



GREENPEACE



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NGO briefing on the Malta/Slovenia – MT/SI proposal for a 'Risk-based prioritisation' of low volume chemicals

NGOs have serious concerns about key points of this proposal and its consequences which we believe to be in conflict with the effective protection of human health and the environment. So-called 'risk-based prioritisation' is proposed for the chemicals between 1-10tpa - 2/3rds of the chemicals to be covered by REACH - this would seriously reduce the effectiveness of the legislation.

We are particularly concerned about the following consequences of the proposal:

- the principle of 'no data, no market' is gone: substances without adequate safety data would continue to be placed on the market
- burden of proof is shifted back to the authorities: 'reversed burden of proof' is eliminated
- it would result in a huge delay in getting basic safety information
- 'available information' only will not set a level playing field for the industry
- the ability to identify safer alternatives is severely restricted
- the requirements for new chemicals are further weakened
- protection for consumers, workers, and the environment is considerably reduced

In a nutshell, for substances between 1-10tpa, the MT/SI proposal foresees:

1. a '**registration**' which contains only minimal physico-chemical data and any 'available' information on substances, crude use categories and rough exposure parameters;
2. an '**evaluation and prioritisation phase**' where a 'dossier evaluation' of 20,000 substances may take place. Then a prioritisation phase is proposed according to certain criteria. Only those dossiers meeting these prioritisation criteria would then have to be supplemented with only parts or the whole of Annex V within 16 years after REACH enters into force (as compared to the Commission proposal which requires the full Annex V for all 20,000 substances within 11 years).

More detailed comments on the key points of the MT/SI proposal

➤ Registration

According to the authors of the proposal, one of the advantages would be that the proposal would lead to more information about certain chemicals (“those thought to be of higher risk”). However, this proposal would seriously undermine the REACH system:

1. The concept of ‘reversed burden of proof’ is eliminated

Industry would be able to register chemicals even without providing safety data. This would result in maintaining those parts of the current system which have failed: shifting again the burden of proof onto the authorities would mean that companies could wait until the authorities have time to act and request more data. This maintains the status quo and thus the very reason for the failure of the current system, in which far too few assessments were processed in a timely manner.

2. The principle of ‘no data, no market’ is gone

The MT/SI proposal would not provide for a systematic submission of basic health and safety information to close the knowledge gap. Even without providing the basic safety information, companies would be allowed to continue marketing chemicals. It would then result in excluding 20,000 of the 30,000 chemicals foreseen for the registration phase-in under the REACH system. The actual test requirements however will be reduced even further to some physicochemical data only, such as flammability and vapour pressure.

3. 16 years to get a boiling point?

The aim of the registration step in REACH is to make the basic safety information available. Annex V in the Commission proposal requests only 14 simple physicochemical data and 5 basic tests (skin and eye irritation, skin sensitisation, mutagenicity for bacteria and short term toxicity on *Daphnia*). For proper classification and labelling purposes 3 more key tests are needed (such as biodegradability). Under the MT/SI proposal only 8 physicochemical data would be required with a deadline of 11 years. Then the Agency may screen the registration dossiers within 2 years. Finally companies would have 3 years to deliver further data on Annex V – but only if requested. In total it would take at least 16 years¹ to receive not even the complete Annex V data set.

4. The requirement to deliver ‘available information’ will not set a level playing field

The stated advantage of obtaining all ‘available’ information is in fact not different from the current REACH proposal, given the Commission proposal already foresees that all existing information is to be provided. In addition, necessary minimum data requirements (Annex V) are set to provide a level playing field – this key element is missing in the MT/SI proposal. We cannot see how a producer would be able to handle (i.e. store or use) his chemicals without physicochemical data which are a prerequisite for any activity with a chemical. Moreover, we doubt that companies could comply with the current legislation and apply the necessary protection for workers and the environment without basic safety data. Legislation should not legitimise this lack of data.

5. The ability to identify safer alternatives is severely restricted

The authors claim that their system would encourage companies to come forward with more data on safe chemicals to secure a market share. Unfortunately, under this proposal the identification of the worst chemicals will be cumbersome and is likely to go on for decades—therefore the incentive to replace existing chemicals is likely to be very low. On the contrary, we believe that the reduced obligation to submit safety data for 20,000 chemicals will reduce

¹ 16 years for the first set of prioritised substances, there is no deadline for data-submission on all substances.

the ability to evaluate potentially safer alternatives under the authorisation and restrictions procedures. It is important to stress that there are already incentives to develop safer alternatives under the current REACH proposal - which would become yet clearer with the introduction of time limits for authorisation and mandatory substitution plans.

6. The requirements for new chemicals are further weakened

The MT/SI proposal further weakens the requirements for new chemicals compared to current legislation: a) the obligation to provide safety data would be raised from 10 kg/annum to 10 tons/annum; and b) instead of requiring the safety data from Annex V and VI (above 1 tpa) only physicochemical data are required. Registration in the Commission's REACH proposal starts from 1tpa. This is already a compromise to treat both the old and new substances equally. To further weaken the already drastically reduced requirements - compared to the Commission proposal and the current legislation - is unacceptable in the context of protecting human health and the environment in Europe.

7. 'Exposure' information is too basic

The authors claim that the MT/SI proposal obliges companies to have a first look at the uses and exposures. NGOs agree that this is very important but we believe that crude use categories and rough exposure parameters are not sufficient for undertaking risk management measures. Therefore and in order to avoid placing the burden of proof on the authorities we recommend the re-instatement of the obligation for a Chemical Safety Report (CSR) for 1-10tpa chemicals. Without the CSR, manufacturers of these 20,000 chemicals would not be required to assess the risk of hazards to human health and the environment. Thus the registrant and the downstream users would not even benefit themselves from their work. No appropriate exposure assessments and risk characterisation would be carried out – and the safe handling of these 20,000 chemicals would still not be guaranteed.

➤ Evaluation and prioritisation phase

It is doubtful that the capacities of the Agency will be able to cover all envisaged tasks. The capacity within the authorities would have to be increased tremendously in order to deal with a range of data coming in at different stages of completeness. This increase of resources is currently not foreseen. Therefore, to be workable more financial and human resources would be an important issue to consider and most likely a hurdle to the MT/SI proposed system.

Furthermore, many open questions remain regarding the procedure that follows once chemicals have been prioritised. It is unclear how decisions are taken as to which Annex V tests will be needed. The authors argue that the chemical companies will want to avoid their chemicals being prioritised and therefore would voluntarily submit hazard data (including endpoints like mutagenicity). We do not think that prioritisation based on no safety data would be an incentive to voluntarily submit hazard data. Instead this would lead to a delay of action and waiting for decision by the authorities. (See above: Registration, point 3)

The MT/SI proposal envisages the use of exposure data for prioritisation. However, such methods have not been approved and standardised yet. This would lead to legal disputes and further delays because all decisions by the Agency can be appealed against. Therefore the claim that this proposal is more workable and simple is certainly not convincing.

➤ Support for SMEs?

The Commission's Joint Research Centre has calculated that from the overall costs of REACH, the biggest part of the costs will originate from the registration of high volume chemicals, as they have the highest requirements for testing. Only about 10% of the total testing costs apply to the 20,000 chemicals in the 1-10tpa range (on average €7,700 per substance). Therefore we cannot see how this proposal would realistically lead to a huge

reduction in registration costs. In addition, it is not proven that the cost reduction would mainly benefit SMEs as no one so far has provided any figures on how many low volume chemicals are actually produced by small companies. Basic tests are necessary to demonstrate the safety of a chemical for health and environment protection. Such costs cannot be considered unnecessary.

The assumption of the authors that registration costs per volume are highest for low volume chemicals is misleading because the turnover per volume is usually higher and the profitability also depends on the margins.

On the other hand, the vast majority of European SMEs are downstream users and will not need to register chemicals but would, on the contrary, benefit from the additional safety information available in the supply chain. Currently the quality of safety data sheets is not sufficient to protect workers properly.

Registrants of lower volume chemicals should be allowed to use the data of the higher volume chemicals, which have to be registered within 3 and 6 years respectively. We are convinced that the proposal “One substance, One registration” is the right tool to reduce costs and work - also for small and medium sized producers.

The MT/SI proposal starts from the assumption that the quality of registration dossiers for low volume chemicals would be lower and concludes that prioritisation would be essential. In our view a clear set of requirements, a quality audit and minimum amount of evaluation would solve this problem in a better way. For the evaluation and authorisation procedures a prioritisation based on risk is already foreseen in the Commission proposal.

Finally, in order to be compliant with the current classification and labelling legislation companies should already have all information required in Annex V of the Commission proposal.

➤ **NGO recommendations for 1-10 tpa chemicals**

- Require Chemical Safety Reports for low volume chemicals;
- Re-introduce three non-animal safety tests in Annex V (biodegradability, algal toxicity and a second mutagenicity test);
- No further limits to the scope of REACH;
- Quality audits for all registration dossiers by an independent third or certified party which has no conflict of interest;
- Perform random spot-checks of dossiers to ensure a high quality.

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