DES/MI-092/04

Ad Hoc Working Party "Chemicals"

The Netherlands view on the main issues

New EU Chemicals Strategy

1. Duty of care (Title I, Chapter 1, article 1):
NL is a proponent of including a general duty of care that defines the industry's responsibility for the safe handling of a substance.

NL is strongly in favour of a well-defined scope for REACH, with practical workability being the focal point. However, in order to ensure that the scope of REACH does not depend only on practical workability it is desirable to divide the scope into a general duty of care for all substances and a specific duty of registration under REACH for a more closely defined group of substances. The general duty of care formulated in generic terms illustrates the principle on which REACH is based, namely the fact that responsibility for the safe handling of substances lies with the industry. The industry is expected to not merely limit itself to meeting the prescribed legal obligations, but to give form and content to socially responsible entrepreneurship.

The responses that have been received from the Internet consultation show that, in addition to the industry, a number of member states may have problems with an open duty of care that is not further defined because of (a) the legal uncertainty and (b) the consequences of enforcement. However, the principle itself is not disputed. In this respect also the proposal of the Commission recognises the duty of care as a basic requirement of industry (see Annex IV, first paragraph). According to NL, a general duty of care is essential to give content to the responsibility taken by the business world. The further development of REACH must be regarded as a practical, detailed elaboration of the general duty of care. The general duty of care also functions as a general safety net obligation for substances that do not come under REACH or which have received full or temporary exemption from parts of REACH. NL therefore argues for a more prominent representation of the duty of care in the regulation without connecting it to full liability. NL is willing to provide as a starting point for discussion a text proposal giving a further description of the content of this general duty of care.

2. Substances in articles (Title II, Chapter 2, article 6)
NL feels the requirements for substances in articles, which are not intended to be released should be clarified.

As for the substances and preparations also for substances in articles the intention of REACH is to improve the actual situation according to the available knowledge about (properties of) substances and its applications. The Netherlands supports the priority setting for registration and notification of dangerous substances in articles and the registration for substances intended to be released from articles. However, the requirements for substances in articles, which are not intended to be released (see article 6.2(d)), are unclear. According to other Community legislation (General

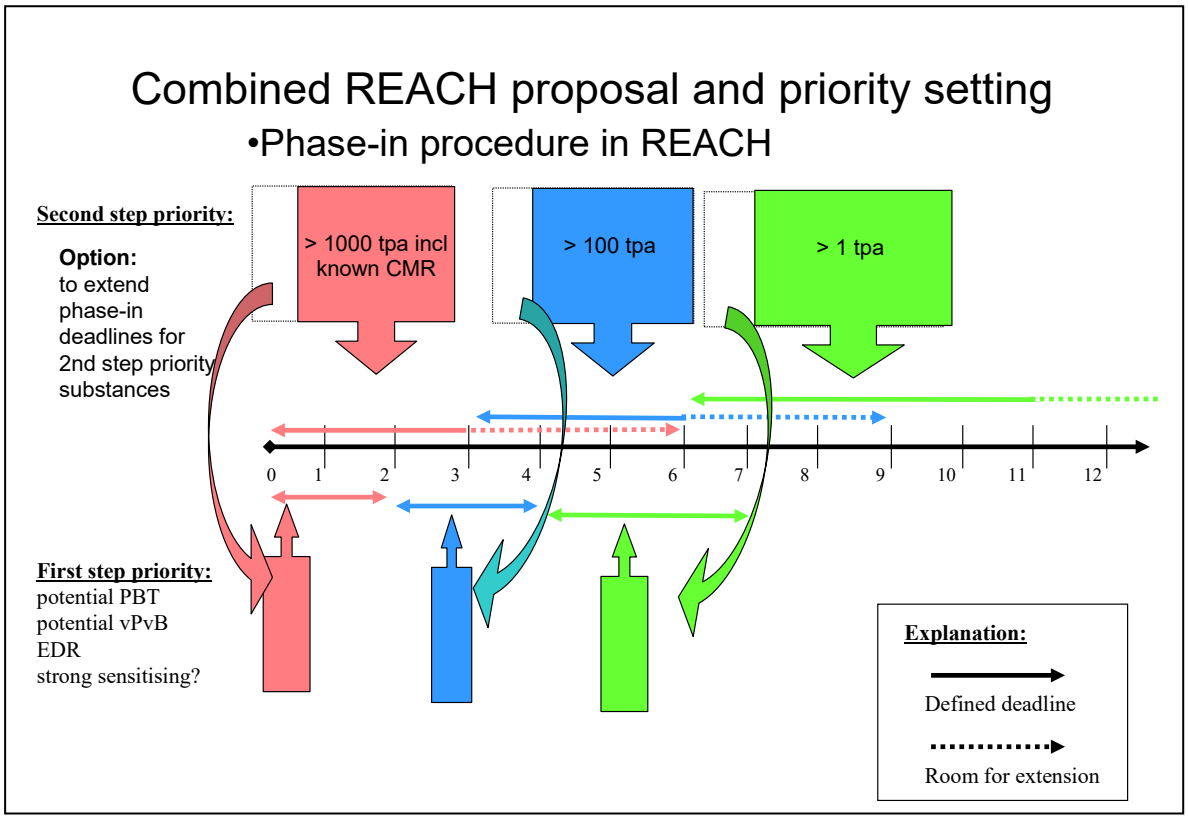
product safety directive) it is not allowed to bring articles on the market which are not safe and cause risk to humans. Therefore, the manufacturer or importer in compliance with the General product safety directive can only claim that the substances in his article causes no risk and therefore no notification will be necessary. Thus, for substances in articles (who are released although it is not the intention) the Agency/the government will, despite REACH, still not get any information. In addition, it is not defined which concentration affects human health or environment.

For substances in articles with properties that fall within the scope of authorisation NL has the impression that REACH intends to follow the authorisation procedure. However, this is not clearly expressed in the proposed article 6.

3. Screening /prioritisation (Title II, article 11, and Title VI, article 43 bis)
NL advocates a prioritisation system for substances that qualify for registration and evaluation and following on advocates, in the longer term, a registration obligation for substances that are not classified as priority substances. This way, the data requirements can be better tailored to the anticipated risks.

In addition to prioritisation on the basis of volume, the proposal also gives priority to substances that are carcinogenic, mutagenic or reprotoxic. The authorisation has been created for these substances. However, this form of prioritisation is inadequate for NL. NL supports an authorisation system that acts as a safety net for hazardous substances and, at a later stage in the consideration in the working group, will submit further proposals on this issue.

Since early in the development of the national chemical substances policy (SOMS) the Netherlands has stressed that, in view of the practical workability, priorities must be set in the duty of registration and evaluation for substances.
Without negatively affecting the duty of registration for all substances together with the submission of data in accordance with the proposed tonnage bands of the substance that is produced or made available in the market, NL wishes to give priority to the very high-risk substances both in the registration phase and in the evaluation phase. To this end, NL has suggested a screening step for priority setting and has developed the ‘quick scan’ approach as a suitable method. The parameters used in the ‘quick scan’ approach are fully in line with Annex IX that advocates the use of available data and models.
NL is not focused exclusively on the introduction of a quick scan approach as such; any approach for priority setting is welcome. In this context it is useful to closely examine the initiative of the European Industry which - albeit be it for an entirely different purpose - has developed the ECETOC model, based on a working method, the first step of which is comparable to the quick scan approach.
Within the proposed tonnage bands the use of the suggested priority criteria for registration separate the first step priority substances from the second step priority substances. The first step priority substances must respect more tighten deadlines with as a bonus to industry more room for submitting a registration for the second step priority substances. The attached figure illustrates the intention of NL. The same method could be applied for setting priorities for evaluation purposes.



The pre-registration procedure could be extended to the inclusion of results from 'quick scan' / screening / priority setting. The results may have the form of conclusions based on the priority criteria or of the underlying screening data. In this respect the suggestion of DK for introducing in the first period a quick and simple registration of all substances and completion with detailed information and test data according to the time schedule as proposed in REACH is interesting.

Data requirements for registration

The data requirements for lower volume substances (especially 1 to 10 ton, and intermediates below 1000 ton) do not meet the minimum data requirements that are necessary (a) to decide on the worker protection measures under the Chemical Agents Directive 98/24/EEC (labour protection) and (b) to evaluate the environmental fate. Information on the short term toxicity and on the ready biodegradability must be part of the minimum data requirements for these substances, or, alternatively, after the first review of the Regulation after 6 years pursuant to article 133(3). Within this time frame alternative testing protocols will be developed and could be introduced when modifying the information requirements. NL is of the opinion that the data requirements must apply to the accumulated tonnage limits for the entire EU; the proposal does not provide automatically for a supplementary obligation for registered parties in the event the accumulated tonnage limits are exceeded. The proposal foresees only in the substance evaluation phase the possibility to consider aggregated tonnage from multiple registrations of the same substance. Together with a prioritisation of the anticipated hazardous characteristics, a more balanced relationship is thus created between the efforts made by the industry in compiling the files and the REACH protection objective for man and the environment.

4. **Compulsory exchange of animal experiment data (Title II, Chapter 2 and Title III)**

   NL endorses the obligation to exchange data gained from animal experiments, but can envisage problems in the implementation and enforcement.

NL is of the opinion that, in view of the aim to limit animal experiments, the exchange of animal experiment data must be made compulsory. REACH assumes a duty of registration for a substance per producer, importer or consortium. The proposal made by the United Kingdom of applying 'one registration per substance' forces the industry to enter into consortia and so promotes sharing of animal experiment data. NL does not see any legal objection in a mandatory participation in a consortium per substance. However, in both models NL can envisage problems with the legal implementation if there is a dispute between the companies regarding the sharing of data.
NL feels that the UK proposal is an important improvement and wishes to support it. The proposal of 'one registration per substance' also covers automatically the lack of a specific obligation for exceeding quantity levels cumulatively by several EU-manufacturers, by several importers from one non-EU manufacturer or by a combination of both. Particularly, the opportunity of a non-EU manufacturer to import via multiple importers a substance in the EU, while registration requirement refers to the quantity level of each importer, may distort the level playing field compared to the EU manufacturers. However, NL will take great care in considering the objections of the Commission to the UK proposal. The pre-registration proposed in REACH provides companies with assistance in forming consortiums in which agreements can be made about apportionment of costs. As, in addition to effect data, exposure data are also of fundamental importance, NL is a proponent of involving downstream users as much as possible in the consultation between companies for the purpose of indicating their own application scenarios by offering downstream users the opportunity to also become a member of such consortiums.
However, NL is concerned about the legal status of decisions made by the Agency in mediating disputes between companies relating to the exchange of animal experiment data and its acceptance by national courts of the associated compensation.

5. **Chain responsibility (Title IV)**

   NL advocates that, in addition to the proposed compulsory information exchange within the chain, possibilities are also built into the proposal that allow the user to ask the supplier to account for his duty of care. For instance, the supplier may give technical support or provide insight into data not published in the MSDS (*Material Safety Data Sheet*).

NL recognises the value of the Safety Data Sheet (MSDS) as a means of transferring information within the chain and supports the proposed improvement of the MSDS. However, NL is of the opinion that a form of chain responsibility is a condition for defining the responsibility of the industry. It is not just the primary producers and importers of substances who are responsible, but also the users of the substances further down the supply chain. This chain responsibility must be regarded as a responsible form of interaction between supplier and user upstream and downstream. A good communication form in particular forms an essential part of this interaction, which is therefore more than a simple transfer of information on paper or

electronically. Downstream users must have the option of calling on the supplier for technical support and the supplier must have the option and/or obligation to obtain an insight into the adverse consequences of the various usage options available downstream. NL attaches great importance to this form of chain responsibility being included in REACH, in which the MSDS must have a clear position. This NL proposal does not represent an extension of the administrative burden, since the initiative lies with the supplier and the user. The supplier is given opportunities for collecting essential information from the downstream user regarding the general exposure pattern and emission scenario related to the uses of the uses of the substance and for monitoring the compliance of the user with the recommended measures for reducing exposure and the workplace and emission to the environment. The user is given extra opportunities for addressing the supplier. This fits in with the policy of placing more responsibility on the business world including downward the supply chain.

6. **Active disclosure of non-confidential information (Title XI)**
   NL advocates active disclosure in accordance with Directive 2003/4/EC and reticence in granting requests for confidentiality of data. NL is in some doubt as to whether determining in advance which data must be kept confidential meets the stipulations of the said Directive.

NL feels that public access to information in the public domain is an essential condition, provided that public security will not be at risk. NL advocates active disclosure by both the Government and the industry in accordance with the recently formulated Information Directive 2003/4/EC based on the Aärhus Treaty.
Next to it NL is devoted to protection of confidential business information according to the conditions as formulated in the above mentioned Information Direction. In this respect NL wonders whether the proposal corresponds with the parameters as formulated in the aforementioned Information Directive (see article 4, subclauses 1 and 2). In the proposed regulation the business interest can be clarified in more detail.

7. **Practical workability and the role of the Agency (Title VI, Title VII, Title VIII, and Title IX)**
   NL stresses the need to limit the administrative procedures to the minimum level required for a good and effective form of collaboration between the member states and the Commission with central control held by the Agency. Pilots for the purpose of testing the feasibility and effectiveness can make a useful contribution to the further streamlining of the proposal and towards achieving good coordination between the proposal and actual practice. In addition to this, NL fails to find a good carry-over in the proposal toward associated legislation in other policy areas.

It is essential that an effective and harmonised implementation of the tasks is guaranteed by the member states. NL welcomes the establishment of an independent agency that will have the control in all implementation tasks, part of which is delegated to the empowered authorities of the member states.
The proposal has suggested procedures to ensure that implementation by the member states run smoothly. However, NL is worried that the procedures thus proposed may hamper effectiveness and form an obstacle to decisive action. In

addition to the companies' obligation to collect and assess information, the objective of REACH is also to guarantee a high level of protection for human life and the environment by means of effective 'chemicals management'. If needed the Commission must be able to take effective control measures in conjunction with the member states (see Counsel Conclusion June 2001, paragraph 18). In order to test the effectiveness and feasibility of the proposed tasks against actual practice, NL is considering setting up pilots as soon as possible, in conjunction with the industry. The experiences gained from these pilots may contribute to further adjustment of the proposal.

Horizontal relationship of REACH with associated legislation

In view of the relationship with chemical substances legislation in other policy areas, it is essential that good coordination is achieved with the tasks in the other policy areas in order to prevent duplication of effort and inconsistency in policy implementation. In this context, NL is considering legislation in the area of labour protection, external safety and accidents, consumer protection, waste, emissions into soil, water and air, drinking water, etc. NL wonders how the tasks of the Agency will be organised in view of the implementation tasks in other policy areas that have been allocated to the member states, e.g. the implementation of the Crop Protection Directive and the Biocides Directive.
With regard to labour protection, in Directive 98/24/EEC NL notes a comparable obligation to the one in the Chemical Safety Report proposed in REACH. It is very well possible that downstream users, in good faith, omit the obligation of a risk inventory & evaluation pursuant to 98/24/EEC if their applications have been included in the general assessment by the manufacturer. NL would like to see a clear reference in the proposal, stating that the REACH obligations do not exempt companies from the obligations pursuant to associated legislation. Furthermore, in the process of authorisation and restriction of the use of chemical substances, it must be made clear that worker protection harmonisation is on a minimum level and Member States may establish stricter requirements on use in the work place. Additionally, it could also be considered whether this aspect should be explicitly included as part of the proposed evaluation of REACH. NL specifically wishes to prevent REACH obligations leading to an unnecessary administrative burden.

8. Competitive power of companies

NL will be interested in perusing the results of the business impact study that forms the basis of the proposal. If doubts occur about the effects or uncertainty on the level of the anticipated direct costs, but particularly also the indirect costs and the level of anticipated revenue respectively, NL will consider the necessity for a further study.

An overview has been provided of the economic consequences of REACH for the business world. Many studies have been carried out and no doubt many more will follow. In general, it may be deduced from these studies that a large part of the expenditure is transferred to the large group of small to medium-sized enterprises that account for the greater part of the number of substances, namely the group of substances in quantities of less than 100 tonnes per year. It is important that the level of burden provides the business world with good insight into the direct costs and benefits. NL would appreciate it if some indication could be given about the possible indirect costs to the business world and benefits in other areas, such as public

health, environment and labour conditions. It is helpful to realise that the economic consequences of REACH constitute a politically sensitive issue that has even tempted the leaders of the three major EU member states, France and Germany and the UK, into writing a joint letter to the Commission. It is therefore in the interest of the Netherlands to ensure a manageable burden on the large group of SMEs, without detriment to the objective of REACH: the creation of a high level of protection for man and the environment.
However, the Netherlands wishes to state that, mainly with regard to the major chemical companies that place a strong emphasis on 'Responsible Care' and 'Product Stewardship', the Netherlands assumed that the obligations proposed in REACH already corresponded to a high degree with the rules of conduct being used by these companies. It is therefore somewhat disappointing to find out that the economic consequences within this category of companies also relate to proposed obligations that come under their own rules of conduct. NL also wishes to stress that a number of studies have been published that counterbalance the Business Impact Studies, which were deployed from a purely economical perspective:

- By order of WWF-UK the London University College (May 2003) carried out research into the social pros and cons whereby, using three different models (two models for 'Disability Adjusted Life Year' - reduction of life expectancy through illness and premature death, a model for loss of service years) an estimate was made of reduced care costs and loss of productivity respectively. The latter model in particular shows more pros than cons as a result of REACH (ratio 2.4 to 11). In this context we must make the comment that only human health was taken into consideration; the advantages to the environment were not considered at all (basic data to make such a consideration (estimate) are completely missing).
- SPRU (Sept 2003) which, by order of WWF, carried out an analysis of the innovative options for the industry as a result of REACH. In addition to strong criticism of the economic consequences that were overestimated by the industry, the report listed a number of positive characteristics of REACH, including a strong tendency towards innovation for the purpose of replacing hazardous substances.

9. **Consequences for non-EU countries and non-EU producers**

NL is devoted to conformity of the European policy and the community legislation rested on that with the international obligations of the EU as agreed upon in the framework of WTO. NL does not have any interest in that the proposal may lead to impeding the importation and marketing of substances in the EU. NL will take care that the limited accessibility of the EU market for products from developing countries as a consequence of the REACH system does not happen.

Although there are no direct indications that the Commission proposal does not sustain the WTO obligations of the EU, it is best to pay attention during the negotiation process to the permanent compliance of these obligations by the EU. Particularly, it is important to take care that the limited accessibility of the EU market for products from developing countries as a consequence of the REACH system does not happen. In designing the regulation, one must consider the possible effects on exporters and producers in developing countries. Also it is important to define adequate transition periods and to provide adequate technical assistance. NL supports the task of the Agency in giving technical assistance to developing

countries, but observes the need of the Agency for sufficient human and financial resources.

10. Authorisation (Title VII)
NL argues that authorization for specific uses of substances with PBT or vPvB characteristics, which are covered by the authorization regime, may only be granted under the condition that within a foreseeable period the discharges, emissions, and losses of these substances to the environment must be eliminated.

NL refers to the Council conclusions with regards to the White Paper (Environment Council of June 2001) stating that the chemical policy should aim to achieve that, within one generation (2020), chemicals are only produced and used in ways that do not lead to a significant negative impact on human health and the environment, which is also in line with the Water Framework Directive and with commitments that Member States and the Community have undertaken in international fora. In the scope of the Water Framework Directive and of OSPAR, it is decided to aim at eliminating the emission of PBT substances within a period of maximal 20 years.

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