

Fifth question: I am not sure in which context my predecessor said this, but I can assure you that it is our goal to bring the authorisation process, including the Candidate List, to its effect, to protect citizens and the environment, and to stimulate substitution and innovation. As an independent Agency we are well set up for being resilient against external pressure.

The Commission confirms in the REACH General Report that most of the substances with confirmed SVHC properties have now been assessed and that addressing data gaps from registration and improving substance evaluation will enable new SVHCs to be identified.

We will be further developing ECHA's "Integrated Regulatory Strategy" to take into account the learnings from the first years of applying REACH with the aim to further streamline the work and push for further integration of our evaluation, restrictions and authorisation work and speed up the identification of and regulatory actions on new substances of concern. Addressing groups of structurally similar substances is a key feature of this strategy and will enable authorities to cover both registered substances and structurally related, non-registered substances in one go which will also support informed substitution of Candidate List substances.

I am looking forward to continue working with you and your colleagues. Civil society organisations play an important role in our work. We rely on targeted and well reflected input from all interested parties, especially into our public consultations, so that we can base our scientific work on the broadest possible basis.

Yours sincerely,

Signed

Bjorn Hansen
Executive Director