LANXESS
Energizing Chemistry

LANXESS Position: How to simplify REACH

Background: In her political guidelines Commission President Ursula von der Leyen announced that she would “put forward a new chemicals industry package, aiming to simplify REACH”. She did not clarify though whether this simplification will be achieved by revising the REACH core legal text or by adapting the existing REACH Regulation, e.g. by using implementing regulation.

LANXESS welcomes any effort to simplify the existing REACH framework which is the most comprehensive European legislation and the most complex chemicals legislation in the world. Emphasis should be put on the following aspects:

1. **Reduce the administrative burden for companies**, e.g.
    - allow for easier targeted dossier updates,
    - accept more non animal testing and read-across in registration dossiers (inter alia) in order to reduce animal testing,
    - establish a clear sequence of evaluation and regulatory processes instead of running several process in parallel,
    - assess data uncertainty in a risk-based approach without applying “box ticking” and “worst-case assumptions” by default.

➡ **Increased dossier quality & reduction in animal testing**

2. **Increase transparency and improve communication** between authorities and industry, e.g.
    - establish a straightforward approach for communicating with member state authorities and ECHA in dossier and substance evaluation,
    - allow (industry) stakeholders to participate in all discussion of ECHA’s scientific groups and committees (closed sessions should be abolished),
    - carry out regulatory management option analyses for all substances under regulatory scrutiny and include always a possibility for (industry) stakeholders to actively provide scientific input (as data owners and study executors).

➡ **Decreased workload for authorities and industry through improved stakeholder communication**

3. **Strengthen the risk-based approach**, e.g.
    - develop guidelines to derive health-based thresholds for endocrine disruptors,

- do not initiate regulatory actions like restriction or authorization for uses of hazardous chemicals that are proven to be safe (i.e. RCR<1 in the risk assessment).

➡ **Faster and more efficient regulatory processes**

4. **Focus on the competitiveness of EU industry**, e.g.
   - always assess whether regulatory measures would put a disproportionate burden on EU industry while risking that environmental and health impacts are exported to countries outside the EU with less strict regulations,
   - revoke registration numbers of companies that submit "empty" registration dossiers,
   - support European industry in data sharing disputes and do not provide access to joint submissions without further scrutiny of the case.

➡ **Establishment of a global level playing field**

All the above can be implemented without a revision of the core legal text, but rather by changing the REACH annexes via implementing regulation and by adapting current guidance and practices. This would only require an overall agreement between ECHA, the EU Commission and the member states.

The suggested measures would not only increase transparency and legal certainty for industry, but would also reduce the overall workload for authorities and industry due to efficiency gains. For example, the acceptance of health-based thresholds for endocrine disruptors would significantly simplify regulatory processes and improve the enforceability of regulatory measures. Improved communication between stakeholders and authorities would strengthen the mutual understanding and lead to pragmatic and efficient solutions. Overall, this would contribute to better achieving the aims of the REACH regulation: high level of protection of human health and the environment, while enhancing the EU competitiveness and innovation.