Opening remarks by Mr Geert Dancet, Executive Director, European Chemicals Agency

Conference on the lessons learnt of applications for authorisation

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Ladies and gentlemen,

Welcome to this two day conference on the lessons learnt on applications for authorisation. I am delighted to see so many of you here and I am aware that many more are following this event online.

Since 2007, when I began my term as an Executive Director at ECHA, there were lots of challenges and scepticism over whether REACH would function. We have now met two registration deadlines successfully so the 'R' in REACH is functioning well. We have also evaluated five percent of the chemicals registered for the first deadline, so the 'E' in REACH is also working.

After making the candidate and authorisation listing work during the first years, ECHA worked intensely during the last two years with all stakeholders to prepare for the applications for authorisation phase, which is the most novel part of REACH when compared to previous legislation. Today, we can note that ECHA's Risk Assessment and Socio-economic Analysis committees

have adopted to date 63 opinions. Taking into account our scientific opinions, the first authorisations have also been granted by the Commission. This gives reassurance that the 'A' of REACH is equally working well.

Let me share my thoughts on why I consider in particular that the application process to be working so well.

First of all, the application process has been fair and transparent.

First, the information gathering stage. We have transparently agreed with all stakeholders involved the dossier formats for applications and public consultations. We have also listened to the calls of accredited stakeholder organisations for an even more open process: About 90% of the information contained in application dossiers is now available to interested parties in the public consultations.

There may be some who try to hide information from the public with unjustified claims of confidential business information. When this is the case, they should know that ECHA will rigorously defend the public's right to know about risks from substances of very high concern, if necessary all the way to court, as is the case right now.
ECHA has also set up a system of "trialogues" between the rapporteurs of the two committees, the applicant and eventual suppliers of alternatives. This system has proven to be a useful forum for exchanging information

on alternatives. Accredited stakeholders have fully participated in these meetings.

Secondly, the committees have formed their opinions based on clear scientific criteria.

Furthermore, each and every one of RAC's and SEAC's deliberations on applications for authorisation has been held in open session, allowing accredited stakeholder organisations to witness the debate. From this year on stakeholders can also express their views in the plenaries while naturally avoiding comments on the applications themselves.

Let me turn to my second consideration.

The application process has had a tangible impact on substitution and proper control of SVHCs. Some companies have decided not to apply for authorisation at all and must cease using Annex XIV substances by the sunset date. For some substances no application arrived to our offices at all. For two of such substances the Forum has agreed to start a pilot project to examine the elimination from the EU market of these substances. Those companies that did apply have found ways to improve risk management measures, thereby reducing the risk to workers or the environment. In fact, even when an authorisation is granted, there is still pressure on the authorisation holders to seek substitution with safer alternative substances or technologies. If they intend to continue the use beyond the expiration date of

the review period, they will have to submit a review report. Companies need to understand that the progress they make on research and development towards safer alternatives will be under the scrutiny of both the committees and the public at large.

Let me turn now to a third experience that is surfacing. The application process has proven to be predictable. Those companies that make genuine and good applications with convincing arguments that no technically and economically feasible alternatives are available have seen their prospect in getting an authorisation validated. And in fact – at least as far as ECHA's committees are concerned – experience has proven this to be the case. In other words, the substitution pressure on European companies wishing to use substances on the authorisation list has been reasonable and in line with the overall objective of the authorisation title of REACH.

Now, how expensive has the application process actually been?

At the start of the application process industry representatives found that their efforts would be challenging and costly. If it were to turn out that applying for authorisation is perceived as a disproportionate burden on companies operating in the EU, then we would have missed the mark.

However, the feedback we have been receiving from those who have actually gone through the process tells a different story. Some applicants had indeed incurred very high costs at the very beginning of the process. However, these have not become the norm. Rather, application costs are clearly on a downward trend.

Based on the information provided by applicants, we estimate that the average cost of preparing an application for authorisation has already fallen by about 30% and is now below 200 000 Euros per applicant and use. In ECHA, we will continue to do whatever we can to reduce unnecessary costs by providing as clear as possible instructions and advice to all applicants.

Finally, what feedback have we received so far in ECHA?

Applicants have told us in our "feedback survey" that the services provided by ECHA (such as the Pre-Submission Information Sessions), the direct communication with applicants and stakeholders and the technical improvements that have already been implemented have been very helpful. The support we are providing to help companies comply with their duties is making a difference.

While I consider the application process to be working well, this does not mean that there is no room for improvement. The purpose of this conference is to get

your feedback and suggestions on how this could take place.

I would like to leave you with two thoughts:

We are investing to further improve the process. ECHA, including its committees for risk assessment and socio-economic analysis, has taken an active role in a joint taskforce with the Commission and Member States. This is a clear sign to all that ECHA, together with the Commission and the Member States, is committed to a workable and predictable application process. One priority on this year's agenda is the streamlining of the application process for certain special cases, such as uses of Annex XIV substances in very low volumes and in the production of legacy spare parts.

Looking ahead, there will be a peak in incoming applications as the latest application date for chromates in early 2016 approaches. This peak will present a challenge to everyone involved. ECHA has equipped itself to meet the challenge by making the opinion-making process more efficient and by significantly strengthening both its internal staff and its committees. However, we rely on open lines of communication with potential applicants who should inform us what is ahead so that we can plan accordingly. If we work together, we can manage the peak that is on the horizon and keep the process running smoothly.

Dear conference participants,

Our experience so far shows that the application process works well, perhaps surprisingly well, given that it is a completely new process. The process stimulates substitution and provides the public with access to important information on SVHCs. The process is predictable and provides a stable regulatory environment in which industry can continue to operate and invest with confidence. Last but not least, the application costs have fallen by 30% from the early days. If we all work together, and listen to each other to further improve the process, it will become more and more affordable and predictable, in particular when applicants and consultants are smart in their work and in making best use of the help they get from ECHA. I am therefore convinced that companies will be able to submit fit-for-purpose applications with a high probability for a successful outcome.

In ECHA, we are committed to playing our part and fully expect the authorisation process to keep delivering benefits for European citizens and the economy as a whole. With a good start behind us, now is the time to keep this momentum going. I see no reason to question that the authorisation system is working. It is. It is affordable. It is predictable. Therefore, I call upon our Commission colleagues to resume their preparations for inclusion of recommended substances to the Authorisation List.

Ladies and gentlemen,

It should be clear that we consider that the application system works and that we have paved out a way for it to work even better this year. This conference is a very good occasion for us to hear to what extent you share our views. I wish you a fruitful and successful meeting and look forward to the outcome.