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Kommentarer til norske myndigheters uttalelse om EU-regelverk for kjemikalier (REACH)

Nedenfor følger punktvis Norges Naturvernforbunds kommentarer til norske myndigheters uttalelse om EUs nye regelverk for kjemikalier (REACH). Norges Naturvernforbund støtter i hovedsak myndighetens uttalelser, men har noen tilføyelser hentet fra en felles uttalelse utarbeidet av European Environmental Bureau (EEB), Friends of the Earth International (FoEI), Greenpeace og Verdens Naturfond (WWF) (<http://www.eeb.org/activities/chemicals/ChemconsEnvNGObriefingfinal.pdf>).

General comments

Norges Naturvernforbund støtter norske myndigheters uttalelse, men vil føye til følgende:

"The Commission wishes that this regulation will be governed by article 95 of the EU treaty, which will prevent Member States providing a higher level of health and environmental protection. We consider that it should instead be under article 175(1), to allow Member States to have a higher level of protection if they wish. This is particularly important to ensure that no Member State experiences a reduction in protection, and in view of the uncertainty as to the eventual shape of this legislation."

1. Duty of care

Norges Naturvernforbund støtter myndighetenes understreking av viktigheten i å integrere substitusjonsplikten i bestemmelsen. Vi mener imidlertid at det er uheldig å bruke formuleringen "unreasonable costs" og forslår i stedet følgende:

"The use of chemicals of very high concern (such as those that accumulate in breast milk) should only be allowed if industry demonstrates an overwhelming societal need, that no safer alternatives are available and that risk reduction measures will be put in place."

2. Chemical safety assesment

Norges Naturvernforbund støtter norske myndigheters uttalelse.

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3. Information flow

Norges Naturvernforbund støtter norske myndigheters uttalelse, men vil føye til følgende:

”Allowing downstream article users, retailers and consumers a right of access to information about chemicals in articles

In order to allow these stakeholders access to information of chemicals in the articles they make, sell or use, a third paragraph should be added to Point 63:

“Producers and importers of articles, and retailers are obliged to provide their customers, on request, the information in Point 6 regarding the substance(s) contained in those article(s). If they do not possess this information, they should obtain it from their supplier(s).”

Deadline for Agency to publish information in its public database

The current text does not give the agency a time limit to publish information on the public database, therefore would amend Point 67.2 (d) to: “(d) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list, making all nonconfidential information in the data base(s) publicly available over the Internet **as soon as possible and in any case within 30 days of receipt**, including a short profile of the hazardous properties, **the chemical safety report, the full registration dossier**, labelling requirements and relevant Community legislation, including authorised uses and restriction measures;”

Decision making on confidentiality

The current proposal allows a single Member State competent authority to determine the European approach to confidentiality on a piece of information, with no opportunity for challenge. This is not acceptable. Two modes of challenge should be built in, first for the other competent authorities and the Agency, the second for other stakeholders:

1) Amend point 102.2 by (i) adding at the end of the first paragraph the following words: “...taking into account the public interest served by disclosure of environmental and health information.” and (ii) Deleting the second paragraph. We believe that it is essential that there is a procedure to allow other Competent authorities or the Agency to challenge decisions on confidentiality, and then obtain an agreed position, for example using one of the agency’s committees; this procedure should replace this paragraph.

2) Insert a new paragraph 102(3), to establishing a review body in accordance with the Aarhus Convention: “102(3). Where a person or authority is denied access to information which has been declared confidential, each Member State shall ensure that there is access to an expeditious procedure established by law that is free of

charge or inexpensive for reconsideration by a public authority or review by an independent and impartial body other than a court of law.

Non confidential information

We consider that the list of information that is never be regarded as confidential should be extended. We therefore propose extending the list of information in Point 102.3 by adding: “ - chemical structure/s of the substance; full Chemical Safety Reports; use categories; total market volumes; and exposure scenarios.” “

4. Registration procedure

Norges Naturvernforbund støtter norske myndigheters uttalelse.

5. Polymers

6. Intermediates

Norges Naturvernforbund støtter *ikke* myndighetenes korte uttalelse, men stiller oss i stedet bak følgende:

“We consider that the minimal amount of safety information proposed is insufficient for an adequate characterisation of these chemicals, which will mean that the system will not workably protect human health or the environment. We therefore propose that the information requirements for isolated intermediates on site and transported should be upgraded to those required for chemicals marketed from 1-10 tonnes per annum, Annex V:

Delete Point 18(2) and Point 18a(2), and replace with:

18(2) A registration for an isolated intermediate on site shall include the following Information:

- a) a technical dossier as specified in Point 11(1)a
- b) a chemical safety report as specified in Point 11 (1)b
- c) The technical dossier referred to in Point 11 (1) (a) shall include under items (vi) to (viii) as a minimum the information specified in Annex V

18a(2) A registration for an isolated intermediate transported shall include the following information:

- a) a technical dossier as specified in Point 11(1)a
- b) a chemical safety report as specified in Point 11 (1)b
- c) The technical dossier referred to in Point 11 (1) (a) shall include under items (vi) to (viii) as a minimum the information specified in Annex V”

7. Data requirements

Norges Naturvernforbund støtter norske myndigheters uttalelse vedrørende vurdering av eksponering og informasjonskrav for kjemikalier med små volum. Dessuten vil vi påpeke at det er svært viktig at utforming av tester og tolkning av

testresultater tar hensyn til det totale eksponeringsbilder for mennesker og miljø. Det er essensielt at additive og synergiske effekter tas med i beregning, i tillegg til de isolerte vurderingene av kjemikaliene.

8. Data sharing/consortia formation

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9. Procedures for downstream users

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10. Evaluation procedure

Norges Naturvernforbund støtter norske myndigheters uttalelse, men ønsker å føye til følgende:

"Evaluation

The system will only be workable and effective if the registration data is accurate, if it isn't (which is a real risk in this system), then the rest of the system will fail to function properly and will not properly protect human health and the environment. We therefore propose that increased efforts are put into checking the data submitted by industry, and that the system should return to that proposed in the White Paper, where all registrations above 100 tonnes per annum are evaluated for accuracy. We also consider that the proposal for approval of testing plans is overly bureaucratic and time consuming and should be replaced by a simplified decision procedure following a guidance document which should be produced by the Commission. Therefore we wish to amend Point 35 as follows:

- delete point 35(2)

- amend point 35(1):

"The evaluating authority shall examine any registration dossier for a substance produced or imported at over 100 tonnes per annum with a view to performing the following tasks:

Insert tasks a) to d) of Point 38(1) (priority evaluation)." "

11. Authorisation procedure

Norges Naturvernforbund støtter norske myndigheters uttalelse, men ønsker å understreke bekymringene knyttet til manglende substitusjonsplikt ved tilføyelse av følgende (hvor en annen omformulering av punkt 48, 3(a) er foreslått):

"Granting of an authorisation

In our view it is essential that authorisation implements the substitution principle, leading to a phase out of the worst chemicals, with their use only continuing where there are no safer alternatives and there is an overwhelming societal need and risk reduction measures are in place. We therefore strongly object to the way in which the current text allows industry to continue using chemicals of very high concern, even when safer alternatives are available. In our view, allowing industry to continue

using chemicals if they claim 'adequate control of risk' will fail to deal with the threat posed by these chemicals, as many have no threshold of action, have low dose effects or will cause long term contamination. The current text will also make the authorisation system unworkable due to a very large number of requests for authorisation being received from companies who wish to continue using chemicals of very high concern, as companies will not need to consider whether safer alternatives are available prior to application. Therefore:

Point 48 (2) should be deleted, removing the 'adequate control' route to authorisation.

All applications for authorisation should go through an improved Point 48 (3), except for any carefully defined exemptions (Point 46 (2) - exemptions should only be allowed if they in practice - not just in theory - ensure at least the level of protection of human health and environment equivalent to that given by authorisation).

Although the route to authorisation defined in 48(3), does allow a consideration of need and alternatives, we consider that this should be strengthened, to ensure that availability of safer alternatives does lead to a phase out of the chemical of very high concern, and that the needs of society are considered; point 48(3) should therefore be amended as follows:

"An authorisation may be granted if there is an overriding societal need for this use of the substance, and this need outweighs any risk to human health and the environment from the use of the substance. This decision shall be taken after consideration of all the following elements:

(a) Any available information on alternative substances or technologies. If such a substitute is available, and this substitute does not itself fulfil the criteria laid out for chemicals of very high concern in Point 44, then the application for authorisation shall be rejected.

(b) The societal need for the substance. An authorisation shall be rejected if there is no overriding societal need for this use of the substance.

(c) The risk management measures proposed, which must be sufficient to minimise the risk posed by the substance, taking into account any other known uses and release of the substance.

(d) If an authorisation is granted the applicant should supply, within one year, a substitution plan."

Reviewing authorisations

All authorisations should be subject to a review to ensure that safer alternatives are brought into use as rapidly as possible, and to ensure an effective response is made to any new information on the safety of the substance. Therefore:

Point 48(6) should be amended to "Authorisations shall be subject to a review period of not more than 5 years. Authorisations may also be subject to other conditions"

Point 49(2) first paragraph should have the following sentence added at the end:

"Authorisations shall be reviewed if new information emerges which could affect the

decision to authorise a use, including new information on availability of safer alternatives”

Control of substances of very high concern in articles (e.g. consumer products)

The current text controls the use of chemicals by a company making an article from raw materials, but the controls do not properly stretch downstream to further companies that may use this article to make other articles (e.g. a company making a chair from dyed fabric, a filling and wood). They also do not protect EU consumers against the import of articles from outside the EU which contain a chemical of very high concern. Therefore:

Point 45(1) Should have the following text added at the end: “An importer or producer of articles shall be subject to the same requirements with respect to the substances included in the articles they import or produce.” “

12. Restrictions procedure

Norges Naturvernforbund støtter norske myndigheters uttalelse.

13. The Agency

Norges Naturvernforbund støtter norske myndigheters uttalelse.

14. Other

Classification and labelling

Norges Naturvernforbund støtter norske myndigheters uttalelse, men vil føye til følgende:

“Labelling of articles containing chemicals of very high concern

We also consider it important that articles containing chemicals of very high concern should be labelled to increase market pressure for the phase out of such chemicals. This can be achieved through adding a second paragraph to Point 63 (Duty of care for those placing articles on the market): “Producers and importers of articles containing substances meeting the authorisation criteria shall ensure that these articles are labelled with a clear notice to that effect and with the authorisation number/s where appropriate.” “

Substances in articles

Norges Naturvernforbund støtter norske myndigheters uttalelse, men vil føye til følgende:

“Substances in articles

(i) The duty of care for articles needs to be extended to ensure that their disposal is properly considered, therefore amend Point 63 to the following: “Without prejudice to Directive 2001/95/EC of the European Parliament and of the Council, producers and importers of articles shall ensure that the articles they place on the market can be

used **and disposed of** in such a way that human health and the environment are not adversely affected as a result of exposure to any substances released from them.”

(ii) The current article 64 will allow importers to bring articles into Europe which contain unregistered chemicals, posing unknown health and environmental hazards – it is also important to create a level playing field between articles made in Europe and those imported into Europe. Therefore change point 64(1) to the following: “An importer or producer of articles shall declare conformity with the registration requirements for any substance contained in those articles in accordance with Title IV.” “

Enforcement and sanctions

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Appendix

Annex I

Norges Naturvernforbund støtter norske myndigheters uttalelse.

Annex IV

Annex V-IX

Norges Naturvernforbund støtter norske myndigheters uttalelse.

Med vennlig hilsen

NORGES NATURVERNFORBUND

Tore Killingland (sign.)
Generalsekretær

Marte O. Kittilsen (sign.)
Fagrådgiver