

Promoting substitution through the authorisation process: role of NGOs and third parties

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Helsinki Exhibition and Conference Centre

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The EEB



- Europe's largest federation of environmental organisations with 140+ member organisations.
- Represent 15 million European citizens, and act as the ears and voice of its members towards the EU decision makers.
- Goal: to enable the citizens of Europe to play their role to protect and improve the environment in Europe
- European wide network: working groups on air, biodiversity, water, waste, chemicals, etc.
- We are present in all ECHA's committes & fora: MB, MSC, SEAC, RAC, NMWG, PBT expert Group, etc.

Aim of Authorisation



"The aim of authorisation is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution" REACH {Art. 55}.

What is substitution?



"Substitution means the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures."

Lohse/Lissner 2003

http://ec.europa.eu/environment/chemicals/pdf/substitution_chemicals.pdf

Substitution shall by preference be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers' safety and health, as the case may be.

EU COUNCIL DIRECTIVE 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

How substitution is considered in REACH?



- (12) This Regulation does not affect the application of Directives on worker protection and the environment,under which employers are required to eliminate dangerous substances, wherever technically possible, or to substitute dangerous substances with less dangerous substances.
- (22) ... Authorisations for the placing on the market and use should be granted by the Commission only if the risks arising from their use are adequately controlled, ... or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable.
- (70) Adverse effects on human health and the environment from SVHC should be prevented through the application of appropriate risk management measures to ensure that any risks from the uses of a substance are adequately controlled, and with a view to progressively substituting these substances with a suitable safer substance.

How substitution is considered in REACH?



- (72) To support the aim of <u>eventual replacement SVHC by suitable</u>
 <u>alternative</u> substances or technologies, <u>all applicants for authorisation</u>
 <u>should provide an analysis of alternatives</u> ... <u>Furthermore, authorisations</u>
 <u>should be subject to time-limited review</u> ...
- (73) **Substitution** of a substance on its own, in a mixture or in an article should be required when manufacture, use or placing on the market of that substance **causes an** <u>unacceptable risk to human health or to the</u> <u>environment</u>, taking into account the availability of suitable safer alternative substances and technologies, and the socio-economic benefits from the uses of the substance posing an unacceptable risk.
- (74) Substitution of a SVHC by suitable safer alternative substances or technologies should be considered by all those applying for authorisations of uses of such substances on their own, in mixtures or for incorporation of substances into articles by making an AoA, the risks involved in using any alternative and the technical and economic feasibility of substitution.

Authorisation process



- ALL applications for authorization must submit an AoA considering their risks and the technical and economic feasibility of substitution
- Authorizations would be limited and would have to be accompanied by a substitution plan (SP).
- Review period: applicant shall submit an update of any substitution plan.
 - If risk is not adequately controlled, update of the SEA, AoA and SP.
 - If risk is adequately controlled: update CSR.

Furthermore: Authorizations may be reviewed at any time if:

- (a) the circumstances of the original authorization have changed so as to affect the risk to human health or the environment, or the socio-economic impact; or
- (b) new information on possible substitutes becomes available.

What is an alternative?



"An alternative is a possible replacement for the Annex XIV substance. It should be able to replace the function that the Annex XIV substance performs. The alternative could be another substance or it could be a technique (e.g. a process, procedure, device, or modification in end product) or a combination of technical and substance alternatives. For example, a technical alternative could be a physical means of achieving the same function of the Annex XIV substance or perhaps changes in production, process or product that removes the need for the Annex XIV substance function altogether."

Public consultation on alternatives 🗼



- An important objective of this Regulation is to encourage and, when possible, to ensure that SVHC are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available.
- Critical that ALL AVAILABLE INFORMATION IS RECEIVED
- All interested parties should participate and provide meaningful information on alternatives.

Trialogue



- Stakeholder representatives should be invited to Committee plenary discussions on authorisation of SVHC
- Transparent decision-making should be an overall goal for ECHA and the presence of stakeholder observers in the opinion-making on applications for authorisation of SVHCs essential for the credibility of this process.
- Even if the case is 'observed' Stakeholder no speaking rights is not democratic.
- NGOs &Trade Union stakeholders will be very active to ensure that authorisations are not granted for SVHC for which feasible alternatives are available in the market

Reasons to substitute



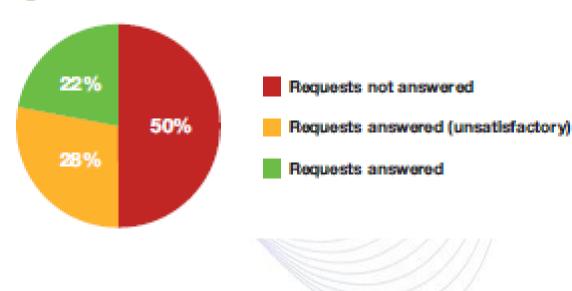
- Best way to protect health & environment
- Authorisation procedures for industry are complex, costly and uncertain
- Main driver for innovation and way out crisis; Substitution creates incentives for green chemistry design, innovation, clean production and safer consumer products.
- To be ahead of the chemicals legislation
- To meet market demands anticipate market opportunities: Competitive advantage by creating a green in fact and in image
- Management and reduction of chemical-related risks

Public access to information

SVHC and the citizens "right to know" became "The Fight to Know"

POSTAGE PAID Return to Sender Please let me know if this product contains haz ardous chemicals









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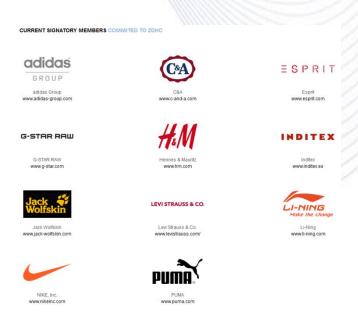
Recommendations to potential applicants



- Is it worth it? think broadly enough; understand the functional uses
- Industrial collaboration and cooperation: Sectoral networks
- Technological (eco)innovation need: motivation, capacity (or facilitation), and opportunities for change
- Don't fall behind: 'Large & DIRTY' Companies are already adopting Green.
 "getting greener and cleaner makes good economic sense"

 Phillip H. Phan, a professor at the Johns Hopkins Carey Business School in Baltimore.

RØADMAP TO ZERO DISCHARGE OF HAZARDOUS CHEMICALS



Recommendations to alternatives producers and **Downstream Users**



- **Know** what's in your products
- Use only green chemicals in products
- Be alert, participate & share your substitution experience!



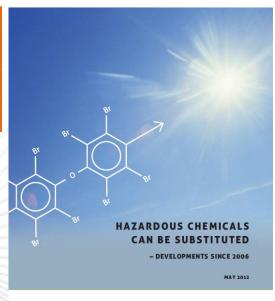
The fast track to a toxic free world















MOVING TOWARDS SAFER ALTERNATIVES Legislation

measure to reduce risks to rity Substances consumers and public healt

Sustainability-Driv

6.02.2013 ChemRisk, ATMI, SingingDog and B28webinars.net provide

an interactive web conference to address urgent issues: the urgent chemical challenges practices to get ahead of the

Substitution may be fast and easy or a more complex cess. Generally it includes

- 1. Define the problem
- 3. Search for alternatives alternatives
- 6. Implement and improve

Your contribution

arch SUBSPORT

ebsites and database



Welcome to SUBSPORT the Substitution Support Portal!

Here you can find information to support your efforts in substituting hazardous substances. Enjoy exploring the portal and please do not hesitate to contact the project team for any comments or

you could not yet find the information you expected. To keep yourself informed about the progress of the portal and other related news you can subscribe to the SUBSPORT newslette











Recommendations to ECHA

- Development guidance documents for submitting information & substitution
- Dissemination of authorization applications; web; Helpdesk; collaborations, ind federations, sustainable chem nets; workshops, etc.
- Encourage participation of interested 3rd parties; Contacting them and organizing supply chain dialogues for applications that may get an authorization
- Provide information and technical support to 3rd parties: ECHA helpdesk; informing, training and coordinating MS helpdesks
- Elaborate alternative assessments for uses that may obtain an authorization
- **Prioritise towards advanced/green chemistry** instead of obsolete chemistry (even if the last ones will pay authorisation fees)

Conclusions

- Urgent need to reduce exposure and phase out and substitute hazardous chemicals
- EU have the opportunity to really facilitate great sustainable innovation and make the chems industry a forerunner world wide
- ECHA must ensure that ALL information on alternatives is gathered in the process
- Downstream users play a key role (acceptability of alternatives, but also as drivers for innovation)
- 3rd parties contribution is key for achieving advanced and sustainable development
- Hazardous and obsolete chemistry has no future



Thank you for your attention!

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