

## Stock-taking conference on the implementation of REACH authorisation

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Reflections**

**Ladies and gentlemen,**

In the past 10 years, I have seen how the REACH authorisation system has developed from its infancy to the mature and robust system that we have today. Looking back and also to the future, I would like to share my reflections about the authorisation system.

**Firstly, we now have evidence that the inclusion of substances to the candidate and authorisation lists as well as the decision-making of authorisation applications effectively stimulate substitution and reduce risks in a business friendly, efficient and effective manner.** We have seen companies who have decided not to apply for an authorisation but rather opted for substitution. And we have seen companies who have applied for authorisation but have clearly recognised the critical focus on risk management that preparing an application brings. We will hear in the next two days from several examples of such cases.

Up until now, we have 174 substances of very high concern in the Candidate list of which 43 substances are on the Authorisation list. ECHA's scientific committees have adopted 167 opinions on applications, most of them during the peak of this and last year. The authorisation system has proven that it can simultaneously handle applications from several applicants with many uses. The system has successfully handled uses considered by some to have 'no alternatives' and the committees have even processed uses with strategic importance for other sectors.

ECHA has continuously improved the authorisation system based on feedback we have received from stakeholders, Member States and, in particular, from the European Parliament and the Commission. It is absolutely clear that even though the authorisation system is a decade old, it is still a new way of regulating substances of very high concern. We all – the applicants, alternatives providers, stakeholders, the Commission and the Member States as well as ECHA including its committees – benefit from working together to improve the efficiency and effectiveness of the authorisation system.

I am relieved that the Commission finally decided to add 12 new substances to the Authorisation List earlier this year. Updating the Authorisation List regularly allows us to continue to harvest the benefits of the authorisation system. Furthermore, regulators should ensure that the authorisation system is predictable as a whole. Predictability is crucial for business.

**I would like to turn to my second reflection – on the challenges ahead.**

Together, we have been able to make the authorisation system work well. But no system is perfect. As far as I can see, there are four main challenges that need to be addressed.

1. A first challenge is that, with the latest update of the Authorisation List, we need to address substances with endocrine disrupting properties for the environment. We have started to work with the Commission, stakeholders and applicants to

establish a predictable process for this. We have already made a lot of progress. This conference gives an opportunity to identify to what extent outstanding issues may remain.

2. The second challenge is to improve the information in the applications and thus the quality of the opinions so that uncertainties are further reduced. This would allow the Commission to shorten the time it takes to decide on authorisations. This would increase the credibility of the entire system and increase the certainty for industry and market operators.
3. Third, a key challenge is that we need to improve the way the so-called 'upstream' are prepared and how their applications are managed. As suppliers they have a business interest in the continued use of the SVHC, which is not the purpose of the authorisation system. I trust that this dilemma will be discussed from different viewpoints during our conference and that further refinements of acceptance criteria for such applications can be concluded. One additional help for the upstream authorisation holders comes from another game changer. This is the information from the downstream user notifications. They have already been and will continue to be a very important source of knowledge to help authorisation holders improve their description of use and narrow down their authorisation needs during, as warranted.
4. The fourth challenge is the review phase of the authorisation system, which we will soon start to apply for the first time. As I see it, during the review the burden of proof should lie completely on the authorisation holders to show convincingly whether the possible alternatives are -- or are not -- suitable for them. This time, the authorisation holders have had enough time and lots of opportunities to collect information to analyse profoundly the suitability of alternatives for them. If there are at that stage still doubts in the minds of the committee members, they should in my view give more weight to the arguments of the providers of alternatives, who I encourage to be more vocal.

### **Now let me turn to my final reflection – what is my preferred way to further develop the system?**

During my 10 years leading ECHA, industry, NGOs, the European Parliament and Member States have challenged ECHA or the European Commission in various ways in their implementation of the authorisation system. It is, of course, perfectly legitimate to disagree with the regulator in all possible forms of contestation.

Another, and in my view better way, is to work together to resolve the problems or weaknesses. That is why we have organised today's conference and I believe that it is up to all of us, parties in this highly sensitive process, to ensure that we collectively make the authorisation system work better and more robust in the future.

### **Dear friends of authorisation,**

This conference is a great opportunity to take stock of where we are at and discuss how we can – together – address the challenges in the authorisation system on which I have given you today my own reflections. Apart from the EU, nowhere in the world do regulators have the power to introduce binding measures that over time replace

chemicals of very high concern for the benefit of society. I believe that we should continue to show leadership and make an authorisation system work to such an extent that countries outside from the EU also wish to benefit from it or even copy it.

Thank you.