

STRATEGY
ON
MANAGEMENT OF
SUBSTANCES

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SUMMARY

General framework

The chemicals management policy has an important function in relation to environmental policy, workers health and safety conditions policy and consumer protection policy. The cabinet's objective in preparing the new chemicals policy, as described in this strategy memorandum, is also to consolidate and strive for synergism in the decision-making process in all related areas of policy making.

Results of 20 years of chemicals policy

National and international chemicals policies have pursued the objective of achieving a responsible approach to chemicals management, aiming at ensuring the highest possible level of safety and protection of man and the environment in relation to the use of, and exposure to, substances. The risk management policy instrument, which is broadly accepted internationally, supports that objective.

Efforts undertaken in this area over the past twenty years have contributed to a cleaner and safer environment for man and ecosystems. This is demonstrated, for example, in reduced emissions of so-called priority substances in the Netherlands, achieved also thanks to measures taken within the framework of target group agreements. The initiative taken by the (international) chemical industry for setting up an action programme for data collection and risk assessment of substances that are used in very large quantities, shows that the industrial community is aware of the necessity of dealing responsibly with substances.

Cause for concern

Despite the progress achieved, in many countries – including the Netherlands – there are concerns regarding the quality of our living and working environment, and the safety of substances and products used. These concerns are understandable, seeing that successful reduction of environmental emissions has been achieved with respect to a very limited number of substances only. At the same time, society has seen a spectacular increase in the production and use of (new) substances. The available spectrum of policy instruments has, so far, proved inadequate in raising the percentage of substances for which successful emission reduction policies are implemented, against the total number of substances produced and used in society today. Moreover, experiences gained in recent years have demonstrated clearly that, although certain environmental problems, e.g. emissions from so-called point-concentrated sources, may be relatively simple to manage and control, many other forms of environmental emission, from a wide spectrum of products and diffuse sources, are far more difficult to control.

Similar concerns are heard in relation to the many substances that, directly or indirectly, often in the form of products, are allowed to penetrate our working and living environments, even though there is no information to determine whether or not they might pose long-term risks to health, e.g. causing damage to the nervous system and reproductive systems as a result of chronic exposure (at home, at work, and in public places).

In addition, there have been reports indicating the presence of hazardous substances in remote natural areas, and which have also been found in the fatty tissues and organs of animals at the top of the food chain, and even in man. These classes of extremely persistent, bio-accumulating substances in the environment are a particular concern, since it is practically impossible to remove them from our living environment. It is these kinds of incidents and reports, along with the persisting of specific occupational hazards associated with exposure to certain substances, which undermine the public's faith in the ability of government and industry to adequately protect our health and living environment.

Problems that need to be solved

The concerns, noted above, are largely associated with the following issues:

- With respect to the greater part of the many thousands of substances that are currently on the market, essential data are not readily available, and – in even fewer cases – accessible to the public. Furthermore, there is often not enough understanding of the quality of the information that is available. As a result, there is no clear understanding of the – potentially – harmful effects on human health and the environment associated with the use of many substances;
- There is uncertainty about whether new human health problems and environmental hazards may be associated with certain substances, e.g. the disruptive effect of some substances on the hormonal system;
- The know-how that is currently available is not being shared across the product chain. This slows down the process of implementing the necessary measures, such as replacing hazardous substances by less hazardous ones, so that we are increasing the environmental burden, even though instruments for relieving it are already available. The result is a less than adequate approach to the implementation of preventive and precautionary measures;
- As a consequence, risk reduction measures are, in many cases, taken in hindsight, instead of preventing problems from happening in the first place. If and when measures are taken, there is no guarantee of their effectiveness, in the absence of sufficient 'risk awareness'. Finally, the concept of prevention is not sufficiently ingrained at all levels in the product chain, e.g. replacing hazardous substances by less hazardous ones;
- The burden of proof, in relation to the risks and harmful effects on human health and the environment caused by substances in products could be exposed to by using substances, rests largely (and sometimes entirely) with the government, which lacks the required instruments to deal with that responsibility;
- Reaching agreement in Europe within the current procedure of risk management is an intricate, time-consuming and labour-intensive affair; thus, to date only a small number of substances have been subjected to risk assessment at a European level, while risk-reducing measures have been actually agreed upon and implemented for an even smaller number of substances.

A new chemicals policy: an ambitious goal

The concerns noted and problems identified call for a new policy on substances, aimed, in the first instance, at realising a cleaner environment and

healthier working and living conditions. In a more operational sense, this means *ensuring that the potential risks and health hazards associated with the use of substances in each stage of their life cycle (from chemical products via (consumer) products to waste, and, in certain cases, reuse) are sufficiently controlled so as to remove, or to reduce to negligible levels, any harmful effects caused by substances on man or the environment. In addition, safety and health hazards in the working environment due to the use of substances must be minimised.*

The cabinet hopes to achieve the above objectives within one generation, i.e. before the year 2020. However, in view of the international dimension of chemicals management policy, the government's success in attaining the stated goal will be closely tied in with the developments in regard to the EU's international policy.

Important elements in the new policy

The new chemicals policy must be cast in a form that will help governments remove the concerns mentioned, and to develop and implement effective solutions to the problems identified.

For this, it is envisaged that, in addition to structural improvements to the present policy instruments, which have proven to be cumbersome and ineffective (including the risk management instrument), new elements must be incorporated in the chemicals policy framework, which include:

- implementation of the precautionary principle (i.e. allowing room for preventative measures);
- the 'public right to know' (public availability of information on the hazards and risks associated with substances and products);
- collecting, on very short notice, information on the potential risks associated with substances and products;
- quality improvement in chemicals policy at the industrial level (responsible approach to ensuring safety of products and production processes);
- lending concrete shape to product chain responsibility (communicating and sharing information relevant to hazards, risks and control measures);
- suspending the use of substances and products posing unacceptable hazards or risks;
- barring the use of carcinogenic, mutagenic, reprotoxic (CMR) substances and very persistent, bio-accumulating, toxic (PBT) substances in consumer products and open applications, and allowing only very restricted use of those substances in industrial applications;
- striving, within one generation, for complete abolishment of emissions of persistent, bio-accumulating, toxic (PBT) substances, by the year 2020.

Tripartite consultation structure in the Netherlands

In 1999, in close conjunction between the national government, the industry and non-governmental organisations, initiatives were undertaken in the Netherlands within the framework of the SOMS programme (SOMS = the Dutch acronym for Strategy On Management of Substances), with a view to exploring and mapping the problems associated with the present policy, and devising and implementing suitable solutions for solving those problems in the Netherlands, and encouraging the implementation thereof within the chemicals policy of the EU. Two years of intensive co-operation between the parties mentioned have also led to an announcement of a declaration of intent from Dutch industry concerning a new approach to chemicals policy.

Strategy On Management of Substances

In the present memorandum, the Dutch cabinet, mindful of the international perspective of the issues in hand, indicates the direction it wishes to pursue in implementing the desired policy innovations, both nationally and in a wider, international context. The chemicals policy, as outlined in the memorandum, in principle encompasses all substances and every possible application thereof. While the new chemicals policy, in the first instance, will be focused on the so-called existing¹ and new² substances, the new policy direction could, in the long run, lead to consequences for medicines, veterinary medicines and agricultural or non-agricultural pesticides that effectively contain the same substances. With the new chemicals policy the government aspires to stimulate the synergy between the interests of the environment, safe working conditions, and consumer protection policy. The emphasis lies, however, on the protection of human health and the environment within the framework of environmental policy.

A responsible, prudent and precautionary approach to substances

As its principle point of departure, the cabinet proposes that it is necessary to anchor the responsibilities of industry, and for industry to pledge a commitment to quality improvement, as a basic condition for arriving at a responsible, prudent and precautionary approach to chemicals management, both within individual companies and throughout the industrial chain. Thus, the new chemicals policy connects to a recent advisory report from the Social and Economic Council, SER, 'Advies over maatschappelijk ondernemen: de winst van waarden' ('Advice on social enterprise: the profit of values', 15 December 2000), advocating an integrated approach to environment policy, workers health and safety policy, and consumer protection measures.

In order to realise the envisaged quality improvements and anchoring of product chain responsibilities, it is the task of the business community to

- create a framework for sustainable enterprise within individual companies, sectors and branches of industry, in which the contours are established for a responsible use of substances and products and associated activities;
- assume responsibility, within the overall policy framework set by the government, for controlling hazards and risks, and taking action in order to minimise the hazards and risks associated with substances in each stage of the life cycle;
- in support of the above activities, generate information on possible hazards and risks associated with substances and products; verify and have verified the information collected and make information available to others (for instance, in the form of adequate and complete safety information sheets and other such documents, customised to users);
- account (publicly) for its actions.

¹ 'Existing substances' are substances that are specified in the EINECS list (approx. 100,000 substances listed). Basic information sets are only required for substances denoted as priority substances.

² 'New substances' include all substances developed or introduced on the (global) market after 18 September 1981. To market a substance that belongs in the latter category, information must be submitted on the possible risk and safety hazards associated with the product.

The government expects from the industrial community

- that it employs demonstrably qualified personnel, who are adequately informed and instructed;
- that it possesses the necessary expertise in the area of safety/health/environment in relation to chemical products;
- that it implements a management structure that offers sufficient guarantees for objective assessment and decision-making in relation to hazards and risks associated with substances;
- that it maintains an adequate, verifiable, controllable and public register of chemical products;
- that it maintains an adequate risk inventory and evaluation system in the area of substances, in conformity with section 5 of the Working Conditions Act (*Arbeidsomstandighedenwet*);
- that it provides assurances with regard to measures to be taken and requirements to be satisfied in order to ensure a responsible, prudent and precautionary approach to chemicals management;

Public accessibility as security

In order to attain some form of assurance with respect to the implementation of the desired quality improvements and the effectiveness of the concept of product chain responsibility, all current facts, knowledge and data on hazards, risks and control measures must be publicly available. Public availability and accessibility of facts and information will enable other parties in society to assess the risks and hazards concerned, and thus stimulates the process of implementing adequate measures.

What will the government do?

The role of the government, on the one hand, is to create a clear and concrete framework within which the industrial community can take its responsibility, and, on the other, to ensure that there is an adequate system of monitoring and enforcement. Further, the government, where possible, will stimulate the industry in adopting the required quality improvements, and anchoring the product chain responsibility. Small and medium businesses (producers and users), are expected to require particular support in the process of improving their quality performance.

In regard to employment conditions, there is some experience of stimulating desired quality improvements and increasing individual responsibility, notably thanks to the 'workplace conditions agreements' concluded with various sectors of industry. The cabinet plans to stimulate acceptance of similar agreements, e.g. 'chain agreements' and 'implementation agreements', supplementing earlier initiatives in the area of workplace conditions and environment policy. The agreements thus concluded will focus importantly on achieving the envisaged integrated approach to working conditions policy and environmental risks and hazards, across industry. The cabinet, furthermore, wishes to encourage industry to set up the infrastructure that is necessary to realise the envisaged quality improvements.

In addition, the government, in support of the quality improvement process, plans to stimulate the implementation of a 'three-tier approach' with a view to generating the necessary information, within a short period of time, on all

substances circulating in society of which little or no information is publicly available concerning potential risks and hazards. In this way, it wishes to stimulate the industry, on the basis of the information generated, to take measures in order to arrive at an adequately responsible, prudent and precautionary approach to chemicals management.

In addition to its role in terms of providing the framework and stimulating industry in implementing the new policy, and monitoring and enforcing the rules, the government will be particularly concerned with ensuring fast and adequate implementation of policy in relation to substances posing serious concern. Finally, the government will ensure that the contents of this memorandum is considered within the wider perspective of the European debate on chemicals management.

From knowing nothing, to doing a great deal: the 'three-tier approach'

The essence of the 'three-tier approach' is that, in response to the level of concern that exists with respect to a certain substance, measures are taken to contain the potential risks and hazards of that substance. Obviously, this involves processes that cannot be dealt with overnight. Hence, in the first phase of the three-tier-approach, it is examined to what extent the phasing of the two other tiers is feasible, e.g. in view of the technical and economic implications of testing a substance. The three-tier approach taken by the government within the framework of the new chemicals policy entails the following phasing and distribution of tasks.

1. Before the end of 2004, the industry is to prepare a 'substances profile' (screening profile) for all substances currently sold or used in the Netherlands, on the basis of the available data concerning the risks associated with that substance (quick scan), whereby the substances are categorised according to five 'levels of concerns', identified by the government. The onus is on the industry to implement the 'in principle' measures. 'In principle' measures are measures which, on the basis of the then available, limited information, must be taken in any event (use of the substance is unacceptable; use of the substance is unacceptable, unless; use of the substance is acceptable, provided);

The government aims to achieve that:

- The industry will have prepared quick-scans for all substances before the end of 2002; Before the end of 2004, based on the above quick-scans, the verified profiles and the categorisation of substances in any of the 5 levels of concern will have been completed and communicated in an understandable manner, accessible to the public;
- As of 2005, far-reaching restrictions (i.e. a complete ban or stringent conditions) will apply in relation to the use and emissions of substances in respect of which no profiles were published before late 2002, or substances for which no verified profiles or classifications were made available to the public in clear and accessible terms by late 2004.
- The industry will take immediate measures (as of 2001) to prevent and contain the hazards and risks associated with all substances, in conformity with the policy framework provided by the government (matrix of 'in principle measures'), to the extent that this is required in view of the risk category of the substance in question, based on the screening profile (or additional information, as required).

If, during the period 2001-2004, it appears from the 'quick scan' that there are serious concerns associated with specific substances, the cabinet will take immediately measures on the basis of the Environmentally Hazardous Substances Act (Wet milieugevaarlijke stoffen -Wms-).

2. Not later than 2010, in respect of substances which, on the basis of the 'quick scan', arouse concerns, or which are produced in larger quantities than a certain production volume per year, the industry will collect additional information, if deemed necessary and will perform risk assessments where required. A possible closer examination of a substance will not result in the postponement of an 'in principle' measure, required on the basis of the 'quick scan';
3. Not later than 2015, the industry will have provided all substances, sold or used in the Netherlands, with a basic set of relevant data, and, where necessary, a risk assessment profile. Not later than 2020, adequate measures will have been taken for all substances, to the point where chemicals policy innovation effort is considered to have been accomplished.

In other words, before the year 2020, the industry will have taken measures for all substances sold and used in the Netherlands, so as to contain the risks and hazards associated with those substances, in conformity with the policy framework provided by the government, and in line with the risk category of the substance in question. The information produced in the course of the three stages of the three-tier approach, and the measures taken on the basis thereof, will be communicated to the public, in an accessible form. This information will be actively communicated by the industrial community, throughout the product chain. The government ensures that there are adequate supervision and monitoring procedures with respect to the above proceedings, and will enforce directives where necessary.

International dimension of new chemicals policy

Not only in the Netherlands, but also in various international contexts the issue of arriving at a new policy on chemicals management has been a topic of debate. Several European countries have, in the past two years, taken a stance in the matter. Furthermore, some countries, notably Canada, have moved on to implement elements of the present memorandum on chemicals policy.

At the request of the EU Environment Council in July 1999, the European Commission has promised to publish a white paper on the subject. This white paper is recently, 13th February, accepted by the Commission (COM(2001)88, 27 February 2001). It is expected that the EU Environment Council will discuss the White Paper in June 2001.

The legal framework for implementation of chemicals policy is founded on European legislation. However, due to the lack of clarity with regard to the European approach to chemicals policy, it seems inopportune, at this point, for national governments to impose new legislation on their own behalf.

In order to provide sufficient assurances as to the effectiveness of the new chemicals policy the cabinet is seeking to anchor the elements of this policy in laws and regulations (notably under the Environmental Protection Act), or to amend the existing legal framework. In addition, the Netherlands' new chemicals policy will be explicitly promoted within the EU, notably in rela-

tion to the debate on the European Union's review of its current chemicals policy, and, eventually, in the wider context of EU legislation. It should be clear that any new approach to chemicals management on a national level must conform to the framework of international policy.

Implementation of new policy

In adopting the above approach, the Dutch cabinet aims to move swiftly and concretely towards compliance by the industrial community with its 'duty to provide for responsible care', by playing an important, role in dealing with, so-called, non-assessed chemicals' (substances of which nothing is known regarding possible hazards and risks), and implementing a range of strong, effective measures with respect to substances showing undesirable properties (e.g. persistent, bio-accumulating, toxic (PBT) substances, carcinogenic, mutagenic, reprotoxic (CMR) substances, and substances that have a disruptive effect on the hormonal system).

The industrial community, meanwhile, has stated by letter (8 January 2001), in which it announces the forthcoming publication of a declaration of intent, what activities it is planning to undertake for the implementation of the Strategy On Management of Substances.

The implementation of the new policy follows a phased approach:

- The various elements of the new policy will be developed and formulated in an Implementation Programme, in which participation is expected of the same parties that co-operated in the SOMS programme, in preparation for this document. As part of this development, several 'experimental plots' for the new chemicals policy will be set up. These 'experimental plots', initiated in the industrial community with active stimulation from the government, will help investigate the options for lending concrete shape to the process of quality improvement and anchoring product chain responsibilities, as referred to earlier. The process of identifying the criteria for the five levels of concern, and the criteria for containing the hazards and risks associated with substances, also form part of the development phase of the new policy. Furthermore, an information provision structure and a (knowledge) infrastructure will be set up to enable effective implementation of the three-tier approach, and to encourage an open, honest communication process in industry and society as a whole, regarding (hazards and risks associated with) the use of substances.
- The implementation of the 'strategy on management of substances' can be concluded with the signing of one or several 'product chain responsibility and implementation agreements', which, subject to certain conditions, could be binding.

A progress report to inform on the above implementation programme and the policy intentions, expressed in the present strategy for achieving a responsible, prudent and precautionary chemicals management policy, is to be presented to the Parliament (Second Chamber of the States General of the Netherlands) by late 2002, in the form of a Memorandum on the Implementation of the 'Strategy on Management of Substances'. At that stage, an indication will be provided whether and in which way elements of the new chemicals policy are to be anchored within national and international legislation.

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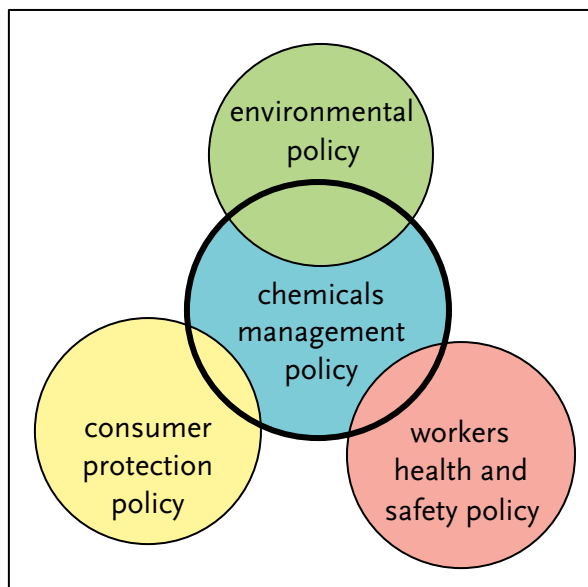
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I. INTRODUCTION

- 1.1 General framework
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- 1.5 Guide to contents

1.1 General framework

The policy³ on substances is closely connected to other policy areas concerning, broadly, the protection of the environment, the securing of acceptable (healthy and safe) working conditions, and consumer protection (environmental policy, working conditions policy, and consumer protection policy). The objective of the cabinet, in proposing a new chemicals policy described in this document, is to achieve the highest possible level of synergy between its policies in the area of the environment, working conditions and consumer protection, in close concert with international policy developments. However, due to the very specific requirements in relation to environmental emissions of substances, the emphasis in this document is primarily on the connections between chemicals policy and environmental policy, from a broad perspective. The proposed new policy is not so much about changing the objectives of the chemicals policy, as defined in the various NMPs (National Environmental Policy Plans) and Water Management Programmes. Rather, it is about introducing important changes with regard to the instruments used to achieve those objectives.



³ In the present strategic policy document, the terms 'substances'/'chemicals' and 'substances policy'/'chemicals policy' refer, respectively, to chemical products (including bio-chemically produced natural products) and product policy for chemical products. Thus, chemical products are subject to the same requirements that apply to other (professional/consumer) products, i.e. product information (composition, purity, properties), directions for use, guarantee, and information on properties that are relevant in relation to safety hazards and risks for health, the environment, etc.).

1.2 Reasons for a new chemicals policy

The use of chemical products (broadly referred to as ‘substances’ or ‘chemicals’ for the present purposes) is entrenched in all aspects of society. National and international (policy) efforts have aimed to ensure that, despite the ever-larger number of substances and production volumes, it remains possible to control the potential risks and health hazards associated with the use of substances in each stage of their life cycle (from chemical products via (consumer) products to waste, and, in certain cases, reuse), so as to secure a high level of protection for man and the environment. In addition to the efforts undertaken by the government, important initiatives have been taken in the industrial community with a view to enabling safe use of substances. The introduction of “Responsible Care” and “Product Stewardship” programmes are notable examples. In addition, the international chemical industry has taken initiatives to fulfil the most pressing information needs (filling the knowledge gap) with respect to some 1,000 substances that are produced in very large quantities. Furthermore, the sector has provided funding for international research into the long-term effects of substances.

Despite these and other efforts, the current policy in regard to chemical products falls short in a number of ways. Many substances that are allowed to penetrate the environment (soil, surface water, air, groundwater) and affect the plant and animal life in that environment, or substances which are used in products (notably consumer products), have properties that pose potential risks and hazards for man and/or the environment. Substances used in professional environments can pose health risks for those who are exposed to them. The fact that the exact nature of the potentially harmful properties of many substances are not (publicly) known causes apprehension as to the quality of our living environment and the products we consume. There are literally thousands and thousands of substances currently sold on the market, but there are only several hundred in respect of which we have sufficient information for assessment, by government agencies, of their potential effects on man and/or the environment. A further several thousand substances have been issued with hazard labels and safety phrases, providing information on potential risks and hazards. The assessment procedures devised by governments, both at a national and an international level, are extremely prudent, but they are also extremely labour-intensive and time-consuming, making it practically impossible to take a proactive stance towards hazardous substances.

Clues as to possible effects (e.g. hormone-disruptive effects) that could not be identified in the form of a risk profile based on the standard knowledge repertoire, have reinforced society’s sense of insecurity.

Several companies are now removing certain persistent substances from their production processes because those substances have been found in human tissue, yet without there being any evidence of significant toxic effects. However, the fact that this precautionary approach is not commonly followed, only sends confusing signals into society.

Society has already been confronted with a number of incidents in the end-user phase of products, e.g. the (alleged) release of softening agents from sucking toys for babies, and certain occupational hazards among workers. Waste matter containing hazardous substances, which has been allowed to re-enter the product chain for recycling purposes, has led to potentially dangerous situations

(‘dioxin chickens’), eroding the public faith in (chemical) product policy yet further. Although these are extreme examples, they illustrate that product chain responsibility is not working as it should. There are numerous cases where the government has been held accountable for the possible consequences of substances used, without there being adequate information at government level or even in industry itself to support or contradict those allegations. As a result, there is a risk of taking an ad hoc approach to substances policy, leaving decision-makers liable to criticism for lacking structure.

The chemicals policy on substances, as it stands today, provides insufficient incentives for industry to take responsibility on a pro-active basis. Moreover, important measures are often delayed until there is agreement within the EU.

Internationally, the above observations have led to initiatives for creating new policy. In recent years, several European countries have formulated statements on the subject (Denmark and the UK in 1999, Sweden in 2000; see enclosure 1). In 1999, the European Environmental Council, as a sequence to the evaluation document of the European Commission concerning the functioning of the four directives that are central in the European substances policy, adopted the general principles for a new chemicals policy, and invited the European Commission to issue a policy vision document by late 2000. This document, the white paper -Strategy for a future Chemicals Policy-, is recently presented by the Commission (7 February 2001 (COM 2001)88).

From the above, it can be concluded that there is broad international support for a thorough revision of the present policy, with the objective of transforming an approach that places the emphasis on measures taken in response to negative effects, into a policy that takes a pro-active approach, focusing on preventing those negative effects. A similar view was expressed in the Netherlands two years ago, when the government consulted with industry and non-governmental organisations to exchange thoughts on the need for a policy revision.

The reasons, as described in the preceding paragraph, that have inspired the innovation process, in essence reflect a situation where the present policy is unable to guarantee a clean and a safe environment. This conclusion was underscored by the parties consulted (i.e. the same parties that co-operated in the SOMS programme), albeit that each of the elements debated did not give rise to similar concerns for all.

1.3 Brief overview of present chemicals policy

For more than a decade, risk management has been one of the pillars of working conditions and environmental policy in the Netherlands. Risk management, as a policy instrument, was introduced in a memorandum entitled ‘Premises for Risk Management’ (*Omgaan met risico’s*), published as an enclosure to the first Dutch National Environmental Policy Plan -NEPP- (*Nationaal Milieubeleids Plan 1 -NMP1-*) (TK, 1988-1989, 21 137, no. 5). In this document, general policy principles were presented with respect to substances, radiation, pesticides, genetically modified organisms, and external safety. Separate documents were subsequently published on radiation (Radiation Protection and Risk Management (*Omgaan met straling*, TK, 1989-1990,

21 483, no.2) and on agricultural pesticides, in the form of a long-term crop protection programme (MJP-G- TK, 1990-1991, 21 677, nos. 3-4), and in a programme of activities, second phase (MJP-G (TK, 1997-1998, 21 677, no. 43). The policy on biotechnology in a broad perspective (including references to genetically modified organisms) was recently publicised in an integral policy document on biotechnology (TK, 2000-2001, 27 428, no.2). With respect to the environmental component of the substances policy, tolerance levels for individual substances were defined in the policy document MILBOWA (TK, 1991-1992, 21990, no. 1), and general risk policy principles were further described in a strategic policy document 'Dissemination of toxic substances' (*Strategienotitie thema verspreiding*) (TK, 1991-1992, 22 767, nr. 1). The systematics and practical approach to environmental standards with respect to substances were further explained in the in the 3d National Environmental Policy Plan (NMP3 (TK, 1998-1999, 26 205, nos. 1-2) and NW4 (TK, 1998-1999, 26 401, nos. 1-2).

In relation to working conditions and substances policy, in addition to several of the above policy principles, reference is made to existing frameworks for assessment and management of safe working conditions by industry and the standards and provisions for legal tolerance levels, as defined in the Working Conditions Act 1998.

Although the strategic policy document 'Dissemination of toxic substances' centres on the dissemination of toxic substances⁴, it also pays particular attention to the policy on environmentally hazardous substances, generally, with the emphasis on a sub-group of some fifty priority substances. The key policy principles, in line with the concepts as described in NMP1, are the prevention of unnecessary environmental pollution, and the preservation or restoration of a certain level of environmental quality. In regard to the latter, achieving the MTR⁵ values in 2000, and realising target values in 2010, were identified as touchstone objectives. These objectives were subsequently laid down in NMP2 and NMP3. Within the framework of NMP4, a policy document on Emission Reduction Targets for Priority Substances (*Notitie Emissiereductiedoelstellingen Prioritaire Stoffen*) will be presented soon to the Parliament. Capping fifteen years of priority substances policy, the document offers a positive view of the chances of meeting the target values stated in NMP1 by the year 2010. In fact, this objective has already been achieved – or is close to being achieved – for most of the substances classified as priority substances.

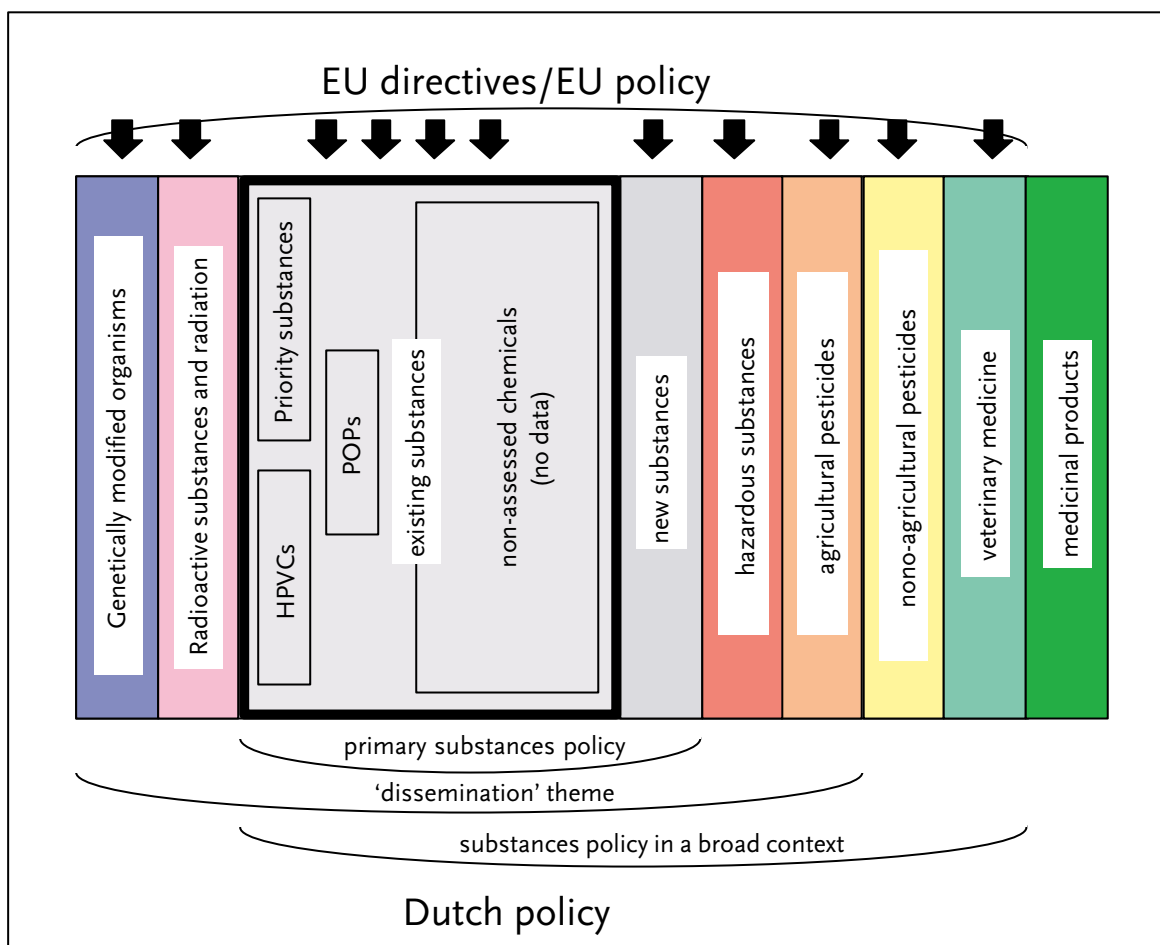
Although medications, veterinary medicines, and agricultural and non-agricultural pesticides are essentially chemical products, the policy on priority substances has been confined to 'existing substances'⁶ and 'new substances'⁷. The allocation of the various substances over several policy areas reflects historic developments in national and European regulation⁸.

⁴ 'Dissemination' in this context covers all substances, including radioactive substances, agricultural and non-agricultural pesticides and substances produced as a by-product of combustion or decomposition and genetically modified organisms. Acidifying and eutrophying substances, and substances that affect the climate and/or the ozone layer are excluded.

⁵ Definitions of MTR (Maximum Tolerated Risk) and Target Value, in the context of policy implementations, are provided in the third National Environmental Policy Plan, and in Enclosure 1 with this document.

The approach to waste substances is gradually being lifted out of the old policy structure. In a European context, it has been sought to connect the policy on primary substances to the risk classification of waste substances. In relation to substances classification, both the European and the national policy follows the principle that every substance classified as hazardous, in conformity with the primary chemicals policy (EEC Directive 67/548), must also be classified as hazardous in the waste processing stage. The same principle applies for preparations, albeit that the Preparations Directive is, in fact, anchored within the applicable waste substances regulations on the basis of a scale of graduation.

Furthermore, in the new Preparations Directive (99/45/EEC), the risk classification of agricultural and non-agricultural pesticides has been brought in line with the principles of the Preparations Directive.



⁶ 'Existing substances' are substances that are specified in the EINECS list (approx. 100,000 substances listed). Basic information sets are only required for substances denoted as priority substances.

⁷ 'New substances' include all substances developed or introduced on the (global) market after 18 September 1981. To market a substance that belongs in the latter category, information must be submitted on the possible risk and safety hazards associated with the product.

⁸ In any event (with exception of a number of product groups) classification and labelling must take place after assessment.

In the Netherlands, the policy on substances and the environment is enforced under the provisions of the Environmentally Hazardous Substances Act (*Wet milieugevaarlijke stoffen - Wms-*).

At the European level, the most important policy instruments are the Hazardous Substances Directive (67/548/EEC); the Existing Substances Directive (793/93/EEC); the Directive for Restrictions on Marketing and Use of Hazardous Substances (76/769/EEC); the Preparations Directive (88/379/EEC).

Under the provisions of the Environmental Control Act (*Wet milieubeheer*) and the Surface Water Pollution Act (*Wet Verontreiniging Oppervlaktewateren*), restrictive measures can be enforced in relation to emissions from substances. For the reduction of emission levels important international instruments include the European Framework Directive on Water Pollution (*Europese Kaderrichtlijn water (2000/60/EG)*), the Integrated Prevention and Pollution Control Directive (IPPC directive; 96/61/EC) and the OSPAR strategy on hazardous substances.

Further to the declaration issued by the third Ministerial Conference on the North Sea, a number of substances have been identified within the framework of OSPAR and the European Union, in respect of which emissions are to be phased out entirely within the next twenty years.

However, the goals of international and national policies on chemicals are not confined to the reduction of emissions of hazardous substances. Both nationally and internationally, directives have been developed with a view to protecting consumers and workers. Despite the present regulatory structures, there is still much work to be done in relation to the protection of man and the environment from non-acute safety risks resulting from exposure to low concentrations over a prolonged period of time with a potentially chronic impact, and exposure to CMR (carcinogenic, mutagenic, reprotoxic) substances. Similarly, European policy with regard to consumer products aims to achieve that substances used in products do not pose a health risk. A point of friction here is that the government has to demonstrate that substances in regard to which no essential data are available could pose a health risk, and propose alternatives.

Meanwhile, the regulatory framework for substances and preparations has been harmonised at EU level to a large extent. Hence, it is logical that efforts to improve the existing policy frames should be undertaken with a keen eye for the international dimension. On the other hand, the Netherlands has experienced that processes developed within those frameworks can, at the implementation level, lead to refinements, improvements and good practices, which in turn can inspire change and innovation within EU regulations. For example, the system presently used in the EU in relation to risk assessment (EUSES) is based on the Dutch 'Uniform Assessment System for Substances' (*Uniform Beoordelingssysteem Stoffen (UBS)*). Another example of a good practice in the Netherlands is the target group consultation structure, a successful initiative that has been developed in a broader European context. The reduction of emissions to the soil, water and atmosphere from a group of fifty priority substances used in Dutch industry, as noted previously, owes largely to agreements (Integrated Environmental Tasks), concluded within the framework of target group covenants (see Policy Document on Emission

Reduction Targets for Priority Substances, presented to Parliament within the framework of NMP4). Finally, the procedures for granting permits also provide an important instrument.

A similar focus on target groups has happened in relation to working conditions policy in the Netherlands. In addition to employers' present obligations under the law to map and control exposure levels, as much as possible, working conditions covenants have been concluded with 'high-risk' sectors of industry, aimed at reducing exposure to solvents, quartz and allergenic substances. The essence of these agreements is to stimulate risk management at the source, especially by using substitutions (TK 1998-1999, 26 375, no. 1). Furthermore, the 'Substitution of Volatile Organic Substances Order' (*Vervangingsplicht Vluchtige Organische Stoffen (VOS)*), which took effect on 1 January 2000, is an important step forward towards workers protection, by imposing restrictions on workplace exposure to solvents posing a possible health hazard. The policy aims to put an end to a condition known as 'Organic Psycho Syndrome' (OPS), an occupational hazard specific to certain sectors of industry. The 'substitution order' is expected to also have a positive effect on the reduction of VOS emissions to the environment (TK 1998-1999, 25 720, no. 13).

International policy on chemicals management has been relatively successful in specific areas. For example, it has stimulated the worldwide ban on environmentally hazardous substances (POPs: Persistent Organic Pollutants), taking effect in 2001. Since 1985, significant emission reductions have been achieved for a few dozen substances, both in the Netherlands and in Europe. Within the EU, risk assessments have been performed on 78 important substances that are produced in large quantities, and measures are currently being prepared for 33. With regard to new substances, an effective information system has been in place since 1981, enabling, in principle, the prevention of problems with new substances introduced on the market.

The EU's Existing Substances Programme, implemented within the framework of the Existing Substances Regulation, at once forms the EU's contribution to the HPVC (High Production Volume Chemicals) programme, covering some 4,000 substances, which was set up in 1991 within the framework of the OECD.

Under the HPVC programme, the OECD member states agree to share the cost of preparing data profiles for the selected substances. The industry is responsible for ensuring that the information is complemented into a basic data set, agreed in advance. However, it is still the government that has to supply proof of any hazards or risks involved with the substances concerned. Recently, some far-reaching developments have taken place in this respect. In the United States, the industrial community has committed itself to collecting information and preparing condensed reports on approximately 2,800 HPVC substances, within a four-year period (Challenge Programme). The ICCA (International Council of Chemical Associations) has started a worldwide initiative, with a view to preparing information and compiling basic data sets for a selection of some 1,000 HPVC substances by 2004. CEFIC, the umbrella organisation for the European chemical industry, has announced that it will perform hazard assessments and initial risk assessments for the HPVCs concerned. Yet, on a more realistic note, it has to be acknowledged that international policy on chemicals management has, in

seven years time, produced basic information sets for 356 (HPVC) substances only, whereas, in the EU, agreement on risk assessment was achieved for only 41 substances, 33 of which are now subject to risk-containing measures. In fact, risk-control measures have been developed with respect to not more than ten substances.

At the end of the day, the present regime for existing substances has produced complete risk evaluations for six substances only. For two of these, restrictive measures were not considered necessary; while, in regard to four substances, risk-containing measures were agreed upon. (Source: ECB, December 2000)

1.4 Objective and scope of present policy document

The present policy document reflects the vision of the Dutch cabinet, by formulating the policy principles and policy intentions of the government in relation to (environmentally hazardous) substances. In NMP₃, presented in February 1998, it was announced that the cabinet would keep the Parliament informed on problems associated with persistent, bio-accumulating, toxic (PBT) substances, hormone-disruptive substances, and substances in respect of which little or no information was available concerning potential health hazards or risks (non-assessed chemicals), and in regard to the approach taken to solve the problems. This document fulfils that promise.

However, the present policy document is more than a reflection of the government's response to problems signalled, and more than a description of the cabinet's proposals for solving those issues. It is a vision that has sprung from an extraordinary socio-political process.

Although, as outlined in the preceding paragraph, some success has been achieved under the current policy regime in the area of environmental protection and working conditions, there is a growing awareness (among the government, industry and interested non-governmental organisations) that a continuation of the present policy would, in the long run, yield insufficient progress in the area of knowledge building and management of substances posing any risk – greater or smaller – to man and/or the environment. Based on that consensus, a broad programme of social interaction and consultation on a new 'Strategy On Management of Substances' (SOMS debate) was initiated in the Netherlands in the period 1999-2000, leading, among other things, to the preparation of the present policy document, as the fruit of what can be described as an 'open process' (see Enclosure 2).

In light of the above, it is important to note the intentions of the industrial community concerning the new chemicals policy programme, as expressed recently in a letter to the Minister of Housing, Spatial Planning and the Environment (8 January 2001), and in which the publication of a Letter of Intent is announced. The position taken by the industrial community demonstrates that it not only supports important elements in the vision of the Dutch cabinet, but that it also intends to act on that vision. In addition, various non-governmental organisations in the area of healthcare, working conditions and the environment have rendered a considerable contribution to the development of the new policy vision.

The purpose of this policy document is to identify, as clearly as possible, the direction which the cabinet feels the policy innovation process should follow, both nationally and internationally, in order to achieve the long-term objectives of the chemicals policy, as described in chapter 2. The cabinet wants to encourage an integrated approach to substances risk management in relation to the environment, working conditions and consumer protection. The contents of this document therefore reflect the government's approach to environment, working conditions and consumer protection policy.

The scope of this policy document was implied in the previous paragraph: the present document addresses, first and foremost, national and international policy with respect to existing (and new) substances. This is not to say that the policy principles and intentions, expressed in this document, have no bearing on policy areas that are primarily concerned with hazardous waste, agricultural pesticides, non-agricultural pesticides, medications and veterinary medicines, merely because a different regime applies to those policy areas. After all, at the end of the day it is not the regime we create to protect the environment that matters the most. The ultimate measure of success of the new policy lies in the quality of our working and living environment. The results achieved with the new chemicals policy, supported by public availability of essential information on hazardous properties of substances, will serve to facilitate the process of further implementing emission reduction policy.

If the policy principles and intentions described in these pages prove to be as successful as it is hoped, the current distinction between existing substances and new substances will eventually disappear.

1.5 Guide to contents

The introduction to this policy document provides a bird's eye view of the present chemicals policy, connections with other policy areas, and the reasons that underlie the present effort to arrive at a new chemicals policy. Chapter 2 provides a description of the problems the new policy hopes to solve, and outlines the ambitious aims of the new approach.

A characteristic element in any approach to chemicals management is the element of permanent insecurity in relation to safety. Until recently, the premise was that a responsible approach to chemicals, in which measures are taken after the risks are established on a scientific basis, would be sufficient in order to answer questions in society concerning the safety of substances. In chapter 3, it is explained that a responsible approach to chemicals management requires policy instruments that can provide better assurances for a prudent and precautionary approach to chemicals management.

The key elements of the new chemicals policy are outlined in chapter 4. These include the general framework of the new policy, the respective responsibilities of the government and the industrial community, measures to be taken, and the importance of making information freely available. Chapter 5 briefly describes how, in the coming two years, the practical realisation and implementation of the new chemicals policy are to take place.

2. FROM THE OLD SYSTEM TO THE NEW

- 2.1 Room for improving (inter)national chemicals policy
- 2.2 An ambitious new chemicals policy
- 2.3 The new strategy: the essentials

2.1 Room for improving (inter)national chemicals policy

There are several tens of thousands of substances on the market, of which a few thousand are produced in very large quantities. Information on the basis of which a reasonable risk assessment can be prepared, is, however, (publicly) available for perhaps a few hundred substances. Save for the policy on new substances, EU and Dutch policies have, until now, focused on a small group of the most widely used substances. For several thousand substances, including CMRs, risk classification and labelling systems have been formalised within the EU, but assessments have been performed for a few dozen. Broad agreements at EU level on risk control have been made for a very limited number of substances. In almost all cases, there is insufficient overview of the management of chemicals in the various stages in the product chain, i.e. production, use and disposal. In regard to all the other substances, risk classification and labelling is left to industry, on the basis of the available information. As a result, adequate control of potential risks in many cases is a mere illusion.

The pace at which the backlog in information and adequate measures is being remedied is extremely slow. With the present policy instruments and distribution of responsibilities between the various parties, it is practically impossible to achieve progress fast.

In view of the above, there is an awareness at all levels in society that the Dutch policy, as well as the policy of the EU, are due for a thorough revision.

In brief, the problems associated with the current chemicals policy can be summed up as follows:

- *Unknown hazards*

It is not possible to guarantee safe use of substances in each stage of the life cycle (from chemical products via (consumer) products to waste, and, in certain cases, reuse) in such a way as to remove, or to reduce to negligible levels, any harmful effects on man (workers and consumers) and/or the environment, because essential knowledge is missing in relation to the risks and hazards associated with many substances. Therefore, the industrial community is unable to acquit itself properly of its responsibilities with respect to the safe production and use of products. In addition, the information that is available to industry is often not available to the public. The process of knowledge building, in relation to the long-term effects of combined and cumulative exposure, is still in its infancy. In some cases, negative effects on the environment cannot be explained on the basis of the present, limited knowledge of the risks and hazards associated with substances. The toxicity of certain water samples, for example, cannot be explained on the basis of the current knowledge of substances found in those samples.

There is uncertainty about the risks and hazards associated with hormone-disruptive substances. Experience teaches that, in the absence of the necessary knowledge, measures are simply not taken. As a result, the industry tends to take a passive or sometimes even defensive approach.

- *insufficient awareness of risks*
People are not sufficiently aware of the risks they are exposed to. Due to the factors noted above, people (notably employers) are often unaware of the risks associated with the substances they buy and use. This can, however, have consequences for others, e.g. employees. Although employers are obliged under risk assessment and evaluation regulations to evaluate the risks workers could be exposed to due to the use of specific substances, recent inspection reports of the Labour Inspection department have taught that those assessments are often inadequate. This is a matter of concern, notably in relation to employment conditions.
- *Unilateral allocation of tasks and responsibilities*
At this moment, the government – certainly in the public opinion – is seen to be responsible for the safety of substances and products. The industrial community has, under the law, a ‘duty of care’ to ensure responsible management of risks and hazards associated with substances and products. However, its duty of care, particularly in the area of the environment, is not sufficiently detailed in terms of specific, concrete tasks.
- *Lack of product chain-thinking in industry*
The industrial community has, until now, played only a small role in assuming a larger approach to its duty of care with respect to the risks and hazards associated with substances and products. As a result, a ‘responsibility vacuum’ has been created. Substances are handled in various stages of the product chain, from producer to end user (including the consumer), whereby various (market) parties play a role. Generally, industry has kept its responsibilities limited to individual actions within the company itself, where there should in fact be a sense of shared, mutual responsibility throughout the product chain, and a willingness to address other ‘links’ in regard to their responsibilities.
Although the law imposes an ‘information duty’ throughout the product chain, the effect is often negligible on account of ineffective communication. Furthermore, companies have been known to appeal to the confidential nature of certain information. This stands in the way of a just and fair allocation of tasks and responsibilities, and can lead to inadequate and inefficient action where there are problems with substances or products at any stage in the substances chain, mostly at the end.
- *Inefficiency of current policy*
Large amounts of money and energy have been invested in evaluating the risks associated with a relatively small number of (important) substances, at the expense of reserving resources for devoting the necessary attention to a large group of other substances. In addition, the current regime has fallen short in the area of control measures. At the same time, developments in the chemical industry are happening so fast that the sluggish

pace at which progress is achieved in regard to risk evaluation and control can, under the present circumstances, only get worse.

In sum, the current policy is inadequate because

- the policy and appertaining measures offer no safeguards for adequate protection of health and the environment;
- the policy provides insufficient assurances to society that substances available on the market and products in which those substances are used are safe;
- the government and interested parties have insufficient controls and insight concerning the measures which companies are required to perform under their 'duty of care', so that the present situation offers insufficient assurances for effective policy implementation;
- the policy offers not enough space for public availability and accessibility of information, so that there is only limited recourse to public accountability and, possibly, liability.
- The policy provides insufficient incentives for manufacturers and (professional) buyers of substances to perform an adequate appraisal of the risks and effects of the use of substances, so control measures are often incorrect or insufficient. This is an issue of concern in relation to environmental protection, working conditions and consumer product safety.

2.2 An ambitious new chemicals policy

The most important objective of the new chemicals policy is to effectuate a cleaner environment, and safer working and living conditions for man.

In operational terms, this means ensuring that the potential risks and health hazards associated with the use of substances in each stage of the life cycle (from chemical products via (consumer) products to waste, and, in certain cases, reuse) are sufficiently controlled so as to remove, or to reduce to negligible levels, harmful effects caused by substances on persons or the environment. In addition, safety and health hazards in the working environment due to the use of substances must be minimised.

The cabinet hopes to achieve the above objectives within the space of one generation, i.e. before the year 2020. However, in view of the international dimension of the chemicals policy, the government's success in attaining its targets will depend largely on developments with regard to EU policy making.

The objective of the cabinet, first and foremost, is to reduce the number of hazardous substances used in production processes and consumer products. By reducing, and, eventually, eliminating hazardous substances from the product chain, it is hoped that a number of other problems will become controllable, too: fewer hazardous substances, less occupational exposure, fewer hazardous emissions, and smaller amounts of hazardous waste. If a certain hazardous substance cannot be replaced, there must be a policy for ensuring adequate control of risks and imposing safety measures.

Because the cabinet feels that the environmental policy objectives formulated in NMP3 are the logical steps to take towards reaching its ultimate aims, those objectives remain in force, meaning that, within a very short period – possibly before 2000 – MTR values for all substances are not to be exceeded due to emissions, whereas, on a longer term – possibly by 2010 – target values are not to be exceeded due to emissions. However, technical and commercial feasibility (ALARA) play a role in relation to attaining target values.

With respect to the assessment of the instruments proposed in this policy document against the objectives for safe working conditions in relation to substances, the general principles as laid down in Directive 98/24/EC on the protection of workers' health and safety in relation to the use of chemical agents at in the workplace (PB L/131/11) apply. This directive is expected to be implemented under national working conditions legislation in 2001. These principles entail that there should be adequate knowledge and assessment of risks associated with substances used in the workplace, and that this should serve as the basis for implementing a risk management strategy to avoid or at least minimise the risks, preferably by replacing high-risk substances with suitable alternatives.

2.3 The new strategy: the essentials

The objectives of the chemicals policy, as defined in the various NMPs and Water Management policy documents, as well as the objectives of the policy in the area of working conditions and consumer protection, stand unchanged in the context of the policy innovations described in this document. It is, essentially, the policy instruments that are at the centre of the discussion. The same is true in regard to the international obligations the Netherlands has assumed as a member state or a contract party.

Central in the current chemicals policy is the prevention of unnecessary environmental pollution, so as to assure that the quality of our working and living environments is good enough to prevent adverse effects on health. These same principles are untouched in the new policy. Furthermore, the government wishes to pursue an integrated approach to environmental issues, meaning that the new policy will deal with the total life cycle of substances. This is a central in the new strategy.

A basic principle in the present working conditions policy is that the employer and the employee have a shared responsibility in ensuring that there is an adequate working conditions policy in the company. The Working Conditions Act creates the legal framework for this. An important element in the present policy is that companies are obliged to prepare an inventory and assessment of risks associated with the working conditions in the company, and that they must develop an adequate approach for dealing with those risks. The new policy, as explained in this document, aims to provide a better structure for the allocation of responsibilities between employers and employees in the process of assessing and managing the risks associated with the use of substances.

The present policy, as defined in the Environmentally Hazardous Substances Act 1985, includes a 'standard of care' (*zorgvuldigheidnorm, art. 2*) which obliges everyone who handles substances to take measures as required to contain the risks associated with that substance as much as possible. Thus, the industry – both manufacturers and traders – has certain responsibilities, which it must be aware of, and act on. This 'standard of care', or 'duty of care' is given a much more prominent place in the new policy.

The risk management instrument has a dominant role in the present policy. In the new situation, risk management will continue to have an important function. Its implementation, however, in contrast with the present situation in regard to environmental policy, will be the responsibility of the industrial community, under the terms of the 'duty of care', explained above.

The new strategy on chemicals policy adds new policy principles to the old, and at the same time outlines a new approach to using elements and principles of the old policy. It provides implementable solutions to the particular issues associated with the use of substances. The allocation of tasks and responsibilities between the various parties is pivotal.

New elements added to existing policy include:

- Implementation of the principle of precaution (scope for precautionary measures);
With a view to international agreements, the new policy allocates high priority to precautionary measures, both at government and industry level.
- The 'public right to know' (public availability of information concerning risks and hazards associated with substances and products);
Information on risks and hazards associated with substances and products must be publicly available and communicated in non-specialist language.
- Stimulating quality improvements in chemicals policy at industry level (prudent and precautionary approach to safety of products and production processes);
- Stimulating product chain responsibility (notably in the area of communication on hazards, risks and risk control measures);
- Collecting information on hazardous properties of substances and products on short notice;
- Banning the use of substances and products that pose unacceptable risks or hazards;
If the production or use of specific substances continues, even if this is generally considered 'not done', a total ban on those substances may be introduced.
- No carcinogenic, mutagenic, reprotoxic (CMR) substances or very persistent, bio-accumulating, toxic (PBT) substances in consumer products and open applications, and minimising industrial use of those substances;
In line with EU policy, which bans the use of CMRs (categories 1 and 2) in preparations for the consumer market, this will be expanded to include PBT substances.
- Total termination of emissions of persistent, bio-accumulating, toxic (PBT) substances within the space of one generation (before 2020).

More than in the past, the government will stimulate, and, where necessary, compel industry to learn its responsibilities and act on them. Industry is responsible for careful, safe and clean production of substances, preparations and products, and must therefore be able and willing to account publicly for its actions.

Because management of substances involves a chain of producers and user groups, each party will be responsible for actively sharing and communicating relevant data within and outside the product chain. Information, or data, in this context is understood to entail more than information bearing directly on risks involved and recommended measures of precaution.

Unnecessary environmental pollution is to be forestalled, by replacing hazardous substances by less hazardous ones on a permanent basis (substitution policy).

Efforts will be made to harmonise those policy areas which, traditionally, are concerned with chemicals management, i.e. environmental policy, consumer protection policy, and working conditions policy.

Risk management will continue to play an important role in the new policy, however, risk control measures will not be postponed until complete risk assessments are available.

The above implies that, in order to achieve the ambitious aims of the new chemicals policy, the general direction for solving the problems identified will be as follows.

- *Precaution* (more emphasis on precautionary measures than in the past, appreciating that measures may need to be reviewed in response to scientific developments);
- *Quality improvement in industry and anchoring of product chain responsibility* (shifting of responsibilities with regard to assessment and management of risks associated with substances, from government to industry, within the given framework of responsibilities. Energising the product chain management concept, i.e. managing the entire life cycle, from chemical product (substances) via (professional and/or consumer) products to waste and reuse, and setting tasks and responsibilities for all links in the product chain);
- *Infrastructure for assessment, decision-making and communication on (risks and hazards associated with) substances* (Broad-based co-operation between parties in the area of information provision and knowledge transfer based on active communication, in line with the principle of product chain responsibility and the 'public right to know', and repairing the information backlog in relation to risks and hazards associated with substances and products);
- *More effective and efficient use of instruments* (Insofar as considered useful, changing the existing regulatory structure to increase flexibility of measures and create space for measures based on commitment; setting up a new international regulation system, more attention for enforcement of present regulations; more attention for monitoring and signalling environmental problems);
- *Anchoring the new policy in EU regulations*

3. RESPONSIBLE, PRUDENT AND PRECAUTIONARY APPROACH TO CHEMICALS

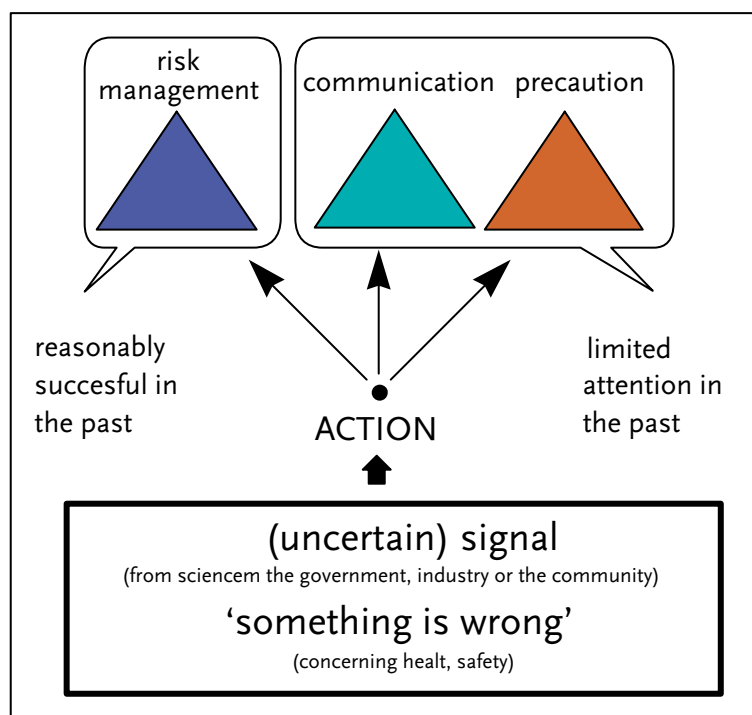
- 3.1 Dealing with uncertainty
- 3.2 Responsible approach to chemicals management
- 3.3 Prudent approach to chemicals management
- 3.4 Precautionary approach to chemicals management
- 3.5 Balancing risk versus social gains and cost

3.1 Dealing with uncertainty

Certain social problems, as observed in NMP₄, are persistent because the existing policy frameworks, along with the traditional (policy implementation) instruments and resources are incapable of solving them. In relation to the present chemicals policy, examples include the enduring problems with non-assessed chemicals (substances we know little or nothing about), PBT (persistent, bio-accumulating, toxic) substances, and substances with hormone-disruptive properties (due to the absence of validated testing methods, it is not always clear which substances are involved and what risks they pose).

A consistent characteristic of these kinds of persistent problems, as outlined above, is the element of uncertainty. With every activity, with each product launch, and with every substance taken in production the question remains to what extent the activity, the product or the substance will prove safe for man and the environment. This question can never be answered with certainty. However, as science advances and better analysing techniques continue to be developed, society is provided with better tools to assess the safety of a substance, a process or a product, and to provide an indication of the extent to which man and the environment may be exposed to potentially hazardous substances. In some cases, however, the advance of science and technology cannot remove the social unease caused by the uncertainty regarding risks and hazards. Both the government and industry have important responsibilities in reacting wisely to these signals. In recent years, signals of concern in society with respect to activities, products or substances have been increasingly intense.

Understandably, the chemicals policy in the past decade has focused strongly on risk management. This policy instrument, which is broadly accepted internationally, hinges on scientific risk assessment (risk analysis) of available data concerning properties and applications, as the basis for subsequent (policy) measures. The measure of success achieved with this policy instrument was described in the previous chapters. Internationally, the risk assessment policy instrument has provided the basis for a certain level of harmonisation – or, at least, interaction between – the policies adopted by individual countries. This has been an important step forward, seeing that substances



and products are increasingly manufactured and sold on international markets. However, it must be recognised that risk management does not offer the tools to enable an adequate and prompt reaction to the problems identified, seeing that, in most cases, prolonged research and elaborate debates are required to map and agree on potentially adverse effects (risk analysis) of substances and products. Without a clear understanding of the properties of a specific substance, any form of risk analysis is bound to produce an inaccurate evaluation, and thus provide insufficient direction for risk management measures.

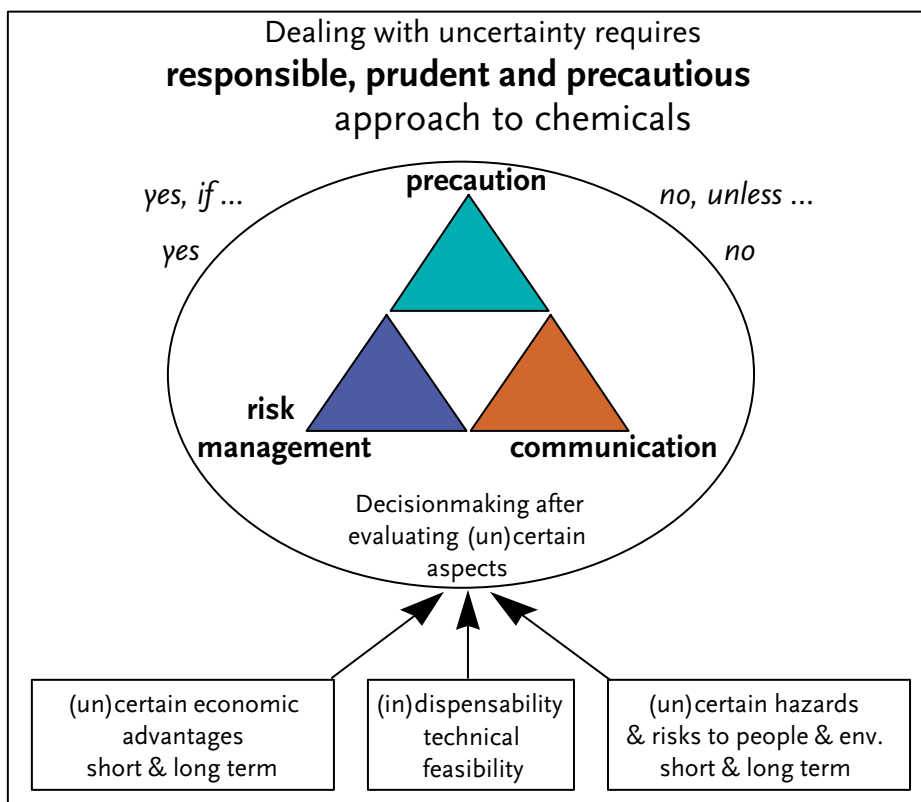
Alternatively, putting off measures until we have more certainty about the potential risks and hazards has the advantage of avoiding unnecessary measures where, in hindsight, it has appeared that measures were not required. A considerable drawback of this approach is that society may face a tall bill if it appears that the delaying of certain risk control measures was not justified, in view of the established risks and hazards for health and the environment. The price society has had to pay for cleaning up the environmental and health problems caused by asbestos, dioxins and PCBs, is an example of this. The fact that society for a long time has been 'left in the dark' about these issues, only reinforces its unease.

In sum, society's needs for (fast) precautionary measures is more urgent now than ever before.

Despite ever-louder calls for precautionary policy, the instrument of precaution, so far, has been used only to a very limited extent in relation to the policy on existing substances. The process of balancing (un)certain short-term economic advantages, versus long-term but uncertain health and environmental hazards, usually comes out in favour of the former. Furthermore, the way the advantages and disadvantages of either approach are spread over various groups plays a role. For those who stand to profit from (un)certain economic advantage, and who are not liable for any adverse consequences in the long run in relation to health, precautionary measures will not be a priority.

In that sense, the market mechanism has failed society. The market punishes a prudent and precautionary attitude, and rewards a bold and careless one. The prevailing philosophy is that any effort designed to innovate the system – including a more elaborate system of precautionary responsibility – is unlikely to succeed on the basis of co-operation. At the same time, it may not be an easy task to introduce a new regulatory system in which the emphasis is shifted away from risk management towards precaution and communication, since European regulation is largely focused on removing trade barriers, rather than being concerned with the protection of the environment and health.

The challenge for now and the future lies in our ability to adequately combine the strong points of risk management and precautionary policy. Both can contribute to an effective solution of the problems associated with substances and products, provided that there is a clear division of responsibilities between the government, the industrial community, and non-governmental organisations, and provided that there is an open communication between the parties concerned and society as a whole in relation to the use of those instruments. In this regard, the new chemicals policy connects to a recent advisory report from SER (*Advice on social enterprise: the profit of values*, 15 December 2000).



Dealing with uncertainty requires a responsible, prudent and precautionary attitude to chemicals management. Just how much prudence and precaution are reflected in the decision-making process depends on how society values economic aspects (certain and uncertain aspects relating to, for example, operating profits), social aspects (public perception of (in)dispensable products, activities) and health aspects (risks, certain or uncertain, for man and

the environment). The outcome of this equation will, in years coming, in ever fewer cases result in an unconditional 'yes' with respect to an activity or product, and, in an increasingly larger number of cases, will produce a 'yes, provided that' or a 'no, unless' verdict, and, in certain cases, an unconditional 'no'. While there is an awareness in all groups of society that certain substances are indispensable (e.g. pesticides and medications), it is just as clear that specific substances, regardless of their risk level, should not be used in certain products, and that certain products should no longer be manufactured or used, for the sake of future generations.

The new chemicals policy is based on a responsible approach to chemicals management (prevention and risk management), a prudent approach to chemicals management (where there is uncertainty regarding possible negative effects, risk management must assume the 'worst case' scenario), and a precautionary approach to chemicals management (risk control measures where there is a (complete) lack of information on risks, or if serious negative effects are suspected).

3.2 Responsible approach to chemicals management

A responsible approach to chemicals management means that there must be an adequate structure for prevention and risk management. This, in turn, means that there must be sufficient information on the substance in question. This is the case in relation to working conditions regulations, where the employer must take precautions on the basis of a sound risk evaluation, to prevent health risks for employees. It also applies in relation to current environmental policy and consumer protection policy, where prevention is a key principle. Prevention can be defined as 'the process of avoiding undesirable effects, based on sufficient foreknowledge'.

A responsible approach to chemicals management, based on available data on hazards and risks, includes replacing high-risk substances by less hazardous ones, and terminating the production of POP-like substances (Persistent Organic Pollutants).

A responsible chemicals policy relies importantly on risk management. On a practical level, this instrument, in the new policy, will be the responsibility of industry, under its 'duty of care'.

The government will create the necessary framework for industry to further develop its duty of care. The environmental quality standards (Maximum Tolerated Risk Levels, Target Values) and environmental quality targets, as well as working conditions standards (MAC values; Maximum Admissible Concentration) and targets form important components of the new policy frame.

Although the new policy strategy proposes simplification and acceleration, the discussion as to the technical feasibility will continue to play a role. More than in the past, there must be an open communication with citizens and with workers who are personally confronted with these issues, so as to generate a sufficient level of transparency and trust, in all levels of society.

3.3 Prudent approach to chemicals management

A responsible approach to chemicals management, by lending structure to risk management, has, nevertheless, certain limitations. In determining the risk level associated with a certain product, the level of exposure of employees, consumers and the environment to a multitude of substances – and thus the cumulative effect and risk resulting from a combination of substances – must be considered, on a structural basis. In addition, the negative effects caused by continued environmental emissions of persistent, bio-accumulating substances – in essence, the total burden on the environment – must be acknowledged.

This is why, in addition to taking a responsible approach to chemicals management, a policy of prudence is necessary. By setting ceiling values for risk assessment safety factors, accounting for a measure of uncertainty, the principle of prudence can be given a more concrete structure. Furthermore, where possible the government strives to attain the target values defined for all substances, which lie at considerably lower levels than the Maximum Tolerated Risk levels, so as to ensure that the total combined exposure to substances does not exceed an acceptable risk level. In relation to working conditions policy, the limit values stipulated under the law serve as touchstone values.

Prudence, furthermore, implies that, without prejudice to industry's duty of care in relation to measures within the framework of the new chemicals policy, the government will play a clearly demarcated role of its own. The government, for instance, will intervene where it considers (potential) risks and safety to be unacceptably high in relation to the social gains of producing/using a certain substance.

3.4 Precautionary approach to chemicals management

The demand in society for precautionary measures reflects an awareness, across the social spectrum, of the importance of controlling the uncertainty factor.

There are various definitions circulating, therefore, there may be some confusion as to the meaning of the precautionary principle. Depending on the area to which the precautionary principle is applied, the implications may be different. Notably, substantial differences may appear as to the conditions under which the principle is (to be) applied. The general intent of the precautionary principle can, nevertheless, be established, as follows: The precautionary principle serves to prevent potential damage to the environment where the risk of such damage is not scientifically ascertained. The precautionary principle provides a basis for justified government intervention. The fact that there is broad international consensus on the precautionary principle was reflected in the formulation of Principle 15 of the Rio Declaration, 1992:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The definition is, however, restrictive, in two ways. First, it requires that there is a question of serious or irreversible damage; there is no mention of potential damage to the environment in a wider sense. Second, it assumes that measures should be cost-effective. Although similar such restrictive formulations appear in other documents, they are usually less rigid than this. In the meantime, the European Commission has provided clarity with regard to the precautionary principle, by issuing an Announcement in which it explains how the precautionary principle might be applied by the Commission and individual member states. The Dutch government has advised its stance in relation to the announcement, in a letter to the Lower House, dated 17 May 2000. The Commission's announcement on the precautionary principle was adopted by member states, as a guideline for application of the principle by the Commission and member states, by virtue of the Resolution of the European Council, dated 7-9 December 2000 (Nice).

Irrespective of the wording of the definition of the precautionary principle, ultimately to be adopted in Europe, there are many activities that everybody accepts as 'not done', because they have a negative effect on our quality of life.

<p>For reasons of precaution, there are certain activities that are not acceptable in society</p> <ul style="list-style-type: none">• Using hazardous waste in animal feed, especially where animals are bred for human consumption (dioxin in chicken meat, etc.)• Using carcinogenic substances in consumer products• Marketing new chemicals that have the same undesirable properties as substances known as extremely hazardous (DDT, PCB-like fire retarders, etc.)

Food produced for human consumption must be clean and safe not only in the consumer's perception, but also by objective standards. In practice, if a consumer has doubts about a product, the manufacturer can expect to have difficulty swaying the argument, even by demonstrating, for instance on the basis of a risk analysis, that there are no significant risks associated with the product. In reality, producers are often prepared to withdraw a product from the market if that product is suspected of carrying certain risks, in order to retain their customers' faith.

As discussed in the previous paragraphs, the demand in society for precautionary measures will increase as long as the uncertainty (in relation to risk assessment) increases. Such a situation is seen in relation to the risks which man and the environment are exposed to on account of the hormone-disruptive effects of certain substances. For industry, implementing (precautionary) measures is not an attractive option if the formal risk assessment is ambiguous, or if no risk assessment is possible. From industry's perspective, economic prospects will tend to prevail over precaution, under the 'duty of care'. This is where the government has an important function.

The question as to what kind of information is required, concerning the effects and risks of a substance, in order to justify precautionary measures – whether or not initiated by way of self-regulation – is central in this strategic policy document. The process of assessing the arguments against and for the use of a certain substance (in a product), with attention for the uncertainties that play a role, essentially is a case-by-case process. The same conclusion

was drawn in the announcement of the European Commission. Furthermore, the European Council in its resolution allows space for national governments to decide who to hold responsible for providing additional information.

Precaution, following from the principles outlined above, is operationalised in the new chemicals policy by reducing the uncertainties relating to the risks and hazards associated with substances, by way of a system of classifying substances in various levels of concern, on the basis of their intrinsic properties.

A precautionary approach to chemicals management is reflected in the new policy in the proposed concept of the 'in principle' measures, serving to provide clarity, in an early stage, as to the general direction of the policy consequences once the risks associated with the substance under review are established using the fast screening method, based on the intrinsic properties of the substance.

Precaution is evident, again, in the policy intention to classify a substance in the 'no, unless' category if insufficient data are available concerning its possible risks. This means is that this substance will not be permitted to penetrate the environment or to be used in products, unless further information is provided within a given timeframe, demonstrating that the substance poses only negligible risks, if any at all.

A precautionary approach to chemicals management also implies that we should avoid using environmentally hazardous substances in products that are used in large quantities, in a wide variety of situations; that we avoid the use of CMR substances and substances stimulating allergic reaction in consumer products, and that we strive to achieve zero emission levels for all substances giving rise to serious concern, and that we do not perform elaborate risk analyses on behalf of risk management measures for substances whose properties are known to pose extreme risks.

In relation to very hazardous substances, effective precautionary risk-containing measures will be determined on the basis of the intrinsic properties of the substance.

Generally speaking, no risk assessment will be required for substances in this category, on account of the fact that the risk is substantial, even if the substance is used in very small quantities.

The prevailing policy with regard to consumer products has excellent connection points with the precautionary approach, based on assessment of substance-intrinsic properties. It is now standard EU policy that substances proven to contain carcinogenic, mutagenic, and reprotoxic (CMR) matter (categories 1 and 2) are banned in preparations for consumer purposes.

3.5 Balancing risk versus social gains and costs

In the previous pages, three complementary methods were described for dealing responsibly and effectively with the uncertainty, hazards and risks associated with substances. Responsibility, prudence and precaution were identified as the three pillars for the approach to be taken by industry. The government, nevertheless, continues to fulfil an important role in the new policy. Ultimately, it is the government that decides if expected (but uncertain) social gains (e.g. economic benefits) and costs justify the (un)certain

risk in relation to man and the environment. Factors such as, for example, the technical feasibility of risk control measures, and the social (in)dispensability of specific substances (less hazardous alternatives may be available) are important. Similarly, the distribution of social gains and costs is an important aspect.

The process of weighing the above-described factors is not a static one, since the prevailing opinion of what constitutes acceptable risk is subject to change.

The fourth National Environmental Plan further specifically addresses the process of balancing risk versus social gains.

4. NATIONAL AND INTERNATIONAL CHEMICALS POLICY: A NEW APPROACH TO AN OLD ISSUE

- 4.1 Basic elements for a new policy
- 4.2 Anchoring product chain responsibility and quality improvement in industry
- 4.3 From knowing nothing, to doing a great deal: the 'three-tier approach'
- 4.4 New infrastructure for assessing, deciding and communicating risks and hazards associated with substances
- 4.5 No hazardous substances in consumer products
- 4.6 Fast-track approach to non-assessed chemicals
- 4.7 Tough measures for persistent, bio-accumulating, toxic substances
- 4.8 Special focus on hormone-disruptive substances
- 4.9 International dimension of the new policy

4.1 Basic elements for a new policy

The primary objective of the new chemicals policy and its operational structure is to provide sufficient connection points for the industrial community to lend practical meaning to the concept of *sustainable enterprise* in relation to a responsible, prudent and precautionary approach to substances. For this, it is necessary that the government should create a new *policy framework* designed to enable the industrial community to realise the proposed *quality improvements* and to anchor the concept of product chain responsibility in relation to substances, by undertaking *activities* and implementing *measures* in order to contain the risks and hazards associated with substances. Such measures and activities require a certain standard of *knowledge concerning potential risks and hazards*. A basic condition for this is that there be an adequate measure of *public availability of knowledge* concerning (the risks and hazards associated with) substances *so as to enable (public) accountability and private accountability*.

In that sense, the new chemicals policy connects to a recent advisory report from SER (*Advice on social enterprise: the profit of values*, 15 December 2000, 15 December 2000)

Policy framework

Within European and national regulatory frameworks, and based on the commitment of parties to agreements in the area of substances and products, the government will create an overall national and international policy framework for safe management of substances and products. This policy provides space for parties to assume their responsibilities in the form of specific actions. The industrial community will create the frameworks for sustainable enterprise in industry, industrial sectors, and individual branches, allocating the specific responsibilities of each party for ensuring safe management of chemicals and products and implementing certain measures. Individual

companies may choose to follow their own programme, e.g. In-Company Environmental Care, Product Stewardship and Responsible Care.

Action and measures

The industrial community undertakes action under its 'duty of care' and in the context of its responsibilities within the framework provided by the government, and accepts its obligation to act in response to information concerning the risks and hazards associated with substances.

Knowledge and communication

The industrial community ensures that there is an adequate information set concerning the risks and hazards associated with substances and products, evaluates information and allows information to be evaluated by others, and makes the information available to parties in the product chain and to others. The government has access to the information on risks and hazards associated with substances and products, and, in specific cases, appraises that information. Other parties, including non-governmental organisations, have access to current information and knowledge of risks and hazards associated with substances and products.

Controlling & accounting

The industrial community accounts for actions undertaken, e.g. in the form of (environmental) annual reports, working conditions evaluations, and so on. The government monitors, enforces and supervises actions taken by industry and measures the quality of the environment and health.

4.2 Anchoring product chain responsibility and quality improvement in industry

Quality improvement in industry

The industrial community has expressed a willingness to take responsibility, and it has done that on a sizable scale already. Examples of initiatives taken in industry include the implementation of the Responsible Care and Product Stewardship programmes, the LRI (Long Range Initiative) programme, which aims to chart the long-term effects of substances, the Chemicals Assessment & Management programme of CEFIC (European Chemical Industry Council), and the ICCA-HPV programme of ICCA (International Council of Chemical Associations), which aims to chart the properties and risks of the most important and widely used chemicals. These programmes, in addition to the regular investments in environmental matters, require a very substantial commitment, both in terms of money and manpower. The vulnerability of these instruments, up until now, has been the absence of external validation and security of compliance with (legal) standards, and the inability of non-governmental organisations to exercise influence.

In society today, it is considered common sense that companies that want to produce and behave in a socially responsible manner should be informed of relevant physical, chemical, toxicological and ecological information on the substances they produce/process. This information must be sufficient in order to take socially responsible decisions with respect to the safety of man and the environment in matters relating to the production of substances or the use

thereof in the production process. Companies must inform themselves, or must be informed, of relevant information concerning the substances/preparations they produce, process or use. The required information flow for this must be set up and maintained by the relevant product chain link.

Further, it is necessary that there is a systematic process for analysing the spreading/infiltration routes and secondary products and waste products, and proper insight into potential applications; there must be assessment of risks associated with production and use; information packages must be prepared depending on scope, use and risk aspects, and effects observed in practice must be monitored.

A responsible management of chemical product implies, furthermore, that the manufacturer disseminates information on the basis of available data; that he provides user directions, training and instruction; that he informs and consults on behalf of employees; and that he verifies that the information has reached the target group and that it is correctly understood. Responsible chemicals management also means that substitutions are considered (substitution), and that there is a structure for balancing the benefits versus possible risks as early as possible in the research and development stage (R&D), with the objective of reducing or avoiding the use of chemical products causing any amount of concern.

In other words, the requirements which industry must satisfy in order to deserve the qualification of 'responsible enterprise' must not be underestimated. By the same token, it must be recognised, while everybody agrees with the above requirements, that the actual facts are far removed from the desired situation, even though many of the requirements formulated have already been given legal status, in line with environmental and working conditions policy.

Nevertheless, there is a genuine intention in industry to deliver the necessary quality improvements.

In the area of working conditions policy, some experience has already been gained in regard to quality improvements and increasing companies' individual responsibility, notably through working conditions covenants with the various industrial sectors.

The cabinet takes the view that quality improvements in industry are necessary in order to be able to implement the new chemicals policy. The envisaged quality improvements and anchoring of product chain responsibility requires that the industrial community should

- create 'sustainable enterprise' frameworks for companies, industrial sectors and branches of industry in which each play a role in taking responsibility in relation to safe chemicals management and associated activities;
- on the basis of its responsibilities, within the general policy frames for controlling risks and hazards set out by the government, undertake action with a view to minimising the risks and hazards associated with substances and products, in each phase of their life cycle;
- generates information for the benefit of the above activities, concerning the risks and hazards associated with substances and products, and that it evaluates and allows others to evaluate that information (verification) and that it makes that information publicly available (e.g. in the form of ade-

- quate and complete safety instruction sheets and other such documentation, customised to user requirements);
- that it accounts (publicly) for actions undertaken.

In order to attain the necessary assurances regarding the actual implementation of the envisaged quality improvements, important information, for example, on risks and hazards, must be made publicly available. Public availability and approachability is condition for critical participation of other groups in society in the evaluation process.

The role of the government in this process, on the one hand, is to set clearly defined frameworks for industry to take its responsibility, and, on the other, to implement adequate structures for monitoring and enforcement.

The government expects from the industrial community

- that it employs demonstrably qualified personnel, who are adequately informed and instructed;
- that it possesses the necessary expertise in the area of safety/health/environment in relation to chemical products;
- that it implements a management structure that offers sufficient guarantees for objective assessment and decision-making in relation to hazards and risks associated with substances;
- good housekeeping procedures;
- that it maintains an adequate, verifiable, controllable and public register of chemical products;
- that it maintains an adequate risk inventory and evaluation system in the area of substances, in conformity with section 5 of the Working Conditions Act (Arbeidsomstandighedenwet);
- that it provides assurances with regard to measures to be taken and requirements to be satisfied in order to ensure a responsible, prudent and precautionary approach to chemicals management.

A company that, in keeping with the above philosophy, produces responsibly, will supply to (or buy from) other certified companies only. The introduction of an eco-audit of some kind, with a view to evaluating the actual implementation of the responsibilities assigned to industry, could have a stimulating effect on companies that are 'lagging behind'. On the other hand, certain elements referred to may need to be formalised in a legal framework.

Product chain responsibility

The cabinet is of the opinion that the necessary quality improvement effort in industry should not be limited to an internal affair. It is necessary, in order to realise effective implementation of the new chemicals policy, to operationalise the concept of product chain responsibility. Effective communication between suppliers and buyers (upstream & downstream) is a precondition, therefore, an adequate structure for transferring information between manufacturer and buyer (bi-directional), geared towards the receiver, must be set up. At the communication baseline, there should at least be a safety information publication, prepared in conformity with legal requirements. Just as important, the information must be tailored to the users. This might be in the form of work instruction sheets on behalf of workers, containing relevant, dependable information based on the data provided by the supplier, and

written in approachable language. In addition, the supplier and the buyer, as two important links in the substance or product chain, must take responsibility not only for their own behaviour, but also for the conduct of the other links in the product chain in relation to safe chemicals management. This implies that there is a collective (product chain) responsibility in relation to every product or substance that could have negative consequences for the environment or the health. This not only requires an efficient communication infrastructure between the various links in the product chain, but a willingness to co-operate and make joint agreements.

This collective responsibility goes further than merely exchanging information. The supplier and the buyer must work together, not only with regard to collecting and exchanging data on risks and hazards associated with substances, but also in preparing risk assessments, evaluating measures to ensure clean and safe working conditions, and taking risk-containing measures for safe use. The responsibility to ensure safe use is not restricted to workers, but includes consumer use, both private and professional. Buyers support, in the form of counselling, training, auditing and monitoring is a further option for lending concrete shape to collective responsibility within the substances chain, with the ultimate objective of encouraging and realising a responsible, prudent and precautionary approach to chemicals management. Substitution of chemical products by suitable alternatives is an important tool.

The government believes that (quality) improvements must be anchored within in industry and in the product chain by concrete provisions and/or systems providing the basis for a quality certification structure within companies and individual product chains. For this, the government wishes to conclude specific agreements with sectors of industry concerning the setting up of the required provisions and/or structures, possibly in the form of product chain agreements.

It is not to be assumed that a product chain responsibility structure, as outlined, will emerge spontaneously across the spectrum. Some form of regulation on behalf of the implementation thereof should provide the necessary incentives. This includes an obligation for buyers of (chemical) products to provide suppliers with data on composition and use, and other essential information that is necessary to enable risk databanks to be prepared on behalf of risk management and risk monitoring. For this, inter-company agreements can be concluded with a view to reducing the environmental burden caused by specific substances or preparations, in products or otherwise, and for these agreements to be made binding under certain conditions. As a further point of attention, there may be an agreement that states that the information provider is responsible for ensuring that the information is fully understood, and that it is applied in accordance with intentions.

4.3 From knowing nothing, to doing a great deal: the 'three-tier approach'

Catching up with the information backlog

At this moment, not enough information is available – in some cases, none – in respect of many substances. The cabinet wants to repair this situation, as soon as possible. To achieve this, the cabinet's new policy is structured

along the lines of a 'three-tier approach', with a view to catching up rapidly with the information backlog, so that there is no reason for delaying measures. This three-tier approach entails

- fast screening procedures for assessing the risks associated with all substances currently in circulation and corresponding measures on the shortest possible term;
- producing, on a medium-long term, additional data on the risks and hazards associated with substances that are deemed to require individual, case-to-case measures;
- the availability, in the long run, of information considered necessary for adequate and individualised measures in relation to all substances in circulation.

The essence of the three-tier approach is that measures are taken in response to the level of concern and hazard and risks associated with the substances concerned. This is, clearly, not an overnight affair. Therefore, it will be evaluated during the implementation of the first stage to what extent the planned phasing for the final two stages is feasible in light of the technical and economic implications of, for example, the process of testing of substances.

The three-tier approach which the government will adhere to in implementing the new policy, constitutes the following steps and allocation of tasks:

1st tier of 'three-tier approach'

Before the end of 2004, industry is to prepare verified "substances profiles" for all substances currently sold or used in the Netherlands, on the basis of the available data concerning the risks associated with that substance (quick scan), whereby substances are categorised according to five "levels of concerns", identified by the government, and verified by a third party. The onus is on the industry to effect "in principle" measures. 'In principle' measures are measures which, on the basis of available information – even where data are incomplete – are to be taken, in any event, unless more detailed information is available to justify more specific measures.

The government envisages the preparation of screening profiles (quick scans) for all substances manufactured or sold in the Netherlands, as described in the documents pertaining to the SOMS programme (RIVM report 601503016, 1999 and enclosure 2 with this document, final report SOMS project 11), reporting relevant information, including, in any event, the substance-intrinsic properties. On the basis of this profile, every substance can, in principle, be classified in a risk/hazard or level of concern category. On the basis of this classification, it can be decided, first, whether and which measures should be taken, and, second, what additional data are required if it is considered necessary for a risk assessment to be prepared for the substance in question.

The industrial community is responsible for carrying out the above activities.

The government wishes to achieve that

- the industry has prepared screening profiles (quick scans) for all substances before the end of 2002;
- verified profiles and a verified classification of substances are made publicly available by industry, in a communicative and approachable form, before the end of 2004;

- as of 2005, far-reaching restrictions (total ban) are enforced concerning emissions and use of all substances in respect of which no profiles were made available by late 2002, and for substances in respect of which no verified profiles or classification were made publicly available in a communicative, approachable form by late 2004.
- industry takes immediate measures (as of 2001) to prevent or contain the risks and hazards associated with all substances currently in circulation, in conformity with the policy framework provided by the government (see matrix of 'in principle measures') as required with a view to the risk category assigned to the substance on the basis of the screening profile (or additional data, as available).

Over the period 2001 - 2004, the cabinet plans to take measures based on the Environmentally Hazardous Substances Act using the available instruments if, at any time during the period, the results of the quick scans performed should give rise to very serious concerns with respect to any substances tested.

2nd tier of 'three-tier approach'

Not later than 2010, industry will collect additional information, and, where necessary, perform risk assessments with respect to all substances which on the basis of the quick scan give rise to concern, or which are produced in quantities in excess of a specified volume per annum. A possible further examination of a substance is no reason for postponing the 'in principle' measures, declared to be applicable on the basis of the quick scan.

Industry is responsible for performing these actions.

The government wishes to achieve that

- by the end of 2004, industry has made (verified) information available in conformity with the base set (Annex VII A⁹) with respect to approx. 1,000 substances in the category High Production Volume Chemicals (HPVC), in accordance with international agreements;
- industry, by the end of 2008, has made (verified) basic information sets available for all other substances used for consumer purposes and for other 'open' purposes (Annex VII A);
- industry has made (verified) basic information sets (Annex VII A) available for substances which are used for other purposes and produced at a volume of 100 metric tons per annum, and for substances produced at volumes in excess of 10 metric tons per annum, by the end of 2010 and 2015 respectively;
- by the end of 2015, industry has made (verified) basic information sets available, in conformity with Annex VIIB, in relation to other substances used for other purposes and produced in quantities of between 1-10 metric tons per annum, supplemented with essential environmental toxicological data.
- industry will implement measures for preventing and containing hazards and risks for all substances, in conformity with the policy framework provided by the government (matrix of 'in principle measures') to such an extent as reflects the risk category of the substance, on the basis of the 'screening' profile or additional data.

⁹ Annexe of 67/548/EC provides information on file to be submitted

3rd stage of 'three-tier approach'

Not later than 2015 industry will have prepared relevant basic information sets, and, where necessary, risk assessments for all substances used or circulating in the Netherlands. Not later than 2020, adequate measures will have been taken for all substances, in line with the ambitious objectives of a new chemicals policy.

Industry is responsible for implementing these activities.

The government wishes to achieve that:

- industry takes measures to prevent and contain hazards and risks for all substances, in conformity with the policy framework provided by the government (matrix of 'in principle measures') to such an extent as reflects the risk category of the substance, as determined on the basis of the screening profile or additional data.

In other words, before the year 2020 industry will have taken measures to contain the risks and hazards for all substances in circulation, in conformity with the policy framework provided by the government, to such an extent as reflects the risk or hazard category of the substance in question.

The information collected in each stage of the three-tier approach, and the measures taken on that basis, will be made publicly available and communicated in a manner that is approachable and practical for all groups in society. The information is actively communicated by industry across the product chain. The government monitors, and, where necessary, enforces effective implementation of the above.

A useful reference in this context is the approach followed in Canada since 1999. In Canada, a two-tier approach is taken, whereby, in the first stage, a total of 23,000 substances that are currently circulating in Canada are classified on the basis of PBT criteria and exposure levels (to be completed within seven years). In the second phase, an initial risk assessment will be performed on selected substances, leading to firm conclusions as to "no further action required", "priority rating for complete risk assessment", or "classified as toxic substance, restrictive measures considered".

Taking ('in principle') measures

The classification of substances in a certain risk category on the basis of a screening profile (1st phase of the three-tier-approach) means that, within the new policy framework, measures are initially coupled to the risk or hazard classification (category of concern). The qualification in terms of five categories of concern, which now appears to have been accepted nationally and internationally, as similar classification systems are used both in the EU and by OSPAR and the UN, can be linked to a variety of policy statements, as shown in the schedule below. The criteria on which a distinction is made in terms of the five categories shown are based on the criteria that are commonly used in the various international organisations. A similar risk classification system is used within the framework of the OSPAR Convention. The UN convention on the prohibition of persistent organic pollutants (POPs), to be signed in 2001, will also include similar criteria. Both sets of criteria are not, however, strictly uniform. The Netherlands will apply very stringent criteria in assigning 'very high concern,' 'high concern' or 'concern' status to substances (including PBTs), in line with its policy of following a prudent and precautionary approach to chemicals management.

Substances in risk/hazard category: (level of concern)	'in principle' policy statement: Substance acceptable?
'Very high concern'	no
'High concern'	no, unless
'Concern'	yes, provided...
'No concern'	yes
'No data'	no, unless

Risk/hazard category 5: no data

(In principle) measures, linked to substances *in respect of which there are no data on possible risks and hazards* must, by necessity, be restrictive in character, in order to deal with the problem of the lack of basic information. If, not later than end of 2004, no information is made available on the basis of which a substance could be assigned a 'concern status', it stands to reason that this substance be subject to a similar regime as stated under category 1.

Risk/hazard category 1: very high concern

The policy statement in regard to substances causing *very high concern* is equally clear. In principle, these substances must not be used, and it is therefore unacceptable that they be allowed to penetrate the environment. Hence, all substances classified in this group will be subject to a prohibition regime.

Risk/hazard category 2: high concern

In addition, there are a number of substances which, based on their screening profiles, fit in the *high concern* bracket. This group would include substances whose properties are comparable to those found in certain substances used today, which are causing (health) problems and are generally perceived as being unacceptable (lead in fuel, asbestos in road construction, etc.). Using substances in this group must be allowed only subject to certain conditions (no, unless), which implies that using them is basically unacceptable, unless under *very stringent* conditions. Such conditions could include a requirement to meet a prescribed long-term target value, using 'best practice' techniques, substitution, etc..

Risk/hazard category 3: concern

The policy with regard to the acceptance of substances classified in this lower risk category (*concern*) is a conditional policy (yes, provided ...), meaning that the use of these substances is permitted, provided that certain basic conditions are satisfied. Such conditions could include a requirement to meet a prescribed long-term target value, using 'best practice' techniques, substitution, etc..

Risk/hazard category 4: no concern

Substances whose screening profiles indicate that there are no significant concerns (*no concern*) can, for the time being, be used without any conditions attached.

In addition to the above 'in principle' policy statements regarding the acceptability of risks associated with substances, it applies, above all, that care must

be observed in each case, as with any other professional activity undertaken in society. The general principles of (environmental) policy regarding emissions to the environment and unnecessary environmental pollution, and so on, remain in force, undiminished, in relation to all categories of concern (including 'no concern').

On behalf of the practical realisation of the new policy, it is essential that a sufficient level of gradation is applied in relation to the above principles. The following example may illustrate the point. The new policy does not provide for a general ban on the use of lead. However, it restricts the use of lead for specific purposes (e.g. in fuel). In keeping with current practice, the use of lead will still be permitted in other products (e.g. car batteries, protective aprons in hospitals). The reason for the restriction lies in the fact that lead, essentially, has certain unacceptable properties, while, at the same time, its environmental emission levels due to specific forms of use, especially due to the very large quantities involved (e.g. fuel) are exceptionally high. Therefore, lead poses unacceptable risks to health, as well as a serious environmental hazard.

The matrix of general 'in principle' measures can be specified in more detailed 'in principle' measures, by linking risk aspects to application areas. The conditional policy statements and pertinent measures will be further developed within the framework of the implementation and enforcement of the new policy under the SOMS implementation programme. The conditional terms 'provided that' and 'unless' will be provided with more specific content, accounting for the aspects noted (production volume/intensity of use, application area, indispensability of substance or product, etc.)¹⁰.

general policy statements on:				
Substances in risk/hazard category: (level of concern)	Site-limited intermediate substances	Substances in industrial applications	Open professional use of substances	Substances in consumer applications
	Substance acceptable?	Substance acceptable?	Substance acceptable?	Substance acceptable?
'Very high concern'	no, unless...	no, unless...	no	no
'High concern'	yes, provided...	yes, provided...	no, unless...	no, unless...
'Concern'	yes, provided...	yes, provided...	yes, provided...	no, unless...
'No concern'	yes	yes	yes	yes, provided ...
'No data'	no, unless...	no, unless...	no, unless...	no, unless...

The conditional policy statements are to result in measures, depending on risk/hazard classification and application area, to help achieve that a substance is either no longer produced, produces zero emissions, produces emissions at levels that do not pose a hazard for the environment provided that a certain target value is not exceeded, poses a negligible risk for people generally, and workers in particular, etc.

¹⁰ In relation to the distinction made between general and more specific 'in principle' measures: the precise content of the clause concerning acceptability of a substance not only depends on the risk category in which a substance is classed, production volume, application area, and indispensability of the substance or product, but also relates to current policy (emission policy, emission test, source-focused approach, BBT, BAT, ALARA, international policy etc.). The 'provided...' and 'unless' clauses reflect all of the above. For certain substances a conditional clause may not suffice if, under an international agreement, the use of that substance ('provided', 'unless'), under current (international) policy, even if that substance is classed in the 'no concern' group.

There is a system in the gradation of acceptability, based on the category of concern, potential risks/hazard, and area of application of the substance concerned.

Substances for consumer purposes

For substances manufactured for consumer purposes (products), the policy is generally more stringent, across the spectrum (i.e. all five levels of concern). Measures will therefore be more severe than with other forms of use. The reason here is that this group of substances is usually marketed in large quantities, so that, consequently, they will eventually end up in the environment in relatively large amounts, whether directly or indirectly.

Furthermore, consumers should be able to assume that there are no substances in consumer products (or an absolute minimum, in exceptional cases) that might cause any amount of concern. Thus it is clear that substances classified in the 'very high concern' group, whose properties are comparable to substances that are considered undesirable, or which are banned already, should not be used for consumer purposes. The use of substances classified as 'high concern' or 'concern' must be prevented, where possible, unless there are compelling reasons (e.g. indispensability) that justify the use of those substances (policy statement: 'no, unless')

Substances for open professional use

With respect to substances manufactured for open professional use, the same considerations apply as explained under 'substances for consumer purposes' (products). The policy decisions are, however, slightly less severe, and so are the measures, on the assumption that an adequate transfer of information from supplier to professional users, concerning hazards and risks associated with the product, can be supported by counselling, training, auditing and monitoring.

Substances for industrial use

Substances designed for industrial purposes can be admitted under a more relaxed regime, once the concept of product chain responsibility, which is one of the important pillars of the new chemicals policy, is firmly anchored. Lending shape to collective (product chain) responsibility requires not only an effective communication structure between the various links in the product chain, but there must also be a willingness to co-operate and make collective agreements. The concept of collective product chain responsibility extends beyond the exchange of information only. Suppliers and buyers must work together, not only in collecting and exchanging data on the risks and hazards associated with substances, but also in preparing risk assessments, evaluating measures for ensuring clean working conditions, and taking risk-containing measures to ensure safe use, not only for workers but also on behalf of the end user/buyer (professional or consumer).

Site-limited intermediate substances

Substances which, in principle, are used in industry only for the benefit of certain production processes are assessed under the least strict regime, because adequate control of the production process including emission control is already a primary concern for the manufacturer. These are mostly substances which are necessary to enable production processes. Thus, the indus-

trial use of site-limited intermediate substances which otherwise would give rise to 'very high concern' is judged more leniently. Nevertheless, there are conditions attached to this form of use, especially in relation to working conditions and environmental emissions. Although the risk of emissions from production processes is limited, there is always a possibility of an error or accident in the production process. Whether there is a calamity, or under regular working conditions, the health and safety of workers and the protection of the environment must be secured, at all times.

In sum, the new rules are

- a strict regime applies in relation to substances classified in the risk/hazard category '*very high concern*', in all areas of application. In principle, the use of these substances in consumer products and other 'open' applications is unacceptable;
- substances classified in the risk/hazard categories '*concern*' or '*high concern*' are not allowed to be used for consumer purposes and other 'open' applications, unless it has been demonstrated that there are no problems to be expected ('no, unless'). For other applications, the rule is that use is acceptable, provided that certain conditions are satisfied with a view to ensuring that there is no, or only minimal risk for people (including workers) or the environment ('yes, provided...');
- substances classified in risk/hazard category '*no concern*' are, for the time being, allowed to be used without further conditions, unless for consumer purposes;
- substances classified in risk/hazard category '*no data*', for reasons of precaution, are not allowed to be used, irrespective of application area, unless it is demonstrated that there are no problems to be expected ('no, unless').

Restrictions on animal testing

The above-described approach, which aims to make up for the information backlog with respect to hazardous substances within a set time frame, implies an intensified use of animal testing in order to fill the knowledge gap in essential areas. The cabinet wishes, however, to emphasise its commitment to EU directive 86/609/EEC concerning the protection of animals for experimental and other scientific purposes.

International acceptance of the results of animal testing has been an important step forward towards restricting animal testing. International acceptance was attained by harmonising testing methods (OECD Testing Guidelines) and harmonisation of testing practices (OECD Good Laboratory Practice). These recommendations are secured in the relevant EU directives for animal testing. In addition, provisions have been included in the EU Substances Directive and in the EU Existing Substances Regulation with a view to stimulating the exchanging of results of animal tests between companies, so that test duplication can be avoided, as much as possible. While, in drawing up the guidelines for animal testing, it was explicitly attempted to reduce the number of animals to be used for testing purposes, it is clear that further international efforts are needed in order to further restrict the use of animals for testing, including the development and validation of alternative methods and compulsory publication of the results of animal tests.

Further to the above, the cabinet wishes to underscore the importance of

observing due care in the planning and performance of animal tests, and, in the course of implementing its three-tier approach, wishes to encourage that the industrial community, inasmuch as scientific integrity allows, should use alternative methods in its approach to complementing the missing data, that results already available on chemically related substances should be used, and that there be co-operation in industry where the same substances are being dealt with.

4.4 New infrastructure for assessing, deciding and communicating risks and hazards associated with substances

(Information) infrastructure

To enable effective realisation of the three-tier approach, successful quality improvement, and the anchoring of product chain responsibility, there must be an open and reliable information structure. This structure is essential in order to ensure efficient communication within the substances chain, as well as within society as a whole. The available information must be validated by an independent party (on behalf of industry), it must be usable for any one who has to deal with the substance in one form or another, and it must be accessible to other parties. In the documents pertaining to the SOMS programme (see enclosure 2, SOMS project 12/13) the requirements for the information provision structure are described. The establishment and operational functionality of this information provision and infrastructure are, primarily, the responsibility of industry. However, the government plays a specific role here as well.

The tasks and responsibilities associated with regard to the setting up and maintenance of the required infrastructure are explored within the framework of this policy document. In the SOMS implementation programme, the requirements for and form of the infrastructure will be further discussed, with attention for the contents of the EU's White Paper on a new chemicals policy.

The envisaged (information) infrastructure must be tailored to accommodate the tasks and responsibilities assigned to the various parties within the framework of the policy innovation effort. A distinction is made in terms of an infrastructure set up primarily by industry, and an infrastructure set up by the Dutch government or within the EU.

Industrial information infrastructure

The cabinet's ambitions in relation to quality improvements in industry, and the realisation that product chain management requires and active exchange of information within the product chain and in society, imply the need for setting up of an (information) infrastructure in industry. Whether or not such an infrastructure might result in the foundation of a body along the lines of a 'substances agency' is an issue that will be addressed in the implementation phase of the policy innovation effort.

What is clear is that all information available to industry in relation to substances should be filed in a central register/databank, in such a manner as ensures that

- it is possible to check companies' substances management,
- information is accessible to the government, workers and other parties,
- in the case of an incident or calamity, important information can be made available to the authorities, on the initiative of the company.

The information generated in the course of the three-tier approach, notably during phase 1, will have to be structured and organised. In view of the time-line involved, it is necessary that there is an operational infrastructure, as described, for the processing and validation of screening profiles and subsequent (verified) classification of the substances screened, by late 2002.

In view of the above, there is a case to argue for an independent secretariat, which, funded by industry and on behalf of industry, could administrate relevant 'product chain information', whereas an independent appraisal of the risk assessments prepared by industry will lend further credence to the assessment procedure.

Government information infrastructure

The government has set up an infrastructure for the implementation of the EU directive concerning 'new substances' (Chemical Substances Bureau at the RIVM (National Institute for Public Health and the Environment)). In addition, the RIVM serves as the knowledge centre on behalf of (inter)national agreements and conventions concerning chemicals policy. Depending on the structure of the information infrastructure to be set up by industry, and provided this structure operates adequately, there may not be a specific need for setting up a separate provision under government administration. In the SOMS implementation programme (see Chapter 5), this issue will be further addressed, depending on the EU's course on a new chemicals policy.

In any case, an infrastructure as outlined will be required in order to

- centrally control a number of the tasks – whether or not cast in a legal or regulatory frame – following from the implementation of laws and regulations and international conventions, and the implementation of the present strategic policy document.
- monitor compliance with any implementation agreements concluded within the SOMS framework;
- set up a public databank of information on substances, specifically geared to the Dutch situation;

The possible role of an independent body (such as the British 'Stakeholders Forum', set up in September 2000), composed of representatives from industry (raw materials industry, industrial (end) users, etc.), the government, and non-governmental organisations (notably consumer organisations, trade unions and environmental organisations) will be examined. The tasks of such a forum could include the assessment of measures taken by industry to improve chemicals management, and assessment (auditing) of documents and procedures used in industry, by independent experts in the areas of health, the environment, chemicals and working conditions.

4.5 No hazardous substances in consumer products

The cabinet wants to ban all hazardous substances in preparations for the consumer market. It is standing policy in the EU that proven CMR substances, in conformity with directive 76/769/EC (category 1 or 3) are no longer allowed to be used in preparations for consumer purposes. It is proposed that a similar policy is followed with respect to suspect mutagenic substances in relation to reproductive cells (classified 3 M), and to discourage the use of suspect carcinogenic or reprotoxic substances (classified C/R). Furthermore, it is not considered responsible to continue using suspect C/R substances, with respect to which no additional data are supplied within three years, in preparations for consumer purposes.

It is proposed, furthermore, that it should be examined if the above policy might be extended to include consumer products other than preparations, so that, under certain conditions, the use of suspect C, M or R substances and PBT substances could be restricted.

The cabinet wants to ensure, by instrument of the new substances policy, that all substances posing concern are no longer permitted to be used (or used only in minimal amounts, in exceptional cases) in consumer products. Conversely, the product policy adopted is to ensure that all products manufactured are safe to the extent that substances posing concern are no longer used (or only in exceptional cases, in minimal amounts) in consumer products.

4.6 Fast track approach to non-assessed chemicals

In NMP₃ (Third National Environment Policy Plan) it was announced that a policy would be developed for non-assessed chemicals (substances in respect of which no data on possible risks and hazards are available). The systematics of the three-tier approach, described earlier, fulfils that promise. Provided that the implementation of the proposals proceeds as planned, the specific problems associated with non-assessed chemicals, i.e. the complete lack of data, should be solved within the next five years.

4.7 Tough measures for persistent, bio-accumulating, toxic substances

Substances giving rise to very high concern include CMR substances and PBT substances. In principle, a very severe policy regime applies for both categories. In the case of extremely hazardous substances (e.g. very persistent and highly bio-accumulating) this implies that these substances should not be permitted to penetrate the environment, and must not be used if it is not possible to prevent environmental emissions. These substances will therefore fall under the prohibition regime. The criteria that underlie the distinctions between 'very high concern', 'high concern' and 'concern', are based on the criteria that are commonly accepted in the international bodies.

Similar criteria are used within the framework of the OSPAR Convention, and criteria along those same lines will be included in the UN convention on the prohibition of persistent organic pollutants (POPs). Both sets of criteria are not, however, entirely uniform. In relation to the identification of 'very

high concern', 'high concern' and 'concern' substances, the Netherlands will opt for more severe criteria (e.g. for PBT substances), in keeping with its views on prudent and precautionary chemicals management.

4.8 Special focus on hormone-disruptive substances

There is considerable uncertainty in regard to the presence of hormone-disruptive substances in the environment. Certain effects that are ascribed to hormone disruption have been observed in aquatic ecosystems, but it has not always been possible to identify the substances causing the disruption. In addition to xenobiotic substances, natural hormones and phyto-oestrogens play a role. The Health Council, in a 1997 report, concluded that there were no indications to suggest that exposure to hormone-disruptive substances posed an acute threat to health. However, the report did point at the potential hazards associated with this type of substances.

The mechanisms that result in hormone disruption are not yet fully understood. At the same time, there is a lack of validated testing procedures for investigating substances on possible hormone-disruptive properties. This is especially relevant for the environment, providing habitats for a large diversity of species, while there is a lack of sufficient knowledge of the endocrine systems in many species.

The industrial community advocates intensified research into hormone-disruptive effects. The chemical industry in the US, Japan and Europe has started up the Long-Range Research Initiative, with a view to researching the above aspects. Many scientific and government institutions have now joined the programme. The (international) environmental movement is breaking new ground for the application of precautionary measures for hormone-disruptive substances. In view of the uncertainty surrounding the issue, and referring to previous observations on risk management and precaution, there is cause for advocating more intensive research on behalf of both risk management and precautionary policy.

On 21 June 1999, the cabinet, on behalf of the Ministry of Economic Affairs, the Ministry of Agriculture, Nature Management and Fisheries, the Ministry of Social Affairs and Employment, the Ministry of Transport, Public Works and Water Management and the Ministry of Health, Welfare and Sport, forwarded a memorandum to the Lower House, in response to questions from Mr Crone, during the debate on the budget (1998) for Housing, Spatial Planning and the Environment. The memorandum emphasised that there were factors of considerable uncertainty concerning the hazards of hormone-disruptive substances, but that the issue deserved serious attention due to the potential risks of exposure, considering that this could affect the hormonal system and cause serious harm to the reproductive system, possibly affecting the children of the person exposed. The memorandum proposed that there should be a serious effort to find ways of identifying the substances concerned, notably the most persistent ones (substances that accumulate in the food chain), in the earliest possible stage, so that they could be incorporated in the existing assessment structure, and thus become controllable under policy measures.

The government continues to stimulate further research into substances in the environment that are believed or suspected to cause hormone-disruptive effects. Since the effects of hormone-disruptive substances seem to be most noticeable in aquatic environments, a National Research Programme for Oestrogen Substances (Landelijk onderzoek Oestrogene Stoffen (LOES)) has been set up by the Ministry of Traffic, Public Works and Water Management, in conjunction with Wetterskip Fryslân (Friesland water board), RIVM and RIWA (Association of River Waterworks), to foster a better understanding of the severity and scope of the problem and the sources responsible for it. Based on current data, there is reason for serious concern regarding the issue of hormone-disruptive substances in the surface water.

Conclusion:

The proposals of the cabinet for a new chemicals policy serve, amongst other, to classify, on short notice, all existing substances on the basis of their intrinsic properties, notably persistence (P) and bio-accumulation (B: ability to accumulate in the food chain), according to categories of concern, and to prescribe measures on the basis thereof. A large number of the substances known to be persistent and bio-accumulating also possess hormone-disruptive properties, which, if allowed to accumulate in organisms, can reach serious effect levels. In other words, (stringent) measures in regard to PB substances are expected to yield results in protecting the environment from hormone-disruptive effects.

Reducing the use of other substances that could cause hormone-disruptive effects will have to be postponed until better methods are available for fast and reliable identification of the most relevant substances.

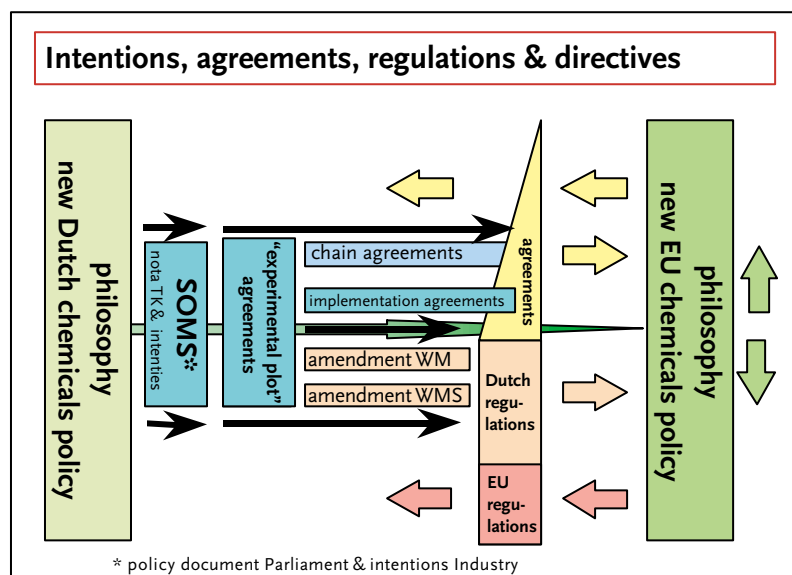
Based on current knowledge, except in relation to PB substances, implementing the precautionary principle would not appear to be feasible, since it is not clear what substances qualify for precautionary measures.

4.9 International dimensions of the new policy

Not only in the Netherlands, but in various international frameworks there is a debate on a new approach to chemicals policy. In recent years, a number of European countries have taken a position in regard to a possible direction of the new chemicals policy. In addition, several countries, including Canada, have adopted and implemented elements of the policy innovation proposed in this document.

The European Commission, at the request of the Environmental Council in June 1999, announced that it would publish a white paper on the subject. The white paper has been presented by the Commission recently (27 February 2001).

The regulatory framework on behalf of the implementation of the chemicals policy is founded on EU regulations. In view of the lack of clarity with respect to the direction of the European chemicals policy, it would not be opportune to develop a specific, national legal framework. Hence, this policy document places the emphasis on measures considered to be achievable in the Netherlands.



In order to create sufficient assurances for successful implementation of the new chemicals policy, and seeing that this policy will be based, in the first instance, on a commitment to take measures under the 'duty of care', as laid down in the law, it is the intention of the cabinet, insofar as the need arises and within its given powers, to anchor elements of the new policy in a legal and regulatory framework (notably under the provisions of the Environmental Management Act), or to amend existing regulations in such a way as ensures that important elements of the new policy are given their proper place. The Dutch policy will be expressly encouraged within the context of the EU, notably in relation to the debate concerning the revision of the existing EU policy on chemicals, and, following from there, in the context of the EU regulatory framework. It speaks for itself that the new chemicals policy at the national level should harmonise and fit in with the international policy to be adopted by the EU following the revision process.

In anticipation of the announced international policy innovation, the playing field for a national policy innovation effort is mainly in the area of enforcement and securing a commitment to more stringent measures, but there is some room in other areas, such as intensifying the present obligations under the 'duty of care', further quality requirements on the part of industry, product chain responsibility, and experimenting with new ways of approaching old problems.

Experience has taught that conceiving and developing new ideas in the area of chemicals policy is not a waste of energy. Some parts of what was originally an authentic Dutch policy have served as the blueprint for later EU policy. In the past period, there has been a very active dialogue between the Netherlands and the European Commission, member states, the European business community, and the Environmental movement, with a view to sharing ideas and exchanging views so as to arrive at a harmonised approach.

The above overview demonstrates that there is a synchronised approach to a new chemicals policy in the Netherlands and in the European Union. However, whilst the new European chemicals policy has not yet been formalised in EU directives, the Netherlands will continue to encourage its vision on

policy innovation in the EU, by actively drawing attention to the strategy described in this document, and the position of Dutch industry. Furthermore, experience gained in projects such as the 'experimental plots' (see Chapter 5), which will eventually be secured in agreements or regulations, will be shared with the EU.

5. IMPLEMENTATION OF NEW CHEMICALS POLICY

- 5.1 SOMS Implementation Programme 2001-2002
- 5.2 Letter of Intent from industry concerning a new chemicals policy
- 5.3 Implementation projects in Dutch industry – the ‘experimental plots’ –
- 5.4 ‘Product chain agreements’ and ‘implementation agreements’

5.1 SOMS Implementation Programme 2001-2002

By agency of the policy described in this document, the cabinet wishes to lend concrete shape to the ‘duty of care’ on the shortest possible term. It intends to achieve this by encouraging a commitment on the part of industry to manage ‘non-assessed chemicals’ (substances of which we have no data on possible risks or hazards), as well as taking powerful and effective measures in relation to substances with undesirable properties (e.g. persistent, bio-accumulating, toxic (PBT) substances, carcinogenic, mutagenic, reprotoxic (CMR) substances, and substances causing hormone-disruptive effects). The industry has announced, by letter dated 8 January 2001 to the Minister for Housing, Spatial Planning and the Environment, a letter of intent in which industry will formulate the activities which it plans to develop with a view to implementing the policy described in this strategic policy document.

The implementation of the new policy has a phased structure:

- In the next stage (in which the same parties that took part in the SOMS programme in preparation for this document are expected to participate) the various elements in the new policy will be developed in further detail, within the framework of a medium-short term Implementation Programme (2001-2002).
 - As part of this development, there will be a number of ‘experimental plots’ to test the air for the new chemicals policy. These ‘experimental plots’, set up by industry, can count on active support from the government. The purpose of the experimental plots is to investigate in what way the quality improvements and anchoring of product chain responsibilities can be given concrete shape, in an effective and efficient manner.
 - To make the three-tier approach concrete, criteria will be defined for the five categories of concern, and criteria will be formulated for reducing risks and hazards associated with the management of chemicals and products, as part of the policy development process.
 - The further translation of the new chemicals policy strategy (as in relation to the implementation process, monitoring and enforcing the new policy, and monitoring the quality of the environment, etc.) into concrete actions and existing activities will be further developed.
 - Finally, the information infrastructure, as referred to above, will be set up.
 - It will be looked into whether an independent body (such as the British ‘Stakeholders Forum’, set up in September 2000), made up of represen-

tatives from the raw materials industry, industrial (end) users, the government and relevant social groups, notably consumer organisations, the trade movement and environmental organisations, might play a role in the new information infrastructure. The tasks of this forum could include, for instance, the assessment of the measures taken by industry for improving chemicals management, and the auditing of documents and procedures of industry by independent experts in the areas of health, the environment, chemicals and working conditions.

- The development and implementation of the 'Strategy On Management of Substances' will be finalised with the signing of one or more 'chain responsibility and implementation agreements' which, as required, can be declared binding under certain conditions.

Below follows a provisional schedule for the actions and the objectives that are central in the implementation programme for the period 2001-2002, and which lend shape to the policy intentions described in the present policy document.

Timetable for SOMS Implementation Programme

first half of 2001

- letter of intent from industry concerning implementation of new chemicals policy
- parliamentary discussion of Strategy Memorandum on Management of Substances in the Second Chamber
- preparation of the Implementation Programme
- establishing the organisation on behalf of the Implementation Programme (stakeholders forum)
- setting up 'product chain management experimental plots' within the framework of policy innovation
- start of Implementation Programme Strategy On Management of Substances
- start of exploration of knowledge infrastructure organisation

second half of 2001

- signing of 'product chain management experimental plots' agreements on behalf of a new chemicals policy programme
- start of implementation of 'product chain management experimental plots' on behalf of a new chemicals policy programme, incorporating, if and where required, the SOMS philosophy in relevant legal and regulatory frameworks
- start with implementation of 'experimental plot knowledge infrastructure' on behalf of a new chemicals policy programme

first half of 2002

- implementation of 'product chain management experimental plots' agreements on behalf of policy innovation programme
- test run of 'knowledge infrastructure' on behalf of a new chemicals policy programme

second half of 2002

- finalisation of 'product chain management experimental plots' agreements for policy innovation
- preparation of 'product chain responsibility and implementation agreements' on behalf of the a new chemicals policy programme
- finalising process of implementing SOMS philosophy in legal and regulatory frameworks
- start of enforcement initiatives on behalf of the a new chemicals policy programme
- implementation of knowledge infrastructure on behalf of a new chemicals policy programme
- Policy Document SOMS Implementation Programme

A policy document under the title of 'Policy Document SOMS Implementation Programme' (*Nota Uitvoeringsprogramma Strategie Omgaan Met Stoffen*) is due to appear by late 2002, reporting to the Parliament on progress achieved in relation to the above implementation programme, and the implementation of the policy intentions formulated in the present strategic document. At that stage, an indication will be provided as to whether and how elements of the new chemicals policy can be anchored in national and international legislation.

5.2 Letter of Intent from industry concerning a new chemicals policy

The Dutch industrial community as a whole, with the chemical industry and several other sectors taking the lead, is prepared to assume its responsibilities under the 'duty of care'. Industry's willingness to play an active role in the process was already apparent in the intensive participation of industry during the two years that the SOMS project has been under way, and will be confirmed in the announced Letter of Intent, to be published in March 2001.

It is expected that, once the strategic policy document has been endorsed by parliament, the industrial community will take the necessary initiatives to implement the strategy, in conjunction with the government. This means that the chemical industry, or sections of the chemical industry, and several other branches of industry will accept a commitment with a view to implementing the policy intentions outlined in this document. It will be further considered to what extent agreements made in regard to policy implementation might be secured in (policy) agreements.

5.3 Implementation projects in Dutch industry – the 'experimental plots' –

One of the decisions made in relation to the SOMS programme is the concept of anchoring product chain responsibility, in the form of clear and unambiguous agreements between the government and the Dutch industry. The links that make up the product chain (e.g. suppliers and buyers) will cooperate in the process of collecting and exchanging information on risks and

hazards associated with substances, and in relation to risk assessment and implementing risk-containing measures.

In the context of the effectuation of the SOMS programme, the government believes that it might be valuable to gain prior practical experience with the implementation of the quality improvement effort that companies will be expected to undertake, and to gain a 'foretaste' of the operationalisation of the product chain responsibility concept by setting up 'experimental plots'. The experiences gained in these experimental plots will be incorporated in the various implementation modalities of the new policy. They will also be presented for consideration within the framework of EU policy, so as to acquaint other member states with the results achieved with the various implementation modalities. In addition, the introduction of the experimental plot concept will encourage involvement in industry at a more individual level.

The government has already commenced an examination of how the experimental plot concept could be developed on behalf of a specific product chain. The intention is to identify specific, representative product chains with which to conclude agreements for concrete application of the experimental plot concept. Eventually, this must result in a number of experimental plot agreements. The government expects that it will have clarity concerning the introduction of experimental plots at some time point during the first half of 2001.

At this moment, experimental plots are considered in relation to the operationalising of product chain responsibility and in the area of knowledge infrastructure. In both cases, past experiences will be incorporated. Furthermore, there are European experimental plots already in certain sectors of industry, including, for instance, the HERA project of the European detergents industry. Similarly, experimental plots could be set up to provide direction to R&D departments in relation to the development of responsible, prudent and precautionary chemicals policy. For experimental plots dealing with the product chain responsibility concept, suitable sectors of industry would be the textile and clothing manufacturing industries, rubber and plastics, paint production, and the soap industry.

5.4 'Product chain agreements' and 'implementation agreements'

One of the decisions made in relation to the SOMS programme is the concept of anchoring product chain responsibility, in the form of clear and unambiguous agreements between the government and the Dutch industry. The links that make up the product chain (e.g. suppliers and buyers) will cooperate in the process of collecting and exchanging information on risks and hazards associated with substances, and in relation to risk assessment and implementing risk-containing measures.

Within the framework of the SOMS implementation programme, efforts will be made to anchor the implementation of the new chemicals policy in the form of 'product chain agreements' and 'implementation agreements'. The industrial community has indicated that it is willing to co-operate with such agreements. Where possible, connections will be sought with existing agreements and working conditions covenants.





Enclosures

ENCLOSURE I THE NEW CHEMICALS POLICY IN A NATIONAL AND AN INTERNATIONAL PERSPECTIVE

diagnosis of present situation

(Environmental) policy pays

Since the early 1900s, many improvements have been brought about in the environment in the Netherlands, notably with the introduction of regulations under the Nuisance Act, following structural changes in such areas as potable water supply and sewer system construction. This has resulted in a lower mortality rate, and better health conditions. Over the past thirty years, the quality of our living environment has been improved by strongly reducing emissions from the (chemical) industry, in the wake of explosive industrial growth in the 1950s and 60s. Life in general, and especially in Europe, has become healthier and safer thanks to the development of a large range of products, from medications to food additives designed to preserve food longer.

The production and use of substances, along with many innovations in the area of substances, have contributed importantly to the well-being of people, increased life expectancy, and a better quality of life. Many of those substances are literally of vital importance (e.g. in relation to health, hygiene and safety), while others contribute to the durability of consumer products and goods. Also, it is important to realise that many of the substances that are around us are safely manufactured and used on a daily basis.

Incidents in relation to substances have, however, brought home the need for sound policy with regard to the assessment and use of substances, and for an industry that is committed to ensuring safe production and processing techniques, and improving processes where required.

The present range of (policy) instruments available in the Netherlands and Europe offers insufficient assurances as to the prevention of serious incidents, such as those recently seen in the Netherlands. Furthermore, the latest series of incidents in the Netherlands have placed a strain on the public's faith in safe food and safe products. It is understandable, therefore, that there are concerns in society in relation to persistent, toxic chemicals that accumulate in organic tissue, and the presence of hormone-disruptive substances in the living environment and in products and food.

In hindsight: How did we achieve environmental improvements?

The previously noted achievements in improving our environment in the Netherlands, and, in some areas in Europe, in most cases have been due to (stringent) regulations within the framework of the EU, as well as being the consequence of agreements between the Dutch government and the industrial community (including covenants). There is an admission policy for (veterinary) medications and pesticides. There are regulations for safe food production and product safety. In each case, there are rules for assessing, usually by government agency, any risks associated with a product for people and/or the

environment, and what measures must be taken to minimise those risks. In addition, a number of companies have taken measures, for instance within the framework of Responsible Care or Product Stewardship, to minimise risks and hazards for the environment and workers. With each of these incentives, risk management plays an important role.

However, there is room for some reserve. The risk instrument has proven to be inadequate, in more than one way, notably because it is

- expensive, as it requires broad and prolonged research,
- time-consuming, as it is largely dependent on scientific consensus,
- usable only with respect to activities/substances already known to be hazardous,
- incomprehensible for non-experts (e.g. ordinary citizens).

It stands to reason, therefore, that the current system has been successful primarily in solving ‘uncomplicated’ problems, but that it has failed to provide solutions for the more intricate (environmental) problems.

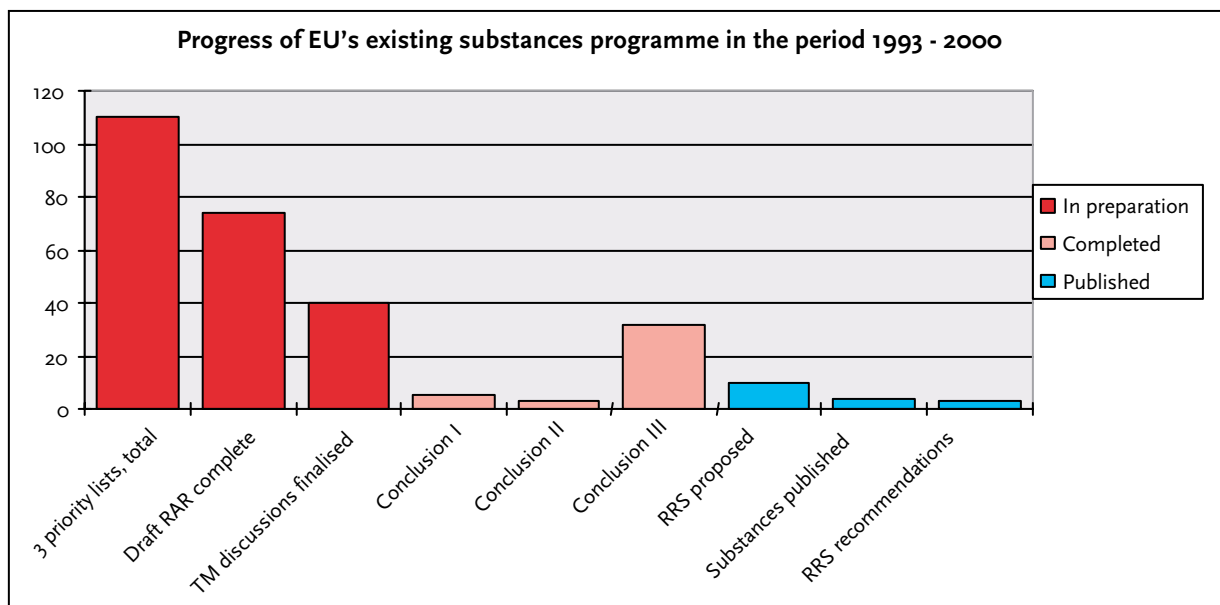
The need for innovation

National and international chemicals policies are due for an overhaul. This view is undisputed in broad circles, in industry, at government level, and in society as a whole. Many potentially hazardous substances continue to be released unrestrained in our living and working environments, or end up in (consumer) products.

In relation to many substances there is insufficient (publicly accessible) information on their properties and possible risks and hazards. Under current national and international policies, the pace at which this backlog is being caught up – and thus the timeline for responsive measures – is inadequate, and, if continued, will lead to research and assessment programmes that would require several generations to complete. On the other hand, there is a general consensus in the various forums dealing with the subject that, to achieve broad, structural improvements, a time space of one generation (20 years) is advisable.

The stagnation of the current policy for existing substances is inevitable, if we consider the effect of a continuation of the current practice of intensive risk assessment, carried out under the government’s responsibility, and with measures taken by the government accordingly. To illustrate, in the Netherlands, after fifteen years of time-devouring and costly assessment procedures, some success has transpired only in respect of the assessment of approximately 50 priority substances (Memo on Priority Substances, 2001). Internationally, the situation is hardly better: of the almost 2,500 substances produced or sold in the EU in large volumes (more than 1,000 metric tons per annum), basic information sets are available for 14% (356) only, while there are no data at all (at least not freely available) for 21% (over 500) of those substances. As concerns substances that are produced in smaller volumes, the situation is even worse. Exploration and assessment of the possible risks associated with a substantial amount of substances sold on the market – or even a selection of priority substances – given the present regime, is bound to take several generations, let alone that adequate measures can be taken.

A second key issue in the current approach is the fact that, because the emphasis has been on risk assessment, backed by government responsibility to appraise the effectiveness thereof, the industry has been more or less invited to take a passive stance. As a result, the pace at which data are being collected and risk assessments performed is determined by the modest resources available to the participating governments of EU member states. Consequently, the prospects for catching up, in the foreseeable future, on the information backlog in respect of existing substances are very concerning.



Without a reorientation on chemicals policy, society's faith in the chemical industry, and the image of this sector of industry in general, stand to suffer. Without a pro-active position of industry with regard to the safety of (consumer) products, public faith in the safety of the products will continue to decrease. If no changes are introduced at policy level, society, and industry in particular, will be unable to provide the necessary assurances that the potential risks and health hazards associated with the use of substances in each stage of their life cycle (from chemical products via (consumer) products to waste, and, in certain cases, reuse) are sufficiently controlled so as to remove, or to reduce to negligible levels, any harmful effects caused by substances on persons or the environment.

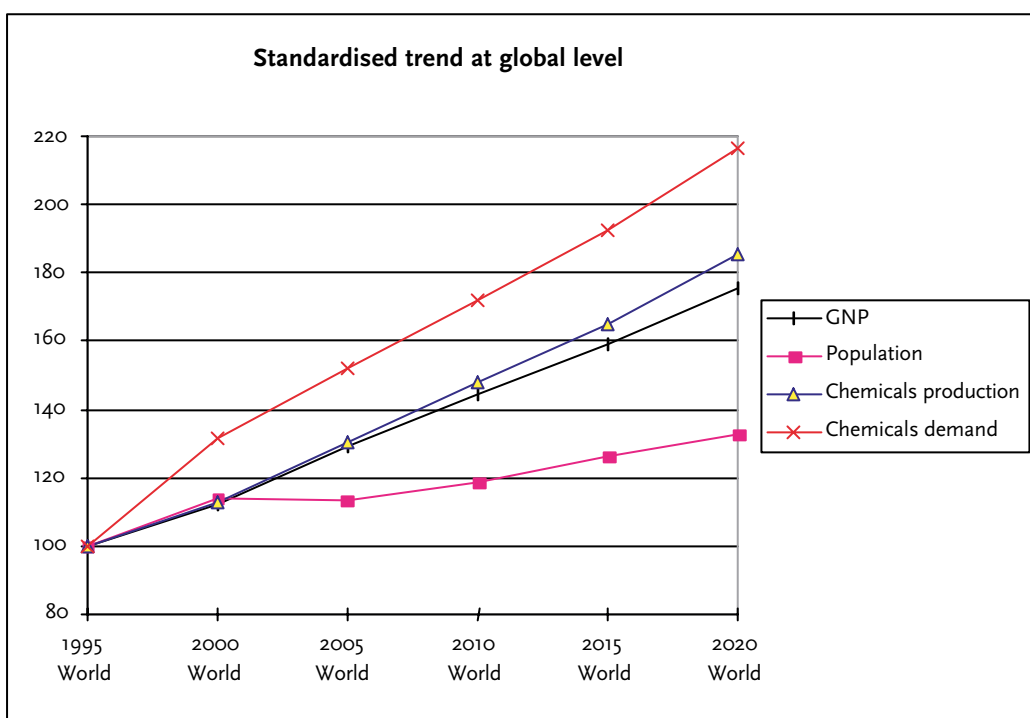
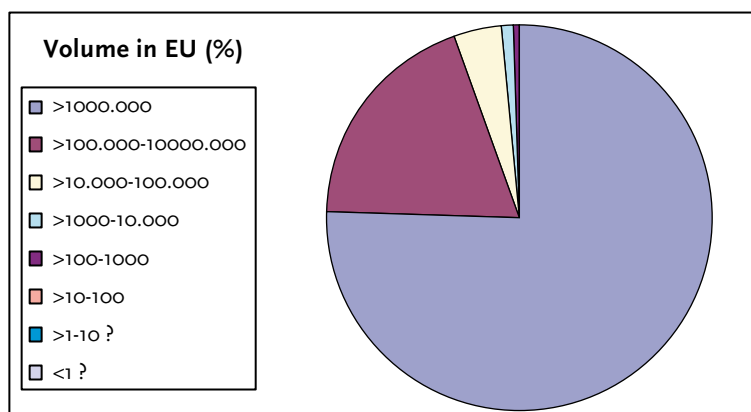
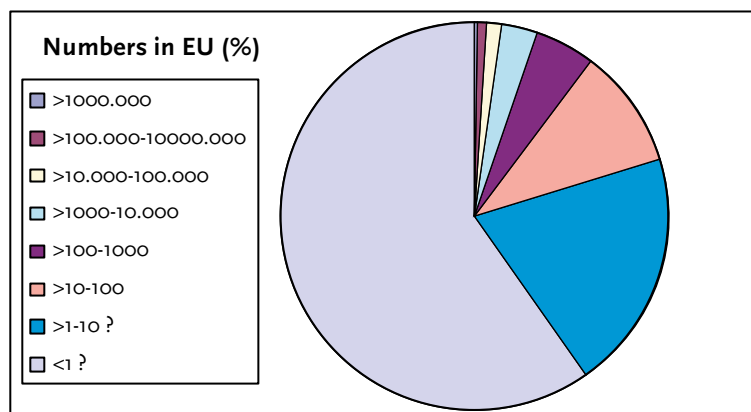
The above analysis becomes even more pungent in light of anticipated developments in the chemical industry. The chemical industry is a sector that operates with an extremely diverse range of processes and products, making it practically impossible to classify the sector under a single common denominator.

Within this diversity, the following main groups are distinguished:

- The base chemicals sector (primarily concerned with the production of basic chemicals in large quantities for further processing into chemical fertilisers, industrial chemicals, plastics, synthetic resins, elastomers, synthetic fibres and colouring agents),
- The special chemicals sector (additives and colouring agents for rubber and plastics, adhesives, ancillary chemicals, soaps and detergents),

- The sector consumer products, personal care (soaps, detergents, bleaching agents, hair care products, aromatic agents),
- The food and health chemicals sector (pharmaceuticals, agricultural chemicals, biotechnology),
- Other products sector (metals, glass, auto industry, paper, textiles, etc.).

It is estimated that a total of some 50,000 substances are produced in the EU, of which a relatively small amount are produced in significant quantities.



The current national and international policies with regard to existing substances are focused on a small group of High Production Volume Chemicals (HPVC).

The following pie charts provide an impression of the distribution in figures and volume in the EU, on the understanding that the estimations for amounts produced under 10 metric tons per annum are not based on actual data.

The charts show that the largest number of substances represent only a small share in terms of production volume, whereas the largest share in terms of production volume leads back to a small group of substances. In view of the total worldwide production output of the chemical industry and derived trends in production increases in relation to the increase of the world population and gross national income (see diagram below), the need for a more effective regulation of the admission of chemicals to world markets becomes very apparent.

Internationally, these observations have led to initiatives with regard to new policy.

Important existing instruments

The most important instruments of European regulation include:

- the Hazardous Substances Directive (67/548/EEC), providing rules for the classification and labelling of substances on the basis of fixed criteria, and for the system of notifying new substances whose introduction can only take place after a prescribed set of information is made available (basic set). The government of the receiving member state prepares a risk assessment in conformity with the principles laid down in Directive 93/67/EEC. If the risk assessment gives rise to concern, the government may propose restrictive measures which can be implemented in the EU by agency of the Prohibition Directive.
- The Existing Substances Regulation (793/93/EEC), enabling substances to be selected, on a priority basis, in respect of which the industry is required to collect additional data in order to provide the necessary basis information set, and which requires EU member states to perform risk assessments in conformity with the principles laid down in Directive 1488/94/EEC and, where applicable, propose recommendations for risk-reducing measures. Here too, recommendations are adopted within the EU by agency of the Prohibition Directive. The first candidate for this list are HPVCs (High Production Volume Chemicals), produced and sold in EU markets in volumes totalling more than 1,000 metric tons per annum over a specific period;
- The Prohibition Directive (76/769/EEC), imposing restrictions in relation to the use and/or marketing of denoted substances;
- The Preparations Directive (88/379/EEC; amended as 99/45/EEG), stipulating the rules for classifying and labelling preparations.

Setting the norm

As described in NMP₃ (1998), the maximum tolerated risk level (MTR) is a scientifically derived value, specified for a specific substance, indicating the concentration level at which there are no adverse effects to be expected or, in the case of carcinogenic substances, at which an annual mortality rate of 10^{-6} can be predicted.

In deriving the MTR value, economic considerations do not play a role. However, economic factors are considered in translation the rules into concrete objectives and targets. The target value is the value that indicates the concentration level at which the effects on man and the environment are believed to be negligible.

In respect of both the MTR value and the target value, there is obligation on industry to pursue the prescribed values (cabinet decision, Fourth Policy Document on Water Management NW4, 1999). NMP3 formulates a policy objective which proposes that, with regard to all substances, transgression of MTR values due to emission should cease to be allowed, on the shortest possible term, and preferably before the year 2000, and that, on a longer term – preferably before 2010 – target values must no longer be exceeded as a result of emissions.

MTR values and target values, as such, provide a usable yardstick for evaluating the results of environmental policy, and assessing the effectiveness of source-focused policy. Note, however, that the general principles of environmental policy, such as the concept of precaution and the stand-still principle, remain in force. As advised in NMP3, the government agencies concerned will use the target values and MTR values as a touchstone for:

- Assessing the quality of the environment;
- Formulating a source-focused policy and allocating priorities accordingly;
- Assessing the need for imposing quality standards by law;
- Setting the norm for product and pesticides policy;
- Recalibrating and formulating objectives and responsibilities for target groups;
- Recalibrating and formulating government objectives;
- Permit granting.

Perspectives for the future

New ideas in other countries

Denmark has presented its view on a new chemicals policy in two reports, i.e. “Non-Assessed Chemicals” (1996) and “A strategy for intensified efforts in the field of chemicals” (1999). The priorities of the Danish government are based largely on its concern over the lack of knowledge concerning the risks associated with substances, and the poor progress achieved with regard to the classification and labelling of substances at EU level. The Danish view reflects the following objectives:

- A fast but cohesive risk assessment procedure.
- Improving the process of generating data on behalf of the assessment of risks and hazards.
- On account of the significant gaps in the available information on individual substances, substances should be grouped in clusters on behalf of group classification.
- Substances with respect of which data are incomplete should be classified in a risk category that corresponds with the most hazardous substance represented in that group, and the classification system should be more elaborate.

- Improved registration of substances and products by introducing an information duty with regard to classified substances, including a time frame, registration of all substances, improved testing strategies, and a more intensive enforcement effort. EU regulation should be enlarged in the area of group classification, information duty for non-assessed chemicals, and should provide more options for restrictive measures.

The *United Kingdom*, in a policy statement entitled “A sustainable production and the use of chemicals” (1999), has defined a new strategy with a view to realising sustainable production and use of chemicals in the future, without causing harm to man or the environment. The key principles of its strategy include:

- Complete information on risks associated with substances must be publicly available.
- Continuation of risk-containing measures whilst ensuring that industry remains competitive.
- Phasing out substances that pose unacceptable risks.
- Stimulating industry’s programme for preparing risk assessments of substances, to be completed by 2015.
- Developing a faster procedure for identifying substances in respect of which risk-containing measures have been indicated.
- Implementing the precautionary principle.
- Setting up a “Stakeholders forum” to advise the government on selection criteria, prioritising, measures and application of the precautionary principle in relation to specific substances.

Sweden has presented its views and objectives in two reports, “New guidelines on chemicals policy” (2000) and “The future environment – the responsibility of all” (2000). The Swedish approach stands out by far-reaching ethical principles, aimed at long-term results:

- Complete data to be available on all substances by 2010,
- No CMR substances in consumer products as of 2007,
- Ban on highly persistent and bio-accumulating substances in products as of 2010,
- No other persistent and bio-accumulating substances to be used in products as of 2015,
- No risk assessments required for persistent and bio-accumulating substances to support measures, and
- Equitable regulations for new and existing substances, but more stringent criteria for the assessment of new chemicals.

Subsequent to the working paper of the European Commission on the functioning of the four EU policy instruments, the Hazardous Substances Directive 67/548/EEC, the Existing Chemicals Regulation 793/93/EEC, the Preparations Directive 88/379/EEC, and the Prohibition Directive 76/769/EEC, the EU Environment Council of June 1999 formulated a number of conclusions providing direction for a future EU policy on substances. On this occasion, the European Commission was invited to publish a policy document on the subject (White Paper) proposing an action programme.

Anchoring new policy in international frames

The chemical industry and associated industries are strongly oriented on international markets, and so is the trade in chemical products. For this reason, the Netherlands pursues a strategy in which national policy is synchronised with international policy as effectively as possible.

The policy in regard to substances, as it has taken shape within the European Union over the past thirty years, has created a high level of harmonisation of laws and regulations, primarily so as to open the door to internal markets for the (chemical) industry, and, theoretically, to provide a basis for controlling the risks associated with hazardous substances for man and the environment. This means that regulation on a national level should be no freer, nor more restrictive than the European regulatory framework, unless under very strict criteria. The setting up of 'experimental plots' in the Netherlands, in order to put new ideas to the test, identify learning points, and share experiences with the European Commission and member states, is one of the alternatives for developing innovative concepts.

The comparative success of the Dutch emission reduction policy in the area of priority substances has been largely due to agreements, laid down in covenants, with the most important target groups (emitters), by using a system of granting permits to individual companies. The approach demonstrates that it is not always necessary to wait for (nationally or internationally) harmonised regulations before taking certain measures and realise certain objectives. The experience gained in the Netherlands with the consultative model provides ample reason to expect that the concepts, developed collectively with the framework of SOMS, will contain attractive elements for all parties.

The European commission is confronted with the limitations of its mandate, which does not allow for bilateral agreements (covenants) under the EU treaty. However, if the results of a new chemicals policy process so justify, the Netherlands will apply itself to encourage application of this legal instrument in the European Union.

White Paper on EU chemicals policy

The European Commission is currently working on a new policy strategy for existing substances. The recent announcement of the Commission in relation to the precautionary principle should be seen in that light. The Commission is expected to publish a White Paper on chemicals policy in early 2001. The present policy document, which is a reflection of the Dutch philosophy on chemicals policy, provides a summary of the policy principles and intentions of the Dutch government, enclosing a Letter of Intent from industry. The complete policy document will be presented to the EC on behalf of its preparation of the White Paper, and will be actively promoted within the EU.

OSPAR.

The objectives concerning the quality of the marine environment, as agreed at the 4th Ministerial Conference on the North Sea (Esbjerg, 1995), have been further developed in OSPAR 'strategy on hazardous substances'. Further to this agreement, parties are committed to pursuing the termination of emissions from hazardous substances within the space of one generation (2020), the ultimate goal being to reduce concentrations of man-made synthetic substances in the marine environment to near-zero, and achieving low-

level concentrations of natural substances emitted to the marine environment. In light of a new chemicals policy effort, the Netherlands has contributed to the development, in 1999, of a system (DYNAMEC) for selecting and prioritising substances that are subject to the OSPAR strategy on hazardous substances. This system enables extremely environmentally hazardous substances to be selected with the aid of a set of criteria for P, B, and T. The system has, to date, enabled 12 substances/substances groups to be added to the original 15 substances/ substances groups listed in the existing work programme for priority action of OSPAR. In the coming period, it will be examined what measures are to be taken in order to meet the overall targets of OSPAR.

The Netherlands will request attention within OSPAR for incorporating the principle of industry's 'duty of care', and its consequences in terms of implementing the DYNAMEC system and required measures.

Water Framework Directive (2000/60/EC)

In October 2000, the European Water Framework Directive was determined. In addition to the 'combined approach' (approach at the source, using Best Practice techniques and taking additional measures if water quality targets are not achieved), a strategy for combating water pollution was advised.

The strategy also includes selection of priority substances and hazardous priority substances. For priority substances, the Commission is to prepare water quality objectives, and proposals for measures to reduce emissions from priority substances on a permanent basis. In relation to hazardous priority substances, the target objective must be to terminate emissions within a period of 20 years maximum, after measures have been established by the Council and the European parliament. In December 2000, the Commission is to present a proposal for the priority substances list and hazardous priority substances.

The Netherlands will promote the harmonisation of the lists of hazardous substances within OSPAR and the EU, and incorporation of the principle of industry's 'duty of care', and its consequences in terms of actions taken in order to implement the Framework Directive.

Elements to be incorporated in SOMS implementation programme

Implementation projects in Dutch industry – the 'experimental plots'

Within the framework of the operationalising of the SOMS programme, the government believes it can be a useful exercise to gain practical experience with the implementation of the quality improvements required in industry, and in regard to the implementation of product chain responsibility, by setting up a number of 'experimental plots'. The experience gained will be incorporated in the implementation modalities of the new policy, and will be presented in the EU so as to inform member states of results achieved with the implementation modalities used in the experimental plots. Furthermore, it is felt that the test garden concept might increase involvement of companies with the policy innovation process, on a more individual level.

The government has begun to examine in what ways experimental plots can be developed on behalf of a specific substances/product chain. The plan is to identify specific, representative product chains and to make agreements for

concrete application of the test garden concept. Eventually, this is to result in a number of test garden agreements. The government expects to have clarity on the introduction of the experimental plots some time in the first half of 2001.

At this moment, experimental plots are considered in relation to the operationalising of product chain responsibility and in the area of knowledge infrastructure. In both cases, past experiences will be incorporated. Similarly, experimental plots could be set up to provide direction to R&D departments in relation to the development of responsible, prudent and precautionary chemicals policy. For experimental plots dealing with the product chain responsibility concept, suitable sectors of industry the textile and clothing manufacturing industries, rubber and plastics, paint production, and the soap industry.

Example: test garden in clothing industry product chain

It has been agreed with parties in the clothing industry product chain that they will prepare a 'positive substances' list. These are substances/chemicals used in the textiles industry that are known to cause no harm, or negligible harm to man and/or the environment.

As the first step, the sector itself will prepare the criteria for selecting the substance, based, for example, on toxicity levels, decomposability, bio-accumulation, etc., in line with the general systematics presented in this policy document.

Most important, it is first examined if sufficient reliable information is available on the properties of the substances, before a positive substances/chemicals list can be prepared. After this, appropriate action is taken so as to prepare the list.

Previous experience with 'experimental plots' in the area of knowledge infrastructure

A so-called 'processing matrix' has been prepared by RIZA (Institute for Inland Water Management and Waste Water Treatment) in the past, especially for the tanker cleaning industry. Based on the known properties of a substance, an indication was provided as to the type of treatment (physical-chemical, biological) required in processing the wastewater flows. With this system, reference was made to a databank of substances properties (e.g. persistence, bio-accumulation and toxicity). In 1998/1999, RIZA decided that the processing matrix was to be further completed and managed by the companies concerned. The ATCN (Association of Tank Cleaning Companies in the Netherlands) established a foundation for this purpose. Agreements were made recently with regard to the management of that infrastructure.

- KIWA is paid to supply expertise on behalf of completion/management of substances databank.
- Budget has been submitted for four-year period.
- SENTER has indicated that it is prepared to fund the project for 50% up to a maximum of NLG 500,000 over four years.
- 20 of 70 ATCN-affiliated companies have joined the programme and provide funding to a total of NLG 100,000. In other words, the first NLG 100,000 of the max. NLG 500,000 subsidy, pledged by SENTER, is already secured .
- Companies that do not wish to join pay for consulting the databank.

How the new policy relates to national regulations

Environmental Protection Act

The strategy for responsible, prudent and precautionary chemicals management, as outlined in this policy document, requires a framework of regulatory instruments that provides sufficient support for the realisation of the new policy. This is especially relevant with respect to formalising responsibilities, stimulating self-regulation, and enabling the government to intervene in the product chain, where intervention is considered necessary. The cabinet intends to ensure that, by agency of the new policy, there are no substances used in consumer products – or, in exceptional cases, only in minimal quantities – that could give rise to concern. Conversely, the product policy adopted is to ensure that all products manufactured are safe to the extent that substances posing concern are no longer used (or only in exceptional cases, in minimal amounts) in consumer products.

This is why it is important that the policy instruments, which focus on products, should be harmonised with the objectives of the new approach to chemicals management.

Section 9 of the Environmental Protection Act (Substances and Products), which is to incorporate the substance and product-related stipulations from the various sector-specific environmental regulations (Environmentally Hazardous Substances Act, Noise Pollution Act, Air Pollution Act, and parts of section 10 on Waste Substances), will be amended to accommodate the objectives of the new policy.

As announced in NMP₃, Section 9 of the Environmental Protection Act (Substances and Products) is currently under review. This section will be extended to include connection points for an integrated product chain approach to substances and products, whereby the accumulative effect on the environment of the substance or product throughout its life cycle is considered. The precautionary principle will play an important role here, as it provides the basis for government intervention where there are reasonable grounds to suspect that a substance or product might cause adverse effects on the environment. In addition, Chapter 9 is to stimulate industry's awareness of the environmental consequences of the substances or products they market, encourage an on-going commitment to improving environmental performance, and instil a sense of responsibility for the provision of relevant information to buyers in the product chain. A possible instrument for this is the introduction of a duty of care. Environmental certification is another important instrument in the process of transferring information within the framework of a product-focused environmental policy. In this context, it could be considered to introduce a certification system to ensure effective and efficient implementation. Such a system could entail a ratification system, along with a ban on misleading certifications or hallmark symbols, to ensure that there is an accepted, uniform system of informing buyers.

An instrument that is potentially highly suitable for stimulating self-regulation is the option, as described earlier (see 4.2) of assigning binding status, under specific conditions, to agreements between companies, designed to reduce the environmental load of substances and preparations, whether or not used in a product.

WVO (Surface Water Pollution Act)

The Surface Water Pollution Act aims to protect the quality of the surface water. Under the Act, it is prohibited to discharge hazardous or pollutant substances to surface waters without a permit. Permit applicants must submit information concerning the nature and volume of raw materials, ancillary substances, intermediate products and end products that could be contained in the wastewater. In addition, information must be provided concerning the nature and composition of the wastewater. In the Implementation Order on the Pollution of National Waters, it is specified what information must be provided when filing the permit application. For non-national surface waters, similar provisions are laid down in orders issued by the water quality management authorities concerned. In the process of applicant's submission of the necessary information, two specific problems may arise. First, the necessary data on the properties of substances may be lacking, second, there is the issue of confidentiality of information. The first problem can only be solved by collecting or generating the necessary information.

The second issue requires co-operation throughout the product chain in the process of assessing substances and preparations, in conformity with the General Assessment System and procedure, as laid down by CIW (Integral Water Management Committee). The producers of substances and preparations have an important role here. The general assessment system, noted above, harmonises with the overall systematics proposed in this policy document.

Monitoring emission effects

The Surface Waters Pollution Act focuses on the emission of specific substances. Further to the substance-specific approach provided under the Act, a total effluent assessment is to be introduced for industrial discharges of complex mixtures of substances, to support the appraisal of the required decontamination efforts.

There are several methods currently in use for determining the acute ecological effects of emissions. In addition, methods are being developed for assessing the long-term, chronic effects of emissions.

The additional assessment will eventually comprise toxicity tests and tests on mutagenicity, bio-accumulation and persistence. In this way, a structured system of effects monitoring could fulfil an important function in evaluating the results of the new policy.

Product chain-oriented approach to emissions and prevention

The environmental policy aims to reduce emissions from point-concentrated and diffuse sources, with the ultimate objective of restoring sustainable water systems. Throughout the product chain, efforts must be made to find ways of reducing emissions, whereby solutions should perhaps be sought at a system level. The government (inspired by the Ministry of Transport, Public Works and Water Management), in keeping with the philosophy explained in this policy document, is planning, on short notice, to gain practical experience in relation to a product chain-oriented approach to the issues described, on a project-basis, in conjunction with industry.

The new policy in relation to implementation practice

Environmental policy, and the way it is implemented, has changed importantly since NMP1. Today, the emphasis in the government's approach to protecting the environment is on the following issues:

- Implementation-focused description of environmental objectives;
- Strengthening the practicability of environmental policy, instead of implementing it;
- More important role for other parties, EU and other government agencies, besides national government; external integration and internationalisation;
- More responsibility for social actors;
- Explicit attention for policy enforceability and enforcement.

In order to be able to introduce the envisaged changes, a spectrum of instruments has been proposed and developed. The laws and regulations tend to be directing, rather than prescribing in character, creating more space for self-regulation, within a given framework. The use of financial and social instruments has been intensified. Covenants have been concluded for the implementation of environmental policy; environmental care systems provide the basis for permit criteria, and so on.

In view of the policy intentions of the government in relation to a new chemicals policy, in addition to the instruments mentioned, it will be determined to what extent instruments such as LCA (Life Cycle Analysis), ERPI (Environmentally Relevant Product Information) and Certification can be applied most effectively in relation to elements of the new policy.

Standardisation and certification

Next to the instruments noted above, Standardisation and Certification are important instruments. To ensure proper implementation and enforcement of environmental policy, standardisation can provide clarity concerning agreements and methods to be applied. Certification helps provide assurances for implementation quality. Both instruments fit into the broader perspective of striving for efficient and effective implementation strategies. Industry will be largely responsible for this. The government, in turn, is provided with a practical tool to use an existing private-enterprise system.

General Evaluation System for Substances and Preparations (GES); Integral Water Management Committee.

In May 2000, the CIWM defined a general evaluation system for the appraisal of substances and preparations, on behalf of the implementation of water emissions policy.

The *General Evaluation System* classifies the *water contamination potential* of substances and preparations, on the basis of their properties, in a number of categories. These categories provide an indication of the effort required in order to restore the effect of emissions to the water. The GES is developed for direct and indirect discharging under the Surface Water Pollution Act, and for direct and indirect discharging under the Environmental protection Act. The GES is in line with European regulation concerning the classifica-

tion, packaging and labelling of substances and preparations. In addition to the system itself, a procedure has been developed for making the information on the water contamination potential of substances and preparations available to the authorities via the user.

It is, notably, the producers of substances and preparations who, on account of their expertise, are in an excellent position to use the GES for substances and preparations, and they are probably the most qualified to perform the routine as efficiently as possible. Information and/or results relating to the evaluation must be made available to the end user, via the product chain. The procedure is in line with environmental policy developments, whereby the responsibility for implementing measures is increasingly shifted towards industry. The system also enables industry to lend concrete shape to *Responsible Care* and *Product Stewardship*.

Government agencies, as well as the industrial community attach importance to proper monitoring of information provided by industry. At this moment there is no clarity yet as to which agency is to perform those checks, or how. The CIW will, however, see to it that there is an effective system of monitoring, in due course. The system for this will need to be given its place within the framework of the permit regulations under the Surface Water Pollution Act and the Environmental Protection Act. A detailed introduction plan for the system has been prepared already. An important aspect of the introduction concerns the training of staff employed by the competent authorities, after which the evaluation system is introduced to permit-requiring companies in regular workshops. Producers and suppliers are informed centrally through their branch associations.

In order to enable government agencies and industry to properly prepare for the use of the system, a transition period will apply. It is assumed by the relevant authorities that, as of 01-08-2002, all permit applications will be processed in conformity with the new system. This deadline coincides with the date on which the European Preparations Directive must have been implemented in Dutch legislation.

Monitoring and enforcing chemicals policy implementation

The present enforcement activities continue to be focused on compliance with current national and international rules. During the implementation phase of the chemicals management strategy, and the anchoring of essential elements thereof in the regulatory system, the policy of monitoring and enforcing will gradually become stricter, in order to ensure proper implementation.

Public accountability of industry in relation to chemicals policy

In the treaty of Rio de Janeiro (UNEP, 1992) and the Convention of Aarhus (UN-ECE, 1998), agreements have been made concerning participation and information on behalf of citizens and interested parties. It will be examined to what extent these agreements have set certain conditions in relation to the implementation of the present policy intentions in regard to chemicals management. If, on behalf of first-line monitoring, more intensive use is to be made of the existing private-enterprise structures, which, through standardisation and certification, will be brought in line with applicable requirements, the emphasis in government enforcement will shift towards second-line monitoring.

Monitoring environmental quality

Intermediate targets for water quality management

Recently, in autumn 2000, the cabinet formulated its intermediate targets for water management. In order to gain a better picture of the condition of the surface water, supplementing the current standards, an additional water quality parameter is to be fixed, ultimately as per 2006, in the form of an MTR value (Maximum Tolerated Risk) and a target value. This additional norm concerns a total parameter for the ecological state of the water (bio-assay). The parameter will ensure that measurements performed include the effects of the tens of thousands of substances in respect of which no individual criteria have been defined yet, and, in respect of which, due to the large diversity of substances, no individual monitoring is possible.

Monitoring

Environmental quality standards have been derived from individual substances (MTRs and target values), on the basis of which the quality of the environment can be tested and the effectiveness of source-oriented policy evaluated. By chemically monitoring substances in the water, the concentration levels of specific substances in the water or sediment can be set off against the environmental quality norm, thus enabling the quality of the environment to be checked on a regular basis.

However, there are substances whose existence, structure or possible risks are unknown. In such cases biological testing systems, which examine the total effect of substances on organisms (bio-assays), can be used to supplement the data obtained by chemical monitoring systems. The advantage here is that possible damage caused by (possibly unknown) substances is immediately exposed in the relevant organisms. These biologic test systems can serve to determine the condition of the quality of the environment, environmental quality trends, the presence of toxic environmental loading, and they can track the source responsible for the contamination.

Within the framework of SOMS, a range of application areas qualify for monitoring. The government, in taking its responsibilities in the area of monitoring and enforcing, might use chemical and biological monitoring in order to arrive at a systematic policy of detection, monitoring and checking. This approach would fit in with the intention to use bio-assays in the near future as a regular monitoring instrument for checking the quality of the national waters, in addition to chemical monitoring. The CIW will develop guidelines for a measuring system, and water managers will eventually report routinely to CIW on the results of the bio-assays. In addition, work is in progress on the implementation of bio-assays on behalf of an effluent appraisal system, and in support of the policy in relation to the spreading of dredge spoil in water.

Returning to the place of biological and chemical monitoring in relation to the SOMS project and the objectives of SOMS, the government is of the opinion that effect appraisal (bio-assays) could have a proper function in relation to the monitoring of effluent at point-concentrated sources, at contamination sources and at end of pipe points. The organisation and adequate performance of the bio-assays and regular reporting on results would be primarily the responsibility of industry.

ENCLOSURE 2 WORKING ON A NEW CHEMICALS POLICY WITH INPUT FROM NON- GOVERNMENTAL ORGANISATIONS: STRATEGY ON MANAGEMENT OF SUBSTANCES (SOMS) PROGRAMME; 1999-2000

In NMP-3 (February 1998), it was announced that the cabinet, in the current planning period, would develop a new approach to chemicals policy. *In February 1999, a 'draft version of a new chemicals policy' was prepared and discussed with the relevant social actors (non-governmental organisations, industrial umbrella organisations, local government). It was agreed then that the policy innovation process would be as open as possible. The social actors expressed their commitment to playing an active role in the process. After approval was given for implementation of the programme by the Minister for Housing, Spatial planning and the Environment, a three-man group dubbed the 'troika', made up of representatives from the industrial community, the environmental movement and the government, began work in March 1999, on the basis of a draft programme, to lend concrete shape to the first phase of the programme, resulting in the SOMS Workplan (August 1999).*

After the workplan was approved by the parties concerned, a number of discussion groups were set up in the period *September 1999 – December 1999* (SOMS part projects 1-9) to work on phase 1 of SOMS (shaping a vision on a new approach to chemicals policy and exploring implementable actions for the period 2001-2004, resulting in actual innovation). The results of this phase served as the basic principles for a more in-depth, joint effort in four groups (SOMS 11-14) to examine, more closely, the policy options explored in the previous phase (phase 2 SOMS, *January 2000 - August 2000*).

The results of phase 1 and 2, in terms of policy options, were processed in the form of a decision document, and published on the Internet. On the basis of the decision document (published in *September 2000*) each party that participated in the SOMS programme wrote a position document (September-October 2000).

In late *November 2000*, the collective results of the SOMS programme over the period February 1999 – October 2000 were recorded on a CD-ROM and published on the Internet.

Based on this information, the present policy document (*Strategy Memorandum on Management of Substances, March 2001*) was prepared. In addition, initiatives were taken in industry to prepare a Letter of Intent in *March 2001*. With this end product of SOMS, the footings are provided for the construction of a chemicals policy programme. Further development and implementation of agreements concluded and agreements following from the European policy innovation process will take place in the period March 2001 – December 2002.

The present strategic policy document, like the decision document noted above, will be presented to the European Commission for the benefit of the current policy innovation process.

The above-mentioned CD-ROM, containing complete information on the SOMS programme generated in the period leading up to the publication of the present policy document (1999-2000), is available on the Internet.

