



Federal Council for Sustainable Development

(FRDO-CFDD)

Advice on the European Commission's "White Paper on the Strategy for a future Chemicals Policy" (COM (2001) 88 final)

- Requested by the Minister for Consumer interests, Health and Environment, Mrs Magda Aelvoet, in a letter of 4 April 2001
- Prepared by the scientific research working group
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1. Summary of this advice

The Council finds that the process initiated by the Commission is very positive. It constitutes a clear signal to industry as well as to social actors and consumers. The



White Paper has been the subject of fruitful and very interesting discussions within the FRDO-CFDD, although not enough time was available to prepare a more detailed advice. The FRDO-CFDD fully supports the general objectives of the White Paper.

- The Council recognises that a political process is at issue. This process must therefore possess democratic legitimacy. This will require transparency in discussions and participation by actors representative of society.
- Procedures and guidelines for risk assessment must be clear and uniform. The system's effectiveness depends to a great extent on the clarity of its provisions. Concepts must be clear and operational with a view to avoiding differences in interpretation. Each party has an interest in seeing these concepts defined correctly so that all those involved can have confidence in the system to be established.
- The introduction of the legislative framework must be speeded up to allow for rapid implementation of the ambitious programme the Commission has established.
- The resources necessary for the implementation of the White Paper's strategy must be provided. For example, the degree of expertise involved in risk assessment should be increased globally on the part of all actors, whether public or private. Particular emphasis should be placed on the public research institutes that will be responsible for verifying the relevance of data provided by industry. This expertise must be improved in terms of both research capacities (human resources) and infrastructures (material resources). Any delay in this area could compromise the credibility of the system.
- As has frequently been emphasised, research efforts must be coordinated at Belgian, European and international level. Scientific knowledge and expertise should be valorised. Here again, human and material investment is needed. Centralised databases must be created. They will be constructed on the basis of equivalent protocols, defined clearly at European or international level.

The main points of disagreement are as follows:

- The basis for risk management. Some believe that risk management should be based on risk analysis. Others maintain that hazard identification is preferable in some cases.
- The substitution principle. Some members of the Council feel that application of the substitution principle should be compulsory, not only as concerns substances, but also other techniques. Others are of the opinion that this principle is only one option in risk management and should be applied only when no other measure provides the necessary guarantees.
- All members agree on the need for a high degree of transparency, but positions differ concerning the content of the information that may be made accessible to the public to enable it to make informed choices without compromising conditions for fair competition.

In conclusion, the FRDO-CFDD takes the view that the process in which the White Paper constitutes one step is particularly important for the implementation of a strategy contributing to sustainable development. This is why:

- The FRDO-CFDD calls for rapid progress towards a directly applicable draft European **regulation** before the end of the Belgian presidency. Working groups on technical themes may be organised with a view to drafting effective legislation that may be applied in an optimal manner by companies.
- The FRDO-CFDD further calls for existing Belgian scientific knowledge and expertise to be valorised at European and international level via the provision of the necessary resources within Belgium. Belgium must assume its responsibilities in



this area and support initiatives relative to risk management, such as the "High Production Volume", in a proactive manner.

- Belgian authorities must promote consultation and initiatives like the White Paper that contribute to sustainable development, as well as coordination among various initiatives. In particular, a link should be established with the European Commission's Green Paper on integrated product policy.

2. Context of this advice

- [1] The public's growing concern about chemicals circulating within the internal market led to discussions at the informal Council of Environment Ministers at Chester in April 1998.
- [2] On 18 November 1998, the European Commission adopted a report setting out the results of an assessment of the functioning of the four main legal instruments of European Union policy on chemicals:
- Directive 67/548/EEC on classification, packaging and labelling of hazardous substances.
 - Directives 88/379/EEC and 99/45/EEC on classification, packaging and labelling of hazardous preparations.
 - Regulation (EEC) 793/93 on the assessment and monitoring of risks posed by existing substances.
 - Directive 76/769/EEC concerning restrictions on marketing and use of certain hazardous substances and preparations.
- [3] At Chester, the Commission also proposed including a reflection meeting bringing together all the concerned parties (member states, industry, consumers, NGOs, scientists, European institutions) in this assessment exercise.
- [4] Based on the results of these activities, the Council adopted, in June 1999, a series of conclusions for a future strategy on chemicals in the European Union, which finally led to the Commission's White Paper, the final version of which was unveiled on 28 February 2001.

3. General considerations

- [5] The Council welcomed the importance placed by the European Commission on actors' participation in the debate.
- [6] The European Commission's White Paper constitutes a useful basis for defining a strategy with a view to developing a policy on chemicals and is worthy of full attention. A considerable number of documents that could contribute to the development of a strategy in regards to this product are available. The Council would like to draw attention to the relationships that could be established in particular with the European Commission's Green Paper on integrated product policy (IPP).
- [7] Certain concepts used in the White Paper must be made clear and operational to avoid ambiguity. Expressions such as "substances of very high concern", "negligible risk" and "acceptable risk", for example, are explained only very vaguely in the White Paper and must be clarified. The Council is aware that the difficulty of defining these concepts is related to the tensions observed as concerns choices between certain socio-economic concerns on the one hand and health and environmental concerns on the other. What importance is assigned to socio-economic costs in comparison to the damage that may be caused to the environment and public health? What does "negligible" or "acceptable" risk signify compared to individual or national economic benefits?



Some criteria are given a partial definition in the "technical guidance document" the Community uses for risk analysis. A scientific basis is necessary in this context.

4. Remarks on certain key elements in the White Paper's strategy for future chemicals policy

As indicated above, the White Paper is a crucial document for future developments at Community level in relation to chemicals.

However, this European Commission White Paper, which at this point is only a reflection document, gives rise to debate on many points.

[8] In the present advice, the Council will limit its remarks to a certain number of issues that it considers to be of primary importance:

- The scope of the system: the REACH system -- establishment of priorities, quantities produced and registration of substances, deadlines to be met by industry -- authorisation of substances of very high concern, imports;
- Principles and objectives: substitution principle, precautionary principle, innovation;
- Hazard identification and management of risks linked to chemicals;
- Quality control and credibility of data on chemicals, as well as international cooperation;
- Transparency
- Communication of risk
- Resources necessary for the system to function correctly
- The various target groups and their respective roles
- Belgium's role during the Belgian presidency of the European Union

4.1. Scope of the system

4.1.1. Reabsorption of the burden of the past

[9] In the current system, the data required for chemicals is different for substances that were already on the market before 1981 (existing substances) and substances introduced after 1981 (new substances). The amount of data required for substances already on the market in 1981 is very small. The EINECS, the European Inventory of Existing Commercial Chemical Substances, is a static list of 100,106 "existing substances" put on the market between 1 January 1971 and 18 September 1981.

Producers and importers of "new substances" must provide basic data (notification) before introducing a substance onto the market. These substances appear on the European List of Notified Chemical Substances (ELINCS). Currently, about 2,700 substances are registered. However, these new substances are mainly produced in quantities of 100 tonnes or less, and the share of new substances on the market does not exceed 1% of the total volume of chemicals.



While existing substances, numbering 100,106, thus constitute the majority of chemicals on the market, data on these substances is relatively scarce and in any case inadequate for a satisfactory assessment of risks of exposure to these substances for the environment, workers or consumers. The new REACH system proposed in the White Paper aims at correcting this problem by introducing a strategy to reabsorb this burden inherited from the past.

- [10] Existing substances deserve their designation as the "burden of the past" given the scarcity of information available from the authorities on these substances. Current legislation does not provide for systematic collection of data on the hazards and risks of existing substances. With Regulation 793/93/EEC, the authorities attempted to introduce systematic collection of data on the risks and hazards of existing substances; based on this data, at present, 140 substances are considered priorities for risk analysis. Industry has cooperated increasingly actively in the provision of data on these substances. So far, barely a dozen substances have been completely analysed by the authorities in terms of the hazards and risks they present. This is due partly to a cumbersome procedure for risk analysis and a lack of resources on the part of the authorities.
- [11] To obtain a high degree of protection of human health and the environment, in a new system, industry must take responsibility for identifying hazards and analysing the risks posed by existing substances within a reasonable time. The time allowed for this is an important issue. To achieve the objectives of this strategy in a satisfactory manner, a detailed process of establishment of priorities, based in part on the number of types of risk data to be developed, preliminary risk analysis during the registration phase and targeted risk analysis during the assessment phase, must be conducted. Initiatives in this area have already been taken: the chemical industry has launched the "ICCA-High Production Volume Initiative" to assess the risks posed by some 1,000 substances produced in the amount of more than 1,000 tonnes a year; Eurométaux is conducting a voluntary analysis of risks associated with copper and lead. The implementation of an analysis of initial risks is moreover part of the voluntary "Product Stewardship" initiative, in which each user of a chemical substance is responsible for safety throughout the life cycle of this substance.

4.1.2. The REACH system: relationship between production volume and risk

The system proposed by the Commission is known as REACH, which stands for Registration, Evaluation and Authorisation of CHemicals. This system will apply to both new substances (those put on the market after 1981) and existing substances (substances put on the market before 1981).

4.1.2.1. Establishing priorities

- [12] When establishing a type of priority list for addressing the burden of the past, the Commission has chosen the volume produced as the essential parameter for the establishment of priorities for evaluation, with risk in second place. The advantages of establishing priorities are as follows:
- Reduction of costs of dossiers to be submitted;
 - Reduction of animal testing;
 - Stimulation of innovation ;
 - Short-term effectiveness.



4.1.2.2. Quantities produced and registration and evaluation of substances

The REACH system provides for different deadlines for registration of data. Substances whose production volume per enterprise is greater than 1,000 tonnes must be registered by the end of 2005 at the latest; more than 100 tonnes, by the end of 2008 at the latest, and more than one tonne, by 2012 at the latest. Evaluation by the authorities also depends on production volume. This evaluation serves to determine which additional tests should be conducted for volumes greater than 100 tonnes: for a volume of more than 1,000 tonnes, the results of level 2 tests must be furnished by 2010 at the latest; for a volume greater than 100 tonnes, the results of level 2 tests must be provided by 2010 at the latest; for a volume above 100 tonnes, data from the level 1 test must be provided by 2012 at the latest.

[13] The following chart summarises the main gaps in the data required by the REACH system based on production volume:

Annual production by enterprise	Gaps identified by the FRDO-CFDD	Solution proposed by the FRDO-CFDD
Greater than 100 tonnes (= current system for new substances)	Ambiguities: tests used, deadlines for evaluation by the authorities of industry proposals, role of actors involved	Clarify these points
Less than 100 tonnes (= current system for new substances)	Lack of data on chronic effects	
Between 1 and 10 tonnes (= new system)	Data dependent on content of registration dossier. Risk of limited information. Less data than under current system.	
Less than 1 tonne	No data, despite significant amounts produced by enterprises	Some members of the Council ¹ believe that each enterprise should declare its production volume to the central agency; others ² do not support this approach

There are gaps or ambiguities in the areas of:

- **Registration: (1)** The threshold for delivery of results of tests will be raised for new substances (one tonne in the new system being proposed, instead of 10 kilos in the current system established after 1981). Consequently, the system proposed by the Commission provides for more thorough knowledge of 30,000 out of an estimated 100,000, but leaves 70,000 without data for the authorities. **(2)** No data on the chronic effects of substances produced in quantities below 100

¹ One of the two chair and vice-chairs, the four representatives of non-governmental organisations for environmental protection, the three representatives of non-governmental organisations for development cooperation, the two representatives of non-governmental consumer protection organisations, the five representatives of workers' organisations, three of the five representatives of the scientific world.

² Three of the four representatives of employers' organisations.



tonnes/year/producer. **(3)** Lack of data on substances produced in quantities below 1 tonne/year/producer but whose total production volume at European level is considerable (particularly worrisome in the case of chemicals classified as carcinogens, mutagens or toxic to reproduction (CMRs), persistent, bio-accumulative and toxic chemicals (PBTs) and endocrine-disrupting chemicals (EDCs). To have an idea of the overall quantity of a substance being produced or imported, producers and importers should communicate the volume of these substances they produce or import within the short term.

- **Evaluation:** Testing procedures for volumes greater than 100 tonnes (industry must apparently formulate a proposal for these tests). In particular, the type of tests to be used, the deadlines for evaluation by the authorities of tests proposed by industry and the role of actors concerned (in this case, industry and the authorities) should be specified.
- **Authorisation:** The start of the procedure and deadlines for granting of authorisation. The first stage in the implementation of the authorisation procedure consists of identifying the substances covered by the authorisation. Once this is done, a specific date by which all applications without authorisation are prohibited will be determined. In contrast to the procedures for registration and evaluation, absolutely no deadline has been set here. The White Paper is also vague concerning the point when the authorisation process may begin (immediately after registration? Or not until after evaluation?). As soon as registration and evaluation data (including QSAR) indicate that a substance has properties that are cause for concern, the authorisation process should begin. Deadlines must also be set for the authorisation process (and may depend on the production volume and whether the substance in question is of concern);

With this system, the White Paper proposed by the Commission leaves several areas of uncertainty. This raises two questions, concerning improved evaluation of quantities of substances produced and the long-term effectiveness of the REACH system.

4.1.2.3. Deadlines to be met by industry

[14] The deadlines referred to in the White Paper are ambitious. Indeed, time must be allowed for drafting and implementation of new legislation. This means that rapid implementation of the legislation is very important. Moreover, the time necessary for industry to comply with new regulatory requirements will depend on various factors: the type of data to be furnished for registration, presentation format and the authority to whom the application is submitted (a central agency for the European Union has yet to be established).

For the registration of substances produced in quantities of between 1 and 10 tonnes/year, a comprehensive safety data sheet should suffice and the workload generated should be manageable considering the number of products in question. According to Fedichem, the preparation of a "base set" for substances produced in amounts of between 10 to 100 tonnes a year will take one to two years; between 100 and 1,000 tonnes, about two to three years; more than 1,000 tonnes, about four years.

Some 2,400 substances are produced at the rate of more than 1,000 tonnes a year, and 7,000 substances are produced in the amount of 10 to 1,000 tonnes a year. If additional data is required, the time necessary will be longer and costs will be higher.

Industry already has a great deal of information about substances produced in large quantities, such as substances covered by industry's voluntary HPV/ICCA programme for the development of risk data on 1,000 substances (>1,000 tonnes/year) by 2004. Data on substances produced in smaller quantities is less plentiful and the workload will therefore be heavier, particularly since few laboratories in Europe are authorised to



conduct all the necessary tests. At this stage, it is very difficult to draw up realistic timetables taking the various factors mentioned into account.

4.1.2.4. Authorisation for substances of very high concern

[15] The White Paper indicates that "For substances of very high concern, authorities will have to give a specific permission before such a substance can be used for a particular purpose, marketed as such or as a component of a product. The scope will be clearly defined and strict deadlines will be set for both industry and authorities" (p. 18). Issuance of authorisation will require the authorities to grant specific authorisation before the substance may be used for specific purposes for which it has been demonstrated that the risk is negligible. This measure applies only to substances that are carcinogenic, mutagenic or teratogenic (CMRs, categories 1 and 2*) or that have been classified as persistent organic pollutants (POPs). According to some members of the Council, the following substances should also be included:

- Persistent and/or bioaccumulative substances (PBs) that do not fall into the category of persistent organic pollutants (POPs). PB substances are worthy of particular attention, as they remain present in the environment and the body for long periods. According to the precautionary principle, it should not be possible for such substances to make their way into the environment, even if little or nothing is known about their potential toxicity. According to the White Paper, a more detailed study is necessary to develop criteria for specifications concerning PBs and VPVBs³ (very persistent, very bioaccumulative substances). Such criteria have, however, already been established (for example, as part of the OSPAR DYNEMC process, proposals by the Netherlands, Sweden, etc.).
- Category 3 CMRs⁴.
- Endocrine disrupting chemicals (EDC). The White Paper states that most endocrine disrupting chemicals also have other effects and consequently will already appear on CMR lists. To prevent certain endocrine disrupters from being overlooked nonetheless, they must be viewed as substances for which a more rigorous approach is necessary.
- Sensitising and allergenic substances.

4.1.3. Imports

[16] The White Paper's prescriptions concern substances marketed as such or as constituents of preparations. Substances marketed or used as constituents of products other than preparations (such as toys or textiles) are not covered. The White Paper further indicates that this should not pose a problem, as most substances in such products would fall within the scope of application of the system: they are marketed as such or as

³ In the specific case of metals, appropriate PBT criteria that take metals' specific characteristics into account should be used.

⁴ Category 1 carcinogenic substances: these are substances known to be carcinogenic in humans. Sufficient proof of a causal relationship between exposure in humans and the development of a cancer exists. Category 2 carcinogens are substances that must be considered carcinogenic in humans. A strong probability that human exposure to a category 2 substance can lead to the development of a cancer has been sufficiently demonstrated, in most cases based on appropriate tests on animals over long periods, and on the basis of other relevant information. A category 3 carcinogen is a substance that gives rise to concern due to its potentially carcinogenic characteristics, but the effects of which cannot be determined due to lack of information. Indices based on appropriate tests on animals exist, but are not sufficient justification for the inclusion of these substances in category 2. Similar definitions apply for the corresponding categories of mutagenic substances and substances that can have harmful effects on reproduction.



constituents of a preparation before being incorporated into products. There is nonetheless a problem if the entire production process takes place outside the European Union. The White Paper recognises this problem, but does not commit itself to a solution. It does propose to establish a working group to study the problem in greater detail. However, to avoid distorting competition, it is necessary for imported products (and not only preparations) to be subjected to the same conditions as European products. Substances whose use is prohibited in Europe must also be banned from imported products, which raises the problem of monitoring of and compliance with international obligations.

4.2. Principles and objectives: substitution principle, precautionary principle, innovation

The object of the new strategy concerning chemicals is to ensure a high degree of protection of the environment and public health. The White Paper cites various objectives:

- Protecting human health and the environment.
- Preserving and strengthening the competitiveness of industry in the European Union.
- Preventing fragmentation of the internal market.
- Increasing transparency.
- Integrating measures with efforts at international level (OECD, United Nations).
- Promoting non-animal experimentation.
- Compliance with the European Union's international obligations within the WTO framework.

The Council supports these objectives and emphasises that a balance must exist between the various following principles and objectives:

- The objective of safety in relation to substances must be ensured both for the safety of workers and consumers and for environmental protection;
- Acceptance or rejection of risk must be the result of a democratic process requiring access to information and a guarantee of the quality of this information⁵ ;
- Data on substances must be reliable, useful and verifiable;
- The competitiveness of European industry (and not only the chemical industry) must be preserved.

4.2.1. Principle of substitution and innovation

[17] The principle of substitution is cited in the White Paper: "Another important objective is to encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available". How precisely this concept is to be made operational remains very vague, however. The White Paper refers to "extending responsibility" to downstream users and "better public information", which should help to create a strong demand for substitute products.

⁵ The Council refers to its advice on the European Commission's Communication on recourse to the precautionary principle (COM(2000) 1), in which the FRDO-CFDD's viewpoint on the democratic process is described in more detail.



- [18] Some members of the Council⁶ assert that effective application of the principle of substitution should lead, where a less harmful alternative is available for a particular application, to the obligation to use this alternative. Moreover, alternatives should not be limited to less harmful substances, but could also include the use of different techniques. The burden of proof as concerns non-use of this alternative for one reason or another falls immediately and in principle on industry, which must demonstrate which uses are necessary.

The principle of substitution has already been taken into account in Directive 98/8/EC concerning the marketing of biocides. It is already present and being applied in various Northern European countries.

These members of the Council call for more explicit consideration of the principle of substitution in the new regulation concerning chemical substances. This principle may be made operational in a scientific manner with the adoption of "comparative assessments", which is intended to facilitate the choice of the least harmful alternative (including alternative techniques) for a particular application.

Where no alternative is available for a specific application of a hazardous substance (CMR categories 1 to 3, PBTs, EDCs), authorisation may be granted only for a specific period of time. Users are thereby strongly encouraged to seek alternatives and innovation is effectively stimulated.

- [19] Other members of the Council⁷ feel that substitution cannot be the only risk control measure and is appropriate only when no other measure can provide the guarantees necessary for a high level of protection of the environment and public health.

One of the objectives of the White Paper consists of protection of the internal market and improvement of competitiveness via measures to stimulate innovation. The European chemical industry can continue to exist only if it meets consumers' and customers' ever higher expectations for the products it provides.

This market-oriented approach may not, however, be implemented at the expense of the environment. Companies are constantly seeking new and better products that are more effective and meet customers' increasingly high demands as concerns health and the environment. From this standpoint, the substitution principle is applied on a daily basis in the development of chemical products.

These members of the Council consider a ban on substances based on their intrinsic hazardous properties (as presented by the authorisation system) is indefensible from a scientific and socio-economic point of view (see danger/risk). Each time a substance or application is banned, a market is lost. A new prohibition must be based on an analysis of risks that supports this ban and takes the socio-economic factors cited above into consideration.

- [20] Companies' competitiveness depends on their capacity for innovation. This innovation is necessary to meet demand from increasingly demanding customers. Although the White Paper refers to improved competitiveness for industry as one of its objectives and also proposes several measures to this end (such as a reduction in the amount of data required for new substances produced in the amount of 1 to 10 tonnes/year/producer),

⁶ One of the two chair and vice-chairs, the four representatives of non-governmental organisations for environmental protection, the three representatives of non-governmental organisations for development cooperation, the two representatives of non-governmental consumer protection organisations, the five representatives of workers' organisations, two of the five representatives of the scientific world.

⁷ The four representatives of employers' organisations.



some provisions will have a negative effect on the capacity for innovation and competitiveness of enterprises:

- The preparation of data by European industry, which operates within a global economy, will result in a distortion of competition;
- The system of authorisation applied to substances used in synthesis of other chemicals will result in relocation of production sites.

4.2.2. Precautionary principle

The precautionary principle applies in the absence of scientific certainty and where there is a risk of serious and/or irreversible damage. This principle thus applies for all substances concerning which there is a great deal of uncertainty. Its implementation requires broad involvement by all social actors and a transparent process of decision-making. The Council refers to its advice on the European Commission's Communication on recourse to the precautionary principle (COM(2000) 1).

4.3. Hazard identification and risk management

[21] Regulation 793/93 was intended to provide a structure for the evaluation of chemical substances. Many substances are classified as hazardous on the basis of their intrinsic physico-chemical, toxicological and ecotoxicological properties (hazard assessment, HA). During a complete risk analysis (RA), in addition to the implementation of hazard identification (HI), exposure to a substance (as concerns workers, consumers and the environment) is also examined as a consequence of its scope of application.

The members of the Council have divergent views as concerns the basis for risk management.

[22] According to some members of the FRDO-CFDD⁸, management of chemical substances must always be oriented towards risk analysis. In other words, risk management must be based on an analysis of risks. Hazard identification, potentially combined with the initial evaluation of potential exposure, must define priorities satisfactorily to provide content for the White Paper's ambitious timetable. This means that the chemicals that present the greatest potential risk must also be the first to be subjected to a risk analysis. Relevant criteria for selection of priority substances must be developed within an international context.

Management of chemicals must be oriented on the basis of risk analysis; hazard identification combined with initial evaluation of exposure, and in particular identification of priority substances, is assigned a very important role in the White Paper. Risk management must begin with hazard identification and be based on the principle of creation of an optimal "win-win" situation oriented as much towards a high level of protection of the environment and public health as towards a cost/benefit analysis. To this end, all risk management options must be left open. Where necessary, the precautionary principle may be invoked.

[23] Other members of the FRDO-CFDD⁹ object to an approach they claim is oriented exclusively according to risk analysis and believe that use of certain substances should

⁸ The four representatives of employers' organisations

⁹ The two chairman and vice-chairmen, the four representatives of non-governmental organisations for environmental protection, the three representatives of non-governmental organisations for development cooperation, the two representatives of non-governmental consumer protection organisations, the five representatives of workers' organisations, four of the five representatives of the scientific world.



be allowed on the basis of a hazard assessment (HA). A risk analysis (RA) never gives an accurate picture, as many elements are not taken into consideration, including:

- Effects on humans and the environment of exposure to a combination of chemicals (synergetic effect);
- The cumulative effect of continuous exposure to persistent and bioaccumulative substances;
- Differences in behaviour of chemicals in different environments;
- etc.

Risk management based on the RA assumes that flows of substances within the economy are completely manageable, which is not the case in practice. The phases of use and disposal are the most difficult to control.

These members of the FRDO-CFDD note that this produces a situation of systematic uncertainty (see the FRDO-CFDD's advice on the precautionary principle)¹⁰. This leads the risk analysis systematically to underestimate the real chances of exposure.

These members consequently have decided that as concerns hazardous substances (CMR categories 1 to 3, persistent substances, bio-accumulative substances, endocrine disrupters), appropriate action must certainly be taken quickly, even if the only information available about these substances relates to their intrinsic qualities. Where safer alternatives exist, production and use of such hazardous substances is indefensible from the standpoint of public health and the environment and is in contradiction with the principle of prevention.

4.4. Quality control, credibility, international cooperation

4.4.1. Quality control and credibility of data

- [24] Industry is responsible for providing data about the dangers of, exposure to and uses of a substance. It is essential that data furnished by industry be of high quality in the interests of efficient application of legislation.
- [25] The White Paper allows in particular for exemption from tests under certain circumstances, including within the framework of certain exposure scenarios. Industry must also furnish these scenarios as it bears the burden of proof.
- [26] To ensure the credibility of the data provided, it must be systematically examined at European level (peer review) by a panel of experts from the authority in question. The evaluation process outlined in the White Paper takes account of this measure, although it applies only to substances produced in larger quantities (upwards of 100 tonnes).

4.4.2. International cooperation

- [27] International cooperation is crucial, and several bodies are working at international level in the area of hazard identification, risk analysis and classification (IFCS, OECD, UNEP, etc.)

¹⁰ Advice on the Commission's Communication on the precautionary principle (COM(2000) 1). Systemic indeterminacy refers to the fact that the development of certain complex systems, such as the climate or ecosystems, cannot always be predicted satisfactorily using scientific methods, not because of insufficient knowledge, but because of their very nature.



Alongside the exchange of information with a view to ensuring efficiency, recognition of various data at international level is very important (for example, the "global harmonised classification system" developed at OECD level and initiatives taken within the UNEP within the Rio + 10 framework) and must gradually be established. Obviously, to achieve this level of efficiency, methods of constitution of data must preferably be determined and/or accepted by independent international bodies.

- [28] The OECD, the US-EPA, Canada and the ICCA all have programmes under way for evaluating the dangers of chemical substances. The European Commission's White Paper will also involve collection of data on the hazards of a whole series of substances. Optimal distribution of resources is necessary to avoid duplication of effort in collection of data on hazards. Use of animals in the various tests will thus be minimised.

As the White Paper indicates, methods must be developed to simplify risk analysis as described in Regulation 793/93/EC. The OECD, CEFIC-AISE and Canada (Alliance for Chemical Awareness) have developed or are developing various procedures for simplifying preliminary, initial, targeted or comprehensive risk analysis. Their work can contribute to provisions for consistent risk analysis in new legislation on new substances.

4.5. Transparency

- [29] Transparency is one of the political objectives of the strategy proposed by the White Paper: "Consumers need access to information on chemicals to enable them to make informed decisions about the substances that they use and enterprises need to understand the regulatory process".

4.5.1. Industry

- [30] Enterprises need transparent guidelines. Simple and clear rules for conducting risk evaluation procedures must be established.

4.5.2. The general public

- [31] A high degree of transparency towards the public is necessary. Everyone has the right to information about the chemicals to which they are exposed. This right is recognised in the White Paper. By way of action in this area, the White Paper provides for all actors ("stakeholders"), including the general public, to have access to "non-confidential information" in the central database system. However, strong emphasis is also placed on the fact that commercially sensitive information "will be suitably protected". Nowhere does the White Paper indicate the criteria for designating information as "confidential" and "commercially sensitive".
- [32] Some members of the Council¹¹ assert that the argument of "confidentiality of data" could lead to incomplete provision of information to all parties, which complicates interpretation. Thus, for example, it is impossible to conduct epidemiological analyses of harmful effects without detailed information on the aspects of substances that make it possible to evaluate exposure, such as the quantities of substances put on the market and/or used. Confidential processing of data must therefore be the exception and not the general rule, and must be clearly justified. Clear criteria must be defined for handling information as confidential or commercially sensitive. A databank must be available to the public (for example, on the Internet) and must contain information about quantities produced,

¹¹ One of the chairman and vice-chairmen, the four representatives of non-governmental organisations for environmental protection, the three representatives of non-governmental organisations for development cooperation, the two representatives of non-governmental consumer protection organisations, two of the five representatives of workers' organisations, three of the five representatives of the scientific world.



quantities put onto the European market and characteristics of chemical substances (including safety data sheets).

According to the White Paper, once the public has more information about the chemicals to which it is exposed, it can make informed choices and avoid products containing hazardous chemicals. The public can make choices only if it is also informed about the substances contained in the products it buys (not only preparations, but also products for home use). Such information must be indicated on the product, or in any case must be easily available (for example, on the Internet). In this context, a link should also be established with the European Commission's Green Paper on integrated product policy.

- [33] However, other members of the Council¹² hold that confidential company information, such as quantities produced, product composition or use of a particular substance may not be made public. Publication of such data contradicts rules of fair competition and provides no added value as concerns safety of use of chemical substances.

4.6. Communication of risk

- [34] Obviously, the consumer/user must be provided with all the information necessary for completely safe use of the product, in particular via clear labelling giving information on the risks associated with the product. Use of safety phrases and instructions for use and the introduction by the OECD of global harmonisation of classification systems are all useful instruments in this respect.

4.7. Resources necessary for correct functioning of the system

- [35] The strategy for future chemicals policy will obviously create work for industry, but also for the authorities, in terms of the independent assessment of data provided by industry. Adequate resources will be necessary if these ambitious goals are to be met. The polluter pays principle must be upheld here. This is why authorities' independence and the competitiveness of industry must be preserved.

According to the White Paper, only 8,000 euros will be invested in testing each of the 20,000 substances (compared to 85,000 for a base set or 250,000 or 325,000 respectively for level 1 and 2 tests). The costs taken into account in the White Paper may appear to be underestimated in certain respects. According to estimates by Fedichem (based on the costs incurred by the current system of notification of new substances):

- Preparation of a "base set" for substances produced in the amount of 10 to 100 tonnes/year will cost approximately 5 to 10 million Belgian francs per substance, or between 123,946 and 247,893 euros.
- Preparation of a "level 1" set for a substance produced in the amount of 100 to 1,000 tonnes/year will cost approximately 20 million Belgian francs or about 495,787 euros.
- Preparation of a "level 2" set for a substance produced in the amount of more than 1,000 tonnes/year will cost approximately 50 to 100 million Belgian francs or between 1,239,467 and 2,478,935 euros.

For the system to function correctly, additional resources are therefore necessary, at European as well as member state level.

- [36] The methodology of risk analysis is not always clear, hence the additional difficulty created by the introduction of deadlines, particularly since too few experts are capable of conducting a risk analysis. Industry needs clear guidelines and comprehensible rules to

¹² The four representatives of employers' organisations.



carry out risk evaluation procedures successfully. Improvements to the methodology must therefore necessarily be accompanied by:

- An expert training programme;
- Resources (both human and material) sufficient for the implementation of political decisions;
- The establishment of guidelines defining common procedures at European Union level; these guidelines would facilitate an evaluation of the relevance and quality of experimental protocols and data.

4.8. The various target groups and their respective roles

[37] Industry is ready to assume its responsibilities as concerns the identification of hazards as well as risk analysis. It is responsible for providing data on the hazards of, exposure to and use of substances.

[38] Evaluation of the data furnished is the task of the authority, which must be responsible for quality control of the data provided for hazard assessment and risk management. On the basis of the data provided, the authority may impose measures for the management of specific risks.

[39] The authority outlines policy on protection of public health and the environment. It also takes positions on industry proposals for appropriate management of risks. Effective communication between the authority and industry will be essential to the assessment of progress in the implementation of chemicals policy.

[40] NGOs must be able to monitor the proceedings from a critical standpoint and comment on them in relation to field of activity (environment, public health, consumer protection, etc.).

Authorities, industry, NGOs and trade unions have an important role to play in informing the public.

4.8. Belgium's role during the Belgian presidency of the European Union

[41] The FRDO-CFDD maintains that the White Paper constitutes a crucial step in the process leading to the implementation of a strategy on chemicals that complies with the principles of sustainable development and contributes to its realisation. The present advice is intended as the FRDO-CFDD's contribution to this process in future discussions at European level.

[42] From this perspective, the Belgian presidency of the European Union offers a unique opportunity. This is why the FRDO-CFDD expects Belgium to put the process that has been initiated on the agenda for the presidency and provide the resources necessary for its implementation. In particular:

- The FRDO-CFDD calls for rapid progress towards a draft European regulation, which would be directly applicable, before the end of the Belgian presidency. Working groups on technical themes may be organised with a view to the drafting of effective legislation that companies can implement in an optimal manner.
- The FRDO-CFDD appeals for the valorisation of existing Belgian scientific knowledge and expertise at European and international level via the provision of necessary resources within Belgium. Belgium must assume its responsibilities in



this area and demonstrate proactive support for initiatives related to risk management, such as the High Production Volume initiative¹³.

- The Belgian authorities must promote consultation and initiatives that contribute, like the White Paper, to sustainable development, and coordination among these various initiatives. A link with the European Commission's Green Paper on integrated product policy should also be established.

¹³ Fedichem proposes to prepare three dossiers concerning data on the risks and hazards presented by the following substances: KOH, Na₂CO₃, NaHCO₃. These dossiers could be submitted to the OECD.



4. Glossary

Burden of the Past: The 30,000 'existing' chemicals estimated to be on the EU market, for which little or no information is available, in particular about their long-term effects on human health or the environment.

CEFIC-AISE: European Chemical Industry Council - International Association for Soap, Detergent and Maintenance Products.

Competent Authorities: A national authority or authorities designated by each Member State to implement legislation.

CMR chemicals: Chemicals classified as carcinogenic, mutagenic or toxic to reproduction under Directive 67/548/EEC (see 'legislation').

ELINCS: European List of Notified Chemical Substances. ELINCS currently contains some 2,700 substances and is an ever expanding list, following notification to Competent Authorities of the placing of a 'new' substance on the market.

EINECS: European Inventory of Existing Commercial Chemical Substances deemed to be on the EU market between 1 January 1971 and 18 September 1981. It is a closed list of 100,106 'existing' chemicals governed by Regulation 793/93/EEC (see 'legislation').

Hazard assessment: Hazard identification and establishment of dose-response relationship for observed adverse effects in the specified (eco)toxicological endpoints.

HPV chemicals: High Production Volume chemicals. Chemicals placed on the EU market in volumes exceeding 1,000 tonnes per year per manufacturer or importer.

ICCA: International Council of Chemical Associations.

IFCS: Intergovernmental Forum on Chemical Safety.

New substances: See White Paper glossary.

OECD: Organisation for Economic Co-operation and Development.

OSPAR: Oslo - Paris Convention for the Protection of the Marine Environment of the Northeast Atlantic.

OSPAR DYNAMEC: OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances.

PBT chemicals: Persistent, bio-accumulative and toxic chemicals.

POPs: Persistent Organic Pollutants.

QSAR: Quantitative Structure Activity Relationship. Models used to predict the properties of chemicals from the molecular structure.

Risk Assessment: See White Paper glossary.

Risk characterisation: Estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance.

Sustainable Development: Enshrined in Articles 2, 6 and 174 of the Treaty, it was defined by the World Commission on Environment and Development (the Brundtland Commission) as development that 'meets the needs of the present generation without compromising the ability of future generations to meet their own needs'. This objective includes the economic, social and ecological aspects of development as set out in the Final Document of the 19th Extra Session of the UN General Assembly, which was held on 23-27 June 1997. These three aspects are mutually dependent, and in order to achieve sustainable development they must be integrated and taken into account in a balanced manner. These notions are at the core of the Fifth EU Environment Action Program 'Towards Sustainability' and the Cardiff Strategy on Integration.

Targeted risk assessment: A less extensive, more specifically focused evaluation (because of a specific concern) than a comprehensive risk assessment.

UNEP: United Nations Environment Programme.

US EPA: United States Environmental Protection Agency.

VPVB chemicals: Very persistent and very bioaccumulative chemicals.

WTO: World Trade Organisation.



5. Annexes

5.1. Number of members present and represented with voting rights at the General Assembly of 22 May 2001

- 2 of 4 chairman and vice-chairman
- 4 of 6 representatives of non-governmental environmental protection organisations
- 3 of 6 representatives of non-governmental development cooperation organisations
- 2 of 2 representatives of non-governmental consumer protection organisations
- 5 of 6 representatives of workers' organisations
- 4 of 6 representatives of employers' organisations
- 2 of 2 representatives of energy producers
- 5 of 6 representatives of the scientific world (*)

Total: 27 of the 38 member with voting rights (*)

(*) one representative of the scientific world has yet to be appointed

5.2. Meetings for the preparation of this advice

The scientific research working group met on 30 March and 18 and 23 April, as well as 7, 9, 10 and 16 May 2001 to prepare this advice.

5.3. Participants in preparation of the advice

Members of the Council with voting rights or their representatives

- Prof. Luc HENS (VUB) – Chairman
- Mr Jean-Pierre JACOBS (Groupement de la Sidérurgie)
- Mrs Esmeralda BORGIO (Bond Beter Leefmilieu, BBL)
- Prof. Jacques KUMMER (Université libre de Bruxelles, ULB)
- Mr Dimitri PEVENAGE (Fedichem)
- Mrs Edilma QUINTANA (Conseil National de la Coopération au Développement, CNCD)
- Mr Patrick VAN den BOSSCHE (AGORIA)
- Mr Martin BESIEUX (Greenpeace)
- Mr Fons BEYERS (Boerenbond)

Other participants

- Mrs Jeanine FERREIRA (Federal environment administration)

Secretariat staff

- Mr Jan DE SMEDT, Permanent Secretary
- Mr Marc DEPOORTERE, Scientific Advisor
- Mr Karim GHARBI, Scientific Advisor