
1. Greenpeace welcomes the recognition in the White Paper of the need to protect the environment and human health from chemicals and the introduction of the concept of the promotion of a “non-toxic environment”.

BUT

At the same time, however, the proposed strategy would seem inadequate to deliver these goals. We welcome also the intention to introduce a single system for all chemicals, both new and existing, but remain concerned that the proposed strategy will still fail to ensure a high level of protection of human health and the environment (as required in the Treaty):

- Even for the 5 000 high production volume existing chemicals, lack of basic knowledge may persist until 2005, with evaluation then extending to 2010. For chemicals produced in quantities between 100 and 1000 tonnes per year, evaluation will not be complete until 2012. For the remaining 25 000 substances with production volumes greater than 1 tonne, the registration process will not even be complete until 2012. Action to address those with hazardous properties may only be taken some time after these dates.

- For the remaining 70 000 existing substances, produced in volumes of less than 1 tonne per year per manufacturer, the registration requirements simply will not apply; nothing may ever be publicly known about these substances, though their manufacture and marketing may continue.

- The White Paper suggests that the new strategy will “support” the aims of the OSPAR Convention 1992, specifically the prevention and elimination of pollution and the protection of the marine environment from the harmful effects of human activities. While the new chemicals strategy may make some contribution towards the implementation of the OSPAR Convention, assuming it leads to restrictions on at least some hazardous substances, it is unlikely to achieve the target of cessation of discharges, emissions and losses of hazardous substances to the marine environment by 2020 which is set out in OSPAR’s Hazardous Substances Strategy. Incidentally, no mention is made within the White Paper of the OSPAR Strategy. Moreover, given that the fundamental underlying basis for regulation remains risk assessment, with the possibility that open uses will be authorised even for substances with intrinsic hazardous properties on the basis of such assessments, it is clear that releases of hazardous substances will inevitably continue. The long timelines involved in the collection and evaluation of data will exacerbate this further.

2. Greenpeace also welcomes the introduction of the precautionary principle and the principle of substitution in the White Paper.

BUT

the extent to which these principles will actually be implemented by the strategy remains unclear:

- The definition of precaution outlined in the introduction to the document is somewhat contradicted by the statement in Chapter 3 that “precise knowledge on the intrinsic properties as well as on the
exposure arising as a result of a particular use and of the disposal is an indispensable prerequisite for decision making...”.

- The proposed authorisation system may be seen to have certain precautionary elements, e.g. in the prohibition of uses of substances of high concern other than those authorised. Nevertheless, the degree of precaution afforded by this approach will ultimately depend on which groups of substances are subject to such authorisation. Greenpeace strongly advocates the inclusion of all hazardous substances within the authorisation scheme, including substances which are persistent, bioaccumulative and toxic (PBT) and those which are very persistent and bioaccumulative (VPVB), in addition to substances that are carcinogenic, mutagenic or toxic to reproduction (CMR). In addition, it will also be necessary for substances which do not meet all the criteria for PBT and VPVB but nevertheless give rise to an equivalent level of concern because of other intrinsic properties (e.g. P and T but not B, endocrine disrupters) to be covered by the prohibition of unauthorised uses, as it is only in this way that the strategy may become truly protective. Greenpeace welcomes the inclusions of substances with POPs characteristics as defined in the future Stockholm Convention on Persistent Organic Pollutants (POPs). Ultimately, however, the authorisation scheme will necessarily be wider than this, to ensure that the goal of a “non-toxic environment” can be truly approached.

- Where registration data alone are sufficient to identify substances as CMR, PBT, VPVB or of equivalent concern, testing to level 1/2 requirements should not be necessary. To require such testing would simply delay urgent action through the collection of unnecessary data.

- Application of the principle of substitution should not simply be “encouraged”, but instead should form a central component of the mechanism for the phase-out of the use of dangerous substances. Any authorisations granted for continued use of hazardous substances should be made with the ultimate aim of their substitution with less hazardous alternatives. The potential for substitution with non-chemical alternatives must also be included. In addition, the application of substitution should be a requirement and extended to all chemicals, not just to hazardous substances subject to authorisation, in order that action is taken throughout industry continuously to reduce the burden of chemicals.

3. Greenpeace welcomes the concept that any continued applications of substances with hazardous properties should be subject to detailed scrutiny and authorisation.

BUT

- As noted above, authorisation, and prohibition of non-authorised uses, should ultimately cover all hazardous substances and, in the short term, at least include CMR, PBT and VPVB substances. Any authorisations should be granted for a limited time period only, subsequent to which the authorisation should be reviewed to allow for technical progress in the development of alternatives. Any authorisations should also be viewed within the general obligation to avoid the use of the(se) substances of (high) concern where ever possible, and as soon as possible. In this context, the OSPAR target for cessation of releases of hazardous substances to the marine environment by 2020 is an important final deadline; no uses of hazardous substances should be permitted to extend beyond this date.

- Authorisation for specific uses of a substance should depend not only on demonstration by the relevant sectors of industry that “risks” are negligible or that socio-economic benefits outweigh risks (Step 2 of the Implementation of the Authorisation Process). Justification of continued use should also require demonstration by industry that the uses are essential to society and that less dangerous alternatives are not available. The role of industry in justifying any claims that no alternatives exist will be an important component of the shifting of the burden of proof and further operationalising of the precautionary principle.
• For all substances subject to authorisation, some level of control on authorised uses must be exercised at EU level, in order to provide a general level of protection, with the option that national decisions regarding authorisations may be more restrictive depending on particular national circumstances. To delegate all responsibility for authorisation of certain substances to national authorities (Chapter 8.1) may lead to widely differing levels of protection (especially to workers, local populations and local environment) across Europe.

• In line with the implementation of the OSPAR hazardous substances strategy, authorisation should not allow the introduction of new hazardous/dangerous substances, unless these are necessary as interim solutions for the substitution of substances of even higher concern.

• Greenpeace is concerned about proposals that the task force established to review available data (Chapter 6) may additionally have the task of recommending substances or groups for exemption from the general obligation of registration. We see no reason for the exclusion of any substances from registration (unless no longer manufactured/imported) and, moreover, stress that any such decisions should be taken in an open and transparent manner and subject to scrutiny.

4. Greenpeace strongly supports commitments to provide the public with information regarding chemicals

BUT

is concerned that the type and extent of information suggested in the White Paper will not fulfil this purpose:

• The strategy offers little detail with regard to how the commitment to provide information will be implemented. In elaborating the strategy, the recommendations seem only to cover access to technical information in databases regarding chemical hazards and uses (Action 9A). Although access to this information would be welcome, of course, it is the labelling of consumer products with information regarding the hazardous substances which they contain which will have greatest relevance to consumers. Indeed, it is only in this way that consumers would become aware of chemical usage and be encouraged to take informed decisions. The commitment to provide this information was made by Ministers at the OSPAR meeting in Sintra in 1998 and it is important that practical steps are now taken to fulfil this.

• In providing information about chemicals and the chemical content of products, account must be taken not only of consumer exposure to chemicals but also of wider public concerns regarding potential releases to, and impacts on, the environment. Proposed reliance on industry and downstream users to provide information on health and environmental effects (Chapter 9) seems unlikely either to generate comprehensive information or gain the confidence of the public.

5. Greenpeace welcomes the concept of increased producer/importer/user responsibility for chemicals,

BUT
is concerned that proposals to achieve this focus largely on the delegation of responsibility for assessments to industry and the commercial sector.

- Such a strategy will place the primary responsibility for identification of potential problems associated with chemicals, and assessment of their significance, with those who have a commercial interest in continued manufacture, import and/or use of those chemicals. Clearly the potential exists for misuse of they system and consequent underestimation of risks. The extent to which oversight from authorities would be employed in, and capable of, capturing any such deliberate underestimation is not clear. Greenpeace sees an essential need for independent evaluations. If such evaluations cannot be conducted by the authorities then they should be conducted by accountable and certified independent bodies with authority oversight.

- In particular, there will be little incentive for companies using chemicals in applications which have not been identified in risk assessments to report such uses (Action 5C), as this may lead to restrictions on such uses.

- No timelines are set for the provision of such information by downstream users.

- Assigning responsibility for assessing different components of a chemical's lifecycle according to the sectors and companies involved at each stage (Chapter 2.3) may result in an inconsistency of approach and outcome and may increasingly separate responsibility for the use and disposal of chemicals from their initial manufacture. Clearly it is important that information on uses is available from industry throughout the chain of manufacturing, use and disposal, but the delegation of responsibility for safety assessments to user companies within that chain would be entirely inappropriate.

- For chemicals produced in quantities less than 100 tonnes per producer per year, there would appear to be no systematic evaluation of data submitted for registration (Chapter 4(b)). Although evaluation may be considered on a case by case basis, depending on the existence of particular concerns, it is difficult to see how such concerns will be identified without some more generic evaluation.

- The high level of current non-compliance even with basic material safety data legislation, as identified by studies in UK and Netherlands, is highlighted in the final chapter (Chapter 10) of the White Paper. Given this background, it is somewhat questionable that increased reliance on self-reporting and assessment within the industrial and commercial sectors will result in effective protection from chemical manufacture and use.

6. **Greenpeace welcomes the proposals that the new strategy should cover chemicals included in preparations and in products (Action 3E), providing the intention is to cover, by this process, consumer products i.e. articles and not just chemical products.**

**BUT**

Given the fact that a substantial proportion of human exposure to chemicals occurs as a result of contact with a variety of consumer products, it is essential that contents of dangerous substances should be controlled and, as far as possible, eliminated. The import of goods containing chemicals which are not otherwise manufactured in Europe will also make it essential for the strategy to address such issues.

- Regulation of chemicals in products should have a fundamental basis in the intrinsic properties of those chemicals, and should not entail an evaluation of potential releases or exposure from each and every product. If measures are introduced to control or avoid the manufacture or use of a chemical as a
substance or preparation, such measures must also extend to presence in manufactured or imported products. Any derogation from this general automatic extension of measures must be subject to authorisation and therefore based on justification that the use in certain products is essential and that no alternatives exist.

7. **Greenpeace recognises the importance of the commitments to reduce reliance on animal testing (Chapter 3.2) and very much supports the development of alternative methods.**

**BUT**

- It should be noted, however, that this goal could be more effectively approached if authorities were prepared to accept the possibility for regulation on the basis of persistence and/or bioaccumulation alone, without the need in every case to demonstrate toxicity. Attention should be paid to the developing national approach in Sweden in this regard. To some extent, such regulatory decisions will become possible if acceptance is gained for inclusion of substances within the authorisation scheme on the basis of persistence and/or bioaccumulation alone (e.g. VPVB substances). To be truly effective however, criteria for VPVB must be set at such a level to ensure that no chemicals are released to the environment which have the potential systematically to increase in concentration in biological tissues or other environmental compartments.

**In addition to the points outlined above,** the White Paper introduces certain other concepts of particular concern.

- The proposed strategy, with a focus on chemicals manufactured, imported and marketed, fails properly to the issue of chemicals generated as unintentional by-products. Some of these may be captured during the assessments of individual components of the manufacture, use and disposal chain for individual chemicals, but hazardous by-products from otherwise seemingly non-hazardous chemicals and products may simply slip through the net. Only by-products with POPs characteristics are included.

- The proposal for “exposure-triggered testing” (Action 3C would introduce elements of exposure assessment (and, therefore, judgements regarding risk) into the fundamental hazard assessment process used to determine basic chemical properties. This may lead to prejudged exclusion of certain possible exposure pathways before sufficient information is available to evaluate them.

- In most cases, thresholds for registration, testing and evaluation (and therefore, ultimately, for control), remain in producer-specific tonnage rather than aggregate tonnage (although the latter more closely reflects the true extent of use and release of the chemicals in question).

- Proposals regarding classification and labelling appear to imply that some elements of the existing classification system are in some way “less relevant” (Action 7A). An increasing focus on CMR properties may lead to increased levels of protection of consumers from these substances, but possibly at the expense of information regarding irritant or other harmful effects on humans and of information aimed at protection of the environment.

- Requirements for property rights on data are understandable from the perspective of investment protection, but Greenpeace is concerned about the potential consequences for the public availability of data.
In conclusion, the White Paper continues to refer to the current problems regarding the manufacture and use of chemicals as “the burden of the past”. Given the extent and complexity of ongoing use and release of chemicals, as substances, preparations or components of products, this reference is somewhat misleading. Moreover, considering the relative weakness of controls proposed within the new strategy, coupled with the long timelines envisaged even for collection of data, it seems likely that the use of chemicals will continue to add to that burden for generations to come.