UNICE
THE VOICE OF BUSINESS IN EUROPE

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THE SECRETARY GENERAL

Dear Member of the Environment Committee

With a view to the upcoming ENVI vote on REACH on 10 October, UNICE would like to share its thoughts on the crucial decision you will have to make on the issue of authorisation and substitution.

From the beginning, the workability of REACH was one of the main concerns to industry – not only for the "big" producers, but also for those further down in the supply chain and especially for SMEs.

Many of these concerns have been addressed by the European Parliament. Amongst those were important issues like the provisions concerning registration, the role of the Chemicals Agency as well as the crucial question on confidentiality of business information.

However, the European Parliament's opinion on **authorisation and substitution of chemicals of high concern,** as expressed in its first reading, is still seen as **highly problematic** to European companies. It could lead to a complete ban of certain substances even though there is a clear socio-economic benefit and no alternative available.

Therefore industry urges the European Parliament to support the main thrust of the Council's common position, which is already a compromise between the original Commission proposal and the EP's 1st reading and which is considered as a workable and smart approach based on the concept of adequate control of risk:

1. Authorisation is granted if adequate control of risk linked to the use of such a substance is demonstrated.

2. Substances for which adequate control cannot be demonstrated could still be granted a time-limited authorisation if socio-economic benefits outweigh the risk, until suitable alternatives are made available.

3. The concept of adequate control is defined under REACH in Annex I section 6. However for certain types of substances it is technically/scientifically not feasible to demonstrate adequate control of risk (substances with no threshold limits, namely for which it was not possible to determine a *DNEL, Derived No Effect Level*, or a *PNEC, Predicted No Effect Concentration*) and therefore these substances would never qualify for an authorisation under the EP proposal. These substances will have to be substituted if there is a suitable

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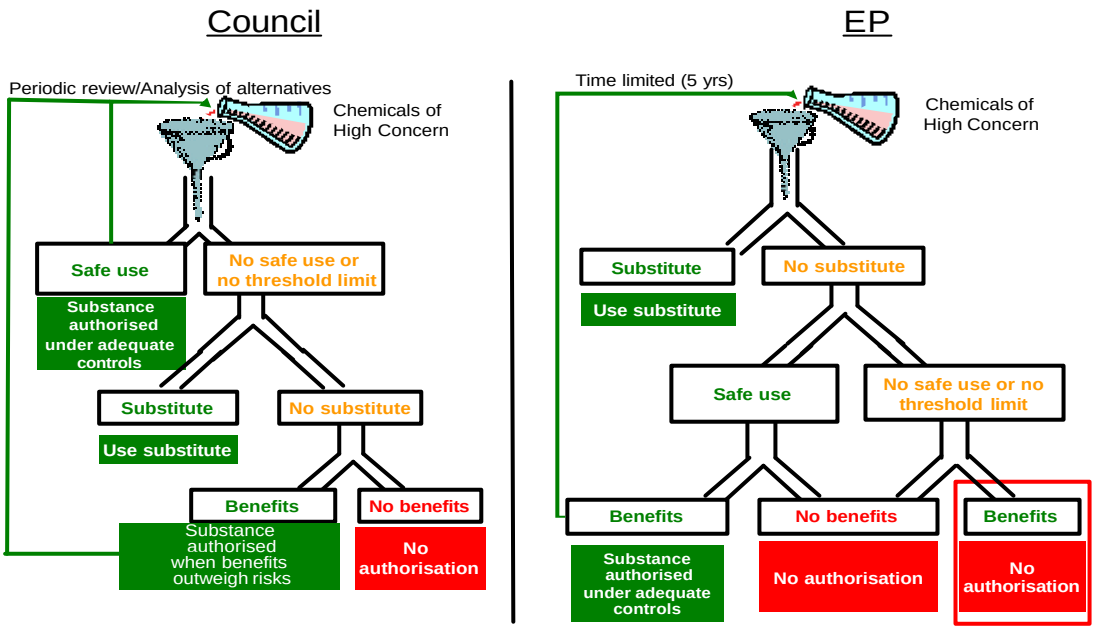
alternative available. If not, and this is where the Council proposal is far more balanced, it is important to grant a time-limited authorisation if their socio-economic benefits outweigh the risks; this authorisation would be accompanied with an analysis of alternatives.

This is illustrated in the flowchart below with a comparison between the Council's and the EP's approaches. The most important difference is that even though there is a clear socio-economic benefit outweighing the risk and no alternative available the EP approach would not authorise substances with no threshold limits, whereas the Council would grant these substances a time-limited authorisation until suitable alternatives are available.

THE COUNCIL AND EP APPROACH COMPARED



We consider the Council common position more balanced as it provides a smarter solution for these substances with no threshold limits.

If you have any further question on industry's position on REACH, do not hesitate to contact us. Thank you for the consideration you might give to our views.

Yours sincerely,

Philippe de Buck