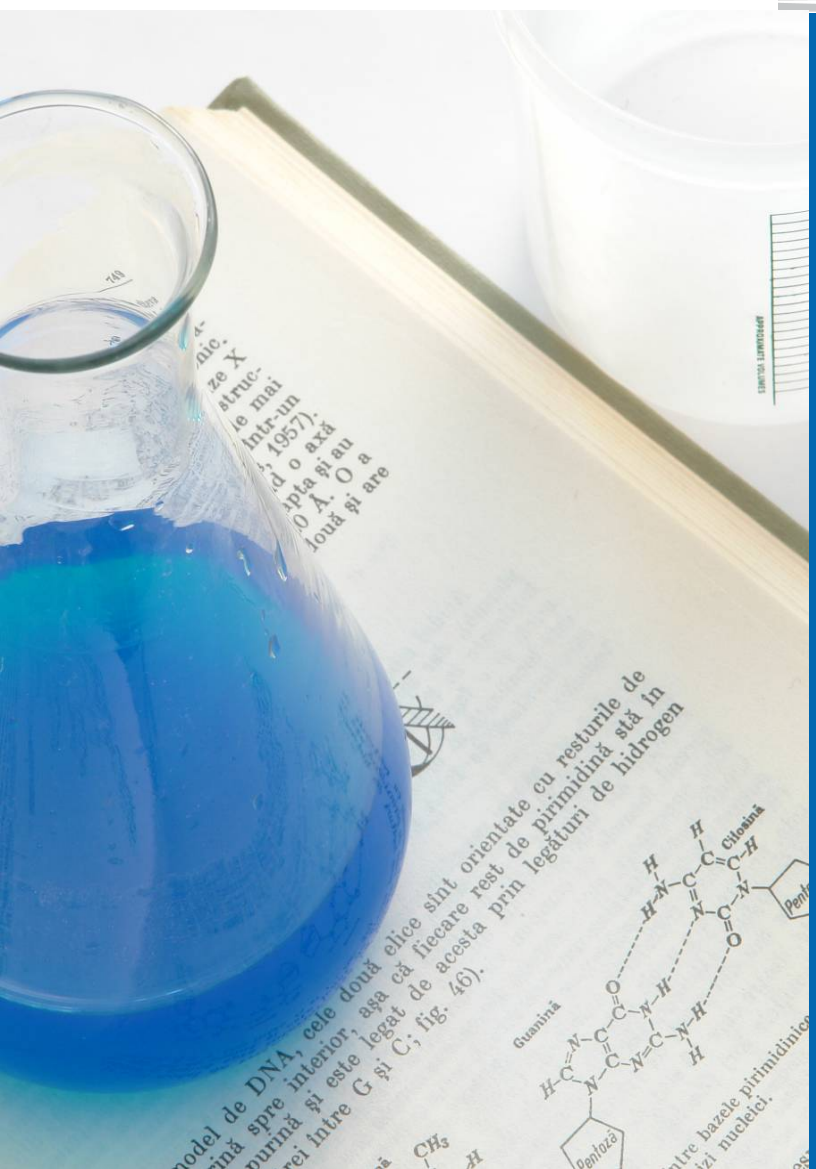

European Commission

Results of the study on the impacts of authorisation

Stock-taking conference on the implementation of REACH authorisation

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Valentina Bertato
European Commission

Background

Why a study on the impacts of authorisation?

We need to go back in time:

- 2012-2013: 3rd ECHA recommendation and 3rd amendment of Annex XIV
- For the first time, they concern substances widely used, in many different sectors and in relatively large volumes

Background

Industrial stakeholders advocacy activities:

- Authorisation requirement is only a burden (cost, administration, regulatory uncertainty)
- There is no added value and it will lead to delocalisation of industries outside of the EU
- Substances are used only in industrial sites, closed system, exposure and emissions reduced to the minimum already
- There are no alternatives for the current uses, they are critical
- Substitution already happened in the past, because of
  - CMR classification
  - OSH legislation

Background

- COM heard these arguments several times, over the years, for many substances: chromates, cobalt salts, borates, aprotic solvents, ..
- Questions:
  - Do we have the full picture?
  - Is authorisation really a disproportionate burden, with no added value?
- To know the answers became even more pressing, when, in the first authorisation applications, we saw
  - "Bridging applications", for a few years, working towards substitution with a concrete timeline
  - Examples of improvement in risk management measures

Background

First ideas for a study on authorisation, to be launched when a sufficient number of substances had gone through the whole process:

- Is it possible to quantify (or at least qualify) the costs and the benefits of authorisation (for HH and for ENV)?
- Can we try to reach the companies that do not contact us to complain about authorisation = those who substituted?
- If it is not possible to find an alternative, is authorisation leading to some improvement in workers' exposure and reducing emissions to the environment?
- Does authorisation lead to changes in the market of SVHCs and their alternatives?

Background

The study was finally launched in September 2016:

- This is the first study to look specifically at the impacts of REACH authorisation
- Methodology used:
  - Literature search (including on-going studies and national activities on authorisation)
  - On-line survey (83 respondents)
  - Interviews (49)

Key findings of the study

Changes in the market for SVHCs and alternatives

- Difficulties to use available market statistics and reports
  - Substances are often grouped
- Indications of some effects on the volume of SVHCs at the inclusion in the Candidate List (and, in one case, at the LAD)

Key findings of the study

- Stakeholder survey: 57% of respondents (n = 46) reported major impacts in the market after SVHC identification
  - Reduction in availability of supply for their use
  - Increase in SVHC price
  - Conditions being imposed on safe handling and use
  - Increase in R&D on alternatives but this diverts funds for new investment and new market opportunities
  - Trigger for substitution where technically feasible
- Alternatives: no clear indications of changes in the market

Key findings of the study

Substitution

- 43% of respondents to the online industry survey said they had substituted a use of a SVHC
- Survey respondents (n=83) identified:
  - Over 60 examples of substitution of SVHCs
  - Over 70 examples of investment in substitution related activities
- In some cases, substitution had very high costs
  - Applying for authorisation would have been less expensive, at least in the short term
  - Importance of regulatory uncertainty (especially for investment plans and long term contracts with customers)
  - Stigma of using a SVHC

Key findings of the study

- When is substitution happening?
  - 30%: at Candidate Listing
  - 23%: at the recommendation
  - 25%: at the inclusion in Annex XIV
- Drivers for substitution
  - REACH authorisation: 59%
  - REACH, but not specifically authorisation: 18%

Key findings of the study

Costs of authorisation

- It was not possible to fully quantify the costs
- Estimation of total costs for the authorities (MS, ECHA, COM)
- Estimation of total costs for industry to apply (excluding fees)
  - This does not include the costs of substitution, R&D, improvements in the process, complying with the conditions

Key findings of the study

Benefits of authorisation

- As usual, this was the most difficult part to quantify
- ECHA looked at the benefits for the applicant in the "meta-analysis" study. In this study we wanted to look at benefits for HH and ENV
- Our key interest: improvement of RMMs and OCs included because of authorisation
- What we would have liked to see: exposure data over the years, to check if there was an effect of authorisation
- Data are available in some MSs, but the consultants could not have access to them (confidentiality reasons)

Key findings of the study

- Survey results: out of 63 companies using SVHCs, 23 (37%) reported improving RMMs/Ocs
  - ~ 50% of investment occurred when the SVHC was still on the Candidate List
  - ~ 83% of respondents indicated that these RMMs did reduce worker exposure
- In public versions of AfAs: 35% report implemented or planned improvement of RMMs.

Conclusions

- Our initial question "Is authorisation only a burden with no added value?" can now be answered:

  no, we see that it achieves its objectives in terms of substitution and improvements in the way SVHCs are used
- Are the benefits higher than the costs?

  It is not possible to answer from the results of the study. Will be part of REACH evaluation excercise
- Interesting findings on the role of the candidate list

Conclusions

- What can be done in the future?
  - Once all the first round of applications (up to the 4th amendment of Annex XIV) has completed the full process: identify remaining challenges based on feedback from applicants, ECHA Committees, MS and other stakeholders
  - Try to quantify the changes in workers' exposure to SVHCs due to authorisation:
    - possible if there are historical data, such as in the chromates case. National studies?
    - analyse the review reports, when a sufficient number is available

Thank you

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