CONFERENCE ON APPLICATION FOR AUTHORISATION

10-11 FEBRUARY

BACKGROUND

- Why this conference, and why is Commission – in close cooperation with ECHA - working on simplification and streamlining of authorisation?

- Authorisation systems are well known and long-established for certain specific product groups such as plant protection products, biocides, medicinal products, or food contact materials that generally cannot have access to the market unless they are authorised….. Authorisation in REACH, however, is a new concept and process for selected general chemicals, based on a different logic. REACH authorisation has been created to address substances of very high concern, aiming at their progressive phase-out and substitution by safer and less hazardous substitutes.

- It has been for all actors a learning-by-doing exercise, as the individual parts of the system have been entering into full operation:

    - experience in the SVHC identification and candidate listing – in the beginning this was maybe a bit too 'mechanic' - which led to the development of SVHC 2020 Roadmap and its Implementation plan

    - experience with the first prioritisations of substances – prioritisation approach updated in 2013

    - inclusion of substances in Annex XIV and the application for authorisation phase: this is now the critical phase

- From the 4th amendment of Annex XIV:

    - a number of Member States started raising concerns on the inclusion on some substances during MSC and REACH Committee meetings

    - Comments questioning at that stage the choice of authorisation as a regulatory option

- Why is this happening?

    - Authorisation has gained speed and it now concerns substances that are more widely used in sectors important from the socio-economic point of view

    - The application for authorisation phase is starting to show results now but there are not yet sufficient examples to increase trust that authorisation works and to show that authorisations are granted for well justified applications

    - The preparation of applications is clearly not an easy task for some sectors and substances (for example when supply chains are very long and complex, i.e. for chromates)

- As a result, part of industry is still strongly objecting to the inclusion of substances in Annex XIV providing the following reasons:
    - The system is too complex, burdensome, expensive and felt to be in some cases disproportionate – we just heard from the Executive Director that costs for applications seem to be on a downward trend, and it would be important to hear today, whether applicants can actually confirm this
    - Authorisation lacks predictability and creates uncertainty on the continuity to use the substance in the future in justified cases, with consequences on investment in Europe. The perception of a part of DUs is that authorisation is more or less an immediate ban.
    - In some cases, it creates a (permanent) competitive disadvantage vis-à-vis third countries
- Parts of these concerns may be linked to misconceptions, but they need to be taken seriously and can help to find ways to improve the perception of and trust in functioning of the authorisation process.

WHAT HAVE WE DONE, AS AUTHORITIES, TO IMPROVE THE SITUATION?

- We have worked on improving predictability and transparency
- Starting from the pre-regulatory phase (including the RMOA) : thanks to the SVHCs Roadmap, we now have
    - Agreed priorities, method of work and criteria for screening and selection of candidate SVHCs
    - RMOA process applied by all authorities (even if still with somewhat different approaches)
    - More predictability and transparency on the ongoing and planned work, including the choice of the best regulatory action(s) for substances that merit our attention
- Is this sufficient? Is this ensuring that authorisation is delivering on its goals? Is it increasing trust in it? Many concerns have been raised on the substances included in 5th ECHA recommendation, and the same could happen for the 6th. The Commission has announced that it will consider taking socio-economic elements into account before taking decisions on the future Annex XIV update. As you know, we had launched a call for submitting such information in parallel with ECHA's public consultation on the draft 6th recommendation. The resonance has been huge – we received more or less 380 submissions.

- While all of this needs to be further analysed, leading hopefully to a ‘smarter choice’ of substances going on Annex XIV, we need to work on improvements to reduce the burden of the application phase and make it more workable, both for applicants and for the authorities. And that’s why we are all here today.

APPLICATION FOR AUTHORISATION PHASE

The Commission and ECHA propose two parallel approaches to streamline and make the implementation of a more workable authorisation system:

- General solutions valid for all authorisation applications
- Ad-hoc solutions for “special cases”

General solutions – for which we need a common vision between COM, ECHA and MS

- Objectives
    - Further streamline and facilitate, lighten the burden for preparation of applications
    - Streamline work of ECHA’s Committees
- What can be done:
        - Give an indication of how a “fit for purpose” dossier should look like
        - Present examples to show what level of detail is needed for a convincing SEA and AoA, what kind of data are needed for a CSR
        - Clearly indicate what parts of the CSR the applicant does not need to "re-develop" (for example, the hazard part in case DNELs and dose response curves already established by RAC are used)

Specific solutions

- Needed to address certain special cases
    - The cost of preparing a full-scale authorisation application is felt to be disproportionate compared to the potential benefits for human health and the environment (in terms of reduced risks related to its substitution by another substance or technology).
    - Substitution cannot be expected in the medium or long term
    - Examples: substances used in very low volumes, substances with risks also addressed by other legislations – such as the occupational safety and health legislation, biologically essential nutrients, substances used in the manufacture of legacy spare parts

You will hear tomorrow what the Commission has started to do for two of such special cases (low volumes and legacy spare parts)

Conclusion

- We want to hear from those of you who already went through the preparation of an AfA and from those who are preparing it now what ECHA and COM can do to simplify the process of preparing an application (your suggestions should be very practical!)
- You can contribute to the public consultation on a simplified authorisation on low volumes and on legacy spare parts that the Commission launched last week
- You can suggest other “special cases” for simplification
- Substitution is one key objective of authorisation, but there will be many cases where this can only be achieved progressively. The misconception that authorisation is a ban should be rectified by all of us.