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UNICE VIEWS ON REACH FOR THE SECOND READING

IN SUMMARY: Main points of concern

The focus during Second Reading must be on helping to deliver a clear and proportionate REACH system as well as increasing workability. To achieve these objectives, decision-makers will have to make important choices on key aspects of the REACH text. In this context:

- We urge all MEPs to support the compromise on **Authorisation** achieved in the Council Common Position.
- The Agency should only publish the list of priority substances of very high concern that are on its work programme for the next two to three years, and not the extensive "**candidate list**" of up to 1,500 substances. We are seeking the support of MEPs to table a new amendment on this crucial issue.
- **Compliance dates for article 7** ("substances in articles") must be delayed from the registration compliance dates, in order to benefit from information generated during the registration step. Therefore, the compliance dates for article 7 that have been brought forward considerably in the Council political agreement should be deferred.
- We ask all MEPs to support the EP 1st reading proposal for the protection of critical **confidential business information** as well as the right to appeal against the Agency's decision.
- **Duty of care** could be referred to as a general principle, but should not be in the legal part of the REACH text as proposed in the EP 1st reading.
- We urge MEPs not to introduce **consumer information** obligations for articles as it would duplicate existing product-specific requirements; this would add no further benefits for consumers but would place a disproportionate burden on small businesses on top of a myriad of other complex obligations.
- **Secondary raw materials** extracted from waste, for which fitness for use is demonstrated, should be excluded from the scope of REACH.

KEY ASPECTS OF REACH STILL NEED TO BE CONFIRMED

With more than two years of heated debate, REACH has often been described as one of the biggest and most complex pieces of EU legislation. And rightly so, because REACH will affect nearly all substances needed for industrial activities. REACH goes right to the heart of industrial production, with new responsibilities not only for chemical producers but also for a whole range of receiving companies such as, importers, formulators, downstream users of substances, chemicals, or preparations alone or in articles.

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In that wide context, finding the right balance, in a proportionate way, for a regulation that will achieve its health and environmental objectives while maintaining EU competitiveness is a real challenge.

Thanks to numerous debates, stakeholder consultations and various impact assessments to inform decision-makers, the European Parliament and the Council have both managed to move several aspects of REACH in the direction of better workability:

- *Registration*:

Although not fully risk-based, as has always been recommended by industry, the *Registration* step has been improved by both the EP and the Council, in particular:
- they introduce more possibilities to waive tests at low volume on the basis of risk; this is less burdensome for SMEs and allows greater dedication of resources to carry out tests that support decision-making;
- they foresee opting-out clauses on joint submission of information;
- R&D materials may be exempted from registration; up to 10 years in the Council common position and 15 years in the EP 1st reading.

- *Use and Exposure Categories:*

Both EP and Council have introduced *Use and Exposure Categories* as a useful tool for communication in the supply chain and in the interest of securing European Intellectual Property Rights.

Nevertheless *Use and Exposure Categories* need to be clearly defined in order to be useful in companies' daily practice. Such a definition has been introduced in the EP 1st reading proposal. Hence amendments 376 and 377 from the EP 1st reading respectively on articles 3.29c and 3.29d should be supported.

- *Scope*

Both EP and Council have made clarifications to the *Scope* and to the question of duplication of legislation. In particular by excluding waste from the scope of REACH (article 2), as specific waste legislation already exists.

However, the mere exemption for waste is not sufficient to ensure a competitive recycling industry. REACH should not hamper recycling and recovery activities as these contribute significantly to the EU objective of sustainable development. Therefore, secondary raw materials extracted from waste, which meet health, safety and environmental requirements as defined e.g. in industry standards and European regulations, should also be excluded from the scope of REACH.

Some amendments have also added major difficulties to REACH:

- *Authorisation:*

The EP proposal on the a*uthorisation* procedure is raising major concerns from industry, in particular due to unrealistic time limits for these authorisations and the introduction of a mandatory substitution principle. Indeed, in its 1st reading the EP proposes:
- A time limit of maximum five years for all authorisations (amendment 235 on article 57.6)
- To reverse the order of the criteria for granting an authorisation and to make them cumulative (amendment 232 on article 57.2), i.e. that there are no suitable alternatives and that socio-economic advantages outweigh the risk and that the risk is adequately controlled.

Industry insists that an *authorisation* should be granted based on adequate control of risk. Also, the review of an authorisation should be defined on a case-by-case basis in consultation with suppliers and users, taking into account product lead times as well as re-testing, re-engineering, safety and reliability requirements, in order to safeguard innovation and production in Europe.

The Council has made a considerable step on authorisation towards the EP 1st reading and has come to a compromise which, by adding more stringent requirements than the Commission's initial proposal, is the maximum manageable for industry. The Council political agreement retains important principles that should under no circumstances be subject to further compromise during the second reading, namely that an authorisation:
- Shall be granted if risk is adequately controlled (article 59.2)
- May be granted due to socio-economic benefits (article 59.4)
- Is not limited to five years, but undergoes periodical review on case-by-case basis
- Application must be accompanied by an analysis of alternatives considering their risks and the technical and socio-economic feasibility of substitution.

UNICE favours the Council common position and encourages the EP not to introduce any further stricter requirements, which would be to the detriment of the ability of companies to innovate in Europe and to compete on world markets.

- *Candidate List:*

The creation of a "candidate list" (in both EP and Council texts, article 58.1) of substances of very high concern only on the basis of their hazardous properties and without consideration of exposure means that substances are put on this list without any proof of their environmental or health risks. Putting a substance on the "candidate list" is not simply a preparatory step for further decision-making, but carries the potential for wide-ranging commercial consequences. The "candidate list" will have a pre-emptive effect, placing heavy burdens on the use of these substances even before they have been adequately and objectively assessed on a sound scientific basis. Certain substances will be pushed out of the market before any proof of their environmental and health risks is established. This would reduce access to a wide

range of substances portfolio in the EU, which is essential for promoting industrial innovation and ensuring companies' competitiveness.

UNICE suggests as an alternative to an extensive "candidate list" of up to 1,500 substances, which might stay on this list for decades before the risk is assessed, only publishing regularly the list of priority substances of very high concern that are on the work programme of the Agency for the next two to three years.
Also, the time limit for stakeholders to comment on proposals to add new substances to the list is foreseen not to be longer than 60 days (article 58). In order to allow industry to offer valuable input into this analysis, we would recommend extending the period in which interested parties may submit comments to 200 days.

A new amendment addressing practicalities for the publication of the list and ensuring adequate time for consultation of industry should be tabled.

- *Compliance dates for substances in articles:*

Compliance dates for Substances in Articles (article 7) must be defined in a way that allows downstream users to benefit from information of registered substances. However the Council has considerably shifted forward the article 7 compliance dates for article manufacturers. This might lead to a shift of responsibilities down the supply chain. Downstream user industries may experience difficulties in being compliant under these tightened deadlines. Also, it could lead to a significant limitation on the use of article 7.6, namely that no registration/notification by an article producer would be necessary if a substance has already been registered for that use.

UNICE strongly encourages the EP to re-introduce a differentiated entry into force of article 7.1 in particular (i.e. registration of substances intended to be released), in order to benefit from information generated during the registration phase and hence avoid unnecessary duplication of tasks, especially for SMEs.

- *Consumer information provisions for articles:*

Consumers should have the right to information necessary to enable them to assess the risks they may face from exposure to chemicals and to take precautions against those risks. The obligation to inform should be proportionate to this objective. It should not, for example, undermine the confidentiality protection awarded to commercially sensitive information (such as the full breakdown of chemical formulas).

Also, article manufacturers are already required by the general product safety directive to provide consumers with information on the risks that they may be exposed to.
It is important that consumer information continues to be addressed in this general product safety directive, and that these requirements are supplemented, as appropriate, in product-specific and environmental legislation. There is therefore no need for or value in adding new obligations in the REACH regulation in addition to this legislation.

UNICE urges MEPs not to introduce consumer information obligations for articles, which are disproportionate to the objectives of REACH or are already covered by

sector-specific legislation. This includes the final two paragraphs of amendments 366 and 166 (i.e. article 31 (new)), which enshrine an unlimited obligation to provide information on the chemical content of articles (which typically amount to many thousands of chemicals) without consideration for commercially sensitive information.

- *Confidential Business Information:*

Critical c*onfidential business information* must be protected in order to avoid losses of legitimate competitive advantages and commercial and industrial damages. As is the case under current chemicals legislation, disclosure of the chemical name of a substance should be protected by confidentiality provisions. To allow an opt-out right under strict conditions (i.e. the possibility for the registrant to submit a justification as to why publication of the name is harmful for his or other parties' commercial interests) would contribute to a fair balance between confidentiality protection and the public's right to know or protection of human health and the environment. A right of appeal against disclosure decisions would strengthen confidentiality.

The EP 1st reading proposal reflects this approach with the protection of confidentiality of a list of sensitive data, if competitiveness is at stake. The EP 1st reading proposal for articles 115.1, 115.2, 116.1 and 116.2 should be supported.

- *Duty of Care:*

The concept of duty of care is defined at national level and has differing legal status across the EU. If a duty of care is introduced into the REACH legal text, as proposed in the EP 1st reading, it would interfere with national liability systems and lead to legal uncertainty. Furthermore it would unnecessarily duplicate the liability system, as compliance with REACH regulation in itself embodies industry's responsibility for the safe management of chemicals.

UNICE supports the Council common position, which refers to duty of care as a principle but does not incorporate it in the legal part of the REACH text.

CONCLUSION

Some key aspects of REACH still raise serious concerns for industry, in particular on the authorisation procedure, the candidate list, compliance dates for substances in articles as well as on the balance between data transparency, consumer access to information and confidential business information.
During the 2nd reading, decision-makers will make important choices on these key aspects and industry urges them to devise a proportionate framework for REACH to be workable in practice for companies.
But even with a more proportionate framework, REACH will remain a considerable challenge for European industries, which will have to implement new rules that do not exist in other parts of the world. It is therefore of utmost importance that an acceptable balance is obtained to ensure that REACH ends up as an efficient tool achieving its health and environmental objectives while safeguarding EU competitiveness, and not as an incentive for investments and production to migrate to countries outside the EU.

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