Outlook on the implementation of the application process going forward

Conference on "Lessons learnt on Applications for Authorisation"

Session 2.2

Outlook from authorities' point of view

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Matti Vainio

Head of Risk Management Implementation Unit

Outline

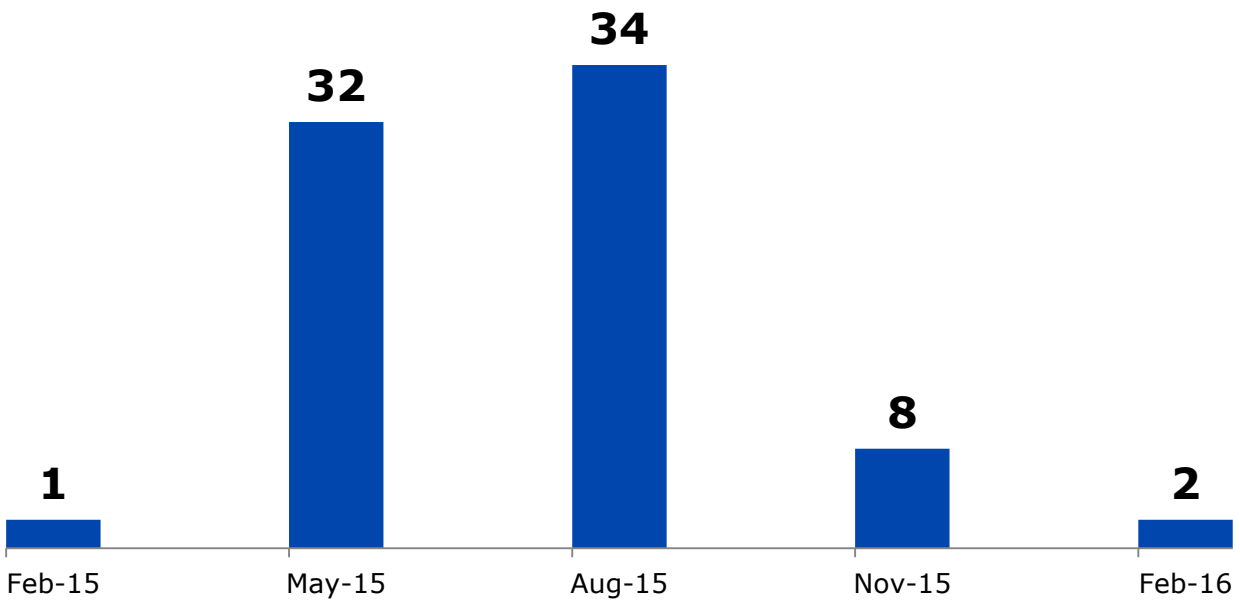
- Overall aim of ECHA
- What is ahead of us
- Improved capacity
- Continued activities
- Improvements
- New services
- Handling “special cases”
- Continued improvement of opinion making process and its documentation
- Take home

Overall aim

- Well focused, business friendly application process
  - Substitution to take place when warranted
  - Application effort should be “fit for purpose”
  - Application preparation costs as low as possible
- Appropriate scrutiny of the applications
  - Have high competence in ECHA including its committees
  - Have clear, well justified opinions that the Commission can use without delay
- Trust of all
  - Transparency and overall scrutiny of stakeholders

Estimated number of applications in 2015-16

Estimated (as of 1 February 2015) incoming applications 77 in total



ECHA improves its capacity

- Internal training of "second line of defense"
- Training of RAC and SEAC members on specific issues
- Training its staff in 2015 on project management, team work, and socio-economic analysis
- Working closely with the applicants to plan for the incoming applications
  - Good planning is in the interest of the applicants and ECHA

ECHA continues those activities that have been valued highly

- Transparent application format with less and less confidential information
- Efficient and caring process giving the opportunity to contribute (PSIS, Trialogues, seminars/ workshops, "Partners' Service)
- Reference dose-response functions and DNELs will be made public as early as possible
  - NB! Working under the REACH Regulation (no risk "acceptable")
  - Need to address specific issues relating to PBTs and vPvBs
- Establishing reference values of certain health outcomes to provide consistency and evidence based underpinning to committees and applicants

ECHA improves the user friendliness and efficiency of some services

- Information and user interface of web-site upgraded
- Recommendations of the Authorisation Application Task Force implemented; for instance:
  - Formats for applying for special cases
  - How RAC and SEAC evaluate special cases
- Feedback from applicants and stakeholders, including the Commission, sought continuously and acted on
- If needed, modifications for the "IUCLID portal for Applications for Authorisation"

ECHA provides new services

- Trial on “What would SME’s like to ask on Applications for Authorisation” on 25 February 2015
- Register of notifications of authorised uses (Article 66) to be operational in mid 2015
- Improved reporting of the statistics of applications on its website

ECHA prepared to handle “special cases”

- Application documentation (formats and instructions) for low tonnage are ready to use as soon as the policy has been elaborated
- Formats for other cases can be made fairly quickly once the policy on these has been elaborated
- Works actively in the Commission/ECHA Task Force on Applications for Authorisation

ECHA improves continuously the opinion making process and its documentation

- The application formats have been adapted twice in 2014
- The opinion formats are being modified and likely to be taken to use in June
  - includes systematic inclusion of conditions and monitoring arrangements for review reports
- Stakeholder participation fine tuned

Take home

- We care
- We want to use the authorisation process to substitute the use of chemicals of concern at lowest possible cost
  - Business friendly and focused on key issues: remaining risks and benefits of authorisation
- Applicants have made and committees have evaluated over 50 opinions on different uses
- We have a well functioning process and are prepared to give opinions of 50-100 applications in 2015-16
- We want to improve the process:
  - in general, simplify and make it even more 'fit for purpose'
  - Specifically, to make the "special cases" requirements work
- We want you to do all this together with you

Thank you!

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