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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals
(REACH), establishing a European Chemicals Agency and amending Directive
1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}**

Original: EN

(presented by the Commission)

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EXPLANATORY MEMORANDUM

BACKGROUND TO THE PROPOSAL

Reasons for and objectives of the proposal

In February 2001 the Commission issued a White Paper on a 'Strategy for a future Chemicals Policy' (ref.: COM(2001) 88 Final) based on a review of the existing EU system for regulating the safe use of chemicals. The Commission concluded that reform of the current legislation was necessary in order to meet the following objectives:

- protection of human health and the environment
- maintenance and enhancement of the competitiveness of the EU chemical industry
- prevention of the fragmentation of the internal market
- increased transparency
- integration with international efforts
- promotion of non-animal testing
- conformity with EU international obligations under the WTO.

General background

There are a number of factors that place the chemicals industry at the heart of the Community's sustainable development strategy. It plays a very important economic role, supplying materials to manufacturing industry, as well as stimulating innovation and supplying products needed to sustain and improve the quality of life. The chemicals industry is also a major contributor to economic development and Europe's balance of payments surplus. Maintaining a competitive and innovative chemicals industry in Europe is therefore a major goal.

At the social level, improving the health and safety of workers and the general public is a key political objective of the Community chemicals policy. Maintaining high levels of employment is also a key objective.

In relation to the environment, the avoidance of chemical contamination of air, water, soil and buildings, as well as preventing damage to biodiversity are also major goals. Improved control of persistent, bioaccumulative and toxic substances is of particular importance in this respect.

The need to advance these objectives has been endorsed at the highest political levels. The European Council in Brussels on 20/21 March 2003 , on the one hand, stressed that competitiveness "must once again be placed centre stage" and that increased business investment in research and development (R & D) and innovation must be promoted. On the other hand, the Council emphasised the need to curb environmental pressures and preserve natural resources within the framework of the comprehensive sustainable development strategy launched at Gothenburg and to promote sustainable development on a global scale,

including a follow up to the goals agreed in Johannesburg in relation, *inter alia*, to sound management of chemicals.

Current chemicals legislation

The present system for general industrial chemicals distinguishes between "existing substances" i.e. all chemicals declared to be on the market in September 1981, and "new substances" i.e. those placed on the market since that date.

There are some 3,000 new substances. Directive 67/548 requires new substances to be tested and assessed for possible risks to human health and the environment before they are marketed in volumes starting at 10 kg. For higher volumes more in-depth testing, focussing on long-term and chronic effects, has to be provided.

In contrast, existing substances amount to more than 99% of the total volume of all substances on the market, and are not subject to the same testing requirements. The number of existing substances reported in 1981 was 100,106, the current number of existing substances marketed in volumes starting at 1 tonne is estimated at 30,000. Some 140 of these substances have been identified as priority substances and are subject to comprehensive risk assessment carried out by Member State authorities under Regulation 793/93.

There is a general lack of publicly available knowledge about the properties and uses of existing substances. The risk assessment process is slow and resource-intensive and does not allow the system to work efficiently and effectively. The allocation of responsibilities is inappropriate because the public authorities are responsible for the assessment instead of the enterprises that produce, import or use the substances. Furthermore, current legislation requires only the manufacturers and importers of substances to provide information, but does not impose similar obligations on downstream users (industrial users and formulators). Thus, information on uses of substances is difficult to obtain and information about the exposure arising from downstream uses is generally scarce. Decisions on further testing of substances can only be taken via a lengthy committee procedure and can only be requested from industry after authorities have proven that a substance may present a serious risk. Without test results, however, it is almost impossible to provide such proof. Final risk assessments have therefore only been completed for a small number of substances.

Under Directive 76/769, restricting the marketing and use of certain dangerous substances and preparations, the Commission has committed itself to carry out risk assessments and adequate analyses of the costs and the benefits prior to any proposal or adoption of a regulatory measure affecting the chemical industry. Indications of unacceptable risk (typically arising from notifications of restrictions at national level) are the subject of reports, which are peer-reviewed by the Scientific Committee on Toxicology, Ecotoxicology and Environment (CSTEE) of the Commission.

Current liability regimes are insufficient to remedy the problems identified in the Commission's review. Liability is usually based on the principle that those who cause damage should pay compensation for that damage. However, in order to be held liable, it is generally required that a causal connection be proven between the cause and the resulting damage. This is often virtually impossible for injured parties if cause and effect occur far apart in time and if adequate test data on the effects of substances are not available. Even if a causal connection can be established, compensation payments awarded by courts of EU Member States are generally not as high as, for example, in the US, and hence have a limited deterrent effect.

Coherence with other policies

Chemicals policy interfaces with a wide range of other policy sectors. In preparing its proposal, the Commission has been careful to avoid duplication of the provisions of other legislation, while not creating loopholes and ensuring that necessary information is made available to other sectors.

RESULTS OF PUBLIC CONSULTATIONS AND IMPACT ASSESSMENTS

Public consultations

Following publication of the White Paper, there was a wide measure of consensus on the need for reform. Both the Council of Ministers and the Parliament clearly favoured development of more effective mechanisms and procedures which would place a greater onus on industry to make available information on the hazards, risks, and risk reduction measures for chemicals currently in use, and which would create greater confidence that dangerous substances were being used safely. Industry welcomed the new policy orientation towards enterprises themselves taking greater responsibility for the safety of their chemicals. At the same time they were concerned about the impact on competitiveness. Environmental non governmental organisations (NGOs) and consumer organisations were strongly supportive of the need for change.

Internet consultation

In May 2003, the Commission decided to launch an Internet consultation to consider the workability of the draft legislation, including the technical requirements, without calling into question the scope and objectives of the system proposed. The consultation took place between 15 May and 10 July 2003. Respondents were able to submit their responses in several ways: through an online questionnaire, or via e-mail, fax and ordinary letter using a standardised template or free text. All responses were published on the Internet; names were withheld for respondents who wished to remain anonymous.

More than 6,000 distinct contributions were received. 42% of these were sent by industry – firms or associations. 142 NGOs, including trade unions, responded.

From the Member States, five governments (A, IRL, F, NL, UK) sent comments, as well as a number of public authorities (A, B, D, DK, FIN, GR, I, NL, S, UK). Public authorities from three Accession countries (LAT, LIT, PL) gave their input as well as authorities and governments from third countries (Australia, Canada, Chile, China, Israel, Japan, Malaysia, Mexico, Norway, Singapore, Switzerland, Thailand, USA). The international organisations Asia-Pacific Economic Cooperation (APEC) and Organisation for Economic Co-operation and Development (OECD) sent comments.

Approximately half of the contributions came from individuals. Many raised issues in relation to animal testing, others voiced fears of job-losses or demanded increased protection of the environment and human health and better information for consumers. In addition, two petitions were submitted, supported by 34,000 individuals and organisations.

Main concerns and how they were addressed

Scope of the system: The inclusion of polymers and of substances in articles in the scheme was criticised by EU industry and foreign trade partners as excessive and difficult to

implement. The requirement for all manufacturers, importers and downstream users to undertake chemical safety assessments was also criticised as going beyond the White Paper proposals.

- Polymers have been exempted from registration and evaluation, but may still be subject to authorisation and restriction. This may be amended by the Commission when sound scientific criteria have been developed for defining which polymers might be registered.
- Substances in articles have been addressed in a lighter way.
- The requirement to undertake chemical safety assessments has been considerably restricted.

Legal certainty: Industry feared that the duty of care would expose them to unlimited liability claims. They also raised concerns about the lack of an appeal mechanism in the Agency.

- Duty of care has been replaced by an explanation of the principles underpinning the Regulation.
- An appeal board has been included in the Agency.

Costs: Industry, some Member States and many foreign trade partners voiced concerns about excessive costs, in particular for low volume chemicals, downstream users and small and medium sized enterprises (SMEs).

- For downstream users, the requirement to undertake chemical safety assessments and produce chemical safety reports has been strictly limited.
- Registration obligations were simplified for 1-10 tonnes (no chemical safety reports need be submitted; testing requirements were reduced).
- Polymers (see above).
- Requirements for intermediates transported under strict control were reduced.

Bureaucracy/ Powers of the Agency: Many stakeholders criticised the fact that REACH was too bureaucratic and that the distribution of tasks (Member States and Agency) was too complex. They also expressed concerns that there would not be a harmonised approach to decision-making.

- Streamlined registration: the Agency will be solely responsible.
- Evaluation: the Agency will have a greater responsibility for the smooth running of the system and monitoring decision-making. The procedures have been restructured and made clearer.
- The system of chemical safety reports has been better co-ordinated with the already existing system of safety data sheets.
- The Agency now has boosted powers with regard to decisions on data sharing, research and development (R&D) exemptions and confidentiality.

Confidentiality and right to information about chemicals: Industry, in particular downstream users, has voiced concerns that they may be forced to disclose business secrets. NGOs have argued for a high level of transparency with regards to chemical composition of articles.

- Stricter protection of confidential business information: some types of information will always be treated as confidential, such as exact tonnage, customers names etc. It will also be possible for companies to claim confidentiality if specific reasons are given and approved.
- All information that is non-confidential will be available on request (EC Regulation on public access), some items are published and freely available.

Substitution: NGOs, some branches of industry and some Member States have urged that there should be stronger provisions for substitution.

- There will be a clearer reference to substitution in the recitals and in the provisions on authorisation; companies will be encouraged to present substitution plans that will influence the authorisation decision.

Animal testing: Limiting animal testing has been one of the guiding principles in the drafting of the proposal. The Scientific Committee on Toxicology, Ecotoxicology and the Environment (CSTEE) voiced concerns that the animal tests envisaged would not yield sufficient information to avoid risks and stated that more tests would be necessary.

- Due to strong public pressure to limit animal testing, the number of tests has not been increased.
- To further reduce the need for animal testing without jeopardising human health and the environment, the use of qualitative or quantitative structure-activity relationship models, (Q)SARs, is encouraged; the text also clarifies that data sharing will be obligatory.

Impact assessments

Specific studies, notably in relation to the likely impact of the system proposed, were also initiated. The outcome of these are taken into account in preparing the impact assessment. As the proposal evolves, its impact will be monitored and followed up. Stakeholders will be involved in this exercise.

As regards the administrative aspects, the White Paper indicated that the administration of the new system would require the creation of a "central entity" which would have a key role in the management of REACH. The appropriate format of the "entity" was then considered to be the European Chemicals Bureau (ECB), part of the Joint Research Centre at Ispra, which would need to be enlarged to take on the extra tasks. Subsequent enquiry has raised serious doubts as to whether an enlarged ECB would be the most effective structure to meet the much-increased demands of the new system. The Commission therefore undertook a feasibility study. Having carefully examined all elements, the Commission concluded that the establishment of a separate Agency is essential for the effective implementation of the proposed REACH system. Accordingly, the proposals provide for a new Agency. The interests of efficiency, continuity and optimum use of available expertise would point to Ispra as the most appropriate site for the Agency.

Collection and use of expertise

Following the publication of the White Paper, the Commission consulted widely with experts. This was done in the course of conferences, stakeholder working groups and in bilateral contacts between the services and stakeholders. The eight technical working groups convened by the Commission in 2001-2002 are of particular note in this regard. The consultation of relevant experts then continued throughout the drafting process.

LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

Article 95 of the EC Treaty is the appropriate legal basis because of the need to ensure a level playing field for all economic actors in the Internal Market while at the same time ensuring a high level of protection of health and the environment.

The choice of this legal basis ensures that the requirements for substances are harmonised and that substances complying with those requirements benefit from free movement throughout the internal market. This rewards the efforts which will be required from economic actors to maintain the level of protection required by this regulation. Moreover, as substances, whether on their own or in preparations or articles are goods circulating within the internal market, it is important that they can do so under harmonised requirements.

Moreover, article 95 paragraph 3 requires a high level of protection to be sought for proposals concerning health, safety, environmental and consumer protection. The REACH Regulation falls within this remit; hence the use of this legal basis does not compromise the level of protection.

Principles of subsidiarity and proportionality

Subsidiarity

In considering the issue of subsidiarity in the sense of Article 5 of the EC Treaty, it should be taken into account that the present legislation on chemicals already provides for an extensive control over the classification, labelling, marketing and use of substances and preparations. The new Regulation will to a large degree replace several existing pieces of legislation and will extend it to areas that have hitherto not been adequately dealt with. The subsidiarity issue therefore only arises with regard to this extension.

As chemicals are being traded across borders and as many of them can lead to cross-border contamination, Member States cannot by themselves achieve the objectives of the proposal sufficiently. Community wide legislation is therefore appropriate. In this context, it should be recalled that the opinions of both the Council and the European Parliament call for a strong system of EU legislation in order to achieve a high level of protection of health and the environment while at the same time ensuring a level playing field for all economic actors in the Internal Market.

Proportionality

An important feature of the new legislation in terms of proportionality (Article 1 paragraph 3 of the proposal) is the fact that the responsibility for the safe management of the risks of chemical substances will be placed on industry. This will permit industry to apply risk

reduction measures from an early point in the life-cycle of the substance concerned and thereby to avoid negative impacts on downstream users and customers. It will also permit Member State competent authorities to direct their resources towards evaluating the quality of the information submitted by industry rather than doing risk assessments themselves.

While the new legislation is designed to cover all those chemical substances that can lead to a certain exposure of citizens or the environment, great care has been taken to ensure that the new legislation does not overreach in terms of scope, costs and administrative burden. This is why the new legislation provides for a tiered approach for certain classes of chemical substances. This is in particular the case with regard to low tonnage substances or special uses (e.g. for research and development).

At the same time this tiered approach leads to a somewhat lighter regime in terms of cost and administrative burden from which SMEs will be able to benefit, without diminishing the protection of health and the environment.

Choice of legal instrument

The use of a Regulation (that replaces some 40 existing Directives) is justified, as it will lead to the direct application of such legislation throughout the Community. In the area of technical legislation, this is a widely used technique that has already met with the support of Member States in other areas of Community competence¹. It is all the more justified in the perspective of an enlarged Community that will soon comprise 25 Member States and will certainly benefit from homogenous and directly applicable rules throughout its territory.

INTRODUCTION TO THE PROPOSAL

This proposal establishes the REACH system and creates a European Chemicals Agency. In a nutshell, REACH consists of the following elements:

- Registration requires industry to obtain relevant information on their substances and to use that data to manage them safely.
- Evaluation provides confidence that industry is meeting its obligations and prevents unnecessary testing.
- Risks associated with uses of substances with properties of very high concern will be reviewed and, if they are adequately controlled, or if the socio-economic benefits outweigh the risks and there are no suitable alternative substitute substances or technologies, then the uses will be granted an Authorisation.
- The Restrictions procedure provides a safety net to manage risks that have not been adequately addressed by another part of the Reach system.

The **Agency** will manage the technical, scientific and administrative aspects of the REACH system at Community level, aiming to ensure that the REACH system functions well and has credibility with all stakeholders.

¹ See the recent Regulation (EC) No. 178/2002 on Food Law, as well as the Commission's recent proposals for Regulations on Fertilisers (COM 2001/508), Detergents (COM 2002/485) and Drug Precursors (COM 2002/494).

1. REASONS AND OBJECTIVES

1.1. General Issues: Subject matter, scope and definitions

This sets out the scope of the REACH system and defines the terms used throughout the Regulation.

The provision on the duty of care helps to ensure that substances are used safely at all stages in their life cycle. This is achieved by requiring all those manufacturing, importing or using substances to fulfil their obligations under the REACH system and under other related legislation.

1.2. Registration

There is a general obligation to register substances manufactured or imported in quantities starting at 1 tonne. Failure to register means that the substance cannot be manufactured or imported.

The registration provisions oblige manufacturers and importers of substances to obtain, where necessary by performing new tests, knowledge on the substances they manufacture or import and to use this knowledge to ensure responsible and well-informed management of the risks which the substances may present.

Manufacturers and importers shall address the risks of any use identified to them by their downstream users. A downstream user has the right not to identify a use, in which case he would have responsibility for performing a chemical safety assessment. Conversely, the manufacturer is not obliged to supply a substance for a use that he feels he cannot support. For purposes of enforcement as well as for reasons of transparency, the registration information is to be submitted to the authorities.

The regulation exempts certain substances that are adequately regulated under other legislation or that generally present such low risks as not to require registration.

Registration requires submission of a technical dossier containing information on the substance and information on risk management measures, as well as – starting at 10 tonnes – the chemical safety report that documents the choice of these measures. The information requirement is modulated by tonnage, since this gives an indication of the potential for exposure. There are provisions on generation of information, which aim to ensure that it is of acceptable quality. To reduce costs for industry and authorities, it provides for joint submission of data.

For the registration of substances in articles, a special regime applies: in the interests of proportionality and, on the one hand, bearing in mind the millions of articles placed on the market in the EU and, on the other hand, the potential some of them may have to cause harm to human health and the environment, certain substances incorporated into articles have to be registered. This is required when the substance in question has hazardous properties and is intended to be released from the article. For substances that are released incidentally to the use of the article, a simple notification is required, on the basis of which the Agency may request a registration. The volume thresholds are as for any substance manufactured in, or imported into, the EU and apply per article type.

These requirements for certain substances in articles are necessary because of their potential impact on human health and the environment. It should be noted that no declaration of

contents in articles is required from importers. The provisions place the same duties on importers and EU manufacturers of articles.

The enforcement activities of the authorities in regard to these provisions is largely expected to focus on cases where there is evidence that a substance released from articles is causing adverse effects on human health or the environment. Guidance will be developed by the Agency to assist producers and importers of articles, and the competent authorities, in implementing these provisions.

Polymers are exempted from the requirement to register. The Commission may introduce certain polymers into the requirement to register following a report into the risks posed by polymers in comparison with other substances and the need, if any, of registering certain types of polymers, taking account of competitiveness and innovation on the one hand and the protection of health and the environment on the other. A limited form of registration is required for certain isolated intermediates. A distinction is made between those intermediates that do not leave the site on which they are used, and those that are transported between sites under controlled conditions. In the latter case, where more than 1,000 tonnes are transported, as the risk of exposure is potentially slightly higher, more information is required.

There are a number of common provisions for all registrations, including the procedure for the Agency to manage registrations. Given that tens of thousands of registrations are expected, a simple completeness check will be performed. If the registration is not rejected within a set deadline, then industry may begin or continue to manufacture or import the substance.

In order to facilitate the transition to the REACH system, provisions are contained that phase-in the registration requirements for substances that are already on the Community market. Finally, notifications under Directive 67/548/EEC are considered to be registrations, since such notifications provide a comparable level of information.

1.3. Data sharing and avoidance of unnecessary animal testing

A number of rules regarding data sharing are set out in order to reduce testing on vertebrate animals and to reduce costs to industry. Relevant data are to be shared, in exchange for payment. For phase-in substances a system is established to help registrants to find other registrants with whom they can share data. They are then required to share data.

1.4. Information in the supply chain

The information through the supply chain provisions ensure that all users of substances have the information they need to use them safely. This requires information to be passed both up and down the supply chain, and between all actors in that supply chain. The primary tool for information transfer is the safety data sheet, as set out in Annex Ia. The REACH regulation replaces the current Safety Data Sheets Directive (91/155/EEC).

1.5. Downstream Users

These provisions oblige downstream users to consider the safety of their uses of substances, based primarily on information from their supplier, and to take appropriate risk management measures. They also allow authorities to have an overview of the uses of a substance as it moves through the supply chain and so can, if necessary, request further information and take appropriate measures.

For an identified use, a downstream user may use the risk management measures prepared by the manufacturer or importer but he must satisfy himself that the relevant exposure scenarios are consistent with his use and that he has implemented all the relevant risk management measures. Guidelines will be developed to ensure that this process is manageable, in particular for small and medium enterprises.

If a downstream user is using a substance in a way not covered by a manufacturer's or importer's chemical safety assessment (including incorporating it into an article) or if he intends to use different risk management measures, then he must send a short report to the Agency. This enables authorities to monitor the unidentified uses and could lead them to evaluate substances having unintended uses giving rise to concern.

Downstream users are not required to submit chemical safety assessments to the authorities because the administrative burden on both industry and authorities would be disproportionate. Furthermore this would require an obligation on downstream users to resubmit all updated safety assessments.

1.6. Evaluation

There are two types of evaluation:

- Dossier evaluation which is twofold again:
 - One aim is to prevent unnecessary animal testing. Therefore the regulation requires authorities to examine proposals for testing in order to check the quality before a test is performed and to prevent the same animal test to be performed repeatedly.
 - Furthermore, the regulation gives authorities the task to check compliance of registration dossiers with the requirements of the registration title.
- Substance evaluation: provides a mechanism for an authority to require industry to obtain and submit more information in case of suspicion of a risk to human health or the environment.

To promote a consistent approach, the Agency will develop guidance on prioritisation of substances for evaluation. Member States then prepare rolling plans of the substances that they wish to evaluate. There is a procedure for resolving disagreements over which Member State should evaluate any substance.

When a draft decision is prepared by a Member State competent authority requiring further information on a substance, it must be accepted by other Member State competent authorities through a written procedure. The Agency is given responsibility for assuring the consistency of such decisions at the draft stage and takes those decisions when agreement is reached between Member States.

Evaluation may lead authorities to the conclusion that action should be taken under the restrictions or authorisation procedures in REACH, or that information should be passed to other authorities responsible for relevant legislation. The common feature of these regulatory activities is that they rely on good data. The evaluation process will ensure that such data is provided and made available to the relevant bodies by the Agency.

1.7. Authorisation

An authorisation system for uses of substances and the placing on the market of substances for such uses is established for the substances of very high concern. The substances selected for the authorisation system have hazardous properties of such high concern that it is essential to regulate them through a mechanism that ensures that the risks related to their use are assessed, weighed and then decided upon by the Community prior to actual use. This is justified because the effects of CMRs category 1 and 2 on humans are generally so serious and cannot normally be reversed so that such effects have to be prevented rather than remedied, and because PBTs/vPvBs accumulate in living organisms, so that accumulation would already have taken place and could not be reversed if regulatory action were only taken *a posteriori*. The same applies to the other substances of equivalent concern that may be made subject to authorisation on a case-by-case basis.

In line with the general REACH approach, the requirements for the applicants under the authorisation approach are risk-based, as he has to demonstrate that the risks related to the use of the substance concerned are adequately controlled or that they are outweighed by socio-economic benefits.

Thus, the authorisation provisions ensure that risks from the use of substances with properties of very high concern are either adequately controlled or authorised on socio-economic grounds, taking account of available information on alternative substances or processes, in which case the authorisations will normally be time-limited. Substances of very high concern are defined as: substances that are category 1 and 2 carcinogens or mutagens; substances that are toxic to the reproductive system of category 1 and 2; substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative; and substances such as endocrine disrupters which are demonstrated to be of equivalent concern.

The authorisation provisions require those using or making available substances with properties of very high concern to apply for an authorisation of each use within deadlines set by the Commission. Deadlines shall be set for a number of substances at a time. These are normally those that are considered to pose the greatest current risk, in accordance with the criteria identified in the text. The intent is that those selected should be those with the ‘Highest Expected Regulatory Outcome’ (HEROS).

The burden of proof is placed on the applicant to demonstrate that the risk from the use is adequately controlled or that the socio-economic benefits outweigh the risks. Downstream users may use a substance for an authorised use provided they obtain the substance from a company for whom an authorisation has been granted and that they keep within the conditions of that authorisation. Such downstream users shall have to inform the Agency of this fact. This is so that the authorities are fully aware of how and where substances of very high concern are being used.

1.8. Restrictions

The restrictions provisions enable risk reduction measures to be introduced across the Community where this is shown to be necessary. The restrictions provisions act as a safety net for the whole REACH system as well as for the Community legislation as a whole because any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions if a risk needs to be addressed.

Proposals for restrictions may consist of conditions for the manufacture, use(s) and/or placing on the market of a substance or of the prohibition of these activities if necessary. They shall

be prepared by Member States or the Commission in form of a structured Dossier. This Dossier is required to demonstrate that there is a risk to human health or the environment that needs to be addressed at Community level and to explore the options for managing that risk.

The restrictions provisions are the result of a balance of the need to ensure that action is taken where required as rapidly as possible, to provide a sound scientific basis for any restriction and to enable all interested parties to participate in the procedure.

Up to now, Directive 76/769 as amended approximated the laws governing the restrictions in the Member States.. The current restrictions are now taken over in a recast version as a starting point for the new restrictions procedure.

1.9. European Chemicals Agency

These provisions create the European Chemicals Agency (Agency) to manage the technical, scientific and administrative aspects of the REACH system, and ensuring consistency of decision making, at Community level.

The Agency manages the registration process, plays a key role in ensuring consistency of evaluation, provides criteria to guide Member States' selection of substances for evaluation and takes decisions requiring further information on substances under evaluation. It also provides opinions and recommendations in the authorisation and restriction procedures and has duties with regard to confidentiality.

In its White Paper on the strategy for a future chemicals policy, the Commission proposed to create a central entity to administer the REACH system and provide scientific and technical support. It also proposed a feasibility study on this entity. This study considered two main options for the structure of the entity: an enlarged European Chemicals Bureau (ECB) within the Commission's Joint Research Centre and an independent central agency. The study concluded that an independent central agency offered a number of advantages over an enlarged ECB.

The first advantage of the Agency is that it can use income from fees to fund staff posts whereas an enlarged ECB could not. The ECB would have to receive the fees into a dedicated line in part B of the Community budget. The other advantages are set out in the White Paper on European Governance², which notes that regulatory agencies:

- Improve the way rules are applied and enforced across the Union. The work of the Committees, the Secretariat and the Forum will meet this goal.
- Increase the visibility for the sector concerned. The existence of a separate, independent body provides a clear focus for discussions and so raises the profile of the sector.
- Have an advantage in drawing on highly technical sectoral know-how. The Agency, in particular the Committees, the Secretariat and the Forum, provide a structure to use this know-how.

² COM(2001)428 final, 25.7.2001.

- Offer cost savings to business. The Agency has a clearly defined role and so can focus on developing the most cost-effective methods and so limit the fees charged to industry.
- Allow the Commission to focus on its core tasks. The task of the Agency is the technical implementation of Reach and this is not appropriate for a Commission service.

The main advantage of an enlarged ECB would be short-term continuity. However, this alone does not outweigh the advantages of an independent Agency which will operate in the long-term. Accordingly, the Agency option was chosen.

In designing the structure of the new Agency, the Commission considered the experience with existing agencies in other fields, in particular those in related fields. It also followed the principles set out in its recent Communication³ on the operating framework for European Regulatory Agencies. The European Agency for the Evaluation of Medicinal Products (EMEA) provided the most useful model because it is the regulatory agency whose role is closest to that of the proposed chemicals Agency, in that it deals with a continuous stream of products requiring evaluation and that there are established Member States' competent authorities (CAs). The European Food Safety Authority (EFSA) model has provided some useful elements for this proposal but it differs from the proposed chemicals Agency in that a significant part of its role is to deal with specific problems as they arise and in an area where not all Member States have long-standing national authorities. A number of new elements have also been developed to address the specific nature of the chemicals sector.

The Agency will be the public face of the new REACH system and will be a key player in ensuring that the system has credibility with all stakeholders and the public.

The Agency will comprise the following elements:

- A Management Board of 15 members.
- An Executive Director, reporting to the Management Board.
- A Committee on risk assessment, a Committee on socio-economic analysis and a Member State Committee. These Committees may be asked to provide opinions under the evaluation, authorisation and restriction procedures. Each Member State may nominate a member to each Committee.
- A Forum for exchange of information on enforcement activities. This Forum implements the White Paper proposal to create a network of enforcement authorities. The tasks of the Forum are essentially a continuation of those previously undertaken by an informal network of Member States authorities. Work in this area would benefit from operating in a more formal framework. Each Member State shall nominate a member to the Forum.
- A Secretariat that will provide technical, scientific and administrative support for the Committees. It will also undertake a number of tasks without reference to the Committees. Involving the Committees would overburden them and would provide no added value.

³ COM(2002)718 final, 11.12.2002.

- A Board of Appeal that will consider any appeals against the decisions of the Agency.

Accession countries, on joining the European Union, will be represented on the Management Board, Committees and Forum on the same basis as existing Member States.

1.10. Classification and Labelling Inventory

The provisions for a classification and labelling inventory ensure that classifications (and consequent labelling) of all dangerous substances manufactured in, or imported into, the EU are available to all to ensure the smooth running of the REACH system. Industry will be required to include all its classifications on the inventory. Any divergences between classifications of the same substance should be removed over time either through co-operation between notifiers and registrants or by EU harmonisation. EU harmonised classifications will only be required for the following properties: Substances that are category 1, 2, and 3 carcinogens, mutagens or toxic to the reproductive system; or respiratory sensitisers.

1.11. Information

These provisions ensure non-confidential information on chemicals is available, for example to allow those exposed to chemicals to make decisions on the acceptability of the related risks. This is done in such a way that the interests of the public's 'right to know' is balanced with the need to keep certain information confidential.

1.12. Competent authorities

These provisions require that there are authorities in each of the Member States with the competence and resources necessary to fulfil the tasks allocated to them.

1.13. Enforcement

These provisions ensure that all Member States take a broadly common approach to enforcement of the Regulation.

1.14. Transitional and final provisions

These provisions ensure that the Regulation enters into force in a practical and effective way. The provisions ensure a smooth start-up as well as introducing the provisions of the Regulation in such a way that the current levels of protection are not reduced.

2. CONTENT OF THE REGULATION

2.1. General Issues

Article 1 – Subject matter

This sets out the purpose of this Regulation, namely to ensure the effective functioning of the common market for chemical substances, whilst ensuring that human health and the environment are not adversely affected by the manufacture or use of chemicals under reasonably foreseeable conditions. This Regulation is underpinned by the precautionary principle whose conditions of application are outlined in the Communication from the Commission on the precautionary principle (COM(2000) 1 final).

Article 2 - Scope

Radioactive substances are excluded from the scope because they are addressed by other legislation. Substances under customs supervision which are in temporary storage, in free zones or free warehouses with a view to re-exportation or in transit are not used within the meaning of REACH and so are also excluded. Non-isolated intermediates are not within the scope. REACH provides information on substances that will support the operation of worker protection and transport legislation, which operate unchanged.

Article 3 – Definitions

The essential terms in this Regulation are defined.

2.2. Registration of substances

Article 4 – Scope

This article exempts substances in applications for which other legislation requires adequate information. Substances listed in Annex II are exempted as their properties and risks are considered to be adequately well known. This follows historical precedent in existing EU legislation. Most of the categories of substance in Annex III are exempted because their risks will be addressed through the assessment of other registered substances. Registered substances which have been exported from the Community and which are subsequently re-imported (e.g. in preparations) are exempted from registration provided that the re-importer possesses the information for the management of the risks as required by the Regulation. Finally, information is required for certain intermediates. This is addressed in Chapter 4.

Article 5 – General obligation to register substances on their own or in preparations

This article lays down the basic obligation to submit a registration to the Agency as central receiving authority in the Community. The obligation is imposed for manufacturers and importers established within the Community who manufacture or import a substance in quantities starting at 1 tonne per year. Below this quantity, there is no requirement to submit information, in view of the more limited potential for exposure and the workability of the system. Creating a manufacture-based system eliminates current problems with the re-import of notified substances and assists worker protection. Monomers have to be registered as any other substance, even if they are used as intermediates, and it is clarified that the lighter rules on intermediates do not apply to them. This is necessary because the polymers resulting from their use as intermediates are not subject to registration. Moreover, this article requires the registration of certain monomers and other substances, which are not yet registered and are present in proportions of more than 2% in polymers.

Article 6 – General obligation to register substances in articles

This article places a duty on producers and importers of articles to register the substances incorporated in them if they meet the criteria for classification as dangerous, are intended to be released during normal and reasonably foreseeable conditions of use, and are present in the article type in quantities of 1 tonne or more per year. The registration requirements will follow those for the different thresholds as laid out in Article 9.

Manufacturers or importers shall also notify the Agency of certain specified information if substances contained in articles meet the criteria for classification as dangerous, are known to be released during normal and reasonably foreseeable conditions of use even though this is

not an intended function of the article in quantities that may adversely affect human health or the environment, and are present in the article type in quantities of 1 tonne or more per year. The Agency shall be able to require the producers and importers concerned to register such notified substances.

To assist enforcement authorities, including customs authorities in the implementation of this Article and to promote consistency, express provision is made for further legislation to be developed.

Article 7 – Exemption from the general obligation to register for product and process orientated research and development (PPORD)

To promote innovation, substances used for product and process orientated research and development (PPORD) are exempted. This exemption shall be for up to 5 years and apply to the quantity of substance being used for PPORD and a limited number of listed customers. Certain information has to be provided to the Agency. The Agency shall be responsible for checking the information provided as well as imposing any relevant conditions. The exemption period may be extended by the Agency for up to a further 5 years upon application as long as this can be justified by the programme of research and development. In the case of development of medicinal products, extension is possible for up to 10 years. Competent Authorities in Member States in which the manufacture, import or PPORD takes place shall be provided with all information submitted in notifying a request for a PPORD exemption. The Agency shall take into account the views of the Competent Authorities concerned when making decisions on PPORD exemptions or extensions.

There is no need for a separate explicit exemption for scientific research and development below one tonne per year because production, import and use of substances, including for such purposes, up to a volume of one tonne per year is already outside the scope of the registration obligation.

Article 8 – Substances in plant protection and biocidal products

These substances are deemed registered only in as far as they are used for biocides and plant protection products because the relevant legislation requires the submission of substantial information. Downstream users, who employ these substances as biocides or plant protection products are deemed to be making an identified use within the meaning of REACH. However, if a downstream user makes another, unidentified, use of such a substance, he shall report this use and can use the information supplied to him to prepare his chemical safety assessment.

Article 9 – Information to be submitted for general registration purposes

Information is required on the identity of the registrant, the identity of the substance, and its intrinsic properties. A chemical safety report (CSR), including details of risk management measures, is required for registrations of substances manufactured or imported in quantities starting at 10 tonnes per year by a manufacturer or importer.

Annexes IV to IX set out the requirements for generating information on the substance to be registered. Further details of these annexes are given below.

Article 10 – Joint submission of data by members of consortia

To reduce costs for industry and authorities, joint submission of data is encouraged. The reduced fee balances encouragement of joint submission with the need to ensure adequate income for the operation of the Agency.

Article 11 – Information to be submitted depending on tonnage

The information requirements are tiered, since the potential exposure increases with volume. The requirements of paragraph 2 ensure that information available to authorities is up to date and apply as soon as a higher tonnage threshold is crossed.

The information required at the different tonnages balances the costs of developing such information and the impact on industry with the benefits to human health and the environment likely to accrue from this information.

Article 133 (3) provides that the information at the 1 to 10 tonne level will be reviewed as part of the first review of the operation of this Regulation, 6 years after the establishment of the Agency. As a result of the review the Commission may through a Committee procedure modify these information requirements. It is recognised that considerable work is currently underway to develop alternative approaches to identifying the information required for registrations. For example, in vitro methods and the use of (quantitative) structure activity relationships ((Q)SARs). The development of such approaches shall also be taken into account in any proposals to modify the information requirements for 1 to 10 tonne registrations.

Article 12 – General requirements for generation of information on intrinsic properties of substances

This article lays down the basic rules for generating information, whether by testing, (Q)SARs or other means. The test methods set out in Annex X have been approved for use under current legislation and so are carried over to REACH. Other methods may be used if the registrant can justify their suitability. This is especially important in the case of data generated before the entry into force of the legislation, for example for existing substances or for substances that were already manufactured or marketed outside the Community. Any new testing is required to adhere to good laboratory practice to ensure the quality of the information and to the legislation on the protection of animals used for experimental and other scientific purposes.

The article also requires registrants wishing to refer to data already submitted to the Agency to demonstrate that they have the agreement of the owner of those data.

Article 13 – Chemical safety report and duty to apply and recommend risk reduction measures

The chemical safety report (CSR) details a chemical safety assessment (CSA). This is a risk assessment in which the registrant takes account of the risk management measures that he either implements himself for his own uses or proposes to downstream users for their uses. The uses addressed in the registrant's CSA are known as identified uses. This is not the classic model of risk assessment as understood by persons involved in chemicals' regulation today. The terms "chemical safety report" and "chemical safety assessment" are chosen to make this change clear.

In the interests of proportionality, CSRs are not required for registrations of substances manufactured or imported in quantities of less than 10 tonnes per year by a manufacturer or importer, on-site isolated intermediates, or transported isolated intermediates. Article 133 (1) empowers the Commission to review the application of the requirement to substances in those quantities 12 years after the Regulation enters into force.

A registrant's CSA shall address all uses identified to the registrant by his downstream users, unless he chooses not to supply the substance for that use. This requirement ensures that those creating or importing substances cannot shift responsibility for assessing the safe management of a substance onto downstream users, who may be ill-equipped to deal with it. It also facilitates the work of authorities.

Certain uses do not need to be addressed in the CSA as they are adequately addressed by other EU legislation.

A CSA does not need to be conducted if the concentration of the substance in a preparation is below defined concentration limits because below these concentration limits the substance is considered not to pose a significant risk to human health and the environment. A CSA only needs to consider the steps of exposure assessment and risk characterisation if the substance meets the criteria for classification as dangerous or is assessed to be a PBT or vPvB. This is because it is only in these cases that there is a significant risk to human health or the environment.

Article 14 - Polymers

In view of the potentially large number of polymer registrations and given that most of them pose a limited risk because of their nature, polymers are exempted from registration for reasons of workability, and to focus resources on substances of more concern. However the Commission is committed to considering how polymers should be addressed in REACH in the future. Before any proposal for introducing certain polymers into the requirement to register is made the Commission shall prepare a report looking at the risks of polymers in comparison with other substances and whether, considering the balance between protecting human health and the environment and ensuring competitiveness and innovation on the other, certain types of polymers should be registered.

Articles 15 and 16 – Registration of on site and transported isolated intermediates

For reasons of workability and to focus resources on substances of more concern, these articles introduce limited registration requirements for certain isolated intermediates. Non-isolated intermediates are excluded from REACH.

A distinction is made between isolated intermediates that remain on site, and those that are transported to other sites under controlled conditions. For the latter type of intermediate, where more than 1000 tonnes per manufacturer per year are transported, more data is required as the risk of exposure is potentially higher.

Article 17 – Joint submission of data by participants of consortia

See Article 10 for explanation.

Article 18 – Duties of the Agency

This article defines the processing of registrations submitted and the role of the Agency at the registration stage of REACH. Registrations will be submitted and handled electronically in order to facilitate the management of many thousands of registrations. The Agency is the central receiving authority for all registrations. It assigns to each of them a registration number and date and will perform a completeness check which, again in view of the large number of registrations to be handled, is essentially an automated process. Having the Agency perform the completeness check ensures the necessary consistency of approach at the registration stage. The Agency shall let the registrant know if the registration is incomplete and, if so, the information needed and a deadline to complete the registration. The result of the completeness check will be referred to the Member State Competent Authority in which the manufacturer or importer is established. The Agency does not explicitly accept registrations because registration is not an approval system.

Article 19 – Manufacturing and import of substances

This article prohibits the manufacture or import of substances that have not been registered in accordance with the registration provisions. It permits the manufacture or import of a substance 3 weeks after the registration date, unless the Agency indicates otherwise. If the Agency requests further information, manufacture or import of a substance is permitted 3 weeks after this further information is submitted unless the Agency indicates otherwise. The deadline is chosen to allow time for a completeness check. If a manufacturer or importer is acting as the lead in a consortium the other members of the consortium are not allowed to manufacture or import the substance until the deadlines have passed for the ‘lead’ registrant.

A longer deadline is not needed for this purpose as the completeness check is largely automated and would unnecessarily delay the manufacture or import of new substances.

Article 20 – Further duties of registrants

This article places a duty on the registrant to inform the Agency of any changes in certain elements of his registration. It ensures that the authorities receive the latest information on safety of chemicals, while not requiring updates for minor changes. The obligation to report significant changes in manufactured or imported volumes provides essential information for the development of a chemicals indicator and keeps the information in the database up-to-date. Significant new knowledge of risks of the substance is such as would lead to changes in the chemical safety assessment.

Article 21 – Specific provisions for phase-in substances

This article phases the vast majority of substances currently being manufactured or marketed into the registration system. The deadlines are chosen, bearing in mind the large number of phase-in substances, to ensure that the process is manageable for both industry and authorities. The registration process for phase-in substances starts with substances manufactured or imported in high volumes, given the high potential exposure, and substances with properties of very high concern.

Article 22 – Notified substances

Because the notification requirements under Directive 67/548/EEC are substantially similar to those for registration, this article provides that previously notified substances shall be deemed registered. Such registrations will have to be updated as for any other registration. It is

intended that the Agency will assure the transfer of the notified data to its central database. If such substances subsequently exceed the next higher tonnage threshold of Article 9, then full information will be required as for any other substance, including information not yet submitted for the lower tonnage threshold.

2.3. Data sharing and avoidance of unnecessary testing

Article 23 – Objectives and general rules

This article sets out the general principles for sharing data and ensuring that unnecessary animal testing is avoided. Paragraph 2 ensures that there are no concerns under Community competition rules. Paragraph 3 allows the Agency to make data that have been in the possession of the Agency for at least 10 years, freely available to others for the purposes of registration.

Article 24 – Duty to inquire prior to registration

This article allows potential registrants of a substance that they have not manufactured or placed on the market at the moment that the REACH system enters into force to obtain data from previous registrants of that substance. Payment for data is required within ten years of the first registration that contains the relevant data, since this is the period when an innovative registrant has most to gain from marketing his substance.

Article 25 – Sharing of existing data involving tests on vertebrate animals between registrants

Registrants are encouraged to reach agreement on data sharing directly or via an arbitration board. However, given the importance of animal protection, the Agency is empowered to make the information available to the subsequent registrant if no deal has been reached. The subsequent registrant is expected to pay an equal share of the costs incurred. If necessary the first registrant can make a claim through the national courts for such an equal share of the costs they incurred in generating the information from the subsequent registrant.

Article 26 – Duty to pre-register for phase-in substances

Registrants wishing to use the phase-in provisions in the registration chapter are required to pre-register information on their substances so as to permit sharing of data that is already available. The provision enables manufacturers and importers of substances in quantities of less than 1 tonne to voluntarily contribute to the sharing of data.

Article 27 – Substance Information Exchange Fora

This article creates a substance information exchange forum (SIEF) composed of all those who have pre-registered the same substance and imposes duties on its participants in order to avoid duplicate animal testing.

Article 28 – Communication within the SIEF prior to registration

This article sets out the steps to be taken by participants of a SIEF to fulfil their duties. Note that the provisions in paragraph 2 are presented only to clarify what actions other participants in the SIEF may take if an owner of a study refuses to provide information. The owner of the study will be in breach of his obligations and will be subject to sanctions. If the owner of a study has already submitted his registration containing the study, the Agency will make it available to other participants of the SIEF.

2.4. Information in the Supply Chain

Article 29 – Requirements for safety data sheets

This article explains that the safety data sheet (SDS) is the instrument for conveying the relevant information from manufacturer, importer or downstream user down the supply chain. SDS are the best instrument to do this because they are now well known and understood by all actors in the supply chain and to require a new instrument would increase costs for little benefit to human health and the environment. The current duties and responsibilities for SDS remain and will be extended by the requirement to convey information from any relevant chemical safety assessment.

It is recognised that to prepare a SDS for a preparation containing many registered substances could be a complicated exercise. The option is therefore open for those preparing SDS for a preparation to carry out a CSA for the preparation as a whole and for the SDS to reflect this CSA rather than the individual CSAs for all registered components of the preparation.

The 16 headings required for SDS are consistent with those agreed in the Globally Harmonised System for the Classification and Labelling of Dangerous Chemicals (GHS). If a CSA was performed, the relevant exposure scenarios examined there provide useful and adequately structured information for others in the supply chain. It is therefore foreseen that they be placed in an annex to the SDS.

Article 30 – Duty to communicate information down the supply chain for substances and preparations for which a safety data sheet is not required

Downstream users and distributors need certain information on substances even if a SDS is not required so that they can take any necessary action. For example, requesting details of the registration of the substance, ensuring that their use complies with any authorisation or restriction. This information needs to be updated in a timely manner so that any appropriate action can be taken as a result.

Article 31 – Duty to communicate information on substances and preparations up the supply chain

This Article specifies the information that must be passed up the supply chain. Information is passed up the supply chain so that identified risk reduction measures can be refined if necessary. For example, this might be exposure information, additional information on the effects of a substance, or information on how the risk reduction measures work in practice.

The system set out in the Regulation will be at its most effective if information is supplied along the length of the supply chain and in both directions.

Article 32 – Access to the safety data sheet information for workers

The information in SDS and that communicated under Article 30 when a SDS is not required shall be made available to workers and their representatives. Making SDS available to workers and their representatives is consistent with the GHS.

Article 33 – Obligation to keep information

This requires all actors in the supply chain to keep all the information generated under the Regulation and make it available as requested. This information should be kept together so

that authorities can have ready and immediate access to it so that any action to help protect human health and the environment can be taken quickly and to ensure that all relevant information is available when decisions are being taken under other parts of the system (e.g. evaluation, restrictions, authorisation).

2.5 Downstream Users

Article 34 – Downstream user chemical safety assessments and duty to apply and recommend risk reduction measures

The system for registration and in particular CSAs has been constructed in such a way that manufacturers and importers cannot pass down to downstream users responsibility for preparing CSAs if the downstream user does not wish them to do so. Downstream users are of course free to assist their suppliers in the preparation of a registration and this possibility is expressly laid down in the text. Moreover, if the downstream user wants the supplier's CSA to address their uses he should tell them in writing. This act makes the downstream user's use an identified use and must therefore be covered, as long as sufficient notice is given, in the manufacturer's or importer's CSA.

Downstream users must prepare chemical safety reports in accordance with Annex XI for uses outside the conditions described in an exposure scenario included in the SDS supplied to them. This provision enables downstream users to keep their use(s) confidential from their supplier if they should wish to do so. However, downstream users need not prepare a chemical safety report:

- if they take more thorough risk management measures than those recommended by their supplier, as in this case, there is no real added value to be gained from an obligation to prepare a chemical safety report, nor
- for non-hazardous substances, nor
- in cases where their supplier would not have had to prepare a chemical safety report.

Downstream users must apply the risk reduction measures identified in the SDS for identified uses and identified in their CSA for unidentified uses. Information on risk reduction measures identified in the SDS for identified uses or identified in the downstream user's CSA for unidentified uses must be passed on as relevant to their downstream users so that they, in turn, can apply the identified risk reduction measures or, if their use is not covered, conduct their own CSA.

Article 35 – Obligation for downstream users to report information

If his downstream use is outside the conditions described in the exposure scenario included in a SDS communicated to him, the downstream user must report the use to the Agency.

The scope of the report is limited so as to minimise the burden on industry and on authorities. It is sufficient, however, to allow authorities to decide whether to take further action under, for example, the evaluation or restrictions provisions or to take enforcement action. A report may, in some exceptional cases, contain proposals for testing. If such tests were drawn from Annexes VII or VIII the authorities would subject them to a dossier evaluation.

A downstream user may, through conducting a CSA or otherwise, conclude that the classification and labelling for a substance is different to that given to them by their supplier. This fact must be reported to the Agency.

A predefined format for reports is used to help downstream users to meet their obligations and to permit the Agency to handle efficiently the downstream user reports.

Updating of reports ensures that the Agency and hence Member States Competent Authorities are always aware of the latest relevant information on the use of a substance and so can, where necessary, take appropriate action.

Downstream users do not have to report if they are using a substance in quantities of less than 1 tonne.

Article 36 – Application of downstream user obligations

Downstream users will receive information on the safe use of their substances through safety data sheets provided by their suppliers. They should also already have performed a risk assessment for worker protection in accordance with Directive 98/24/EC. Nevertheless it is prudent to delay the application of the provisions of Article 35 to allow time for new safety information to flow down the supply chain and for downstream users to complete and update their risk or chemical safety assessments, if required. Application of the provisions of Article 36 is delayed until after a substance is registered, to avoid unnecessary reporting.

2.6. Evaluation of substances

Article 37 – Scope

Since polymers are exempted from registration, they are also exempted from evaluation. However, this exemption is also subject to the review foreseen in Article 133 (3) and may be adapted accordingly.

Article 38 – Competent Authority

This article sets out how the evaluating Member State competent authority is identified.

For dossier evaluations this shall be the competent authority of the Member State in which the manufacture takes place or the importer is established. This is because the dossiers are examined individually anyway and it avoids language and communication problems. In the case of consortia, the competent authority of the Member State in charge of the dossier of the ‘leader’ is the competent authority for evaluation.

For substance evaluations a different rule applies: Member States are required to establish evaluation rolling plans covering three years and listing the substances they intend to evaluate. This is to enable Member States to plan for and assign resources to substance evaluation. A specific allocation mechanism is foreseen for the event that more than one Member State plans to evaluate the same substance, to avoid duplication of work and encourage swift evaluation of the substance concerned. A factor taken into account when applying this mechanism is each Member State’s proportion of the total Community gross domestic product.

Article 39 – Examination of testing proposals

This article requires the evaluating authority to perform a dossier evaluation of all proposals for testing to fulfil the information requirements in Annexes VII and VIII. These annexes are chosen because they contain the tests that are the most expensive and require the greatest number of vertebrate animals to be used. It is therefore important for animal welfare reasons that the authorities are convinced that such testing is appropriate. Furthermore experience with present legislation has shown there is rarely any disagreement between industry and authorities over whether to perform the animal tests now contained in Annex V and VI.

Downstream users may make proposals for testing if their use is not an identified use and not therefore covered by the information in the safety data sheet.

If the authority agrees with a proposal, it drafts a decision requiring the test to be carried out and setting a deadline. This is so that the obligations on the registrant are clear and other authorities will know when the data will be available.

Article 40 – Compliance check of registrations

A competent authority may check that any registration it is responsible for is in compliance with the Registration requirements. If not, the competent authority may prepare a draft decision requiring the registrant to supply the missing information. Information is missing when no data was submitted or when the data submitted was insufficient.

Article 41 – Check of information submitted and follow-up to dossier evaluation

Once any additional information required under articles 39 and 40 has been submitted the competent authority shall examine the registration and additional information and draft a further decision if yet further information is required.

Once a dossier has been evaluated the competent authority may decide that further action should be taken to manage the substance in question. This may mean proposing action under Authorisation or Restrictions or by referring relevant information to the authorities responsible for other legislation.

Article 42 - Procedure and time periods for examination of testing proposals

This article sets a deadline of 120 days for completing dossier evaluations of testing proposals for non phase-in substances. This is to ensure that industry receives permission to perform any testing and so can collect all relevant information within the deadlines foreseen. It also sets deadlines for performing dossier evaluations of testing proposals for phase-in substances in order to make the operation of the system more predictable and transparent for all stakeholders.

It gives precedence to evaluations of testing proposals in view of the need to meet the deadlines set and reflecting the importance of animal protection.

Article 43 - Procedure and time periods for compliance check

A competent authority shall have a maximum of 12 months to complete a compliance check once started, including preparing a draft decision.

Article 44 – Request for further information

This article enables the responsible competent authority to draft a decision requiring further information to clarify whether a substance presents a particular risk to human health or the environment. For example, the substance may appear to be similar to another that has particular properties that have not been identified yet for the substance in question.

A competent authority shall have a maximum of 12 months to complete a substance evaluation, including preparing a draft decision.

Article 45 – Coherence with other activities

To ensure consistency of decision-making, an evaluation must take account any previous evaluation of the substance. Any decisions under evaluation requiring further information on a substance previously evaluated can only be justified if further information has become available or circumstances have changed.

Article 46 – Check of information submitted and follow-up to substance evaluation

Once any additional information required under Article 44 has been submitted the competent authority shall examine the registration(s) and additional information and draft a further decision if yet further information is required.

Once a dossier has been evaluated the competent authority may decide that further action should be taken to manage the substance in question. This may mean taking action under Authorisation or Restrictions or by referring relevant information to the authorities responsible for other legislation.

Article 47 – Further information on on site isolated intermediates

For reasons of workability, this article excludes isolated intermediates on site from dossier and substance evaluation. However, Member States may ask for additional information and take necessary action on such a substance if they can demonstrate that its use gives rise to a risk equivalent to the level of concern arising from the use of substances subject to authorisation.

Article 48 – Registrants' rights

Registrants or downstream users potentially affected by an evaluation decision shall have the right to comment on the draft decisions being prepared by a competent authority and to have those comments taken into account.

In normal circumstances a registrant shall not be responsible for producing the additional information required by evaluation if they have either stopped the manufacture or import of the substance, and informed the Agency that this is the case, or if they decide to stop manufacturing or importing the substance in light of the additional information requirements as a result of evaluation, and again have informed the Agency that this is the case. Only if there is a potential long-term risk to man or the environment and the registrant in question is responsible for contributing significantly to the exposure to that substance shall the registrant be responsible for providing the additional information. This is to avoid, in all but the most extreme cases, registrants being retrospectively liable.

Article 49 – Adoption of decisions under evaluation

This article creates a procedure for securing agreement on evaluation decisions among Member State competent authorities before such decisions are taken by the Agency, without the necessity for a time consuming and resource intensive comitology procedure in every case. In case of disagreement, the Agency's Member State Committee provides a technical forum to resolve differences, again without the need for comitology. The Executive Director of the Agency is given the right to initiate this procedure in order to ensure consistent decision-making. Any Member State can require that a decision be taken by comitology.

Article 50 – Cost sharing in case of performance of tests involving vertebrate animals without an agreement reached between registrants

In the interests of animal welfare it is essential to ensure that information is shared. The *quid pro quo* is that costs are also shared. This article ensures the sharing of costs and information when additional information is required under evaluation. An arbitration board may be used to decide on claims for remuneration. If agreement cannot be reached on cost sharing then national courts shall make a decision.

Article 51 – Obligations for Member States to report to the Agency

In the interests of ensuring that the burden is fairly shared, every Member States shall prepare a report annually on the evaluations of testing proposals conducted over the previous year.

2.7. Authorisation

Article 52 – Aim of authorisation

The aim of the authorisation system is to ensure the good functioning of the internal market and that the substances of very high concern are used either in a way where the risks are adequately controlled or are replaced by suitable alternative substances or technologies. The reasoning behind this aim is explained above, under section 1.7.

Article 53 – General provisions

This article specifies that substances included in Annex XIII can only be used and placed on the market by those companies who have been granted an authorisation and their customers, for the particular uses authorised, and in accordance with any conditions set in that authorisation, unless a specific use of that substance has been exempt from the authorisation requirement.

Substances of very high concern subject to authorisation but which are yet not on Annex XIII may continue to be used as long as they fulfil the other requirements placed on them under the Regulation and other applicable legislation.

The authorisation process shall not apply to the use of substances in preparations where the substance is not present in sufficient concentration for the preparation itself to be classified as having one of the properties that make substances on their own subject to authorisation. It shall also not apply to PBT or vPvB substances present in concentrations below 0.1%, this limit being the same as for CMR substances.

To help encourage innovation, the authorisation process shall not apply to substances being used solely for scientific research and development purposes or for product and process-orientated research and development purposes in quantities under 1 tonne.

Certain uses of substances are not subject to authorisation because their human health and environmental effects are considered to be addressed by equivalent Community legislation. It would be unreasonable to subject such uses to two systems with the cost and resources this would imply. The Commission will propose a modification of the legislation on medicinal products for human use and veterinary use respectively to address risks related to the environment. This will be part of the benefit/risk assessment which has to be positive as a prerequisite for approval of the medicinal product.

However uses in cosmetic products and in food contact materials addressed by Community legislation only consider human health impacts. Whilst these impacts do not need to be considered again, if a substance for these uses is identified as a PBT, vPvB or of equivalent concern to the environment it shall be subject to authorisation for those effects because the environmental impact has not been considered previously.

Article 54 – Substances to be included in Annex XIII

This specifies the properties of substances that make them subject to the authorisation process. Clear and objective criteria are available for the identification of substances that are category 1 and 2 carcinogens, mutagens, toxic to the reproductive system, and for some PBTs and vPvBs. However, some PBTs, vPvBs are not possible to identify through the application of the numeric criteria in the Regulation. Some substances of equivalent concern are also not possible to identify through objective criteria, although some endocrine disrupters will have already been identified through the CMR criteria. If these can be identified through other scientific or technical evidence on a case-by-case basis and are considered to be of an equivalent level of concern as regards their effects on human health or the environment to those identified through application of the objective criteria, they shall also be subject to the authorisation process. PBTs, vPvBs, and other substances considered to be of equivalent concern (e.g. some endocrine disrupters), shall be identified on a case-by-case basis following the process described in Article 56.

Persistent organic pollutants (POPs), as a sub-set of vPvBs, are subject to authorisation. However, the Stockholm Convention requires prescribed restrictions to be put in place for particular POPs. The application of prescribed restrictions for particular POPs is incompatible with the authorisation process; a company would not apply for authorisation for a use they know will not be granted. These POPs will therefore be subject to restrictions under the restrictions process to ensure that the Community meets its obligations under the Stockholm Convention and the United Nations Economic Committee for Europe (UNECE).

Article 55 – Inclusion of substances into Annex XIII

This Article specifies what information has to be included in Annex XIII when a substance is included: first of all the identity of the substance as well as its properties that make it subject to the system. As it could be expected that very few, if any, new substances having these properties would be placed on the market, most of the substances with these properties of very high concern have already been used. Therefore, transitional arrangements are necessary for those substances that are already on the market at the moment when a substance is included in the Annex, in order not to force companies to interrupt their business until an authorisation can be granted to them. The Annex therefore specifies a ‘sunset date’ and a deadline. The

‘sunset date’ is the date by which unauthorised uses shall be prohibited. This is required so that authorities and applicants can plan, knowing when a decision should be reached. The deadline is the date by which applications for continued use of the substance must be received. Again this gives certainty to applicants in planning the preparation of their application and to authorities in planning the work necessary to process an application. If applications for authorisation are received by the deadline given, the uses concerned may be continued until a decision is taken even if this is after the ‘sunset date’. This is to ensure that concerns do not have uses prohibited by default if the authorities have not taken a decision.

Certain uses may be exempted from the requirement to be authorised. Such a decision needs for example to take account of the application of other EU legislation to the use in question and whether the use is sufficiently controlled so ensuring that the risks to human health and the environment are adequately controlled. This would allow the authorisation process to concentrate on the uses of substances that are likely to pose the greatest risk rather than devoting resources to considering uses that are known to be adequately controlled and corresponds to the principle of proportionality. If as a result of the REACH system or of developing Community legislation, further uses are justified to be exempt from the authorisation requirement, such exempted uses can be added to the Annexes at a later stage in accordance with Article 130.

Whilst the authorisation process is designed to address substances of very high concern some will still be of higher concern than others. This shall address primarily substances with the ‘highest expected regulatory outcome’ (HERO) i.e. the control will have a greater impact on the protection of human health and the environment. The Agency shall prepare a draft list of priority substances for inclusion on Annex XIII so that there is a technical basis for a political decision taken by the Member States. Priority shall be given to substances with PBT or vPvB properties, wide dispersive use or high volumes. Third parties are given the opportunity to comment on the draft list. This list and the final list agreed through the regulatory procedure shall take account of the resources available for considering applications for authorisation. If the list includes too many substances and/or the deadlines are too short the system will not be able to cope. There is therefore no benefit in placing more substances on Annex XIII than can reasonably be dealt with.

Prior to being placed on Annex XIII any substance subject to authorisation may be subject to the restrictions process as there may be risks that need to be addressed at Community level in advance of any authorisation decision. However once substances are placed on Annex XIII they may not be subject to the restrictions process, addressing the risks to human health and the environment from the intrinsic properties set out in Article 54. If certain uses of these substances need not be authorised, conditions for such uses shall be added in Annex XIII when these uses are exempt from the authorisation requirement. However, substances for which all uses are prohibited, shall be banned under the general restrictions in Title VIII. An example for this are POPs. These may have been subject to authorisation but under the terms of the Stockholm Convention these may, once added to the list of POPs, need mostly be banned or otherwise restricted. This shall be carried out through the restrictions process.

Article 56 – Identification of substances referred to in Article 54 (d), (e) and (f)

This sets out the process by which PBTs, vPvBs and other substances which are considered on a case by case basis to have equivalent levels of concern as regards their effects on human health or the environment (e.g. some endocrine disrupters) shall be identified and agreed at Community level before they can be included in Annex XIII. The proposal shall be presented by a Member State in the form of a Dossier (see Annex XIV).

Article 57 - The granting of authorisations

The Commission shall be responsible for the granting or refusing of authorisations. The authorisation application and decision shall not address risks to human health and/or the environment of emissions of the substance from an installation for which a permit was granted in accordance with the IPPC Directive (Directive 96/61/EC) or from a point source governed by requirement for prior regulation under the Water Framework Directive (Directive 2000/60/EC) or arising from the use in a medical device as these emissions are adequately controlled under other Community instruments which are applied by the Member States. Therefore, this is necessary not to interfere with such other competences and to avoid differences between the decisions taken under different regulatory regimes as well as the resources in examining an impact twice.

Authorisations shall be granted if the risk to human health and the environment posed by a use is adequately controlled. A description of the notion of adequate control is given in section 6 of Annex I. If the risk is not considered to be adequately controlled, an authorisation may be granted if socio-economic benefits outweigh the risk to human health and the environment and if there are no suitable alternative substances or technologies. In this case alternatives will be carefully analysed. If the use posed a high risk and a reasonable alternative (taking into account cost, availability, and efficacy) were available this will be a key consideration in making an authorisation decision.

Authorisations granted have to specify whom the authorisation is given to, the substance and use authorised as well as any conditions that apply. This is important for the holder of the authorisation and also for their downstream users who would have to abide by the conditions of the authorisation. Authorisations may be subject to a review period and/or monitoring requirements. Review periods for authorisations may be established, for example, because of the use, the potential availability of an economic substitute, or the type of substance may make it inappropriate to grant an indefinite authorisation. Authorisations granted for socio-economic reasons shall normally be time-limited. Therefore, if such an authorisation is applied for an unlimited time, this has to be justified.

Authorisation decisions are taken after consideration of the effects on human health and the environment of the effects that required the substance to be authorised in the first place (specified in Annex XIII). They shall not consider other effects, for example, flammability. If a substance needs to be restricted because of effects not leading to authorisation they may be addressed through the restrictions process. The authorisation process concentrates on this limited number of effects because it will focus resources on the effects of highest concern thus enabling the system to efficiently process the highest number of substances and uses.

Article 58 – Review of authorisations

Authorisation decisions may need to be amended or withdrawn as a result of a review which can be done at any time when there is a change of circumstances. Such a change of circumstances can for example be changes in the scientific basis for an authorisation decision or that environmental quality objectives as defined under the IPPC Directive or Water Framework Directive are not met because of diffuse emissions to water or the air. Emissions from point sources however are dealt with under those Directives.

Authorisations may therefore be amended or even withdrawn if necessary, subject to the setting of deadlines for the original applicant to update their case, if further information comes to light that places doubt on the appropriateness of the original authorisation. While a

review is ongoing, the Commission is empowered to suspend the authorisation in cases of serious and immediate risk, provided proportionality is taken into account.

A streamlined procedure is provided for renewal of time-limited authorisations.

Article 59 – Applications for authorisations

Any grouping of substances, uses, and/or applicants will need to be justified in the application. The uses applied for can be for the applicant's own uses or for uses by their downstream users. The possibility of grouping is to enable the authorisation process to be as efficient as possible with no reduction in protection as well as allowing the possibility for sharing the burden of application between a number of applicants.

The information accompanying an application includes a chemical safety report detailing their chemical safety assessment. The assessment only needs to address the properties that led to an authorisation being required (specified in Annex XIII: CMR, PBT, vPvB etc). If the applicant has already submitted a registration for the substance they do not have to resubmit the chemical safety report as this will already have addressed the risk management measures required for the substance and use in question.

Bearing in mind the conditions for granting an authorisation, an applicant may submit a socio-economic analysis (SEA) of the impact of a granted or refused authorisation, in accordance with Annex XV, as well as an analysis of alternatives and a substitution plan, if this is considered to be appropriate. An authorisation decision shall be based on the information made available to the authorities. If an application for authorisation is turned down on the basis that the risks to human health and the environment are not adequately controlled, and no SEA has been submitted, the 'sunset date' will still apply. The applicant would therefore need to make a new application for authorisation for the use including a SEA. The implications of this are that the use in question would be prohibited until the authorisation were granted.

Article 60 – Subsequent applications for authorisation

This allows a subsequent applicant for authorisation to make use of the chemical safety report and, if applicable, a socio-economic analysis and available information on alternative substances or preparations, submitted previously if permission is given by the previous applicant. This is to save applicant and authority resources by avoiding repeat work for no benefit.

Article 61 – Procedure for authorisation decisions

This sets out the process that will be followed. Applications for authorisations must be made to the Agency. Once received, the Agency has 10 months in order to prepare an opinion. If the applicant has been given permission to refer to a previous authorisation application this shall be reduced to 5 months. The opinion shall take account of the information made available to it by the applicant as well as any other information available. The setting of deadlines gives industry certainty on which to base commercial decisions and also encourages the authorities to come to decisions as rapidly as is reasonably possible.

When an application is received, non-confidential information on the identity of the substance and use(s) applied for will be put on the Agency's website. This is so that other interested parties can make the Agency aware of alternative substances or processes that may be less harmful to human health and the environment. The information posted on the website must

however not be so detailed as to allow others access to commercially important and sensitive information.

The Agency shall prepare two opinions. One shall address the risk posed to human health and the environment and the second socio-economic factors. In the interests of fairness and openness the applicant will be given 2 months to comment on the opinions if they wish to do so, with the Agency given up to a further two months to amend its draft opinion if it sees fit. Once the opinion has been finalised, to aid transparency, it shall be made available to the Commission, Member States and the applicant and its non-confidential parts shall be published on the Agency website. The Commission shall then adopt its decision on the application under the advisory committee procedure.

Article 62 – Obligation of holders of authorisations

In order for customers to know if a substance has been subject to and granted an authorisation, any label for a substance on the market for an authorised use (this could include its use in a preparation or in an article) shall include its authorisation number. The downstream user will then be able to check easily on the Agency website whether they are using the substance within the conditions of its authorisation.

Article 63 – Downstream Users

A downstream user may, according to Article 54 paragraph 2, use a substance within the conditions of an authorisation given to an actor further up the supply chain. In this case he shall notify the Agency if he is using a substance for such an authorised use. This is to enable the Member State authorities to check that the risks posed by substances of very high concern are being adequately controlled and/or within the conditions of an authorisation.

2.8. Restrictions on the manufacturing, marketing and use of certain dangerous substances and preparations

Article 64 – General Provisions

This article sets out in general terms that all restrictions for substances set out in Annexes XVI and XVII have to be followed by all who manufacture, use or place those substances on the market. The division into two paragraphs results from the different background of the restrictions: paragraph 2 and Annex XVII deal with restrictions that have their origin in the Stockholm Convention or the UNECE Protocol on Persistent Organic Substances, i.e. in a broad international agreement, paragraph 1 and Annex XVI deal with all other restrictions.

As a starting point, the restrictions included in Directive 76/769/EEC as amended are taken over in Annex XVI in a recast version.

The restrictions in Annex XVI do not apply to substances being used for scientific research and development purposes and for product and process orientated research and development, if these substances are used in amounts of less than 1 tonne. The restrictions in Annex XVII do not apply to substances being used for laboratory scale research or as a reference standard. Thereby the exemption is tighter than the one applying to substances included in Annex XVI.

The Restrictions in Annex XVI or XVII do not apply to substances that are waste and where authorities have given permission for it to be treated in a waste treatment installation (e.g. being destroyed or recycled). The requirements on waste in the Community's earlier

implementation of the Stockholm Convention and the UNECE protocol will also apply as they may be more restrictive.

Article 65 – Introducing new and amending current restrictions

This article specifies the conditions that have to be fulfilled in order to include a substance in Annex XVI and XVII as well as the procedure that has to be followed: the regulatory committee decides directly on restrictions for substances which meet the criteria as carcinogenic, mutagenic or toxic, categories 1 and 2, and for which the Commission proposes restrictions for consumer use as well as for substances for which restrictions are included in the Stockholm Convention or the UNECE protocol. For all other restrictions however the process in Articles 66 to 70 has to be followed. For the first two categories of substances, a sound scientific basis has already been provided either within the classification procedure or during the international agreement procedure whereas Articles 66 to 70 ensure that such a scientific basis is prepared for the other restrictions as well. Provision is also made to ensure an appropriate interface with the Directive on cosmetic products, as REACH should not be used as the tool to address issues which are only relevant to cosmetic products.

Article 66 – Preparation of a Proposal

This article details that either Member States or the Commission - via the Agency - may prepare a proposal for restrictions and what has to be done for proposed restrictions to be considered.

Proposals for restrictions shall be based on a risk assessment that identifies why Community-wide action is required. To help ensure that the process for restrictions can work quickly - the previous system for introducing restrictions was criticised as being too slow - risk assessments must adhere to certain requirements that are set out in Annex XIV. If Member State risk assessments do not in the opinion of the Agency meet those requirements, the proposal for restrictions shall not be considered further until these shortcomings are addressed.

In the interests of consistency across EU legislation, both Member States and the Agency shall take into account any risk assessment on the substance under any EU legislation.

To help ensure transparency in the process and that all those with an interest in a proposed restriction have the opportunity to provide relevant information to help in the decision making process, all risk assessments satisfying the requirements set out in Annex XVI are published on the Agency web-site. All interested parties are invited to both comment on the risk assessment and to provide information on the socio-economic impact of the restrictions proposed.

Article 67 – Agency opinion: Committee for risk assessment

This article details the process that shall be followed within the Agency for the preparation of an opinion on the risk assessment on which the proposed restrictions are based and any comments submitted.

Deadlines are specified to ensure that the process is as fast as possible commensurate with the need for accuracy, fairness and a high level of protection for human health and the environment.

The opinion shall be prepared by a risk assessment rapporteur and shall be adopted by the Committee for Risk Assessment. This is to ensure that expertise available in the Agency in the field of risk assessment is fully brought to bear on the opinion.

Article 68 – Agency opinion: Committee for socio-economic analysis

This article details the process that shall be followed within the Agency for the preparation of an opinion on the socio-economic impact of the proposed restrictions.

Deadlines are specified to ensure that the process is as fast as possible commensurate with the need for accuracy, fairness and a high level of protection for human health and the environment. The deadline is longer than that for the Committee for Risk Assessment so that their opinion can be taken into account.

The opinion shall be prepared by a socio-economic analysis rapporteur and shall be adopted by the Committee for socio-economic analysis. This is to ensure that expertise available in the Agency in the field of socio-economic analysis is fully brought to bear on the opinion.

It is recognised that many interested parties will either not have the resources or the information to prepare a full socio-economic analysis. For this reason, information that contributes to one may also be submitted for consideration by the Committee and its rapporteur.

Article 69 – Submission of an opinion to the Commission

This article requires the Agency to give the opinions of the two Committees as well as any supporting material, if required, to the Commission so that it can make a proposal based on full information and the expert opinion of the two Agency Committees.

The article also requires the Agency to let the Commission know if either or both of the Committees have failed to develop an opinion within the deadlines given in Articles 67 and 68.

The opinions shall be published on the Agency's web-site in the interests of transparency and openness.

Article 70 – Commission decision

This article requires the Commission to draft an amendment or addition to Annex XVI within 3 months of receiving the two opinions from the two Agency Committees or 3 months after the deadlines in Articles 67 and 68 if no opinion has been provided.

The deadline is provided to help ensure that proposals for restrictions are introduced as rapidly as is reasonably possible commensurate with the need for fairness, accuracy and a high level of protection for human health and the environment.

It is the responsibility of the Commission to consider the evidence from, and opinions of, the two Agency Committees. The Commission shall weigh up the evidence and make a proposal. The Commission may exceptionally come forward with a proposal that is not in accordance with the opinion of either Committee. In this case, the Commission shall make a detailed explanation of the proposal and the reasons for its differences with the opinions of the two Committees.

2.9. Agency

Article 71 – Establishment and responsibility of the Agency

This article establishes the European Chemicals Agency which will contribute to a high level of protection of human health and the environment in the context of the operation of the internal market. The Agency is responsible for ensuring that it operates properly the tasks assigned to it by this regulation and for co-ordinating the resources of Member States competent authorities under the REACH system. This co-ordination role, as opposed to giving the Agency a role as a pan-European regulator, is consistent with the principle of subsidiarity.

Article 72 – Composition of the Agency

This article sets out the structure of the Agency:

- the Management Board;
- the Executive Director;
- the Committee for Risk Assessment, which prepares the Agency's opinion on risks to human health and the environment under the authorisation and restriction procedures;
- the Committee for Socio-economic Analysis, which prepares the Agency's opinion on any question related to the socio-economic analysis of substances;
- the Member State Committee, which co-ordinates work on evaluation, classification and labelling and identification of substances of very high concern;
- the Forum on exchange of information on enforcement, which co-ordinates a network of Member States' enforcement authorities but does not prepare Agency opinions;
- the Secretariat to support the Committees and the Forum and to execute the administrative parts of the Reach system; and
- the Board of Appeal, which considers any appeals against the decisions of the Agency.

They are described in more detail below.

The second paragraph allows the Committees and the Forum to establish working groups. These could be used, for example, to prepare the work of a Committee under a particular procedure such as restrictions or to address specific technical issues. The Risk Assessment Committee has different, but related, tasks under the restrictions and authorisation procedures. It might be useful to establish working groups for each of these, while the Committee assures coherence between the approaches taken in each working group.

The third paragraph allows the Committees and the Forum to seek specialist advice from appropriate external sources as necessary.

Article 73 – Tasks of the Agency

This article provides that the Agency shall advise the Member States and the Community within the context of the REACH System.

The second paragraph sets out the tasks to be performed by the Secretariat, without participation of the Committees. These tasks are essentially administrative, requiring a good understanding of the REACH system but limited technical expertise judgement, so it would be inappropriate to involve the Committees. Tasks (a)-(c) require dissemination of information to Member States and other interested parties. Task (d) provides for the establishment and maintenance of the database that is the primary store of information that will be available to the Competent Authorities as well as the source of non-confidential information to be made available on request. Task (e) requires the Agency to make publicly available information on which substances have been, and are, subject to evaluation. Task (f) requires the preparation of documents for companies concerning their obligations under the REACH system. As these documents are not expected to be highly technical, it is appropriate to allocate this task to the Secretariat. Task (g) establishes a help desk to support Member State competent authorities' own help desks. The Member States competent authorities' help desks provide advice to companies and the Agency's help desk promotes a harmonised approach by the Member States competent authorities. The Agency's help desk does not provide advice direct to industry because maintaining the language capabilities and knowledge of local conditions needed to respond to many thousands of potential enquiries in an enlarged Union would require a disproportionate investment of resources. Task (h) involves the preparation of descriptive documents to help non-industry stakeholders understand the REACH system.

The third paragraph sets out the tasks to be performed by the Committees. Tasks (a) to (e) provide for the work under the relevant procedures leading to the adoption of opinions or recommendations for substances to be included in Step 1 of authorisation or to be classified at Community level. Task (f) provides for technical support to Community participation in international harmonisation activities, since the Agency's expertise makes it the natural contact point in such work. Task (g) gives the Commission the right to request ad hoc opinions on specific issues related to the safety of substances.

The fourth paragraph sets out the work of the Forum. This is based largely on the work of the existing informal network of Member State competent authorities. The tasks are largely self-explanatory. The work of the Forum will be undertaken by the Member States' representatives with administrative and logistical support from the Agency. The Agency itself will not have a monitoring role with regard to enforcement. It is expected that the Forum will have an important role to play in assuring the effective working of the REACH system.

The fifth paragraph explains that the Board of Appeal shall decide appeals against any Agency decision.

Article 74 – Powers of the Management Board

This article defines the powers of the Management Board in accordance with the principles laid out in the Commission Communication on the operating framework for European regulatory agencies.

Article 75 – Composition of the Management Board

This article defines the composition of the Management Board in accordance with the principles laid out in the Commission Communication on the operating framework for European regulatory agencies.

Article 76 – Chairmanship of the Management Board

Article 77 – Meetings

Article 78 – Voting

These articles are self-explanatory.

Article 79 – Duties and Powers of the Executive Director

This article defines the powers of the Executive Director in accordance with the principles laid out in the Commission Communication on the operating framework for European regulatory agencies.

The tasks listed in the second paragraph are generally self-explanatory but certain points merit a little more discussion. Task (c) will require the Executive Director to follow closely the work of the Committees to ensure that they meet the deadlines set down in the legislation. The timely co-ordination of the work of the Committees under task (e) will in particular require that the Risk Assessment Committee provides timely information to the Socio-economic Committee and that the latter Committee provides timely feedback to the former.

The tasks in the third paragraph relate to annual activities on reporting, work planning, accounting and budget forecasting.

Article 80 – Appointment of the Executive Director

This article provides a transparent procedure for the selection and appointment of a suitable candidate.

Article 81 – Establishment of the Committees

This article provides that each Member State may nominate candidates to the Risk Assessment and Socio-economic Analysis Committees.. The Management Board will appoint at least one member from each Member State having made a nomination to that committee. The Member States shall appoint one member each to the Member State Committee. The members shall have the technical expertise relevant to the Committee on which they serve. It is intended that the members of the Risk Assessment and Socio-economic Analysis Committees shall give their views as experts and not as representatives of their Member State. It is nevertheless appropriate to draw the members from the Member States because this will give the Committees access to the collective expertise of the Member States, will promote mutual acceptance of decisions and so support the harmonisation of regulatory practices across the Community.

In order to provide a good range of expertise on each Committee, the Committees may co-opt up to five further members. Recognising that Committee members cannot have the expertise needed to discuss all issues that may come before a Committee, members may be accompanied by scientific and technical advisers having the expertise relevant to a particular

item. Meetings of the Committees shall be open to the Commission and to the Executive Director of the Agency.

Committee members shall ensure appropriate co-ordination between the work of Member States competent authority and that of their Committee in order to promote a common European approach. In this context it is useful to note that members of the equivalent committees within the EMEA spend around a quarter of their time at the Agency and the rest back in their Member State. It is expected that members of the Committees will spend at least a similar proportion of their time at the Agency.

The Member States are required to provide scientific and technical support to the work of the Committees and working groups. This is the Agency's primary means of "co-ordinating the scientific and technical resources put at its disposal by the Member States" as required in Article 71. Member States are not permitted to give instructions to members of the Risk Assessment Committee and of the Committee for Socio-Economic Analysis that might conflict with an objective scientific and technical analysis of the issues under discussion.

To facilitate the work of the committees, opinions may be adopted by a majority of Committee members, with due recording of minority views.

Article 82 – Establishment of the Forum

This article provides that each Member State shall nominate a member to the Forum. The members shall have expertise relevant to the Forum. It is intended that the members shall give their views as experts and not as representatives of their Member State. In order to provide a good range of expertise on the Forum, it may co-opt up to five further members. Recognising that Forum members cannot have the expertise needed to discuss all issues that may come before it, members may be accompanied by scientific and technical advisers having the expertise relevant to a particular item.

Forum members shall ensure appropriate co-ordination between the work of Member State competent authority and that of the Forum in order to promote a common European approach to enforcement and to ensure that the Forum's work is informed by practical experience.

The third paragraph provides the Agency's primary means of "co-ordinating the scientific and technical resources put at its disposal by the Member States", here in particular by its competent authorities, as required in Article 71. The Member States are required to provide scientific and technical support to the work of the Forum and its working groups. They are not permitted to give instructions to Forum members that might conflict with an objective scientific and technical analysis of the issues under discussion. They are also required to monitor the quality and independence of the work of the Forum and its working groups to ensure that all members are fulfilling their role appropriately.

Article 83 – Rapporteurs of committees and use of experts

Rapporteurs may be appointed where a Committee's opinion is required under the evaluation, restrictions or authorisation procedures. A Committee may also appoint a co-rapporteur. This may prove particularly useful where the co-rapporteur has better access to expertise, perhaps within his Member State competent authority, related to a particular aspect of a dossier.

The Committees should develop the modalities for replacement of a rapporteur or co-rapporteur in their rules of procedure.

The third paragraph provides for contracts to pay for the work of rapporteurs, non-governmental experts serving on working groups and any expert performing other functions for the Agency. The Executive Director is responsible for managing such contracts. In this context, it should be noted that a rapporteur is not expected to work alone but rather to co-ordinate the work of a team of experts who prepare the report for the Committee.

The fourth paragraph provides, where appropriate, for calls for expressions of interest. This is not expected to be appropriate in the case of rapporteurs.

The fifth paragraph gives the Agency the discretion to engage experts to discharge other specific tasks. These could include cases where the Commission requests ad hoc opinions on specific issues, as provided for in Article 73(3)(f).

Article 84 – Qualification and interests of members of committees and boards

The identity and qualifications of members of Committees should be published in the interests of transparency. Members may request that their identity not be published if they are concerned for their personal safety. This is a concern in certain Member States for animal protection issues.

To ensure the provision of objective advice, servants of the Agency shall make declarations of interests and not discuss or vote on issues relating to those interests.

Article 85 – Establishment of the Board of Appeal

This article sets out the membership of the Board of Appeal, how they shall be appointed and their voting rights.

Article 86 – Members of the Board of Appeal

This article sets out the term of office of members of the Board of Appeal, who may serve on it, under what conditions they might be removed, and how potential conflicts of interest will be dealt with.

Article 87 – Decisions subject to appeal

This article explains that appeals can be brought against decisions taken:

- to reject a registration,
- to grant, reject or place conditions on an application for a PPORD exemption,
- under the evaluation provisions;
- to grant or reject a declaration that information be kept confidential, and
- to deny access to information.

Any decision being appealed against shall not apply until the appeal is considered.

Article 88 – Persons entitled to appeal, time limit and form

This article provides that the person to whom a decision is directed has 1 month to appeal against that decision.

Article 89 – Examination and decisions on appeal

Decisions on appeals shall be made within 30 days. Those involved in the appeal shall have the right to present their case to the Board.

Article 90 – Actions before the Court of Justice

Appeals against the decisions of the Board of Appeal, or proceedings against the Agency for failing to make a decision, can be made to the Court of Justice. The Agency has to comply with the judgement of the Court of Justice.

Article 91 – Complaints to the ombudsman

This article is necessary to make the provisions on the Agency consistent with Article 195 EC-Treaty.

Article 92 – Conflicts of opinion with other bodies

Other agencies, particularly EMEA and EFSA, have responsibilities that relate to those of the Agency. It is conceivable that these other agencies may adopt opinions related to certain substances that differ from those of the Agency. This article therefore provides a mechanism for resolution of such differences. Similarly, there are Community scientific committees that may be called on to provide opinions that relate to substances and so this mechanism applies to them also. The relationship of Member State competent authorities to the Agency is extensively addressed in the REACH system and so it would be inappropriate for this mechanism to apply to them. Relevant national bodies within individual Member States are also not covered, since Member State competent authorities are expected to consider the views of such bodies in formulating their own views.

Article 93 – The budget of the Agency

This article sets out the provisions related to the establishment of the budget of the Community Agency. The budget will be funded through a Community subsidy, through fees collected, more particularly for registration and authorisation, and through voluntary contributions from Member States. All substances produced or imported in volumes starting at 100t are subject to evaluation and so a higher fee for registration of such substances is charged to fund this evaluation work. Other substances may be subjected to evaluation on the initiative of authorities but it would be inappropriate to charge a fee to industry for this. Similarly it would be inappropriate to charge a fee when a restrictions procedure is started. These and other activities of the Agency will be funded from a general reserve drawn from the basic registration fee and from the subsidy from the Community budget.

The Commission proposes that the Community subsidy should, over a number of years, approximate to the cost to the Community budget under existing legislation of supporting the European Chemicals Bureau. It is important to note that the Community subsidy will vary substantially over the first decade of the Agency's life while substances are phased into the system. This is because the registration deadlines for phase-in substances will yield very large fee incomes in certain years but relatively little in others.

Article 94 – Implementation of the Agency's budget

This article sets out the standard provisions related to the implementation of the budget of a Community Agency.

Article 95 – Fees

This article empowers the Management Board to set and adjust the fees to be paid by industry to fund the work of the Agency. This will assist the Agency in balancing its budget in the

light of experience with the operation of the REACH system. This is to allow the costs incurred by the Agency under the respective parts of this Regulation to be reflected in the fee structure.

Article 96 – Combating fraud

This article sets out standard provisions related to combating fraud.

Article 97 – Financial regulation

This article sets out standard provisions concerning the adoption of the Agency's financial Regulation.

Article 98 – Legal personality and seat of the Agency

This article grants legal personality to the Agency, allowing it to buy and sell property, start legal proceedings and so forth.

Under the present chemicals legislation, the European Chemicals Bureau of the Commission's Joint Research Centre fulfils a role analogous to that of the Agency. It will be the centre of the Commission's detailed preparatory work for the REACH system and, immediately following the entry into force of the REACH system, it will temporarily fulfil the role of the Agency. Given the importance of continuity in chemicals regulation and the Agency's need to recruit quickly a core of experienced staff, the Commission proposes that the Agency should have its seat in the same location as the present European Chemicals Bureau.

Article 99 – Liability of the Agency

This article sets out standard provisions related to the liability of the Agency and gives the Court of Justice jurisdiction over disputes or arbitration. For the liability of servants towards the Agency reference is made to Article 101.

Article 100 – Privileges and immunities of the Agency

This article accords the Agency the privileges and immunities applicable to the European Communities.

Article 101 – Staff rules and regulations

This article subjects the staff of the Agency to the rules and regulations applicable to officials and other staff of the European Communities and nominates the Agency as the appointing authority within the meaning of those staff rules and regulations. The Management Board, in agreement with the Commission, is enabled to adopt the necessary implementing provisions.

Article 102 – Duty of confidentiality

This article imposes a normal duty of confidentiality on servants of the Agency.

Article 103 – Participation of third countries

This article provides for the participation of third countries in the work of the Agency. They may participate to a degree that the Agency deems appropriate for a particular country at a particular time. This may be useful in, for example, preparing candidate countries for their future role as Member States or in promoting co-operation with members of the European Economic Area.

Article 104 – International harmonisation of regulations

This article provides for international organisations having interests in the harmonisation of international regulations to participate as observers in the work of the Agency. The aim is to provide a focus for Community input to such activities. The Agency will agree on the terms for such participation.

Article 105 – Contacts with stakeholder organisations

This article provides for the involvement of industry, consumer protection, worker protection and environmental protection organisations in the work of the Agency. The aim is to promote transparency and so secure widespread acceptance of the work of the Agency among key stakeholders.

Article 106 – Rules on transparency

This article provides for rules to ensure that the Agency operates in an appropriately transparent manner. The rules will be subject to approval by the Agency and the Commission.

Article 107 – Relations with relevant Community bodies

This article provides that there should be no duplication of competences between the Agency and the European Food Safety Authority, the European Agency for the Evaluation of Medicinal Products or the Commission's Advisory Committee on Safety, Hygiene and Health Protection at Work. In view of the need to ensure effective co-operation with the European Food Safety Authority on substances that are used in plant protection products the Executive Director is required to develop rules of procedure for co-operation. There is also a need for co-operation on worker protection issues with the Advisory Committee and so the Executive Director is again required to develop rules of procedure.

The Commission and the Agency shall consider the possibility of exchanging staff with a view to enhancing understanding of their respective roles under this Regulation.

Article 108 – Formats and software for submission of information to the Agency

To aid the efficient operation of the REACH system and to help actors in the supply chain meet their duties under REACH, formats for submitting information will be made available free of charge and software packages will be made available on the Internet.

2.10. Classification and Labelling Inventory

Article 109 – Scope

This article outlines what the Title applies to.

Article 110 – Obligation to notify the Agency

This article specifies the information that must be provided by all those who place substances on the market. As the duty to classify and label already applies to all substances placed on the market, this information shall be required from the first phase-in deadline (three years after entry into force of the Regulation). Classification and labelling data are part of the normal information requirements for registration. Therefore, if a registration was already submitted, there is no need to notify the information again. Subsequently, if further information comes to

light, as a result of the REACH system or otherwise, the entry shall be updated. It is anticipated that for some substances the classifications notified or registered will vary. Over time it is expected that notifiers and registrants will work together to agree an entry.

Article 111 – The classification and labelling inventory

This article details the information that will be included in the inventory. This inventory will be widely available as a source of information on substances and also act as an encouragement to industry to harmonise their classification and labelling proposals when entries for the same substance differ.

Article 112 – Harmonisation of classification and labelling

This article specifies that once the Regulation comes into force only substances having one or more of certain dangerous properties may be added to Annex I of Directive 67/548/EC. The purpose of this requirement is to concentrate resources on looking at the classification of those substances with properties of very high concern. The other provisions of the Regulation should adequately deal with properties of lesser concern.

Article 113 – Transitional arrangements

All substances placed on the market are subject to classification and labelling requirements. Notifications to the Agency for the classification and labelling inventory can therefore be made rather quickly, at the date of the first phase-in deadline.

2.11. Information

Article 114 – Reporting

The Regulation will introduce a new and comprehensive system for the management of industrial chemicals. It is necessary therefore for the operation of the system to be monitored at the levels of the Member State, the Agency and the Commission so that issues and problems can be identified. This establishes the need for all Member States, the Agency and the Commission to report on the operation of all aspects of the Regulation.

Article 115 – Access to information

One of the objectives of the new system is to make information on chemicals more widely available. Some items are published and freely available in accordance with Article 74 (2) (d). Certain non-confidential information shall be made available by the Agency on request in accordance with Regulation 1049/2001 but when such a request for access is made, the third parties concerned by this information may submit a declaration asking that it be kept confidential. For this it has to justify that disclosure of the information could actually harm him commercially. Appropriate procedures are foreseen. Directive 2003/4/EC applies to requests to obtain information from Member State Competent Authorities, but if the data concerned come from the Agency, it is the Agency who decides whether access can be granted.

Article 116 – Confidentiality

This article identifies what information shall not be treated as confidential and hence is made available on the database, and what shall always be automatically treated as confidential and hence will not be made available. All other information may be claimed to be confidential in

accordance with Article 115 (2) if it can be demonstrated that disclosure of the information could actually harm the party concerned commercially. The minimum information required to adequately control a substance cannot be kept confidential, including basic information on the hazards of a substance, guidance on safe use, those elements of the safety data sheet not considered to be confidential and information needed to identify the substance.

Article 117 – Cooperation with third countries and international organisations

This article allows data held by the Agency to be exchanged, under appropriate confidentiality arrangements, with third countries or international organisations fulfilling tasks under legislation similar to REACH. This is in order to avoid duplication of work internationally and to share experience. Any such arrangement has to be in compliance with the EC Treaty.

2.12. Competent authorities

Article 118 – Appointment of competent authorities

In order to ensure that competent authorities are able to fulfil the duties allocated to them under the REACH system, this article requires Member States to create such authorities and to allocate them sufficient resources to perform their duties.

Article 119 – Co-operation between competent authorities

Co-operation between competent authorities is important to the good functioning of the REACH system.

Article 120 – Public communication of information on risks of substances

In certain cases, the provision of information to the public may be the most appropriate risk management measure. Member State competent authorities, rather than the Agency, are the appropriate bodies to provide such information given the importance of cultural and linguistic elements in a successful information campaign.

Article 121 – Other responsibilities of the competent authorities

Given that the REACH system places a number of new obligations on industry, it is important that companies, especially small and medium sized enterprises, know where to go for advice. Many competent authorities already offer advice to industry but this article formalises that requirement. It is expected that competent authorities will create help desks, with appropriate information available on-line. It is appropriate to give this task to competent authorities rather than the Agency because they have the language capabilities and knowledge of local conditions needed to respond effectively.

2.13. Enforcement

Article 122 – Tasks of the Member States

This requires the Member States to establish appropriate approaches to enforcement of the Regulation. The experience of the Chemical Legislation European Enforcement Network (CLEEN) with activities looking at the enforcement of various pieces of chemical legislation across a number of Member States will be a valuable resource in establishing such approaches. The Forum to be set-up under the auspices of the Agency will continue the work

of CLEEN in developing a consistent approach to the enforcement of chemicals legislation through controls and other activities.

Article 123 – Sanctions for non-compliance

This requires the Member States to establish sanctions for non-compliance with this Regulation. The sanctions imposed must be proportionate to the extent and impact of the non-compliance. The experience of CLEEN points to the need to harmonise to some degree the sanctions imposed, taking account the need for subsidiarity. The Forum should enable Member States to establish a coherent approach to sanctions.

Article 124 – Report

This requires Member States to report on their enforcement activities and the sanctions imposed for non-compliance over the previous calendar year. This information will be useful to the Forum in identifying any action that might usefully be taken..

2.14. Transitional and final provisions

Article 125 – Free Movement Clause

This is the explicit complement to the various requirements in the Regulation and covers those substances on their own, in preparations, or in articles that are complying with the provisions of the Regulation.

Article 126 – Safeguard clause

Despite the thorough and far reaching nature of the Regulation it is possible that effects of a substance may be identified by a Member State that need to be addressed urgently.

Article 127 – Motivation of decisions

In the interests of transparency and legal certainty, the reasons for all decisions taken by the various authorities must be given.

Article 128 – Amendments to the annexes

This enables the Commission to revise Annexes I to XVII to the Regulation through a Committee procedure, as these relate to scientific and technical matters and do not touch the fundamental rules established in the body of the Regulation.

Article 129 – Implementing legislation

This enables the Commission to complement the Regulation through the Comitology procedure. This is essential to enable the Commission to adopt measures that will ensure that the implementation of REACH can be carried through efficiently.

Article 130 – Committee procedure

Two Committee procedures are proposed: the advisory committee and the regulatory committee as established under Decision 1999/468/EC. The committee procedure proposed in particular articles of the regulation depends on the measure to be taken, i.e. the advisory procedure for individual decisions and the regulatory procedure for measures of general application.

Article 131 – Transitional measures regarding the Agency

For some of the provisions in the Regulation to act as anticipated, a managing body must be operational from the day the Regulation comes into force. Until the Agency becomes operational, the Commission fulfils this role, especially in respect of appointment of personnel.

Article 132 – Transitional measures regarding restrictions

Extensive work has been performed under Directive 76/769/EC and Regulation 793/93. It is likely that some of that restrictions identified in these pieces of legislation will not have been taken all the way through to a Commission decision before this Regulation comes into force, including repealing Directive 76/769/EC and Regulation 793/93. This enables such restrictions to still be brought forward and implemented without having to go through all the new procedures set out in this regulation.

Article 133 – Review

This Regulation carefully balances workability with the need to protect human health and the environment and maintain and enhance the competitiveness of EU industry. The first paragraph of this Article sets out the requirement for the Commission to review 12 years after the Regulation comes into force whether the CSA requirements in this Regulation are adequate or whether it is necessary to extend them to substances manufactured or imported in quantities of less than 10 tonnes per year, and to amend the Regulation accordingly. Paragraph 2 contains the review and adaptation provision discussed above under section 2.2, with regard to Articles 14 and 37. Similarly, paragraph 3 provides for review and possible modification of information requirements for substances of 1 tonne or more, but less than 10 tonnes per year.

Article 134 – Repeal

This establishes which directives and regulations are to be replaced by this Regulation that covers their relevant provisions.

Article 135 – Entry into Force and Application

This establishes when the Regulation enters into force and when the duties under various parts of the Regulation apply. Not all duties apply when the Regulation first enters into force because other duties may need to be met first.

The Registration provisions shall apply 60 days after the Regulation enters into force so that the Commission and the Agency has sufficient time to ensure all the systems are in place to receive registrations. It is also undesirable to postpone the registration provisions too long as this would prevent new substances coming onto the market.

The provisions in Articles 81 and 82 applying to the risk assessment and socio-economic analysis committees and the Forum apply one year after the Regulation enters into force to allow for the appointment of an Executive Director, a number of other personnel, to informally convene the Committees and the Forum, and to discuss working methods.

The restrictions provisions in Articles 66 to 70 apply 18 months after the Regulation enters into force to ensure that the necessary Committees are in place. The Commission can use Article 132 to bring in restrictions based on existing work.

The provisions for substance evaluation apply two years after the Regulation enters into force when it is likely that a number of registrations will be available for substance evaluation.

3. ANNEXES

Annex I – General provisions for assessing substances and preparing chemical safety reports

Together with safety data sheets, the Chemical Safety Report will be a key tool for development of risk assessments under Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. In consultation with stakeholders, the Commission will investigate how the assessment requirements under Directive 98/24/EC and those of the REACH system can be made compatible with respect to guidance and software.

Annex Ia – Guide to the compilation of safety data sheets

The safety data sheet is the main tool used in industry for communicating information on the risks of dangerous substances and preparations through the supply chain. Annex Ia is the old annex to the safety data sheet directive (91/155/EEC) that explains what information should be included under each of the 16 safety data sheet headings. It has been integrated with the concept of chemical safety assessments and chemical safety reports introduced by REACH. The CSR developed in accordance with Annex I, and in particular the exposure scenarios, should be used to complete the safety data sheet.

Annex Ib – Chemical Safety Assessments for Preparations

This short annex sets out a methodology for undertaking chemical safety assessments for preparations. This differs in a number of technical aspects from the methodology used for substances, set out in Annex I. Chemical safety assessments for preparations are permitted by article 30(2).

Annex II – Exemptions from obligation to register in accordance with Article 4 (2) (a)

Annex II and III list substances that are exempted from registration based on current practice. This annex exempts individual substances following historical precedent.

Annex III – Exemptions from obligation to register in accordance with Article 4 (2) (b)

This annex lists types of substances for which registration would be inappropriate.

Annex IV – Information requirements referred to in Article 9

Annex IV contains a guidance note on how to use Annexes IV to IX, and sets out the basic information required on: general registrant information, identity of substance, information on manufacture and use(s) of the substance(s), and guidance on safe use.

Annex V – Standard information requirements for substances manufactured or imported in quantities of 1 tonne or more

Annex VI – Additional standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more

Annex VII - Additional standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more

Annex VIII - Additional standard information requirements for substances manufactured or imported in quantities of 1000 tonnes or more

Annex IX – General rules for adaptation of the standard testing regime set out in Annexes V to VIII

Progressively more information is required on a substance with increasing tonnage, with only Annex V required for lower tonnages and V-VIII for the highest.

Annexes V-VIII contain specific rules concerning the applicability of individual information requirements, which aim to ensure both that no unnecessary information is required and that registrants are required to consider when further information is appropriate. Annex IX sets out more general rules concerning the adaptation of the specific rules in Annexes V to VIII.

Annex X – Testing methods

This Annex takes over the testing methods currently contained in Directive 67/548/EEC.

Annex XI – General Provisions for Downstream Users to assess substances and prepare Chemical Safety Reports

Annex XI sets out a clear methodology that enables downstream users to undertake chemical safety assessments and prepare chemical safety reports for uses that they make of a substance that are not covered by the safety data sheet supplied to them. Downstream users will use the information provided by their suppliers via the safety data sheet and information from other sources to develop (an) exposure scenario(s), and, if necessary, refine the hazard assessment or risk characterisation, for their own use, or other uses down the supply chain.

Annex XII - Criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances

This Annex sets out the identification criteria for PBTs and vPvBs.

Annex XIII – List of substances subject to authorisation

This Annex will contain the substances for which uses have to be authorised, specifying the information set out in Article 55.

Annex XIV - Dossiers

This Annex sets out the requirements for a proposal for any restriction, as well as proposals for harmonised classification and labelling, and the identification of substances as PBT, VPVB or of equivalent concern.

Any proposal has to be based on a risk assessment following the relevant sections of Annex I, and has to justify why action at Community level is necessary.

These requirements are specified to ensure that adequate information is available for interested parties to comment on the risk assessment and the associated proposed restrictions and for the Agency's Committees to develop an informed opinion.

This Annex was considered to be necessary because risk assessments submitted to the Commission were of such variable consistency and content that it was difficult to make considered decisions based on them. This meant that risk assessments sometimes had to be repeated resulting in a considerable delay to restrictions being introduced.

Annex XV - Socio-Economic Analysis

This Annex outlines such of the issues that may be addressed in a socio-economic analysis, or information that could be provided by interested parties to help the Agency's Socio-Economic Analysis Committee develop an opinion.

The Annex does not specify requirements because socio-economic analyses can be carried out on a range of levels (e.g. international, national, regional, local) and to address a wide variety of impacts (e.g. social, consumer, industry) and it was considered that no one set of requirements could meet all these needs.

The socio-economic analysis or contribution to it, is therefore the responsibility of the person submitting the information. They must decide on the most appropriate methodology to take and information to submit.

It is possible that with experience the Agency's Socio-Economic Analysis Committee may be able to recommend to the Commission more precise requirements for inclusion in this Annex.

Annex XVI – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles

This Annex lists all the substances which are subject to restrictions and indicates the nature of the restrictions for these substances on their own, in preparations or in articles. These restrictions may be either conditions for the manufacture, use or the placing on the market or prohibitions of any of these activities. The restrictions in this Annex are essentially those carried over from Directive 76/769/EEC. That Directive will be repealed with the entry into force of this Regulation. Over the coming years the Annex will be revised as new restrictions are adopted following the provisions of this Regulation.

Annex XVI follows the rules set out within the Inter Institutional Agreement concerning recasting techniques (OJ C 77/1, 28.03.2002). Annex XVI has been drawn up in order to recast the legislation dealing with restriction of chemicals, Directive 76/769/EEC that has been adapted or amended many times.

The recast presented in Annex XVI does not intend to bring about changes of substance to the text. In particular, Annex XVI does not contain any additions of substances not previously restricted under Directive 76/769/EEC.

However, a number of minor changes were introduced (highlighted with adaptation markers), e.g. with the objective of harmonising the presentation with that of Directive 67/548/EEC. This applies to entries n° 26, 31a, 31b, 31c, 31d, 31e, 31g, 31i, 33, 39. Some of these minor

changes have been added in order to improve the readability of the text. This applies to entries 6.1, 6.2, and 23.1. It is also the case for entries 28, 29 and 30 (ex entries 29, 30 and 31) that have been merged into one block because their respective provisions are similar. Consequently, redundant provisions have been deleted.

Some deletions have been introduced in order to update the text and withdraw for example old date references. It applies e.g. to entries 1.1(a), 1.1(b), 1.1(c), 1.1(d), 1.1.e, 1.5, 18.2, 23.1.2, 23.4, 24.1, 24.2.(a), 24.3, 42.2. Some additions have also been included in order to update references to several directives quoted in the consolidated text. This applies e.g. for entries 3, 5.3.(a), 5.3(c), 12(1), 28, 29 and 30 (paragraphs 1 and 2) and 32.

A few changes became necessary for PCB because the substance in question was included in Annex XVII instead of Annex XVI as a result of the Persistent Organic pollutants Convention (so called “POPs convention”). This concerns entries 1(c), 1.4 and 1.6.

In some cases, changes were introduced because the Regulation addresses itself to operators instead of Member States. This applies e.g. to entries 1.6 and Appendix 7(point 7).

Annex XVII – Persistent Organic Pollutants (POPs)

This Annex will list all the substances and the details of restrictions from the Stockholm Convention and the UN ECE Protocol on Persistent Organic Pollutants. By including these restrictions in this Annex and thereby in Community law, the European Community fulfils part of its obligation under the international Convention.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals
(REACH), establishing a European Chemicals Agency and amending Directive
1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission⁴,

Having regard to the opinion of the Economic and Social Committee⁵,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁶,

Whereas:

- (1) The free movement of substances, on their own, in preparations and in articles, is an essential aspect of the internal market and contributes significantly to the health and well-being of consumers and workers, and to their social and economic interests, as well as to the competitiveness of the chemical industry.
- (2) The efficient functioning of the internal market for substances within the Community can be achieved only if requirements for substances do not differ significantly from Member State to Member State.
- (3) A high level of health and environmental protection should be ensured in the approximation of legislation on substances, with the goal of achieving sustainable development; that legislation should be applied in a non-discriminatory manner whether chemical substances are traded on the internal market or internationally.
- (4) To preserve the integrity of the internal market and ensure a high level of protection for human health, especially the health of workers, and the environment, it is necessary to ensure that substances manufactured in the Community comply with Community law, even if they are exported.
- (5) The assessment⁷ of the operation of the four main legal instruments governing chemicals in the Community (Council Directive 67/548/EEC of 27 June 1967 on the

⁴ OJ C [...], [...], p. [...].

⁵ OJ C [...], [...], p. [...].

⁶ OJ C [...], [...], p. [...].

⁷ Commission Working Document SEC(1998) 1986 final, referred to in White paper Strategy for a future Chemicals Policy, COM (2001)88 final, 27.2.2001.

approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁸, Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations⁹, Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances¹⁰ and Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations¹¹) identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field.

- (6) Substances under customs supervision which are in temporary storage, in free zones or free warehouses with a view to re-exportation or in transit are not used within the meaning of REACH and are therefore to be excluded from its scope.
- (7) An important objective of REACH is to encourage the substitution of dangerous substances by less dangerous substances or technologies where suitable alternatives are available. This regulation does not affect the application of directives on worker protection, especially Council Directive 90/394/EEC concerning exposure to carcinogens at work according to which employers are required to eliminate, wherever technically possible, or to substitute dangerous substances with less dangerous substances.
- (8) Responsibility for the management of the risks of substances should lie with the enterprises that manufacture, import, place on the market or use these substances.
- (9) For these reasons, the registration provisions require manufacturers and importers to generate data on the substances they manufacture or import, use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration requires them to submit a dossier containing all this information to the Agency. Registered substances should be allowed to circulate on the internal market.
- (10) The evaluation provisions provide for follow-up to registration, by checking that registrations are in compliance with the requirement of the Regulation and by allowing for generation of more information on the properties of substances. Member States will evaluate such substances if they have reasons for suspecting that such substances present a risk to health or the environment, after having included them in their rolling plans.
- (11) Although the information yielded on substances through evaluation should be used in the first place by manufacturers and importers to manage the risks related to their substances, it may be used to initiate the authorisation or restrictions procedures under

⁸ OJ 196, 16.8.1967, p.1. Directive as last amended by Directive 2001/59/EC (OJ L 225, 21.8.2001, p.1).

⁹ OJ L 187, 16.7.1988, p. 14.

¹⁰ OJ L 84, 5.4.1993, p.1.

¹¹ OJ L 262, 27.9.1976, p. 201.

REACH or risk management procedures under other Community legislation; therefore it should be ensured that this information is available to the appropriate authorities and may be used by them for the purpose of such procedures.

- (12) The authorisation provisions provide for authorisations for the placing on the market and use of substances of very high concern to be granted by the Commission if the risks arising from their use are adequately controlled or the use can be justified for socio-economic reasons.
- (13) The restrictions provisions allow the manufacturing, placing on the market and use of substances presenting risks that need to be addressed, to be made subject to total or partial bans or other restrictions, based on an assessment of those risks.
- (14) There is a need to assure effective management of the technical, scientific and administrative aspects of the present Regulation at Community level. A central entity should therefore be created to fulfil this role.
- (15) A feasibility study on the resource requirements for a central entity¹² concluded that an independent central entity offered a number of long-term advantages over other options. A European Chemicals Agency, hereinafter referred to as “the Agency”, should therefore be established.
- (16) Experience has shown that it is inappropriate to require Member States to assess the risks of all chemical substances. This responsibility should therefore be given, in the first place, to the enterprises that manufacture or import substances, but only when they do so in quantities exceeding a certain volume, to enable them to carry the associated burden. Those enterprises should take the necessary risk management measures in accordance with their assessment of the risks of their substances.
- (17) In order to undertake chemical safety assessments of substances effectively, manufacturers and importers of substances should obtain information on these substances, if necessary by performing new tests.
- (18) For purposes of enforcement and evaluation and for reasons of transparency, the information on these substances, as well as related information, including on risk management measures, should be submitted to authorities, except in defined cases where such submission would be disproportionate.
- (19) Scientific research and development normally takes place in quantities below 1 tonne per year, there is no need to exempt such research and development because substances in those quantities do not have to be registered in any case. However, in order to encourage innovation, research on products and process oriented research and development should be exempted from the obligation to register for a certain time period where a substance is not yet intended to be placed on the market to an indefinite number of customers because its application in preparations or articles still requires further research and development performed by a limited number of known customers.
- (20) Since also producers and importers of articles should be responsible for their articles, it is appropriate to impose a registration requirement on substances, which are

¹² Feasibility Study on the Resource Requirements for a Central Entity, final report, June 2002: <http://europa.eu.int/comm/environment/chemicals/cereport.pdf>

intended to be released from articles. In the case of substances which are likely to be released from articles in sufficiently high amounts and in such a way as to adversely affect human health or the environment, the Agency should be notified and should be empowered to request that a registration be submitted.

- (21) The requirements for undertaking chemical safety assessments by manufacturers and importers should be prescribed in detail in a technical annex to allow them to meet their obligations. To achieve fair burden sharing with their customers, manufacturers and importers should in their chemical safety assessment address not only their own uses and the uses for which they place their substances on the market, but also all uses which their customers ask them to address.
- (22) A chemical safety assessment should not need to be performed for substances in preparations in certain very small concentrations which are considered as not giving rise to concern. Substances in preparations in such low concentrations should also be exempt from authorisation. These provisions should apply equally to preparations that are solid mixtures of substances until a specific shape is given to such a preparation that transforms it into an article.
- (23) One of a group of multiple registrants should be allowed to submit information on behalf of the others according to rules which ensure that all the required information is submitted, while allowing sharing of the costs burden.
- (24) Requirements for generation of information on substances should be tiered according to the volume of manufacture or importation of a substance, because these provide an indication of the potential for exposure of man and the environment to the substances, and should be described in detail in technical annexes.
- (25) If tests are performed, they should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes¹³, and good laboratory practice, set out in Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances¹⁴.
- (26) The generation of information by alternative means offering equivalence to prescribed tests and test methods should also be allowed, for example when this information comes from valid qualitative or quantitative structure activity models or from structurally related substances. To this end the Agency, in collaboration with Member States and interested parties shall develop appropriate guidance. It should also be possible not to submit certain information if appropriate justification can be provided.
- (27) Prescribed test methods should be consolidated, for reasons of transparency as well as to facilitate good application of the requirements by enterprises.

¹³

OJ L 358, 18.12.1986, p. 1.

¹⁴

OJ L 15, 17.1.1987, p. 29.

- (28) For reasons of workability and because of their special nature, specific registration requirements should be foreseen for intermediates; polymers should be exempted from registration and evaluation until those that need to be registered due to the risks posed to human health or the environment can be selected in a practicable and cost-efficient way on the basis of sound technical and valid scientific criteria.
- (29) To avoid overloading authorities and enterprises with the work arising from the registration of substances already on the internal market, this registration should be spread over an appropriate period of time, without introducing undue delay. Deadlines for the registration of these substances should therefore be set.
- (30) Data for substances already notified in accordance with Directive 67/548/EEC should be eased into the system and should be upgraded when the next tonnage quantity threshold is reached.
- (31) In order to provide a harmonised, simple system, all registrations should be submitted to the Agency. To ensure a consistent approach and efficient use of resources, it should perform a completeness check on all registrations and take responsibility for any final rejections of registrations.
- (32) To ensure that the information available to the authorities is kept up-to-date, an obligation to inform the Agency of certain changes to the information should be introduced.
- (33) The sharing and joint submission of information should be encouraged to increase the efficiency of the present Regulation throughout the Community.
- (34) It is appropriate to reduce to a minimum the number of vertebrate animals used for experimental purposes in accordance with the provisions of Directive 86/609/EEC; wherever possible the use of animals should be avoided by recourse to alternative methods validated by the European Centre for Validation of Alternative Testing Methods or other international bodies.
- (35) This Regulation should be without prejudice to the full and complete application of the Community competition rules.
- (36) In order to avoid duplication of work, and in particular to reduce testing involving vertebrate animals, the requirements concerning preparation and submission of registrations and updates should encourage registrants to check the databases established at the Agency and to take all reasonable steps to reach an agreement on the sharing of information.
- (37) It is in the public interest to ensure the quickest possible circulation of test results on the human health or environmental hazards of certain substances to those enterprises which use them, in order to limit any risks associated with their use. Sharing of information is therefore encouraged, within conditions that ensure a fair recompense for the company that has undertaken the tests.
- (38) In order to respect the legitimate property rights of those generating testing data, the generator of such data should be given a claim for compensation against those registrants who benefit from this data during a period of 10 years.

- (39) In order to allow a potential registrant to proceed with his registration, even if he cannot reach agreement with a previous registrant, the Agency, on request, should make available any summary or robust study summary of tests already submitted. The registrant who receives these data should be obliged to pay a contribution to the costs to the generator of the data.
- (40) In order to avoid duplication of work, and in particular to avoid duplication of testing, registrants of phase-in substances should pre-register as early as possible to a database managed by the Agency. A system should be established in order to help registrants to find other registrants and form consortia. In order to ensure the smooth functioning of that system they should fulfil certain obligations. If a member of a substance information exchange forum (SIEF) does not fulfil his obligations, he is breaching the regulation and should be sanctioned accordingly but other members should be enabled to continue preparing their own registration.
- (41) Part of the responsibility for the management of the risks of substances is the communication of information on these substances to other professionals; this is also indispensable for those others to meet their responsibility.
- (42) As the existing safety data sheet is already being used as a communication tool within the supply chain of substances and preparations, it is appropriate to develop it further and make it an integral part of REACH.
- (43) In order to have a chain of responsibilities, downstream users should be responsible for assessing the risks arising from their uses of substances if those uses are not covered by a safety data sheet received from their suppliers, unless the downstream user concerned takes more protective measures than those recommended by his supplier or unless his supplier was not required to assess those risks or provide him with information on those risks; for the same reason, downstream users should manage the risks arising from their uses of substances.
- (44) The requirements for undertaking chemical safety assessments by downstream users should also be prescribed in detail in a technical annex to allow them to meet their obligations.
- (45) For enforcement and evaluation purposes, downstream users of substances should be required to report certain information if their use is outside the conditions of the exposure scenario detailed in the safety data sheet communicated by their original manufacturer or importer and to keep such reported information up-to-date.
- (46) For reasons of workability and proportionality, it is appropriate to exempt downstream users using low quantities of a substance from such reporting.
- (47) A significant number of animals would have to be used in testing to fulfil the more demanding information requirements in respect of certain substances, if those information requirements were automatically applied. Significant costs for enterprises may be associated with testing. It is therefore necessary to ensure that generation of such information is tailored to real information needs; to this end evaluation should require Member States to prepare decisions and the Agency to decide on the programmes of testing proposed by manufacturers and importers for such substances. The Member State where the manufacture takes place or the importer is established should be responsible for the evaluation of testing proposals.

- (48) In addition, it is necessary to provide confidence in the general quality of registrations and to ensure that the public at large as well as all stakeholders in the chemicals industry have confidence that enterprises are meeting the obligations placed upon them; accordingly, it is appropriate that the same Member State is empowered to check the compliance of registrations submitted to this end.
- (49) The Agency should also be empowered to require further information from manufacturers, importers or downstream users on substances with suspected risk to health or the environment, including for reason of their presence on the internal market in high volumes, on the basis of evaluations performed by Member State competent authorities. Member States should be made to program and provide resources to this end, through the establishment of rolling plans. If a risk equivalent to the level of concern arising from the use of substances subject to authorisation arises from the use of isolated intermediates on site, Member States should also be allowed to require further information, when justified.
- (50) Collective agreement among Member State authorities on their draft decisions provides the basis for an efficient system that respects the principle of subsidiarity, while maintaining the internal market. If one or more Member States or the Agency do not agree to a draft decision, it should be made subject to a centralised procedure. The Agency should take the decisions following from the application of these procedures.
- (51) Evaluation may lead to the conclusion that action should be taken under the restriction or authorisation procedures or that risk management action should be considered in the framework of other appropriate legislation. Information on the progress of evaluation proceedings should therefore be made public.
- (52) To ensure a sufficiently high level of protection for human health and the environment, substances with properties of very high concern should be treated in a precautionary manner which requires enterprises using them to demonstrate to the granting authority that the risks are adequately controlled. If this is not the case, uses may still be authorised if enterprises show that the benefits to society from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies. The granting authority should then verify that these requirements are met through an authorisation procedure on the basis of applications by enterprises. As authorisations should ensure the high level of protection throughout the internal market, it is appropriate that the Commission should be the granting authority.
- (53) Experience at the international level shows that substances with characteristics rendering them persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, present a very high concern, while criteria have been developed allowing the identification of such substances. For certain other substances concerns are sufficiently high to address them in the same way on a case-by-case basis.
- (54) Workability and practicality considerations both on the side of enterprises, who have to prepare application files and take appropriate risk management measures, and on the side of authorities, who have to process authorisation applications, warrant that only a limited number of substances may be subjected to the authorisation procedure at the same time and that realistic deadlines be set for applications, while allowing certain uses to be exempted.

- (55) The Agency should provide advice on the prioritisation of substances to be made subject to the authorisation procedure, to ensure that decisions reflect the needs of society as well as scientific knowledge and developments therein.
- (56) A total ban on a substance would mean that none of its uses can be authorised. It would therefore be pointless to allow the submission of applications for authorisation; in such a case the substance should be removed from the list of substances for which applications can be submitted.
- (57) In order to provide a harmonised approach to the authorisation of the uses of particular substances, the Agency should provide opinions on the risks arising from those uses and on any socio-economic analysis submitted to it by third parties.
- (58) To allow effective monitoring and enforcement of the authorisation requirement, downstream users benefiting from an authorisation granted to their supplier should inform the Agency of their use of the substance.
- (59) In order to accelerate the current system the restriction procedure should be restructured and should replace Council Directive 76/769/EEC, which has been substantially amended and adapted several times. The Acquis of the harmonised rules under the current Annex of that directive should be taken over in a recast version in the interest of clarity and as a starting point for this new accelerated restriction procedure. This recast follows the rules set out within the Inter Institutional Agreement concerning recasting techniques (OJ C 77/1; 28.03.2002). This recast has been inserted as Annex XVI in the Volume VI of the REACH Regulation.
- (60) It is the responsibility of the manufacturer, importer and the downstream user to identify the appropriate risk management measures needed to ensure a high level of protection for human health and the environment from the manufacturing, placing on the market or use of a substance on its own, in a preparation or in an article. However, where this is considered to be insufficient and where Community legislation is justified, appropriate restrictions should be laid down in this Regulation.
- (61) In order to protect human health and the environment, restrictions on the manufacturing, placing on the market or use of a substance on its own, in a preparation or in an article may include any condition for, or prohibition of, the manufacturing, placing on the market or use. Therefore it is necessary to establish an Annex introducing new and amending current restrictions.
- (62) In order to prepare a restriction proposal and in order for this legislation to operate effectively, there should be good co-operation, co-ordination and information between the Member States, the Agency, other bodies of the Community, the Commission and the interested parties.
- (63) In order to give Member States the opportunity to submit proposals to address a specific risk for human health and the environment, they should prepare a Dossier in conformity with requirements set out in detail in an Annex. The Dossier should give the justification for needing Community wide action.
- (64) In order to provide a harmonised approach to restrictions, the Agency should fulfil a role as co-ordinator of this procedure by e.g. appointing the relevant rapporteurs and checking the conformity with the requirements of the relevant Annexes.

- (65) In order to give the Commission the opportunity to address a specific risk for human health and the environment that needs to be addressed Community wide, it should be able to entrust the Agency with the preparation of a restriction dossier.
- (66) For reasons of transparency, the Agency should publish the relevant dossier including the suggested restrictions while requesting comments.
- (67) In order to finalise the procedure in due time, the Agency should submit its opinions on the suggested action and its impact on the basis of a draft opinion prepared by a rapporteur.
- (68) In order to speed up the procedure for restrictions, the Commission should prepare its draft amendment within three months after the receipt of the Agency's opinions.
- (69) The Agency should be central to ensuring that the chemicals law and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public. The confidence in the Agency of the Community institutions, the Member States, the general public and interested parties is therefore essential. For this reason, it is vital to ensure its independence, high scientific, technical and regulatory capacities, transparency and efficiency.
- (70) The structure of the Agency should be suitable for the tasks that it should fulfil. Experience with similar Community agencies provides some guidance in this respect but the structure should be adapted to meet the specific needs of the present Regulation.
- (71) In the interests of efficiency, the staff of the Agency Secretariat, should perform essentially technical-administrative and scientific tasks without calling on the Member States' scientific and technical resources; the Executive Director should ensure the efficient execution of the Agency's tasks in an independent manner. To ensure that the Agency fulfils its role, the composition of the Management Board should aim to secure the highest standard of competence and a broad range of relevant expertise in chemicals safety or Regulation.
- (72) The Agency should have the means to perform all the tasks required to enable it to carry out its role.
- (73) The Management Board should have the necessary powers to establish the budget, check its implementation, set the structure and amount of the fees, draw up internal rules, adopt financial regulations and appoint the Executive Director.
- (74) It is appropriate for the Management Board of the Agency to include representatives from other interested parties, such as industry, NGOs or academia in order to ensure the involvement of stakeholders.
- (75) Through the Committee for Risk Assessment and the Committee for Socio-economic Analysis, the Agency should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence.
- (76) Through the Member States Committee, the Agency should aim to reach agreement amongst Member States authorities on specific issues which require a harmonised approach.

- (77) It is necessary to ensure close co-operation between the Agency and the competent authorities working within the Member States so that the scientific opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis rely on the broadest possible scientific and technical expertise appropriate which is available within the Community; to the same end, the Committees should be able to rely on additional particular expertise.
- (78) The Agency should also provide a Forum for Member States to exchange information on and to co-ordinate their activities related to the enforcement of chemicals legislation. The currently informal co-operation between Member States in this respect would benefit from operating within a more formal framework.
- (79) A Board of Appeal should be set up within the Agency to guarantee legal rights of appeal for the operators affected by decisions taken by the Agency.
- (80) The Agency should be financed partly by fees paid by enterprises and partly by the general budget of the European Union. The Community budgetary procedure should remain applicable as far as any subsidies chargeable to the general budget of the European Union are concerned. Moreover, the auditing of accounts should be undertaken by the Court of Auditors¹⁵.
- (81) Where the Commission and Agency judge it to be appropriate, it should be possible for other countries to participate in the work of the Agency.
- (82) The Agency should contribute, through collaboration with organisations having interests in the harmonisation of international regulations, to the Community's and Member States' role in such harmonisation activities.
- (83) The Agency should provide the infrastructure needed for enterprises to meet their obligations under the data-sharing provisions.
- (84) It is important to avoid confusion between the missions of the Agency and the European Agency for the Evaluation of Medicinal Products (Emea) established by Council Regulation (EC) No 2309/93¹⁶, the European Food Safety Authority (Efsa) established by Council Regulation (EC) No 178/2002¹⁷ and the Advisory Committee on Safety, Hygiene and Health Protection at Work created by Council Decision 74/325/EEC¹⁸. Consequently, the Agency should establish rules of procedure where co-operation with the Efsa or the Advisory Committee on Safety, Hygiene and Health Protection at Work is necessary. It is necessary to establish that this Regulation is otherwise without prejudice to the competence conferred on the Emea, the Efsa and the Advisory Committee on Safety, Hygiene and Health Protection at Work by Community legislation.
- (85) The feasibility study on the resource requirements for a central entity concluded that the most significant challenge to the effective functioning of the Agency was likely to

¹⁵ Article 91 of Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities, OJ L 357, 31.12.2002, p. 72.

¹⁶ OJ L 214, 24.8.1993, p. 1.

¹⁷ OJ L 31, 1.2.2002 p. 1.

¹⁸ OJ L 185, 9.7.1974, p. 15.

be its ability to attract the right staff, including those working in the European Chemicals Bureau of the European Commission's Joint Research Centre; the location should therefore enable the Agency to obtain the right staff in the start-up period as well as in the longer term.

- (86) In order to achieve the functioning of the internal market for substances on its own or in preparations, while at the time ensuring a high level of protection for human health and the environment, rules are established for a classification and labelling inventory.
- (87) The classification and labelling for any substance either subject to registrations or covered by the scope of Article 1 of Directive 67/548/EEC and being placed on the market should therefore be notified to the Agency.
- (88) To ensure a harmonised protection for the general public, and, in particular, persons who come into contact with certain substances, an inventory should record the classification in accordance with Directive 67/548/EEC and Directive 1999/45/EC agreed by manufacturers and importers of the same substance, if possible, as well as decisions taken at Community level to harmonise the classification and labelling of some substances.
- (89) Resources should be focussed on substances of the highest concern. Therefore substances should only be added to Annex I of Directive 67/548/EEC when they meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3 or as a respiratory sensitisier. Provisions should be set out to allow Competent Authorities to submit proposals to the Agency. The Agency should give its opinion on the proposal while parties concerned should have the possibility to comment. The Commission should take a decision afterwards.
- (90) Regular reports by the Member States and the Agency on the operation of the Regulation will be an indispensable means to monitor the implementation of chemicals law as well as trends in the area; conclusions drawn from findings in the reports will be useful and practical tools in reviewing the Regulation and, where necessary, formulating proposals for amendments.
- (91) Community citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals. A transparent means of achieving this is granting them free and easy access to basic non-confidential data held in the Agency's database including short profiles of the hazardous properties, labelling requirements and relevant Community legislation including authorised uses and risk management measures.
- (92) Apart from their participation in the implementation of Community legislation, Member State competent authorities should play a role in the communication on risks of substances and on enterprises' obligations arising from chemicals legislation, because of their closeness to stakeholders in the Member States; at the same time, close co-operation between the Agency, the Commission and the Member States competent authorities is necessary to ensure the coherence and efficiency of the global communication process.
- (93) In order for this legislation to operate effectively, there must be good co-operation and co-ordination between the Member States, the Agency and the Commission regarding enforcement.

- (94) In order to ensure compliance with this Regulation, Member States should put in place effective monitoring and control measures.
- (95) In order to ensure transparency, impartiality and consistency in the level of enforcement activities by Member States, it is necessary to set up an appropriate framework for sanctions with a view to imposing effective, proportionate and dissuasive sanctions for non-compliance, as non-compliance can result in damage to human health and the environment.
- (96) The necessary inspections should be programmed, carried out and their results should be reported.
- (97) The measures necessary for the implementation of this Regulation and certain amendments to it should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹⁹.
- (98) It is essential that chemicals are regulated in an effective and timely manner during the transition to full applicability of the provisions of this Regulation and, in particular, during the start-up period of the Agency; provision should therefore be made for the Commission to fulfil the functions of the Agency at least in the start-up period; if necessary, the Commission should be able to appoint an Executive Director ad interim until the Agency's Management Board can appoint an Executive Director itself.
- (99) To take full advantage of the work performed under Regulation (EEC) No 793/93 as well as under Directive 76/769/EEC and to avoid such work going to waste, the Commission should be empowered during the start-up period to initiate restrictions based on such work already performed without following the full procedure foreseen for restrictions under this Regulation.
- (100) It is appropriate for the provisions of this Regulation to enter into force in a staggered way to smoothen the transition to the new system; moreover, a gradual entry into force of the provisions should allow all parties involved, authorities, enterprises as well as stakeholders, to focus resources in the preparation for new duties at the right times.
- (101) This Regulation replaces Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC²⁰, Commission Directive 93/105/EEC of 25 November 1993 laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC²¹, Commission Directive 2000/21/EC of 25 April 2000 concerning the list of Community legislation referred to in the fifth indent of Article 13(1) of Council Directive 67/548/EEC²², Council Regulation (EEC) No 793/93 and Commission Regulation (EC) 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council

¹⁹ OJ L 184, 17.7.1999, p. 23.

²⁰ OJ L 227, 8.9.1993, p. 9.

²¹ OJ L 294, 30.11.1993, p. 21.

²² OJ L 103, 28.04.2000, p. 70.

Regulation (EEC) No 793/93²³; for the sake of consistency it also replaces and amends certain articles as well as the annexes of {POPs Regulation} which already address matters covered by this Regulation.

- (102) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of this Regulation to lay down rules for chemical substances and to establish a European Chemicals Agency. This Regulation does not go beyond what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.
- (103) The Regulation observes the fundamental rights and principles which are acknowledged in particular in the Charter of Fundamental Rights of the European Union²⁴. In particular, it seeks to ensure full compliance with the principles of environmental protection and sustainable development guaranteed by its Article 37,

HAVE ADOPTED THIS REGULATION:

TITLE I GENERAL ISSUES

CHAPTER 1 SUBJECT MATTER AND SCOPE

Article 1 Subject matter

- 1. This Regulation lays down provisions on substances within the meaning of Article 3 (1). These provisions shall apply to the manufacture, import, placing on the market or use of such substances on their own, in preparations or in articles, if so stated.
- 2. The purpose of this Regulation is to ensure the free circulation of such substances on the internal market.
- 3. The present Regulation is based on the principle that it is up to manufacturers, importers and downstream users to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle²⁵.

Article 2 Scope

- 1. This Regulation shall not apply to:

²³ OJ L 161, 29.6.1994, p. 3.

²⁴ OJ C 364, 18.12.2000, p. 1.

²⁵ As set out in the Communication from the Commission on the precautionary principle, COM (2000) 1

- (a) radioactive substances within the scope of Council Directive 96/29/Euratom²⁶;
 - (b) substances, on their own, in a preparation or in an article, subject to customs supervision, provided that they do not undergo any treatment or processing, and
 - in temporary storage, or
 - in a free zone or free warehouse with a view to re-exportation, or
 - in transit;
 - (c) non-isolated intermediates.
2. This Regulation shall apply without prejudice to:
- (a) Council Directive 89/391/EEC²⁷;
 - (b) Council Directive 90/394/EEC²⁸;
 - (c) Council Directive 98/24/EC²⁹;
 - (d) Community legislation on the carriage of dangerous substances and dangerous substances in preparations by rail, road, inland waterway, sea or air.

CHAPTER 2 **DEFINITIONS**

Article 3 *Definitions*

For the purposes of this Regulation:

1. *Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
2. *Preparation* means a mixture or solution composed of two or more substances;
3. *Article* means an object composed of substance(s) and/or preparation(s) which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does;
4. *Polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a

²⁶ OJ L 159, 29.6.1996, p. 1.

²⁷ OJ L 183, 29.6.1989, p. 1.

²⁸ OJ L 196, 26.7.1990, p. 1.

²⁹ OJ L 131, 5.5.1998, p. 11.

range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises:

- (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant, as well as
- (b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a ‘monomer unit’ means the reacted form of a monomer substance in a polymer;

5. *Registrant* means the manufacturer or the importer submitting a registration;
6. *Manufacturing* means production and extraction of substances in the natural state;
7. *Manufacturer* means any natural or legal person established within the Community manufacturing a substance within the Community;
8. *Import* means the physical introduction into the customs territory of the Community;
9. *Importer* means any natural or legal person established within the Community who is responsible for import;
10. *Placing on the market* means supplying or making available, whether in return for payment or free of charge to a third party. Import into the customs territory of the Community shall be deemed to be placing on the market;
11. *Downstream user* means any natural or legal person established within the Community other than the manufacturer or the importer who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer covered by the exemption of Article 4 (2) (c) shall be considered as a downstream user;
12. *Use* means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;
13. *Distributor* means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, to third parties;
14. *Intermediate* means a substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter called *synthesis*);
 - (i) Non-isolated intermediate means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes

- tanks or other vessels in which the substance(s) are stored after the manufacture.
- (ii) On site isolated intermediate means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one more legal entities;
 - (iii) Transported isolated intermediate means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;
15. *Site* means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;
16. *Actors in the supply chain* means all manufacturers and/or importers and/or downstream users;
17. *Communicate down the supply chain* means that each actor in the supply chain communicates to the downstream user whom he supplies with a substance;
18. *Communicate up the supply chain* means that a downstream user communicates to the actor in the supply chain who has supplied him with a substance;
19. *Competent authority* means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;
20. *Phase-in substance* means a substance which over the 15 years preceding the entry into force of this Regulation meets at least one of the following criteria:
- (a) it was manufactured in or imported into the Community, or the accession countries joining it on 1 May 2004, by a manufacturer or importer and is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS),
 - (b) it was manufactured in the Community, or the accession countries joining it on 1 May 2004, but not placed on the market by the manufacturer or importer,
 - (c) it was placed on the market in the Community, or the accession countries joining it on 1 May 2004, and between 18.9.1981 and 31.10.1993 inclusive it was also placed on the market by the manufacturer or importer and was considered as having been notified in accordance with Article 8 (1) first indent of Directive 79/831, but not meeting the definition of a polymer in Directive 92/32,
- provided the manufacturer or importer has documentary evidence of this.
21. *Notified substance* means a substance for which a notification was submitted and which could be placed on the market in accordance with Directive 67/548/EEC;
22. *Product and process orientated research and development* means any scientific development related to product development, the further development of a substance

- in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;
- 23. *Scientific research and development* means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year;
 - 24. *Registrant's own use* means an industrial or professional use by the registrant;
 - 25. *Identified use* means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user and that is covered in the safety data sheet communicated to the downstream user concerned;
 - 26. *Undesirable use* means a use by downstream users which the registrant advises against;
 - 27. *Robust study summary* means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;
 - 28. *Per year* means per calendar year unless stated otherwise;
 - 29. *Restriction* means any condition for or prohibition of the manufacture, use or placing on the market.

TITLE II **REGISTRATION OF SUBSTANCES**

CHAPTER 1 **SCOPE**

Article 4 *Scope*

1. The provisions of this Title shall not apply to the extent that a substance is used:
 - in medicinal products for human or veterinary use within the scope of Council Regulation (EEC) No 2309/93³⁰, Directive 2001/82/EC of the European Parliament and of the Council³¹ and Directive 2001/83/EC of the European Parliament and of the Council³²;
 - as food additives in foodstuffs within the scope of Council Directive 89/107/EEC³³;
 - as flavourings in foodstuffs within the scope of Commission Decision 1999/217/EC³⁴;
 - as additives in feedingstuffs within the scope of Council Directive 70/524/EEC³⁵;
 - in animal nutrition within the scope of Council Directive 82/471/EEC³⁶.
2. The following shall be exempted from Title II:
 - (a) substances included in Annex II;
 - (b) substances covered by Annex III;
 - (c) substances on their own or in preparations, registered in accordance with the present Title, exported from the Community by an actor in the supply chain and re-imported into the Community by another actor in the same supply chain who:
 - shows that the substance being re-imported is the same as the exported substance;
 - shows he has been provided with the information in accordance with Articles 30 and 31 relating to the exported substance.

³⁰ OJ L 214, 24.8.1993, p. 1.

³¹ OJ L 311, 28.11.2001, p. 1.

³² OJ L 311, 28.11.2001, p. 67.

³³ OJ L 40, 11.2.1989, p. 27.

³⁴ OJ L 84, 27.3.1999, p. 1.

³⁵ OJ L 270, 14.12.1970.

³⁶ OJ L 213, 21.7.1982, p. 8.

3. On site isolated intermediates or transported isolated intermediates shall be exempted from Chapters 2 and 3 of Title II, without prejudice to Chapters 4 to 6.

CHAPTER 2

GENERAL OBLIGATION TO REGISTER AND INFORMATION REQUIREMENTS

Article 5

General obligation to register substances on their own or in preparations

1. Any manufacturer of a substance in quantities of 1 tonne or more per year shall submit a registration to the Agency.

Any importer of a substance, either on its own or in a preparation, in quantities of 1 tonne or more per year shall submit a registration to the Agency.
2. For monomers that are used as on site isolated intermediates or transported isolated intermediates, Articles 15 and 16 shall not apply.
3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the non-registered monomer substance(s) or other non-registered substance(s):
 - if the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s), and
 - if the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.
4. A submission for registration shall be accompanied by the fee as set by the Agency.

Article 6

General obligation to register substances in articles

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if:
 - it is present in those articles in quantities totalling over 1 tonne per producer or importer per year (each article type shall be considered separately); and
 - it meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC; and
 - it is intended to be released during normal and reasonably foreseeable conditions of use.
2. Any producer or importer of articles shall notify the Agency of any substance contained in those articles in accordance with paragraph 3, if:
 - it is present in those articles in quantities totalling over 1 tonne per producer or importer per year; and

- it meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC; and
 - the producer or importer knows, or is made known, that the substance is likely to be released during normal and reasonably foreseeable conditions of use, even though this release is not an intended function of the article; and
 - the quantity of the substance released may adversely affect human health or the environment.
3. If the conditions in paragraph 2 are met, the information to be notified shall include the following, in the format specified by the Agency in accordance with Article 108:
- (a) his identity and contact details;
 - (b) the registration number(s) referred to in Article 18 (1), if available;
 - (c) the identity of the substance(s) as specified in section 2 of Annex IV;
 - (d) the classification of the substance;
 - (e) a brief description of the use(s) of the article;
 - (f) the tonnage range of the substance (e.g. 1-10 tonnes, 10-100 tonnes, etc.).
4. The Agency may take decisions requiring producers or importers of articles to register, in accordance with Title II, any substance contained in those articles and notified in accordance with paragraph 3.
5. Paragraphs 1 to 4 shall not apply to substances that have already been registered for that use by an actor up the supply chain.
6. Paragraphs 1 to 4 shall apply 3 months after the deadline specified in Article 21 (3).
7. Legislation for the implementation of this Article may be adopted in accordance with the procedure referred to in Article 130 (3).

Article 6a
Only representative of a non-Community manufacturer

1. A natural or legal person established outside the Community who manufactures a substance imported into the Community on its own, in preparations or in articles may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations imposed on importers under Title II.
2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 33, he shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet.

3. If a representative is appointed in accordance with the present article, the non-Community exporter shall inform the importer(s) within the same supply chain of the appointment. These importers shall be considered as downstream users for the purposes of the present Regulation.

Article 7

Exemption from the general obligation to register for product and process orientated research and development (PPORD)

1. Articles 5 and 19 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development with a number of listed customers and in a quantity which are limited to the purpose of product and process orientated research and development.
2. For the purpose of paragraph 1, the manufacturer or importer shall notify the Agency of the following information in the format specified by the Agency in accordance with Article 108:
 - (a) the identity of the manufacturer or importer;
 - (b) the identity of the substance;
 - (c) the classification of the substance, if any;
 - (d) the estimated quantity,
 - (e) the list of customers referred to in paragraph 1 and
 - (f) sufficient information on the research and development programme to enable the Agency to take informed decisions under paragraphs 4 and 7.

The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.

3. The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Agency, and shall forthwith communicate that number and date to the manufacturer or importer concerned.
4. The Agency shall check the completeness of the information supplied by the notifier. It may decide to impose conditions with the aim to ensure that the substance or the preparation or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2 (e) in reasonably controlled conditions and will not be made available to the general public at any time either on its own or in a preparation or article and that remaining quantities will be re-collected for disposal after the exemption period.
5. In the absence of any indication to the contrary, the manufacturer or importer of the substance may manufacture or import the substance not earlier than four weeks after the notification.

6. The manufacturer or importer shall comply with any conditions imposed by the Agency in accordance with paragraph 4. 7. The Agency may decide to extend the five-year exemption period by a further maximum of five years or, in the case of substances to be exclusively used in the development of medicinal products for human or veterinary use, for a further maximum of 10 years, upon request if the manufacturer or importer can demonstrate that such an extension is justified by the research and development programme.

8.

The Agency shall forthwith communicate any draft decisions to the competent authorities of each Member State in which the manufacture, import or product and process orientated research takes place.

When taking decisions as foreseen under paragraphs 4 and 7, the Agency shall take into account any comments made by such competent authorities.

9. The Agency and the competent authorities of the respective Member States shall always keep confidential the information submitted in accordance with this Article.
10. An appeal may be brought against Agency decisions under paragraphs 4 and 7 in accordance with Articles 87 to 89.

Article 8

Substances in plant protection and biocidal products

1. Active substances manufactured or imported for use in plant protection products only and included either in Annex I to Council Directive 91/414/EEC or in Commission Regulation (EEC) No 3600/92, Commission Regulation (EC) No 703/2001, Commission Regulation (EC) No 1490/2002, Commission Decision 2003/565/EC and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of the Directive shall be considered as registered for the manufacture or import for the uses covered by such an inclusion and therefore as fulfilling the requirements of Chapter 2 of Title II as well as Article 20.
2. Active substances manufactured or imported for use in biocidal products only and included either in Annex I, IA or IB to Directive 98/8/EC or in {Second Review Regulation, not yet adopted by Commission}, until the date of the decision referred to in Article 16 (2), second subparagraph of Directive 98/8/EC, shall be considered as registered for the manufacture or import for the uses covered by such an inclusion and therefore as fulfilling the requirements of Chapter 2 of Title II as well as Article 20.

Article 9

Information to be submitted for general registration purposes

1. A registration required by Article 5 or by Article 6 paragraphs 1 or 4 shall include the following information in the format specified by the Agency in accordance with Article 108:

- (a) a technical dossier including:
 - (i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex IV;
 - (ii) the identity of the substance(s) as specified in section 2 of Annex IV;
 - (iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex IV; this information shall represent all the registrant's identified use(s);
 - (iv) the classification and labelling of the substance as specified in section 4 of Annex IV;
 - (v) guidance on safe use of the substance as specified in Section 5 of Annex IV
 - (vi) summaries of the information derived from the application of Annexes V to IX;
 - (vii) robust study summaries of the information derived from the application of Annexes V to IX, if required under Annex I;
 - (viii) a statement as to whether or not information has been generated by testing on vertebrate animals;
 - (ix) proposals for testing where required by the application of Annexes V to IX;
 - (x) a declaration whether he agrees that his summaries and robust study summaries of the information derived from the application of Annexes V to VIII with regard to tests not involving vertebrate animals are shared against payment with subsequent registrants; and
- (b) a chemical safety report when it is required according to Article 13.

Article 10
Joint submission of data by members of consortia

1. When a substance is intended to be manufactured in the Community by two or more manufacturers and/or imported by two or more importers, they may join in a consortium for the purposes of registration. Parts of the registration shall then be submitted by one manufacturer or importer acting, with their agreement, on behalf of other manufacturers and/or importers in the following way:

Each participant of the consortium shall submit separately the information specified in Article 9 (1) (a) (i) to (iii) and (viii).

The one manufacturer or importer submitting on behalf of the other participants of the consortium shall submit the information specified in Article 9 (1) (a) (iv), (vi), (vii) and (ix).

The participants of the consortium may decide themselves whether they submit the information specified in Article 9 (1) (a) (v) and (b) separately or whether the one manufacturer or importer submits this information on behalf of the others.

2. Each registrant who is a participant of a consortium shall pay only one third of the fee for registration.

Article 11
Information to be submitted depending on tonnage

1. The technical dossier referred to in Article 9 (1) (a) shall include under items (vi) to (viii) as a minimum the following:
 - (a) the information specified in Annex V for substances manufactured or imported in quantities of 1 tonne or more per year per manufacturer or importer;
 - (b) the information specified in Annexes V and VI for substances manufactured or imported in quantities of 10 tonnes or more per year per manufacturer or importer;
 - (c) the information specified in Annexes V and VI and testing proposals for the provision of the information specified in Annex VII for substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer;
 - (d) the information specified in Annexes V and VI and testing proposals for the provision of the information specified in Annexes VII and VIII for substances manufactured or imported in quantities of 1000 tonnes or more per year per manufacturer or importer.
2. As soon as the quantity of a substance that has already been registered reaches the next tonnage threshold the appropriate additional information required by paragraph 1 as well as any updates of the other elements of the registration in the light of this additional information shall be submitted to the Agency.

Article 12
General requirements for generation of information on intrinsic properties of substances

1. Information on intrinsic properties of substances may be generated by other means than tests, in particular from the use of qualitative or quantitative structure-activity relationship models or from information from structurally related substances, provided the conditions set out in Annex IX are met.
2. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted according to the test methods laid down in Annex X.

Information on intrinsic properties of substances may be generated according to other test methods provided that the conditions set out in Annex IX are met.

3. Laboratory tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and with the provisions of Directive 86/609/EEC.
4. If a substance has already been registered, a new registrant is entitled to refer to studies and test reports (hereinafter referred to as "studies") for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that he can submit a letter of access from the previous registrant(s) allowing the use of the studies.

However, a new registrant shall not refer to such studies to provide the information required in section 2 of Annex IV.

Article 13
Chemical safety report and
duty to apply and recommend risk reduction measures

1. Without prejudice to Article 4 of Council Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with the present Chapter if the registrant manufactures or imports it in quantities of 10 tonnes or more per year.

The chemical safety report (CSR) shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and Annex I for either each substance on its own or in a preparation or a group of substances.

2. A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a preparation if the concentration of the substance in the preparation is less than the lowest of:
 - (a) the applicable concentrations defined in the table of Article 3 (3) of European Parliament and Council Directive 1999/45/EC, or
 - (b) the concentration limits given in Annex I to Council Directive 67/548/EEC, or
 - (c) the concentration limits given in Part B of Annex II to European Parliament and Council Directive 1999/45/EC, or
 - (d) the concentration limits given in Part B of Annex III to European Parliament and Council Directive 1999/45/EC, or
 - (e) the concentration limits given in an agreed entry in the classification and labelling inventory established under Title XI, or
 - (f) if the substance meets the criteria in Annex XII, 0.1%.
3. A chemical safety assessment of a substance shall include the following:
 - (i) Human health hazard assessment
 - (ii) Human health hazard assessment of physicochemical properties

- (iii) Environmental hazard assessment
 - (iv) PBT and vPvB assessment
4. If as a result of steps (i) to (iv) the manufacturer or importer concludes that the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC or is assessed to be a PBT or vPvB, the chemical safety assessment shall also consider the following steps:
- (v) Exposure assessment
 - (vi) Risk characterisation
- The exposure assessment and the risk characterisation shall address all manufacturer's and importer's identified uses.
5. The chemical safety report need not include consideration of the risks to human health from the following end uses:
- (i) in food contact materials within the scope of Council Directive 89/109/EEC.
 - (ii) in cosmetic products within the scope of Council Directive 76/768/EEC³⁷.
6. Any manufacturer or importer shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets they supply in accordance with Article 29.
7. Any manufacturer or importer required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

³⁷

OJ L 262 , 27.09.1976, p. 169

CHAPTER 3

OBLIGATION TO REGISTER AND INFORMATION REQUIREMENTS FOR POLYMERS

Article 14

Polymers

Polymers are exempted from registration under Title II.

CHAPTER 4

OBLIGATION TO REGISTER AND INFORMATION REQUIREMENTS

FOR CERTAIN TYPES OF ISOLATED INTERMEDIATES

Article 15

Registration of on site isolated intermediates

1. Any manufacturer of an on site isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to the Agency for the on site isolated intermediate.
2. A registration for an on site isolated intermediate shall include the following information to the extent that the manufacturer can submit it without any additional testing in the format specified by the Agency in accordance with Article 108:
 - (a) the identity of the manufacturer as specified in section 1 of Annex IV;
 - (b) the identity of the intermediate as specified in section 2 of Annex IV ;
 - (c) the classification of the intermediate, and
 - (d) any available existing information on physicochemical, human health or environmental properties of the intermediate.

Article 16

Registration of transported isolated intermediates

1. Any manufacturer or importer of a transported isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.
2. A registration for a transported isolated intermediate shall include the following information in the format specified by the Agency in accordance with Article 108 :
 - (a) the identity of the manufacturer or importer as specified in section 1 of Annex IV;
 - (b) the identity of the intermediate as specified in section 2 of Annex IV;
 - (c) the classification of the intermediate, and
 - (d) any available existing information on physicochemical, human health or environmental properties of the intermediate.
3. A registration for a transported isolated intermediate in quantities of more than 1000 tonnes per year, shall include the information specified in Annex V in addition to the information required by paragraph 2. For the generation of this information, Article 12 shall apply.

4. Paragraphs 2 and 3 shall only apply to transported isolated intermediates the transport of which to other sites takes place under strict contractual control, (including toll or contract manufacture) and where the synthesis of (an)other substance(s) from that intermediate takes place on those other sites under the following strictly controlled conditions:
- (a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, transportation (including transport by rail, road, inland waterway, sea or air and pipeline transfer), purification, cleaning and maintenance, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;
 - (b) where there is potential for exposure, procedural and control technologies are available which minimise emission and the resulting exposure;
 - (c) only properly trained and authorised personnel handle the substance;
 - (d) in case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
 - (e) transport operations are in compliance with the requirements of Council Directive 94/55/EC;
 - (f) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;
 - (g) Substance handling procedures are well documented and strictly supervised by the site operator;
 - (h) the registrant operates a system of product stewardship and monitors users to ensure compliance with the conditions listed above.

If the above conditions are not fulfilled, the registration shall include the information specified in Article 9.

Article 17
Joint submission of data by participants in consortia

1. When an on site isolated intermediate or transported isolated intermediate is intended to be manufactured in the Community by two or more manufacturers and/or imported by two or more importers, they may join in a consortium for the purposes of registration. Parts of the registration shall then be submitted by one manufacturer or importer acting, with their agreement, on behalf of other manufacturers and/or importers in the following way:

Each participant of the consortium shall submit separately the information specified in Article 15 (2) (a) and (b) and Article 16 (2) (a) and (b).

The one manufacturer or importer submitting on behalf of the other participants of the consortium shall submit the information specified in Article 15 (2) (c) and (d) and Article 16 (2) (c) and (d) and (3), where relevant.

2. Each registrant who is a participant of a consortium shall pay only one third of the fee.

CHAPTER 5

COMMON PROVISIONS FOR ALL REGISTRATIONS

Article 18
Duties of the Agency

1. The Agency shall assign a number to each registration, which is to be used for all correspondence regarding the registration, and a registration date, which shall be the date of receipt of the registration at the Agency. The Agency shall forthwith communicate the registration number and the registration date to the manufacturer or importer concerned.
2. The Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required by Articles 9 and 11 or Article 15 or 16 are present within three weeks from the registration date or, in the case of registrations of phase-in substances submitted within 2 months before the relevant deadline of Article 21, within 3 months from that deadline. The completeness check shall not comprise an assessment of the quality or the adequacy of any data or justifications submitted.
 - (a) If a registration is incomplete, the Agency shall inform the registrant, within three weeks from the registration date, as to what further information is required in order for the registration to be complete in accordance with this Title, while setting a reasonable deadline for this. The registrant shall submit such further information to the Agency within the deadline set. The Agency shall confirm the submission date of the further information to the registrant. The Agency shall perform a further completeness check, considering the further information submitted.
 - (b) The Agency shall reject the registration, if the registrant fails to complete his registration within the deadline set.
3. The Agency shall communicate the registration dossier together with the registration number, the registration date, the result of the completeness check and any request for further information and deadline set in accordance with paragraph (2) (a) to the competent authority of the relevant Member State within 30 days of the registration date. The relevant Member State shall be the Member State within which the manufacture takes place or the importer is established.

The Agency shall forthwith communicate to the competent authority of the relevant Member State any further information submitted by the registrant.
4. An appeal may be brought against Agency decisions under paragraph 2 in accordance with Articles 87 to 89.

Article 19
Manufacturing and import of substances

1. Subject to Article 21, substances shall not be manufactured in the Community or imported unless they have been registered in accordance with the relevant provisions of this Title.

A registrant may start the manufacture or import of a substance, if there is no indication to the contrary from the Agency in accordance with Article 18 (2) within the three weeks after the registration date, without prejudice to the 4th subparagraph of Article 25 (4).

In the case of registrations of phase-in substances submitted within 2 months before the relevant deadline of Article 21 as referred to in Article 18 (2), a registrant may continue the manufacture or import of the substance for 3 months from that deadline or until rejection by the Agency, whichever is the earlier.

2. If the Agency has informed the registrant that he is to submit further information in accordance with Article 18 (2) (a), the registrant may start the manufacture or import if there is no indication to the contrary from the Agency, within the three weeks after receipt by the Agency of the further information necessary to complete his registration, without prejudice to the 4th subparagraph of Article 25 (4).
3. If one manufacturer or importer submits parts of the registration on behalf of other manufacturers and /or importers, as provided for in Article 10 or 17, those other manufacturers and/or importers may only manufacture the substance in the Community or import it after the expiry of the time-limit laid down in paragraph 1 or 2 and provided there is no indication to the contrary from the Agency in respect of the registration of the one manufacturer or importer acting on behalf of others.
4. This Article shall also apply to on site isolated intermediates or transported isolated intermediates.

Article 20
Further duties of registrants

1. Following registration, registrants shall be responsible on their own initiative for immediately informing the Agency in writing of the following in the format specified by the Agency in accordance with Article 108:
 - (a) any change in their status (manufacturer or importer) or identity (e.g. name, address);
 - (b) any change in the composition of the substance as given in Annex IV;
 - (c) significant changes in the annual or total quantities manufactured or imported by him;
 - (d) new uses for which the substance is manufactured or imported of which he may reasonably be expected to have become aware;

- (e) significant new knowledge of the risks of the substance for man and/or the environment of which they may reasonably be expected to have become aware;
- (f) any change in the classification and labelling of the substance;
- (g) any update or amendment of the chemical safety report.

The Agency shall communicate this information to the competent authority of the relevant Member State.

2. In case Article 10 or 17 were applied, each registrant shall submit separately the information specified in paragraph 1 (c).

CHAPTER 6

TRANSITIONAL PROVISIONS APPLICABLE TO CERTAIN TYPES OF SUBSTANCES: PHASE-IN SUBSTANCES AND NOTIFIED SUBSTANCES

Article 21 *Specific provisions for phase-in substances*

1. Article 19 shall not apply for a period of 3 years after the entry into force of this Regulation:
 - (a) to phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548 and manufactured in the Community or imported in quantities reaching 1 tonne or more per year per manufacturer or per importer at least once following the entry into force of this Regulation; and
 - (b) to phase-in substances manufactured in the Community or imported in quantities reaching 1000 tonnes or more per year per manufacturer or per importer at least once following the entry into force of this Regulation.
2. Article 19 shall not apply for a period of 6 years after entry into force of this Regulation, to phase-in substances manufactured in the Community or imported in quantities reaching 100 tonnes or more per year per manufacturer or per importer at least once following the entry into force of this Regulation.
3. Article 19 shall not apply for a period of 11 years after entry into force of this Regulation to phase-in substances manufactured in the Community or imported in quantities reaching 1 tonne or more per year per manufacturer or per importer at least once following the entry into force of this Regulation.

Article 22
Notified substances

1. A notification submitted in accordance with Directive 67/548/EEC shall be considered as a registration for the purposes of this Title and the Agency shall assign a registration number within one year of entry into force of this Regulation.
2. When the quantity of a notified substance manufactured or imported per manufacturer or importer reaches the next higher tonnage threshold under Article 11, the additional required information corresponding to that tonnage threshold as well as all the lower tonnage thresholds shall be submitted in accordance with Articles 9 and 11, unless it was already submitted in accordance with those Articles.

TITLE III

DATA SHARING AND

AVOIDANCE OF UNNECESSARY TESTING

CHAPTER 1

OBJECTIVES AND GENERAL RULES

Article 23

Objectives and general rules

1. In order to avoid unnecessary animal testing, testing on vertebrate animals for the purposes of this Regulation shall only be undertaken as a last resort. It is also necessary to take measures limiting unnecessary duplication of other tests.
2. The sharing and joint submission of information in accordance with this Regulation shall concern technical data and in particular information related to the intrinsic properties of substances. The registrants shall refrain from exchanging information concerning their market behaviour in particular on production capacities, production or sale volumes, imported volumes or market shares.
3. Any summaries or robust study summaries of studies submitted in the framework of a registration at least 10 years previously may be made freely available by the Agency to any other registrants or potential registrants.
4. With regard to tests not involving vertebrate animals, this Title only applies to potential registrants if previous registrants have given a declaration in accordance with Article 9 (1) (a) (x).

CHAPTER 2

RULES FOR NON-PHASE-IN SUBSTANCES

Article 24

Duty to inquire prior to registration

1. Before testing on vertebrate animals is carried out in order to meet information requirements for the purposes of registration, paragraphs 2 to 4 shall apply.
2. The potential registrant shall consult the database referred to in Article 73 (2) (d) in order to find out whether the same substance has already been registered.
3. The potential registrant shall inquire from the Agency, whether a registration has already been submitted for the same substance. He shall submit to the Agency with the inquiry
 - (a) his identity and

- (b) the identity of his substance, as referred to in sections 2.1 and 2.3 of Annex IV and
- (c) which information requirements would require new studies involving vertebrate animals to be carried out by him and
- (d) which information requirements would require other new studies to be carried out by him.

4. If

- (a) the same substance has previously not been registered, the Agency shall inform the potential registrant thereof;
- (b) the same substance has previously been registered less than 10 years ago, the Agency shall inform the potential registrant without delay of the names and addresses of the previous registrant(s) and of the relevant summaries or robust study summaries of the studies, as the case may be, already submitted by them involving vertebrate animals.

These studies shall not be repeated.

The Agency shall also inform the potential registrant of the relevant summaries or robust study summaries of the studies, as the case may be, already submitted by the previous registrants not involving vertebrate animals for which the previous registrants have given a declaration in accordance with Article 9 (1) (a) (x).

The Agency shall simultaneously inform the previous registrants of the name and address of the potential registrant;

- (c) another potential registrant made an inquiry for the same substance, the Agency shall inform both potential registrants without delay of the name and address of the other potential registrant and of the studies involving vertebrate animals required of both of them.

Article 25 *Sharing of existing data between registrants*

1. In the case of substances previously registered less than 10 years ago as referred to in Article 24 (4) (b), the potential registrant shall ask the previous registrant(s) for the information involving tests on vertebrate animals he requires in order to register. He may ask the registrants for any information on tests not involving vertebrate animals for which the previous registrants have given a declaration in accordance with Article 9 (1) (a) (x).
2. The potential and the previous registrant(s) for the same substance shall take all reasonable steps to reach an agreement on the sharing and making available of studies involving any type of test. Such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order.

3. If an agreement on the sharing of studies has been reached, the previous registrant(s) shall grant a letter of access to the potential registrant for the studies concerned within two weeks of receipt of payment.

The new registrant shall refer to these studies in his registration dossier and shall submit the letter of access from the previous registrant(s).

4. If there is failure to reach such an agreement, the potential registrant may inform the Agency and the previous registrant(s) thereof at least 1 month after receipt, from the Agency, of the name and address of the previous registrant(s).
 - (a) The previous registrant(s) shall have 1 month from the receipt of the information referred to in the preceding sentence to inform the potential registrant and the Agency of the cost incurred by him for the study concerned. On request of the potential registrant the Agency shall take the decision to make available to him the summaries or robust study summaries, as the case may be, of the studies concerned, or the results thereof, on receipt of proof that he paid fifty percent of the cost shown by the previous registrant(s) to the latter(s).
 - (b) If the previous registrant(s) fail(s) to inform the potential registrant and the Agency of the cost within the deadline, the Agency, on request, shall take the decision to make available to the potential registrant the summaries or robust study summaries, as the case may be, of the studies concerned as required by him. The previous registrant(s) shall have a claim on the potential registrant for fifty percent of the cost, which shall be enforceable in the national courts.
 - (c) An appeal may be brought against Agency decisions under this Article in accordance with Articles 87 to 89.

5. The registration waiting period in accordance with Article 19 (1) for the new registrant shall be extended by a period of 4 months, if requested by the previous registrant.

CHAPTER 3

RULES FOR PHASE-IN-SUBSTANCES

Article 26

Duty to pre-register for phase-in substances

1. In order to make use of the transitional regime of Article 21 each potential registrant of a phase-in substance shall submit the following information to the database managed by the Agency in the format specified by the Agency in accordance with Article 108:
 - (a) the name of the substance and, where applicable, the group of substances, including its Einecs and CAS number, if available;
 - (b) his name and address and the name of the contact person;
 - (c) envisaged deadline for registration/tonnage band;

- (d) an indication of the physicochemical, toxicological and ecotoxicological endpoints/properties for which he has relevant studies or information available to him for the purpose of registration information requirements, if any, and
- (e) if studies referred to under (d) include tests on vertebrate animals and if not, whether he considers to give a declaration in accordance with Article 9 (1) (a) (x) with his registration.

The potential registrant may limit the information to be submitted under the first subparagraph to those endpoints/properties for which tests were required.

2. The information referred to in paragraph 1 shall be submitted at the latest 18 months before
 - the deadline laid down in Article 21 (1) for phase-in substances manufactured or imported in quantities of 1000 tonnes or more per year
 - the deadline laid down in Article 21 (2) for phase-in substances manufactured or imported in quantities of 1 tonne or more per year.
3. Registrants not submitting the information required under paragraph 1 shall not be able to rely on Article 21.
4. Manufacturers and importers of phase-in-substances in quantities of less than 1 tonne per year as well as downstream users may submit the information referred to in paragraph 1 to the database managed by the Agency in the format specified by the Agency in accordance with Article 108.
5. The Agency shall record the information submitted in accordance with the previous paragraphs in a database. It shall grant access to these data held on each substance to the manufacturers and importers who have submitted information on that substance in accordance with the previous paragraphs. Member State competent authorities shall also have access to this data.

Article 27 Substance Information Exchange Fora

1. All manufacturers and importers who have submitted information to the database in accordance with Article 26 for the same phase-in substance are participants of a substance information exchange forum (SIEF).
2. The aim of each SIEF is to minimise the duplication of tests by exchanging information. SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies and arrange for them to be carried out.

Article

28

Sharing of data involving tests on vertebrate animals 1. Before testing on vertebrate animals is carried out in order to meet the information requirements for the purpose of registration, a participant of a SIEF shall inquire whether a relevant study is available by consulting the database referred to in Article 26 and by communicating within his SIEF. If a relevant study is available within the SIEF, a

participant of the SIEF who would have to carry out a test on vertebrate animals shall request that study within two months of the deadline in Article 26(2).

Within two weeks of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall take all reasonable steps to reach an agreement on how to share the cost among them. If they cannot reach an agreement on how to do this, the cost shall be shared equally. The owner shall provide the study within two weeks of receipt of payment.

2. If a relevant study involving tests on vertebrate animals is not available within the SIEF, the participant shall contact other participants of the SIEF who submitted information about the same or a similar use of the substance and who might need to carry out that study; they shall take all reasonable steps to reach an agreement on who carries it out on behalf of other participants.
- 3.. If the owner of such a study refuses to provide either proof of the cost of that study or the study itself to another participant(s), then the other participant(s) shall proceed as if no relevant study were available within the SIEF, unless a registration containing the summary or robust study summary, as the case may be, of the study has already been submitted by another registrant. In this case, the Agency shall take the decision to make available to the other participant(s) that summary or robust study summary, as the case may be. The other registrant shall have a claim on the participants for an equal share of the cost, which shall be enforceable in the national courts.
4. An appeal may be brought against Agency decisions under this sub-paragraph in accordance with Articles 87 to 89.
5. The owner of the study who refused to provide either the costs or the study itself shall be sanctioned in accordance with Article 123.

TITLE IV INFORMATION IN THE SUPPLY CHAIN

Article 29 Requirements for Safety Data Sheets

1. The person responsible for placing a substance or preparation on the market, whether the manufacturer of a substance, importer of a substance or preparation, downstream user or distributor, shall supply the recipient, who is a downstream user or distributor of the substance or preparation, with a safety data sheet in accordance with Annex Ia, if the substance or preparation meets the criteria for classification as dangerous according to Directives 67/548/EEC or 1999/45/EC.
2. Any actor in the supply chain required to carry out a chemical safety assessment as part of their registration for a substance according to Article 13 or in accordance with Article 34 shall ensure that the information in the safety data sheet is consistent with the information in this assessment.

If the safety data sheet is developed for a preparation, the actor in the supply chain may prepare a chemical safety assessment for the preparation in accordance with Annex Ib. In that case, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the preparation instead of with the chemical safety report for each substance in the preparation.

3. Any person who is responsible for placing a preparation on the market, whether the manufacturer, importer, downstream user or distributor, shall supply, on request of a downstream user, a safety data sheet in accordance with Annex Ia, if the preparation does not meet the criteria for classification as dangerous according to Articles 5, 6 and 7 of Directive 1999/45/EC, but the preparation contains in an individual concentration of $\geq 1\%$ by weight for non-gaseous preparations and $\geq 0,2\%$ by volume for gaseous preparations at least one substance posing health or environmental hazards, or one substance for which there are Community workplace exposure limits.
4. The safety data sheet need not be supplied where dangerous substances or preparations offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of health, safety and the environment, unless requested by a downstream user.
5. Downstream users may require that the safety data sheet is supplied in the official language(s) of the Member States where the substance or preparation is placed on the market.
6. The safety data sheet shall be dated and contain the following headings:
 1. identification of the substance/preparation and of the company/undertaking;
 2. hazards identification;
 3. composition/information on ingredients;

4. first-aid measures;
5. fire-fighting measures;
6. accidental release measures;
7. handling and storage;
8. exposure controls/personal protection;
9. physical and chemical properties;
10. stability and reactivity;
11. toxicological information;
12. ecological information;
13. disposal considerations;
14. transport information;
15. regulatory information;
16. other information.

Where a chemical safety assessment is performed the relevant exposure scenarios shall be placed in an annex to the safety data sheet.

7. For identified uses, a downstream user shall use appropriate information from the safety data sheet supplied to him.
8. A safety data sheet shall be supplied on paper or electronically at the latest at the time of the first delivery of a substance following the entry into force of this Regulation. Suppliers shall update it without delay on the following occasions:
 - (a) as soon as new data which may be necessary to enable appropriate risk management measures to be identified and applied become available;
 - (b) once the substance has been registered;
 - (c) once an authorisation has been granted or refused;
 - (d) once a restriction has been imposed.

The new dated version of the information, identified as 'Revision: (date)' shall be provided free of charge to all former recipients whom they supplied the substance or preparation within the preceding 12 months.

Article 30

Duty to communicate information down the supply chain for substances and preparations for which a safety data sheet is not required

1. All actors in the supply chain of a substance on its own or in a preparation who do not have to supply a safety data sheet in accordance with Article 29 shall communicate the following information down the supply chain to the immediate downstream user or distributor:
 - (a) the registration number(s) referred to in Article 18 (1), if available;
 - (b) whether the substance is subject to authorisation and any authorisation granted or denied under Title VII in this supply chain;
 - (c) any restriction imposed under Title VIII;
 - (d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied.
2. Information shall be communicated in writing at the latest at the time of the first delivery of a substance following the entry into force of this Regulation. Suppliers shall update this information and communicate it down the supply chain without delay on the following occasions:
 - (a) as soon as new data which may be necessary to enable appropriate risk management measures to be identified and applied become available;
 - (b) once the substance has been registered;
 - (c) once an authorisation has been granted or refused;
 - (d) once a restriction has been imposed.

This new information shall be provided free of charge to all former recipients whom they supplied the substance or preparation within the preceding 12 months.

Article 31
***Duty to communicate information on
 substances and preparations up the supply chain***

Any actor in the supply chain of a substance or a preparation shall communicate the following information to the next actor or distributor up the supply chain:

- new information on hazardous properties, regardless of the uses concerned; and
- any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Distributors shall pass on this information to the next actor or distributor up the supply chain.

Article 32
Access to the safety data sheet information for workers

Workers and their representatives shall be granted access by their employer to the information provided in accordance with Article 29 and 30 in relation to substances they use or may be exposed to in the course of their work.

Article 33
Obligation to keep information

All actors in the supply chain shall assemble and keep available all the information they require to carry out their duties under this Regulation for a period of at least 10 years after they last manufactured, imported, supplied or used the substance on its own, or in a preparation. They shall submit this information or make it available without delay upon request to any competent authority of that Member State in which the actor in the supply chain is established or to the Agency, without prejudice to Titles II and VI.

TITLE V **DOWNSTREAM USERS**

Article 34

Downstream user chemical safety assessments and duty to apply and recommend risk reduction measures

1. A downstream user may provide information to assist in the preparation of a registration.
2. Any downstream user shall have the right to make a use known in writing to the manufacturer, importer or downstream user who supplies him with a substance with the aim to make this an identified use. In doing so, he shall provide sufficient information to allow his supplier to prepare an exposure scenario for his use in the supplier's chemical safety assessment.
3. For registered substances, the manufacturer or importer shall comply with the obligation in Article 13 before he next supplies the substance to the downstream user making the request, as long as the request was made at least one month before the supply, or within 1 month after the request, whichever is the later. For phase-in substances, the manufacturer or importer shall comply with this request and with the obligations of Article 13 before the relevant deadline in Article 21, as long as the downstream user makes his request at least 12 months before the deadline in question.
4. A downstream user of a substance on its own or in a preparation shall prepare a chemical safety report in accordance with Annex XI for any use outside the conditions described in an exposure scenario communicated to him in a safety data sheet.

If the downstream user implements or recommends an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to him, he need not prepare a chemical safety report.

The downstream user need not prepare a chemical safety report if:

- a safety data sheet is not required to be communicated with the substance; or
 - a chemical safety report is not required to be completed by his supplier.
5. Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control the risks which are either
 - (a) identified in the safety data sheet(s) supplied to him, or
 - (b) identified in his own chemical safety assessment.
 6. Downstream users shall keep their chemical safety report available and up to date.
 7. Article 13 paragraphs 2 and 5 shall apply *mutatis mutandis*.

Article 35
Obligation for downstream users to report information

1. Before commencing a particular use of a substance that has been registered by an actor up the supply chain in accordance with Article 5 or 16 any downstream user shall report to the Agency the information referred to in paragraph 2, if a safety data sheet is communicated to him that includes an exposure scenario and the downstream user is using the substance outside the conditions described in that exposure scenario.
2. The information reported by the downstream user shall include the following in the format specified by the Agency in accordance with Article 108:
 - (a) his identity and contact details;
 - (b) the registration number(s) referred to in Article 18 (1), if available;
 - (c) the identity of the substance(s) as specified in section 2 of Annex IV;
 - (d) if known, the identity of the manufacturer(s) or the importer(s);
 - (e) a brief general description of the use(s);
 - (f) a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his chemical safety assessment.
3. The downstream user shall update this information without delay in the event of a change in the information reported in accordance with paragraph 1.
4. A downstream user shall report to the Agency in the format specified by the Agency in accordance with Article 108 if his classification of a substance is different to that of his supplier.
5. Reporting in accordance with this Article shall not be required in respect of a substance, on its own or in a preparation, used by the downstream user in quantities of less than 1 tonne per year.

Article 36
Application of downstream user obligations

1. Downstream users shall be required to comply with the requirements of Article 34 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.
2. Downstream users shall be required to comply with the requirements of Article 35 at the latest 6 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

TITLE VI **EVALUATION OF SUBSTANCES**

CHAPTER 1 **SCOPE AND COMPETENT AUTHORITY**

Article 37 *Scope*

Polymers are exempted from evaluation under the present Title.

CHAPTER 2 **DOSSIER EVALUATION**

Article 38 *Competent authority*

1. For the purposes of Articles 39 to 43, the competent authority shall be the competent authority of the Member State within which the manufacture takes place or the importer is established.

If several manufacturers or importers have joined in a consortium according to Articles 10 or 17, the competent authority shall be the competent authority of the one manufacturer or importer submitting data to the Agency on behalf of the others according to Articles 10 or 17.

Article 39 *Examination of testing proposals*

1. The competent authority shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes VII and VIII for a substance.
2. On the basis of the examination under paragraph 1, the competent authority shall draft one of the following decisions and that decision shall be taken in accordance with the procedure in Articles 48 and 49:
 - (a) a decision requiring the registrant(s) or downstream user(s) concerned to carry out the proposed test and setting a deadline for submission of the summary of the test result, or the robust study summary if required by Annex I;
 - (b) a decision in accordance with point (a), but modifying the conditions under which the test is to be carried out;
 - (c) a decision rejecting the testing proposal.
3. The registrant shall submit the information required to the Agency.

Article 40
Compliance check of registrations

1. The competent authority may examine any registration in order to verify any of the following:
 - (a) that the information in the technical dossier(s) submitted pursuant to Article 9 complies with the requirements of Articles 9, 11, 12 and Annexes IV to VIII,
 - (b) that the adaptations of the standard information requirements and their justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes V to VIII and with the general rules set out in Annex IX.
2. On the basis of an examination made pursuant to paragraph 1, the competent authority may prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and that decision shall be taken in accordance with the procedure in Articles 48 and 49.
3. The registrant shall submit the information required to the Agency.

Article 41
Check of information submitted and follow-up to dossier evaluation

1. The competent authority shall examine any information submitted in consequence of a decision taken under Articles 39 and 40, and draft any appropriate decisions in accordance with Article 39 and 40, if necessary.
2. Once the dossier evaluation is completed, the competent authority shall use the information obtained from this evaluation for the purposes of Articles 43a (1), 56 (3) and 66 (2), and shall transmit the information obtained to the Commission, the Agency and the other Member States. The competent authority shall inform the Commission, the Agency, the registrant and the competent authorities of the other Member States on its conclusions whether or how to use the information obtained.

Article 42
Procedure and Time Periods for examination of testing proposals

1. A competent authority that starts evaluating a testing proposal under Article 39 shall notify this to the Agency.
2. The competent authority shall prepare a draft decision in accordance with Article 39 (2) within 120 days of receiving a registration or downstream user report containing a testing proposal from the Agency.
3. In the case of phase-in substances, the competent authority shall prepare the draft decisions in accordance with Article 39(2):
 - (a) within 5 years after the entry into force of this Regulation for all registrations received within the deadline referred to in Article 21 (1) containing proposals

- for testing in order to fulfil the information requirements in Annexes VII and VIII, and
- (b) within 9 years after the entry into force of this Regulation for all registrations received within the deadline referred to in Article 21 (2) containing proposals for testing in order to fulfil the information requirements in Annex VII only;
 - (c) after these deadlines for any registrations containing testing proposals received within the deadline referred to in Article 21 (3).
4. When the competent authority of a Member State finishes its evaluation activities under Article 39 in respect of a phase-in substance, it shall notify the Agency.

Article 43
Procedure and Time Periods for compliance check

1. A competent authority that starts evaluating the compliance of a registration under Article 40 shall notify this to the Agency.
2. The competent authority shall prepare a draft decision in accordance with Article 40 (2) within 12 months from the start of the evaluation of the substance.
3. When the competent authority of a Member State finishes its evaluation activities under Article 40 in respect of a phase-in substance, it shall notify the Agency.

CHAPTER 3
SUBSTANCE EVALUATION

Article 43a
Criteria for substance evaluation

In order to provide a harmonised approach, the Agency shall also develop criteria for prioritising substances with a view to further evaluation. Prioritisation will be on a risk based approach. The criteria for evaluation shall include consideration of hazard data, exposure data and tonnage bands. The Agency shall take a decision on the criteria for the prioritisation of substances for further evaluation. Member States shall use these criteria for preparing their rolling plans.

Article 43a bis
Competent authority

1. If a Member State, either as a result of a dossier evaluation by its competent authority referred to under Article 38 or from any other relevant source, including information in the registration dossier(s), has reasons for suspecting the substance presents a risk to health or the environment, for example from:
 - structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate suggesting that the substance or one or more of its transformation products has/have properties of concern or is persistent and liable to bio-accumulate; or

- aggregated tonnage from the registrations submitted by several registrants; this Member State shall include the substance concerned in a rolling plan with the aim of becoming competent authority for the purposes of Articles 44 to 46.
2. A rolling plan referred to in paragraph 1 shall cover a period of three years, updated annually, and shall specify the substances the Member State is planning to evaluate each year. The Member State shall submit the rolling plan to the Agency and the other Member States by 28th February each year. The Agency may make comments and Member States may send their comments to the Agency or express their interest in evaluating a substance by the 31 March of each year.
 3. In the case where there have been no comments on a rolling plan or no other Member State has expressed an interest, the Member State shall adopt this rolling plan. The competent authority shall be the competent authority of the Member State that has included the substance in its definitive rolling plan.
 4. In the case where two or more Member States have included the same substance in their draft rolling plans or, after submission of the rolling plans, have expressed an interest in evaluating the substance, the competent authority for the purpose of Article 44 to 46 shall be determined according to the following procedure:

The Agency shall refer the matter to the Member State Committee in order to agree which authority shall be the competent authority, taking into account the principle that the allocation of substances among Member States shall reflect their proportion of the total Community Gross Domestic Product. Wherever possible, priority shall be given to Member States that have already performed dossier evaluations of the substance in question under Articles 39 to 43.

If within 60 days from the referral the Member State Committee reaches unanimous agreement, the Member States concerned shall adopt their definitive rolling plans accordingly. The competent authority shall be the competent authority of the Member State that has included the substance in its definitive rolling plan.

If the Member State Committee fails to reach a unanimous agreement, the Agency shall submit the conflicting opinions to the Commission, which shall decide which authority shall be the competent authority, in accordance with the procedure referred to in Article 130 (3), and the Member States shall adopt their definitive rolling plans accordingly.

5. As soon as the competent authorities have been determined, the Agency shall publish the definitive rolling plans on its website.
6. The competent authority identified in accordance with this article shall evaluate all substances on its rolling plan in accordance with the present Chapter.

Article 44

Request for further information

1. If the competent authority considers that further information for the purposes of clarifying the suspicion, referred to in Article 43a (1), including, if appropriate, information not required in Annexes V to VIII, is required, it shall prepare a draft

decision, supported by a justification, requiring the registrant(s) to submit the further information. The decision shall be taken in accordance with the procedure in Articles 48 and 49.

2. The registrant shall submit the information required to the Agency.
3. A draft decision requiring further information from registrant(s) shall be prepared within 12 months from the publication of the rolling plan on the Agency's website.
4. When the competent authority finishes its evaluation activities under this Article, it shall notify the Agency within 12 months from the start of the evaluation of the substance. If this deadline is exceeded, the evaluation shall be deemed to be finished.

Article 45
Coherence with other activities

1. The competent authority shall base its evaluation of a substance on any previous evaluation under this Title. Any draft decision requiring further information under Article 44 can only be justified by a change of circumstances or acquired knowledge.
2. In order to ensure a harmonised approach to requests for further information, the Agency shall monitor draft decisions under Article 44 and shall develop criteria and priorities. Where appropriate, implementing legislation may be adopted in accordance with the procedure referred to in Article 130 (3).

Article 46
Check of information submitted and follow-up to substance evaluation

1. The competent authority shall examine any information submitted in consequence of a decision taken under Article 44, and draft any appropriate decisions in accordance with Article 44, if necessary.
2. Once the substance evaluation has been completed, the competent authority shall use the information obtained from this evaluation for the purposes of Articles 56 (3) and 66 (2) and shall transmit the information obtained to the Commission, the Agency and the other Member States. The competent authority shall inform the Commission, the Agency, the registrant and the competent authorities of the other Member States on its conclusions whether or how to use the information obtained..

CHAPTER 4
EVALUATION OF INTERMEDIATES

Article 47
Further information on isolated intermediates on site

1. For on site isolated intermediates, neither dossier nor substance evaluation shall apply. However, where a risk equivalent to the level of concern arising from the use of substances to be included in Annex XIII under Article 54 can be demonstrated arising from the use of an on site isolated intermediate, it may:

- a) require the registrant to submit further information directly related to the risk identified. This request shall be accompanied by a written justification; and
 - b) examine any information submitted and, if necessary, take any appropriate risk reduction measures to address the risks identified in relation to the site in question.
2. The procedure outlined in paragraph 1 shall be undertaken only by the competent authority of the Member State, in whose territory the site is located.

CHAPTER 5

COMMON PROVISIONS

Article 48
Registrants' rights

1. The competent authority shall communicate any draft decision under Articles 39, 40 or 44 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. The competent authority shall take any comments received into account and may amend the draft decision accordingly.
2. If a registrant has ceased the manufacture or import of the substance, he shall inform the competent authority of this fact with the consequence that his registration shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration.
3. The registrant may cease the manufacture or import of the substance upon receipt of the draft decision. In this case, he shall inform the competent authority of this fact with the consequence that his registration shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration.
4. Notwithstanding paragraphs 2 and 3, further information may be required in accordance with Article 44 if
 - the competent authority prepares a dossier in accordance with Annex XIV concluding that there is a potential long-term risk to man or the environment justifying the need for further information, and
 - the exposure to the substance manufactured or imported by the registrant(s) concerned contributes significantly to that risk.

The procedure in Articles 66 to 70 shall apply mutatis mutandis.

Article 49
Adoption of decisions under evaluation

1. The competent authority of a Member State shall notify its draft decision in accordance with Article 39, 40 or 44 to the Agency, together with any comments by the registrant or downstream user, and specifying how these comments have been taken into account. The Agency shall circulate this draft decision, together with the comments, to the other Member States' competent authorities.

2. Within 30 days from circulation, the other Member States' competent authorities may propose amendments to the draft decision to the Agency with a copy to the competent authority. The Agency may propose amendments to the draft decision within the same period with a copy to the competent authority.
3. If the Agency does not receive any proposals or does not make any proposal itself within 30 days, it shall take the decision in the version notified under paragraph 1.
4. If the Agency receives a proposal for amendment, it may modify the draft decision. The Agency shall refer a draft decision, together with any amendments proposed, to the Member State Committee established pursuant to Article 81 (3) (hereinafter referred to as "the Member State Committee") within 15 days from the end of the 30-day period referred to in paragraph 2. The Agency shall do the same if it has made a proposal for amendment in accordance with paragraph 2.
5. The Agency shall forthwith communicate any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days. The Member State Committee shall take any comments received into account.
6. If within 60 days from the referral the Member State Committee reaches a unanimous agreement on the draft decision, the Agency shall take the decision accordingly.

If the Member State Committee fails to reach a unanimous agreement, it shall adopt an opinion in accordance with Article 81 (8) within 60 days from referral. The Agency shall transmit that opinion to the Commission.

7. Within 60 days from receipt of the opinion, the Commission shall prepare a draft decision to be taken in accordance with the procedure referred to in Article 130 (2).
8. An appeal may be brought against Agency decisions under paragraphs 3 and 6 in accordance with Articles 87 to 89.

Article 50

Cost sharing in case of performance of tests involving vertebrate animals without an agreement reached between registrants

1. If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study equally.
2. In the case referred to in paragraph 1, the registrant or downstream user who performs the test, shall provide each of the others concerned with a copy of the test.
3. The person performing and submitting the study shall have a claim against the others accordingly. The others shall have a claim for a copy of the study. Any person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the study performed. All claims shall be enforceable in the national courts. Any person may choose to submit their claims for remuneration to an arbitration board and accept the arbitration order.

Article 51
Obligations for Member States to report to the Agency

By 28 February of each year, each Member State shall report to the Agency on the progress made over the previous calendar year towards discharging the obligations incumbent upon the competent authorities within that State in relation to the examination of testing proposals. The Agency shall publish this information on its web-site without delay.

TITLE VII **AUTHORISATION**

CHAPTER 1 **AUTHORISATION REQUIREMENT**

Article 52 ***Aim of authorisation***

The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled or that these substances are replaced by suitable alternative substances or technologies.

Article 53 ***General provisions***

1. A manufacturer, importer or downstream user shall not place on the market a substance for a use or use it himself if that substance is included in Annex XIII, unless the use(s) of that substance on its own, in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself:
 - has been authorised in accordance with Articles 57 to 61, or
 - has been exempted from the authorisation requirement in Annex XIII itself in accordance with Article 55 (2), or
 - the date referred to in Article 55(1)(c)(i) has not been reached, or
 - the date referred to in Article 55(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken, or
 - in the case when the substance is placed on the market, the use has been authorised to his immediate downstream user.
2. A downstream user may use a substance meeting the criteria of paragraph 1 provided that the use is within the conditions of an authorisation granted to an actor up his supply chain for that use.
3. Paragraphs 1 and 2 shall not apply to the use of substances which are waste and are treated in a waste treatment installation within the conditions of a permit under Council Directive 75/442/EEC and/or Council Directive 91/689/EEC, without prejudice to {Proposal for a Regulation of the European Parliament and of the Council on persistent organic pollutants and amending Directives 79/117/EEC and 96/59/EC}.

4. Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development or product and process orientated research and development in quantities not exceeding 1 tonne per year.
5. Paragraphs 1 and 2 shall not apply to the following uses of substances:
 - (a) uses in plant protection products within the scope of Council Directive 91/414/EEC³⁸;
 - (b) uses in biocidal products within the scope of Directive 98/8/EC³⁹ of the European Parliament and of the Council;
 - (c) uses as medicinal products for human or veterinary use within the scope of Council Regulation 2309/93⁴⁰ and Directives 2001/82⁴¹ and 2001/83⁴² of the European Parliament and of the Council;
 - (d) uses as food additives within the scope of Council Directive 89/107/EEC⁴³;
 - (e) uses as additives in animal feeding stuffs within the scope of Council Directive 70/524/EEC⁴⁴;
 - (f) uses as flavourings in foodstuffs within the scope of Commission Decision 1999/217/EC;
 - (g) uses as an on site isolated intermediate or as a transported isolated intermediate;
 - (h) use as motor fuels covered by Directive 98/70/EC;
 - (i) uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.
6. For substances that are subject to authorisation only because they meet the criteria in Article 54 (a) to (c) or because they are identified in accordance with Article 54 (f) only because of hazards to human health, paragraphs 1 and 2 shall not apply to the following uses of these substances:
 - (a) uses in cosmetic products within the scope of Council Directive 76/768/EEC⁴⁵;
 - (b) uses in food contact materials within the scope of Council Directive 89/109/EEC.
7. Paragraphs 1 and 2 shall not apply to the use of substances when they are present in preparations

³⁸ OJ L 230 , 19.08.1991, p.1

³⁹ OJ L 123 , 24.04.1998, p. 1

⁴⁰ OJ L 214 , 24.08.1993, p. 1

⁴¹ OJ L 311 , 28.11.2001, p. 1

⁴² OJ L 311 , 28.11.2001, p. 67

⁴³ OJ L 040, 11.02.1989, p. 27

⁴⁴ OJ L 270, 14.12.1970, p. 1

⁴⁵ OJ L 262 , 27.09.1976, p. 169

- for substances referred to in Article 54 (d) to (f), below a concentration limit of 0.1%;
- for all other substances, below the concentration limits specified in Directive 1999/45/EC which result in the classification of the preparation as dangerous.

Article 54
Substances to be included in Annex XIII

The following substances may be included in Annex XIII in accordance with the procedure in Article 55:

- (a) substances meeting the criteria for classification as carcinogenic category 1 or 2 according to Directive 67/548/EEC;
- (b) substances meeting the criteria for classification as mutagenic category 1 or 2 according to Directive 67/548/EEC;
- (c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 according to Directive 67/548/EEC;
- (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria of Annex XII;
- (e) substances which are very persistent and very bioaccumulative in accordance with the criteria of Annex XII;
- (f) substances, such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties which do not fulfil the criteria of subparagraphs (d) and (e) and which are identified as causing serious and irreversible effects to humans or the environment which are equivalent to those of other substances listed in this Article on a case-by-case basis in accordance with the procedure set out in Article 56.

Article 55
Inclusion of substances into Annex XIII

1. Whenever a decision is taken to include into Annex XIII substances referred to in Article 54, such a decision shall be taken in accordance with the procedure referred to in Article 130 (3). It shall specify for each substance:
 - (a) the identity of the substance;
 - (b) the intrinsic property/ies of the substance referred to in Article 54;
 - (c) transitional arrangements:
 - (i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted, (hereinafter referred to as “the sunset date”);

- (ii) a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use or place on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;
 - (d) review periods for certain uses, if appropriate;
 - (e) uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.
2. Uses or categories of uses may be exempted from the authorisation requirement. In the establishment of such exemptions, account shall be taken of, for example:
- (a) existing specific Community legislation imposing minimum requirements relating to the protection of health and/or the environment for the use of the substance (eg. binding occupational exposure limits, emission limits, etc);
 - (b) existing legal obligations to take appropriate technical and management measures to ensure compliance with any relevant health, safety and environmental standards in relation to the use of the substance.
- Exemptions may be subject to conditions.
3. Prior to a decision to include substances in Annex XIII, the Agency shall recommend priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:
- (a) PBT or vPvB properties;
 - (b) wide dispersive use; or
 - (c) high volumes.
- The number of substances included in Annex XIII and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time foreseen.
- 3a. Before the Agency sends its recommendation to the Commission it shall make it publicly available on its website, clearly indicating the date of publication. The Agency shall invite all interested parties to submit comments within three months of the date of publication, in particular on:
- (a) the fulfillment of the criteria in Article 54 (d), (e) and (f);
 - (b) which uses should be exempt from the authorisation requirement.
- The Agency shall update its recommendation taking into account the comments received.
4. After inclusion of a substance in Annex XIII, this substance shall not be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIII.

5. Substances for which all uses have been prohibited under Title VIII or by other Community legislation shall not be included in Annex XIII or shall be removed from it.

Article 56

Identification of substances referred to in Art. 54 (d), (e) and (f)

1. To identify substances referred to in Article 54 (d), (e) and (f) the procedure set out in paragraphs 2 to 7 shall apply prior to any recommendations according to Article 55 (3).
2. The Commission may ask the Agency to prepare a dossier in accordance with Annex XIV for substances, which in its opinion meet the criteria set out in Article 54 (d), (e) and (f). The Agency shall circulate this dossier to the Member States.
3. Any Member State may prepare a dossier in accordance with Annex XIV for substances which in its opinion meet the criteria set out in Article 54 (d), (e) and (f) and forward it to the Agency. The Agency shall circulate this dossier to the other Member States.
4. Within 30 days from circulation, the other Member States or the Agency may comment on the identification of the substance in the dossier to the Agency.
5. If the Agency does not receive any comments, it may include this substance in its recommendations according to Article 55 (3).
6. Upon receipt of comments from another Member State or on its own initiative, the Agency shall refer the dossier to the Member State Committee within 15 days from the end of the 30-day period referred to in paragraph 4.
7. If within 30 days from the referral the Member State Committee reaches a unanimous agreement on the identification, the Agency may include that substance in its recommendations according to Article 55 (3). If the Member State Committee fails to reach a unanimous agreement, it shall adopt an opinion within 30 days from the referral. The Agency shall transmit that opinion to the Commission, including information on any minority view within the Committee.

CHAPTER 2
THE GRANTING OF AUTHORISATIONS

Article 57

The granting of authorisations

1. The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title.
2. An authorisation shall be granted if the risk to human health and/or the environment from the use of a substance arising from the intrinsic properties specified in

Annex XIII is adequately controlled in accordance with Annex I, section 6 and as documented in the applicants' chemical safety report.

The Commission shall not consider:

- (a) the risks to human health and the environment of emissions of the substance from an installation for which a permit was granted in accordance with (IPPC) Directive 96/61/EC ; or
 - (b) the risks to and via the aquatic environment of discharges of the substance from a point source governed by requirement for prior regulation as referred to in Article 11 (3) and legislation adopted under Article 16 of (WFD) Directive 2000/60;
 - (c) the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC, Council Directive 93/42/EEC or Directive 98/79/EC.
3. If an authorisation cannot be granted under paragraph 2, an authorisation may be granted if it is shown that socio-economic benefits outweigh the risk to human health and/or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements:
 - (a) the risk posed by the uses of the substance;
 - (b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;
 - (c) the analysis of the alternatives submitted by the applicant under Article 59 (5) and any third party contributions submitted under Article 61 (2);
 - (d) available information on the health and/or environmental risks of any alternative substances or technologies.
 4. A use shall not be authorised if this would constitute a relaxation of a restriction set out in Annex XVI.
 5. An authorisation shall only be granted if the application is made in conformity with the requirements of Article 59.
 6. Authorisations may be subject to conditions, including review periods and/or monitoring. Authorisations granted in accordance with paragraph 3 shall normally be subject to a time-limit.
 7. The authorisation shall specify:
 - (a) the person(s) to whom the authorisation is granted;
 - (b) the identity of the substance(s);
 - (c) the use(s) for which the authorisation is granted;

- (d) any conditions under which the authorisation is granted;
 - (e) any review period;
 - (f) any monitoring arrangement.
8. Notwithstanding any conditions of an authorisation, the holder shall ensure that the level of exposure is reduced to as low as is technically possible.

Article 58
Review of authorisations

1. Authorisations granted in accordance with Article 57 (3) subject to a time limit shall be considered to be valid until the Commission decides on a new application provided that the holder of the authorisation submits a new application at least 18 months before the expiry of the time limit. Rather than re-submitting all elements of the original application for the current authorisation, the applicant may submit the number of the current authorisation, except:
 - if he cannot demonstrate that the risk is adequately controlled, he shall submit an update of the socio-economic analysis, analysis of alternatives and substitution plan contained in the original application;
 - if he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report;
 - if any other elements of the original application have changed, he shall also submit updates of these element(s).
2. Authorisations may be reviewed at any time if the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact.

In such cases, the Commission shall set a reasonable deadline by which the holder(s) of the authorisation may submit further information necessary for the review and indicate by when it will take a decision in accordance with Article 61.

2. In its review decision the Commission may, taking into account proportionality:
 - amend the authorisation or
 - withdraw the authorisation from the time of the decision, if under the changed circumstances it would not have been granted.

In case of serious and immediate risk for human health or the environment, the Commission may suspend the authorisation pending the review, taking into account proportionality.

3. If an environmental quality standard referred to in (IPPC) Directive 96/61/EC is not met, the authorisations granted for the use of the substance concerned may be reviewed.

4. If the environmental objectives as referred to in Article 4(1) of the (WFD) Directive 2000/60/EC are not met, the authorisations granted for the use of the substance concerned in the relevant river basin may be reviewed.
5. If a use of a substance has been prohibited in Annex XVII, the Commission shall withdraw the authorisation for that use.

If a use of a substance has been made subject to conditions in Annex XVII, the Commission shall amend the authorisation accordingly.

Article 59
Applications for authorisations

1. An application for an authorisation shall be made to the Agency.
2. Applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance. Applications may be made by one or several persons.
3. Applications may be made for one or several substances, and for one or several uses. Applications may be made for the applicant's own use(s) and/or for uses for which he intends to place the substance on the market.
4. An application for authorisation shall include the following information:
 - (a) the identity of the substance(s), as referred to in section 2 of Annex IV ;
 - (b) the name and contact details of the person or persons making the application;
 - (c) a request for authorisation, specifying for which use(s) the authorisation is sought; this request shall cover the use of the substance in preparations and/or the incorporation of the substance in articles, where this is relevant;
 - (d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIII.
5. The application may include:
 - (a) a socio-economic analysis conducted in accordance with Annex XV;
 - (b) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution, where appropriate accompanied by a substitution plan, including research and development and a timetable for proposed actions by the applicant ;
6. The application shall not include:
 - (a) the risks to human health and the environment of emissions of the substance from an installation for which a permit was granted in accordance with (IPPC) Directive 96/61/EC ; or

- (b) the risks to and via the aquatic environment of discharges of the substance from a point source governed by requirement for prior regulation as referred to in Article 11 (3) and legislation adopted under Article 16 of (WFD) Directive 2000/60/EC;
 - (c) the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC, Council Directive 93/42/EEC or Directive 98/79/EC.
7. An application for an authorisation shall be accompanied by the fee as set by the Agency.

Article 60
Subsequent applications for authorisation

1. If an application has been made for a use of a substance, a subsequent applicant may refer, by means of a letter of access granted by the previous applicant, to the parts of the previous application submitted in accordance with Article 59 (4) (d) and (5).
2. If an authorisation has been granted for a use of a substance, a subsequent applicant may refer, by means of a letter of access granted by the holder of the authorisation, to the parts of the holder's application submitted in accordance with Article 59 (4) (d) and (5).

Article 61
Procedure for authorisation decisions

1. The Agency shall acknowledge the date of receipt of the application. The Agency's Committees for Risk Assessment and Socio-economic analysis shall give their draft opinions within ten months of the date of receipt of the application.
2. The Agency shall make available on its web-site broad information on uses, taking confidentiality into account in accordance with Article 116, for which applications have been received, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.
3. In preparing its opinion, each Committee referred to in paragraph 1 shall first check that the application includes all the information specified in Article 59 that is relevant to its remit. If necessary, a Committee shall ask the applicant for additional information to bring the application into conformity with the requirements of Article 59. Each Committee shall also take into account any information submitted by third parties.
4. The draft opinions shall include the following elements:
 - (a) Risk Assessment Committee: an assessment of the risk to health and/or the environment arising from the use(s) of the substance as described in the application;

- (b) Socio-economic Analysis Committee: an assessment of the socio-economic factors associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 59 (5).
5. The Agency shall send these draft opinions to the applicant by the end of the deadline set out in paragraph 1. Within 1 month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment. Receipt of the draft opinion is deemed to have occurred 7 days after the Agency has sent it.
- If the applicant does not wish to comment, the Agency shall send these opinions to the Commission, the Member States and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment;
- If the applicant wishes to comment, he shall send his written argumentation to the Agency within 2 months of the receipt of the draft opinion. The Committees shall consider the comments and adopt their final opinions within 2 months of receipt of the written argumentation, taking this argumentation into account where appropriate. Within a further 15 days the Agency shall send the opinions, with the written argumentation attached, to the Commission, the Member States and the applicant.
- 6. The Agency shall make the non-confidential parts of its opinions and any attachments thereto publicly available on its website, in accordance with Article 116.
 - 7. In the case of Article 60 (1) the Agency shall treat the applications together, provided the deadlines for the first application can be met.
 - 8. The Commission shall prepare a draft authorisation decision within 3 months of receipt of the opinions from the Agency. A final decision granting or refusing the authorisation shall be taken in accordance with the procedure referred to in Article 130 (2).
 - 9. Summaries of the Commission decisions, including the authorisation number, shall be published in the Official Journal of the European Union and will be made publicly available in a database established and kept up to date by the Agency.
 - 10. In case of Article 60 (2), the deadline set out in paragraph 1 shall be shortened to 5 months.

CHAPTER 3

AUTHORISATIONS IN THE SUPPLY CHAIN

Article 62 *Obligation of holders of authorisations*

Holders of an authorisation shall include the authorisation number on the label before they place the substance on the market for an authorised use.

Article 63
Downstream Users

1. Downstream users using a substance in accordance with Article 53 paragraph 2, shall notify the Agency within 3 months of the first supply of the substance. They shall only use the format specified by the Agency in accordance with Article 108.
2. The Agency shall establish and keep up to date a register of downstream users who have notified in accordance with paragraph 1. The Agency shall grant access to this register to the competent authorities of the Member States.

TITLE VIII

RESTRICTIONS ON THE MANUFACTURING, MARKETING AND USE OF CERTAIN DANGEROUS SUBSTANCES AND PREPARATIONS

CHAPTER 1

GENERAL ISSUES

Article 64 *General Provisions*

1. A substance on its own, in a preparation or in an article, for which Annex XVI contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development, or product and process orientated research and development in quantities not exceeding 1 tonne per year.
2. A substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance for laboratory scale research or the use of the substance as a reference standard.
3. Paragraphs 1 and 2 shall not apply to the use of substances which are waste and are treated in a waste treatment installation within the conditions of a permit under Council Directive 75/442/EEC and/or Council Directive 91//689/EEC, without prejudice to {Proposal for a Regulation of the European Parliament and of the Council on persistent organic pollutants and amending Directives 79/117/EEC and 96/59/EC}.

CHAPTER 2

THE RESTRICTIONS PROCESS

Article 65 *Introducing new and amending current restrictions*

1. When there is an unacceptable risk to human health or the environment arising from the manufacture, use and/or placing on the market of substances which needs to be addressed on a Community wide basis, Annex XVI shall be amended in accordance with the procedure referred to in Article 130 (3) by adopting new restrictions, or amending current restrictions in Annex XVI, for the manufacture, use and/or placing on the market of substances on their own, in preparations or in articles, pursuant to the process set out in Articles 66 to 70. This shall not apply to the use of a substance as an on site isolated intermediate, except in the case of paragraph 3.

2. For substances which meet the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, and for which restrictions to consumer use are proposed by the Commission, Annex XVI shall be amended in accordance with the procedure referred to in Article 130 (3). Articles 66 to 70 shall not apply.
3. Notwithstanding Article 55 (4), at the latest at the inclusion of a substance into the Stockholm Convention or the UNECE Protocol on Persistent Organic Pollutants, the Commission shall present a draft for the inclusion of that substance in Annex XVII. The draft measures shall as minimum implement the obligations arising from these international commitments for the Community. Annex XVII shall be amended in accordance with the procedure referred to in Article 130 (3). Articles 66 to 70 shall not apply.
4. Restrictions addressing only the risks to human health of the use of a substance in cosmetics products within the scope of Council Directive 76/768/EEC shall not be included in Annexes XVI or XVII.

*Article 66
Preparation of a proposal*

1. If the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed at Community level, it shall ask the Agency to prepare a dossier which conforms to the requirements of Annex XIV. If this Dossier demonstrates that action on a Community wide basis is necessary, beyond any measures already in place, the Agency shall suggest restrictions, in order to initiate the restrictions process.

The Agency shall refer to any Member State Dossier, chemical safety report or risk assessment submitted to it under any part of this regulation. It shall also refer to any relevant risk assessment submitted by third persons for the purpose of other Community regulations or directives. To this end other bodies, such as agencies, established under Community law and carrying out a similar task shall provide information to the Agency on request.

- 2.(a) If a Member State considers that the manufacture, placing on the market or use of a substances on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed at Community level, it shall prepare a Dossier which conforms to the requirements of Annex XIV. If this Dossier demonstrates that action on a Community wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in the format outlined in Annex XIV, in order to initiate the restrictions process.

Member States shall refer to any Dossier, chemical safety report or risk assessment submitted to the Agency under any part of this Regulation. Member States shall also refer to any relevant risk assessment submitted for the purpose of other Community regulations or directives. To this end other bodies, such as agencies, established under Community law and carrying out a similar task shall provide information to the Member State concerned on request.

- (b) The Agency's Committees for Risk Assessment and for Socio-economic analysis shall check whether the dossier submitted conforms to the requirements of Annex XIV. Within 30 days of receipt, the Agency shall inform the Member State suggesting restrictions, whether the Committees find that the Dossier conforms. If the Dossier does not conform, the reasons shall be given to the Member State in writing within 45 days of receipt. The Member State shall bring it into conformity within 30 days of the date of receipt of the reasons from the Agency, otherwise the procedure under this Chapter shall be terminated.
3. The Agency shall make publicly available on its website all dossiers conforming with Annex XIV including the suggested restrictions according to paragraphs 1 and 2 of this Article without delay, clearly indicating the date of publication. The Agency shall invite all interested parties to submit individually or jointly within 3 months of the date of publication:
 - (a) comments on Dossiers and the suggested restrictions;
 - (b) a socio-economic analysis, or information which can contribute to one, of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions. It shall conform to the requirements in Annex XV.

Article 67
Agency opinion: Committee for risk assessment

Within 9 months from the date of publication referred to in Article 66 (3) the Agency's Committee for Risk Assessment shall formulate an opinion on the suggested restrictions based on its consideration of the relevant parts of the dossier. This opinion shall take account of the Member State dossier and the views of interested parties referred to in Article 66 (3) (a).

Article 68
Agency opinion: Committee for socio-economic analysis

1. Within 12 months of the date of publication referred to in Article 66 (3), the Agency's Committee for Socio-economic Analysis shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to Article 66 (3) (b), if there are any. The Agency shall publish the draft opinion on its web-site without delay. The Agency shall invite interested parties to give their comments on the draft opinion within a deadline set by the Agency.
2. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received within the deadline set. This opinion shall take account of the comments and socio-economic analyses of interested parties submitted under Articles 66 (3) (b) and 68 (1).
3. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed by a Member State or the Commission, the Agency may

extend the deadline for the opinion of the Committee for Socio-economic Analysis by a maximum of 90 days.

Article 69
Submission of an opinion to the Commission

1. The Agency shall submit to the Commission the opinions of the Committees for Risk Assessment and Socio-economic Analysis on restrictions suggested for substances on their own, in preparations or in articles. If one or both of the Committees do not formulate an opinion within the deadline given in Articles 67 (1) and 68 (1) the Agency shall inform the Commission of that fact, and give the reasons why.
2. The Agency shall publish the opinions of the two Committees on its web-site without delay.
3. The Agency shall provide to the Commission on request all documents and evidence submitted to, and/or considered by it.

Article 70
Commission decision

1. If the conditions of Article 65 are fulfilled, the Commission shall prepare a draft amendment to Annex XVI, within 3 months of receipt of the opinion of the Committee for Socio Economic analysis or the end of the deadline established under Article 68 if that Committee does not form an opinion, whichever is the earlier.

Where the draft amendment is not in accordance with any of the opinions of the Agency, the Commission shall annex a detailed explanation of the reasons for the differences.

2. A final decision shall be taken in accordance with the procedure referred to in Article 130(3).

TITLE IX AGENCY

Article 71 Establishment of the Agency

A European Chemicals Agency is hereby established.

Article 72 Composition of the Agency

1. The Agency shall comprise:
 - (a) a Management Board, which shall exercise the responsibilities set out in Article 74;
 - (b) an Executive Director, who shall exercise the responsibilities set out in Article 79;
 - (c) a Committee for Risk Assessment, which shall be responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of the present Regulation relating to risks to human health or the environment;
 - (d) a Committee for Socio-economic Analysis, which shall be responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of the present Regulation including the socio-economic analysis of the effect of possible legislative action on substances;
 - (e) a Member State Committee, which shall be responsible for resolving divergences of opinions on draft decisions proposed by Member States under Title VI and preparing the opinion of the Agency on proposals for classification and labelling under Title X and proposals for identification of substances of very high concern to be subjected to the authorisation procedure under Title VII;
 - (f) the Forum for Exchange of Information on Enforcement (hereinafter referred to as “the Forum”), which shall co-ordinate a network of Member States authorities responsible for enforcement of this Regulation;
 - (g) a Secretariat, which shall provide technical, scientific and administrative support for the Committees and the Forum and ensure appropriate co-ordination between them. It will also undertake the work required of the Agency under the procedures for pre-registration, registration and mutual recognition of evaluation as well as preparation of guidance, database maintenance and information provision;
 - (h) a board of appeal, which shall decide on appeals against decisions taken by the Agency.

2. The Committees referred to in Article 72 (c), (d) and (e) (hereinafter “the Committees”) and the Forum may each establish working groups. For this purpose they shall adopt, in accordance with their rules of procedure, precise arrangements for delegating certain tasks to these working groups.
3. The Committees and the Forum may, if they consider it appropriate, seek advice on important questions of a general scientific or ethical nature from appropriate sources of expertise.

Article 73
Tasks of the Agency

1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of the present Regulation.
2. The Secretariat shall undertake the following tasks:
 - (a) performing the tasks allotted to it under Title II; including facilitating the efficient registration of imported substances, in a way consistent with the EU’s international trading obligations to non-EU countries;
 - (b) performing the tasks allotted to it under Title III;
 - (c) performing the tasks allotted to it under Title VI;
 - (d) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list, making the non-confidential information identified in Article 116 (1) in the data base(s) publicly available over the Internet, and making other non-confidential information in the databases available on request;
 - (e) making publicly available information as to which substances are being, and have been evaluated within 90 days of receipt of the information at the Agency, in accordance with Article 116 (1);
 - (f) providing technical and scientific guidance and tools where appropriate for the operation of the present Regulation in particular to assist the development of chemical safety reports by industry and especially by Small and Medium sized Enterprises (SMEs);
 - (g) providing technical and scientific guidance on the operation of the present Regulation for Member State competent authorities and providing support to the competent authorities’ help desks established under Title XII;
 - (h) preparing explanatory information on the present Regulation for other stakeholders;
 - (i) at the Commission’s request, providing technical and scientific support for steps to improve co-operation between the Community, its Member States,

international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries.

3. The Committees shall undertake the following tasks:
 - (a) performing the tasks allotted to them under Title VI;
 - (b) performing the tasks allotted to them under Title VII;
 - (c) performing the tasks allotted to them under Title VIII;
 - (d) performing the tasks allotted to them under Title X;
 - (e) at the Commission's request, providing technical and scientific support for steps to improve co-operation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;
 - (f) at the Commission's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations and/or articles.
4. The Forum shall undertake the following tasks:
 - (a) spreading good practice and highlighting problems at Community level;
 - (b) proposing, co-ordinating and evaluating harmonised enforcement projects and joint inspections;
 - (c) co-ordinating exchange of inspectors;
 - (d) identifying enforcement strategies, as well as minimum enforcement criteria;
 - (e) developing working methods and tools of use to local inspectors;
 - (f) developing an electronic information exchange procedure;
 - (g) liaising with industry and other stakeholders, including relevant international organisations, as necessary.
5. The Board of Appeal shall decide on appeals against decisions taken by the Agency.

Article 74
Powers of the Management Board

The Management Board shall appoint the Executive Director pursuant to Article 80 and an accounting officer as laid out in Article 43 of Commission Regulation No 2343/2002⁴⁶.

It shall adopt:

- (a) by 30 April each year, the general report of the Agency for the previous year and forward it by 15 June at the latest to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee, the Court of Auditors;
- (b) by 31 October each year the work programme of the Agency for the coming year and forward it to the Member States, the European Parliament, the Council and the Commission;
- (c) the final budget of the Agency before the beginning of the financial year, adjusting it, where necessary, according to the Community contribution and any other revenue of the Agency;
- (d) the fee structure of the Agency.

It shall establish and adopt the internal rules and procedures of the Agency.

It shall perform its duties in relation to the Agency's budget pursuant to Articles 93, 94 and 101.

It shall exercise disciplinary authority over the Executive Director.

It shall establish its rules of procedure.

It shall appoint the Chairman, the members and alternates of the board of appeal.

It shall forward annually to the budgetary authority any information relevant to the outcome of the evaluation procedures.

Article 75
Composition of the Management Board

1. The Management Board shall be composed of six representatives from Member States nominated by the Council and six representatives nominated by the Commission, as well as three individuals from interested parties nominated by the Commission without voting rights.
2. Members shall be appointed on the basis of their relevant experience and expertise in the field of chemicals safety or Regulation.

⁴⁶ Commission Regulation on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities

3. The duration of the term of office shall be four years. The term of office may be renewed once. However, for the first mandate, the Commission and the Council shall each identify three of their nominees for whom this period shall be six years.

Article 76
Chairmanship of the Management Board

1. The Management Board shall elect a Chairman and a Deputy-Chairman from among its members. The Deputy-Chairman shall automatically take the place of the Chairman if he/she is prevented from attending to his/her duties.
2. The terms of the office of the Chairman and the Deputy-Chairman shall be two years and shall expire when they cease to be members of the Management Board. The term of office shall be renewable once.

Article 77
Meetings

1. The meetings of the Management Board shall be convened by its Chairman.
2. The Executive Director shall take part in the meetings of the Management Board, without voting rights.
3. The Management Board may invite the Chairmen of the Committees or the Chairman of the Forum, as referred to in Article 72 (c) to (f), to attend its meetings without voting rights.

Article 78
Voting

The Management Board shall establish rules of procedure for voting, including the conditions for a member to vote on behalf of another member. The Management Board shall act by a two-thirds majority of all members with the right to vote.

Article 79
Duties and powers of the Executive Director

1. The Agency shall be managed by its Executive Director, who shall perform his/her duties in the interests of the Community, and independently of any specific stakeholder interests.
2. The Executive Director shall be the legal representative of the Agency. He/she shall be responsible for:
 - (a) the day-to-day administration of the Agency;
 - (b) managing all the Agency resources necessary for carrying out its tasks;
 - (c) ensuring that the time limits laid down in Community legislation for the adoption of opinions by the Agency are complied with;

- (d) ensuring appropriate and timely co-ordination between the Committees and the Forum;
 - (e) concluding and managing necessary contracts with service providers;
 - (f) the preparation of the statement of revenue and expenditure and the execution of the budget of the Agency;
 - (g) all staff matters;
 - (h) providing the secretariat for the Management Board;
 - (i) preparing draft opinions of the Management Board concerning the proposed rules of procedure of the Committees and of the Forum;
 - (j) making arrangements for the execution of any further function(s) allotted to the Agency by delegation from the Commission.
3. Each year, the Executive Director shall submit the following to the Management Board for approval:
- (a) a draft report covering the activities of the Agency in the previous year, including information about the number of registration dossiers received, the number of substances evaluated, the number of applications for authorisation received, the number of proposals for restriction received by the Agency and opined upon, the time taken for completion of the associated procedures, and the substances authorised, dossiers rejected, substances restricted; complaints received and the action taken; an overview of the activities of the Forum;
 - (b) a draft programme of work for the coming year;
 - (c) the draft annual accounts;
 - (d) the draft forecast budget for the coming year.

Article 80
Appointment of the Executive Director

1. The Commission shall propose candidates for the post of the Executive Director based on a list following publication of the post in the Official Journal and other press or internet sites as appropriate.
2. The Executive Director of the Agency shall be appointed by the Management Board on the grounds of merit and documented administrative and management skills, as well as his/her relevant experience in the fields of chemical safety or regulation. The Management Board shall take its decision by a two-thirds majority of all members with a right to vote.

Power to dismiss the Executive Director shall be with the Management Board, according to the same procedure.

3. The term of the office of the Executive Director shall be 5 years. It may be prolonged by the Management Board once for another period of up to 5 years.

Article 81
Establishment of the Committees

1. Each Member State may nominate candidates to membership of the Risk Assessment Committee. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website. The Management Board shall appoint the members of the Committee from this list, including at least one member from each Member State that has nominated candidates. Members shall be appointed for their role and experience in regulation of chemicals and/or for their technical and scientific expertise in reviewing risk assessments of substances.
2. Each Member State may nominate candidates to membership of the Socio-economic Analysis Committee. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website. The Management Board shall appoint the members of the Committee from this list, including at least one member from each Member State that has nominated candidates. Members shall be appointed for their role and experience in regulation of chemicals and/or for their expertise in socio-economic analysis.
3. Each Member State shall appoint one member to the Member State Committee.
4. The Committees should aim to have a broad range of relevant expertise among their members. To this end the Committees may co-opt a maximum of five additional members chosen on the basis of their specific competence.

Members of the Committees shall be appointed for a term of three years which shall be renewable.

The members of each Committee may be accompanied by advisers on scientific, technical or regulatory matters.

The Executive Director or his/her representative and representatives of the Commission shall be entitled to attend all the meetings of the Committees and working groups convened by the Agency or its committees. Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of the Committee members, or the Management Board.

5. The members of each Committee appointed following nomination by a Member State shall ensure that there is appropriate co-ordination between the tasks of the Agency and the work of their Member State competent authority.
6. The members of the Committees shall be supported by the scientific and technical resources available to the Member States. To this end, Member States shall provide adequate scientific and technical resources to the members of the Committees that they have nominated. Each Member State competent authority shall facilitate the activities of the Committees and their working groups.
7. The Member States shall refrain from giving the members of the Risk Assessment Committee and the Socio-Economic Analysis Committee, their scientific and

technical advisers and experts any instruction, which is incompatible with their own individual tasks or with the tasks, responsibilities and independence of the Agency.

8. When preparing an opinion, each Committee shall use its best endeavours to reach a consensus. If such a consensus cannot be reached, the opinion shall consist of the position of the majority of members and the minority position(s), with their grounds.
9. Each Committee shall establish its own rules of procedure.

These rules shall in particular lay down the procedures for appointing and replacing the Chairman, replacing members, the procedures for delegating certain tasks to working groups, the creation of working groups and the establishment of a procedure for the urgent adoption of opinions. In the case of the Member State Committee, the chairperson shall be an employee of the Agency.

These rules shall enter into force after receiving a favourable opinion from the Commission and the Management Board.

Article 82
Establishment of the Forum

1. Each Member State shall appoint, for a three-year term, which shall be renewable, one member to the Forum. Members shall be chosen for their role and experience in enforcement of chemicals legislation and shall maintain relevant contacts with the Member State competent authorities.

The Forum should aim to have a broad range of relevant expertise among its members. To this end the Forum may co-opt a maximum of five additional members chosen on the basis of their specific competence. These members shall be appointed for a term of three years, which shall be renewable.

The members of the Forum may be accompanied by scientific and technical advisers.

The Executive Director of the Agency or his/her representative and representatives of the Commission shall be entitled to attend all the meetings of the Forum and its working groups. Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of Forum members, or the Management Board.

2. The members of the Forum appointed by a Member State shall ensure that there is appropriate co-ordination between the tasks of the Forum and the work of their Member State competent authority.
3. The members of the Forum shall be supported by the scientific and technical resources available to the Member States competent authorities. Each Member State competent authority shall facilitate the activities of the Forum and its working groups. The Member States shall refrain from giving the Forum members, their scientific and technical advisers and experts any instruction, which is incompatible with their own individual tasks or with the tasks and responsibilities of the Forum.
4. The Forum shall establish its own rules of procedure.

These rules shall in particular lay down the procedures for appointing and replacing the Chairman, replacing members and the procedures for delegating certain tasks to working groups.

These rules shall enter into force after receiving a favourable opinion from the Commission and the Management Board.

Article 83

Rapporteurs of Committees and use of experts

1. Where, in accordance with the provisions of Article 73, a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XIV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing. A member of a Committee shall not be appointed rapporteur for a particular case if he/she indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.
2. Member States shall transmit to the Agency the names of experts with proven experience in reviewing chemical risk assessments and/or socio-economic analyses or other relevant scientific expertise, who would be available to serve on working groups of the Committees, together with an indication of their qualifications and specific areas of expertise.

The Agency shall keep an up-to-date list of experts. The list shall include the experts referred to in the first subparagraph and other experts identified directly by the Secretariat.

3. The provision of services by Committee members or any expert serving on a working group of the Committees or Forum, or performing any other task for the Agency shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and the employer of the person concerned.

The person concerned, or his/her employer, shall be remunerated in accordance with a scale of fees to be included in the financial arrangements established by the Management Board. Where the person concerned fails to fulfil his/her duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration.

4. The performance of services for which there are several potential providers may result in a call for an expression of interest, if the scientific and technical context allows, and if it is compatible with the duties of the Agency, in particular the need to provide a high level of protection of human health and the environment.

The Management Board shall adopt the appropriate procedures on a proposal from the Executive Director.

5. The Agency may use the services of experts for the discharge of other specific tasks for which it is responsible.

Article 84

Qualification and interests of members of committees and boards

1. The membership of the Committees and of the Forum shall be made public. Individual members may request that their names not be made public if they believe that such publication could place them at risk. The Executive Director shall decide whether to agree to such requests. When each appointment is published, the professional qualifications of each member shall be specified.
2. Members of the Management Board, the Executive Director and members of the Committees and of the Forum shall make a declaration of commitment to fulfil their duties and a declaration of interests, which could be considered to be prejudicial to their independence. These declarations shall be made annually in writing.
3. At each of their meetings, members of the Management Board, the Executive Director, members of the Committees and of the Forum and any experts participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall neither participate in the discussion of nor in any voting on the relevant agenda points.

Article 85

Establishment of the Board of Appeal

1. The Board of Appeal shall consist of a chairperson and two other members.
2. The Chairperson and the two members shall have alternates who shall represent them in their absence.
3. The Chairperson, the other members and the alternates shall be appointed by the Management Board on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures from a list of qualified candidates adopted by the Commission.
4. The qualifications required for the members of the Board of Appeal shall be determined by the Commission according to the procedure in Article 130 (2).
5. The Chairperson and the members shall have equal voting rights.

Article 86

Members of the Board of Appeal

1. The term of office of the members of the Board of Appeal, including the chairperson and the alternates shall be 5 years. It may be prolonged once.
2. The Members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions.

3. The members of the Board of Appeal may not perform any other duties in the Agency. The function of the Members may be a part-time function.
4. The members of the Board of Appeal may not be removed either from office or from the list during their respective term, unless there are serious grounds for such removal and the Commission, after obtaining the opinion of the Management Board, takes a decision to this effect.
5. Members of the Board of Appeal may not take part in any appeal proceedings if they have any personal interest therein, or if they have previously been involved as representatives of one of the parties to the proceedings, or if they participated in the decision under appeal.
6. If a member of the Board of Appeal considers for reasons mentioned in paragraph 5 that he shall not take part in any appeal proceedings, he shall inform the Board of Appeal accordingly. Members of the board may be objected to by any party to the appeal proceedings on any of the grounds mentioned in paragraph 5, or if suspected of partiality. No objection may be based on the nationality of members.
7. The Board of Appeal shall decide as to the action to be taken in the cases specified in paragraphs 5 and 6 without the participation of the member concerned. For the purposes of taking this decision, the member concerned shall be replaced on the Board of Appeal by an alternate.

Article 87
Decisions subject to appeal

1. An appeal may be brought against the decisions of the Agency, which have been taken pursuant to Articles 7, 18, 25 (4) third subparagraph, 28 (2) first subparagraph, 49, 115 (4) and 116.
2. An appeal lodged pursuant to paragraph 1 shall have suspensive effect.

Article 88
Persons entitled to appeal, time limit and form

1. Any natural or legal person may appeal against a decision addressed to that person.
2. The appeal, together with the statements of grounds thereof, shall be filed in writing to the Agency within 1 month of the notification of the decision to the person concerned, or in the absence thereof, of the day on which it became known to the latter, unless otherwise provided in this Regulation.

Article 89
Examination and decisions on appeal

1. The board of appeal shall examine whether it is well founded within 30 days. Parties to the appeal proceedings shall be entitled to make oral presentation during this procedure.

2. The board of appeal may exercise any power, which lies within the competence of the Agency.

Article 90
Actions before the Court of justice

1. An action may be brought before the Court of Justice of the European Communities, in accordance with Article 230 of the Treaty, contesting a decision taken by the board of appeal or, in cases where no right of appeal lies before the board of appeal, by the Agency.
2. Should the Agency fail to take a decision, proceedings for failure to act may be brought before the Court of Justice in accordance with Article 232 of the Treaty.
3. The Agency shall be required to take the necessary measures to comply with the judgement of the Court of Justice.

Article 91
Complaints to the ombudsman

Any citizen of the Union and any natural or legal person residing or having its registered office in a Member State shall have the right to submit to the Ombudsman complaints concerning instances of maladministration in the activities of the Agency in accordance with Article 195 of the Treaty.

Article 92
Conflicts of opinion with other bodies

1. The Agency shall take care to ensure early identification of potential sources of conflict between its opinions and those of other bodies established under Community law, such as Community Agencies (e.g. the European Food Safety Authority and the European Agency for the Evaluation of Medicinal Products) and Scientific Committees (e.g. the Scientific Committee for Toxicology, Ecotoxicology and the Environment, CSTE, and the Scientific Committee on Cosmetic Products and Non-food Products intended for the Consumer, SCCNFP), carrying out a similar task in relation to issues of common concern.
2. Where the Agency identifies a potential source of conflict, it shall contact the body concerned in order to ensure that any relevant scientific or technical information is shared and to identify the scientific or technical points which are potentially contentious.
3. Where there is a fundamental conflict over scientific or technical points and the body concerned is a Community Agency or a scientific committee, the Agency and the body concerned shall work together either to solve the conflict or to submit a joint document to the Commission clarifying the scientific and/or technical points of conflict.

Article 93
The budget of the Agency

1. The revenues of the Agency shall consist of:
 - (a) a subsidy from the Community, entered in the general budget of the European Union (Commission Section);
 - (b) the fees paid by undertakings;
 - (c) any voluntary contribution from the Member States.
2. The expenditure of the Agency shall include the staff, administrative, infrastructure and operational expenses.
3. By 15 February of each year at the latest, the Executive Director shall draw up a preliminary draft budget covering the operational expenditure and the programme of work anticipated for the following financial year, and shall forward this preliminary draft to the Management Board together with an establishment plan.
4. Revenue and expenditure shall be in balance.
5. Each year the Management Board, on the basis of a draft drawn up by the Executive Director, shall produce an estimate of revenue and expenditure for the Agency for the following financial year. This estimate, which shall include a draft establishment plan, shall be forwarded by the Management Board to the Commission by 31 March at the latest.
6. The estimate shall be forwarded by the Commission to the European Parliament and the Council (hereinafter referred to as the “budgetary authority”) together with the preliminary draft budget of the European Union.
7. On the basis of the estimate, the Commission shall enter in the preliminary draft budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the EC Treaty.
8. The budgetary authority shall authorise the appropriations for the subsidy to the Agency.
The budgetary authority shall adopt the establishment plan for the Agency.
9. The budget of the Agency shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.
10. Any modification to the budget, including the establishment plan, shall follow the procedure referred to in paragraph 5.
11. The Management Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of its budget, in particular any projects relating to

property such as the rental or purchase of buildings. It shall inform the Commission thereof.

Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of 6 weeks from the date of notification of the project.

Article 94
Implementation of the Agency's budget

1. The Executive Director shall perform the duties of the authorising officer and shall implement the Agency's budget.
2. Monitoring of the commitment and payment of all the Agency's expenditure and of the establishment and recovery of all the Agency's revenue shall be carried out by the Accounting Officer of the Agency.
3. By 1 March at the latest following each financial year, the Agency's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of the general Financial Regulation.
4. By 31 March at the latest following each financial year, the Commission's accounting officer shall forward the Agency's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for that financial year shall also be forwarded to the European Parliament and the Council.
5. On receipt of the Court of Auditors' observations on the Agency's provisional accounts, pursuant to Article 129 of the general Financial Regulation, the Director shall draw up the Agency's final accounts under his own responsibility and forward them to the Management Board for an opinion.
6. The Management Board shall deliver an opinion on the Agency's final accounts. 7. By 1 July of the following year at the latest, the Executive Director shall send the final accounts, together with the opinion of the Management Board, to the Commission, the Court of Auditors, the European Parliament and the Council.
8. The final accounts shall be published.
9. The Director shall send the Court of Auditors a reply to its observations by 30 September at the latest. He shall also send this reply to the Management Board.
10. The European Parliament, upon a recommendation from the Council, shall, before 30 April of year N + 2 give a discharge to the Director in respect of the implementation of the budget for year N.

Article 95
Fees

The structure and amount of the fees referred to in Article 93 (1) (b) will be set by the Management Board and will be made public.

Article 96
Combating fraud

1. In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council shall apply without restrictions to this Agency.
2. The Agency shall be bound by the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by OLAF and shall issue, without delay, the appropriate provisions applicable to all of its staff.
3. The decisions concerning funding and the implementing agreements and instruments resulting from them shall explicitly stipulate that the Court of Auditors and OLAF may carry out, if necessary, on-the-spot checks of the recipients of the Agency's funding and the agents responsible for allocating it.

Article 97
Financial regulation

The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They may not depart from Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities⁴⁷ unless specifically required for the Centre's operation and with the Commission's prior consent.

Article 98
Legal personality and seat of the Agency

1. The Agency shall be a body of the Community and shall have legal personality. In each Member State it shall enjoy the most extensive legal capacity accorded to legal persons under their laws. In particular it may acquire and dispose of movable and immovable property and may be a party to legal proceedings.
2. The Agency shall be represented by its Executive Director.
3. The Agency shall be located at Ispra, Italy.

⁴⁷ OJ L 357, 31.12.2002, p. 72 with Corrigendum in OJ L 2, 7.1.2003, p. 39.

Article 99
Liability of the Agency

1. The contractual liability of the Agency shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction pursuant to any arbitration clause contained in a contract concluded by the Agency.
2. In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties.
The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damages.
3. The personal financial and disciplinary liability of its servants towards the Agency shall be governed by the relevant rules applying to the staff of the Agency.

Article 100
Privileges and immunities of the Agency

The Protocol on the Privileges and Immunities of the European Communities shall apply to the Agency.

Article 101
Staff rules and regulations

1. The staff of the Agency shall be subject to the rules and regulations applicable to officials and other staff of the European Communities. In respect of its staff, the Agency shall exercise the powers which have been devolved to the appointing authority.
2. The Management Board, in agreement with the Commission, shall adopt the necessary implementing provisions.
3. The Agency's staff shall consist of officials assigned or seconded by the Commission or Member States on a temporary basis and of other servants recruited by the Agency as necessary to carry out its tasks.

Article 102
Duty of confidentiality

Members of the Management Board, members of the Committees and of the Forum, experts and officials and other servants of the Agency, shall be required, even after their duties have ceased, not to disclose information of the kind covered by the duty of professional secrecy.

Article 103
Participation of third countries

The Management Board may, in agreement with the relevant Committee or the Forum, invite representatives of third countries to participate in the work of the Agency. The conditions for participation shall be determined beforehand by the Commission.

Article 104
International harmonisation of regulations

The Management Board may, in agreement with the relevant Committee or the Forum, invite representatives of international organisations with interests in the field of chemicals regulation to participate as observers in the work of the Agency. The conditions for participation shall be determined beforehand by the Commission.

Article 105
Contacts with stakeholder organisations

The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of industry, consumer protection, worker protection and environmental protection organisations. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.

Article 106
Rules on transparency

To ensure transparency, the Management Board, on the basis of a proposal by the Executive Director, in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of chemicals which is not of a confidential nature.

Article 107
Relations with relevant Community Bodies

1. The Agency shall cooperate with other Community bodies to ensure mutual support in the accomplishment of their respective tasks in particular to avoid duplication of work.
2. The Executive Director, having consulted the Committee on Risk Assessment and the European Food Safety Authority created by Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴⁸, shall establish rules of procedure concerning substances used in plant protection products. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.

This Title shall not otherwise affect the competences vested in the European Food Safety Authority.

⁴⁸ OJ L 31, 1.2.2002, p. 1.

3. This Title shall not affect the competences vested in the European Agency for the Evaluation of Medicinal Products created by Regulation (EC) No ... [insert number when new proposal – COM/2001/0404, COD 2001/0252 – is enacted] of the Parliament and of the Council⁴⁹.
4. The Executive Director, having consulted the Committee on Risk Assessment, the Committee on Socio-economic Analysis and the Advisory Committee on Safety, Hygiene and Health Protection at Work created by Council Decision 74/325/EEC⁵⁰, shall establish rules of procedure concerning worker protection issues. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.

This Title shall not affect the competences vested in the Advisory Committee on Safety, Hygiene and Health Protection at Work.

Article 108

Formats and software for submission of information to the Agency

The Agency shall specify special formats and make them available free of charge, and software packages and make them available on its website for any submissions to the Agency by Member States, manufactures, importers or downstream users.

⁴⁹ OJ L

⁵⁰ OJ L 189, 9.7.1974, p. 15

TITLE X

CLASSIFICATION AND LABELLING INVENTORY

Article 109

Scope

This Title shall apply to:

- (a) substances subject to registration by a manufacturer or importer ;
- (b) substances within the scope of Article 1 of Directive 67/548/EEC, which meet the criteria for classification as dangerous according to that Directive, and which are placed on the market either on their own, or in a preparation above the concentration limits specified in Directive 1999/45/EC which result in the classification of the preparation as dangerous.

Article 110

Obligation to notify the Agency

- 1. Any importer or manufacturer, or group of importers or manufacturers, who place on the market a substance within the scope of Article 109, shall notify the Agency of the following information in order for it to be included in the inventory in accordance with Article 111, unless submitted as part of the registration:
 - (a) the identity of the manufacturer or importer responsible for placing the substance(s) on the market;
 - (b) the identity of the substance(s) as specified in part 2 of Annex IV ;
 - (c) the hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;
 - (d) the resulting hazard label for the substance(s), resulting from application of Articles 23 to 25 of Directive 67/548/EEC;
 - (e) specific concentration limits, where applicable, resulting from the application of Article 4 (4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.
- 2. In submitting this information, the manufacturer or importer shall use the format specified by Article 108.
- 3. Where this obligation results in different entries on the inventory for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory.
- 4. The information listed in paragraph 1 shall be updated by the notifier(s) whenever:
 - (a) any new scientific or technical information is generated, which results in a change to the classification and labelling of the substance;

- (b) notifiers and registrants of differing entries for a single substance come to an agreed entry in accordance with paragraph 3.

Article 111
The classification and labelling inventory

1. A classification and labelling inventory, listing the information referred to in Article 110 (1), both for information notified under Article 110 (1) as well as for information submitted as part of a registration, shall be established and maintained by the Agency in the form of a database. The non-confidential information in this database identified in Article 116 (1) shall be publicly accessible. The Agency shall grant access to the other data on each substance in the inventory to the notifiers and registrants who have submitted information on that substance.

The Agency shall update the inventory when they receive updated information in accordance with Article 110 (3).

2. In addition to the above information, the Agency shall record, where appropriate, against each entry:
 - if for the entry there is a harmonised classification and labelling at Community level by inclusion in Annex I of Directive 67/548/EEC;
 - if it is an agreed entry of two or more notifiers or registrants ;
 - the relevant registration number(s), if available.

Article 112
Harmonisation of classification and labelling

1. Harmonised classification and labelling at Community level shall, from the entry into force of this regulation, only be added to Annex 1 of Directive 67/548/EEC for classification of a substance as carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3, or as a respiratory sensitisier. To this end, Member State competent authorities may submit proposals to the Agency for harmonised classification and labelling in accordance with Annex XIV.
2. The Agency's Member State Committee shall formulate an opinion on the proposal, giving parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission, which shall take a decision in accordance with Article 4 (3) of Directive 67/548/EEC.

Article 113
Transitional arrangements

The obligations set out in Article 110 shall apply from the deadline established under Article 21 (1).

TITLE XII **INFORMATION**

Article 114 ***Reporting***

1. Every ten years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement in the format specified by Article 108. However, the first report shall be submitted five years after the entry into force of this Regulation.
2. Every ten years, the Agency shall submit to the Commission a report on the operation of this Regulation. However, the first report shall be submitted five years after the date of the notification required in Article 131 (2).
3. Every ten years, the Commission shall publish a general report on the experience acquired with the operation of this regulation, including the information referred to in paragraphs 1 and 2. However, the first report shall be published six years after the date of the notification required in Article 131 (2).

Article 115 ***Access to information***

1. Access to non-confidential information submitted in accordance with this Regulation shall be granted for documents held by the Agency in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council. The Agency shall make such information available on request, in accordance with Article 73 (2) (d).
2. Whenever a request for access to documents is made under Regulation (EC) No 1049/2001 to the Agency, the Agency shall perform the consultation of the third party foreseen in Article 4 (4) of Regulation (EC) No 1049/2001 in the following way:

The Agency shall inform the registrant, potential registrant, downstream user, applicant or other party concerned of this request. The party concerned may submit a declaration within 30 days identifying the information covered by the request which he considers to be commercially sensitive and disclosure of which might harm him commercially and which he therefore wishes to be kept confidential from all persons other than the competent authorities, the Agency and Commission. He shall give a justification in each case.

Such a declaration shall be considered by the Agency, which shall decide, on the basis of the justification, whether to accept this declaration before deciding whether to grant the request for access to documents. The Agency shall inform the party concerned who may appeal against a decision by the Agency not accepting the declaration to the Board of Appeal within 15 days of the decision in accordance with Articles 87 to 89. Such an appeal shall have suspensive effect. The Board of Appeal shall decide on the appeal within 30 days.

3. Access to non-confidential information submitted in accordance with this Regulation shall be granted for documents held by competent authorities of the Member States in accordance with Directive 2003/4/EC of the European Parliament and of the Council. Any Member State shall ensure that a system is established under which any party concerned may appeal with suspensive effect against decisions taken in relation to access to documents.
- 3a. As long as an appeal is pending or can still be introduced, the Agency and any competent authority of a Member State shall continue to keep the information in question confidential.
4. The Agency and any competent authority of a Member State shall apply Article 116 when taking a decision under Article 4 of Regulation (EC) No 1049/2001 and Article 4 of Directive 2003/4/EC, respectively. However, where Member States have received information via the Agency, the Agency will take the decision whether to grant or refuse access in accordance with paragraphs 4 and 5.
5. Any total or partial refusal by the Agency of access to documents under Article 8 of Regulation (EC) No 1049/2001 may be appealed by means of a complaint to the Ombudsman or to the Board of Appeal in accordance with Articles 87 to 89.
6. The Management Board shall adopt the arrangements for implementing Regulation (EC) No 1049/2001 within six months of entry into force of this regulation.

Article 116
Confidentiality

1. The following information shall not be considered as confidential:
 - (a) the trade name(s) of the substance;
 - (a') the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC;
 - (b) if applicable, the name of the substance as given in Einecs;
 - (c) physicochemical data concerning the substance and on pathways and environmental fate;
 - (d) the result of each toxicological and ecotoxicological study;
 - (e) any derived no-effect level (DnEL) or predicted no-effect concentration (PnEC) established in accordance with Annex I;
 - (f) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;
 - (g) the guidance on safe use provided in accordance with section 4 of Annex IV;

- (h) the information contained in the safety data sheet, except for the name of the company/undertaking or where the information is considered confidential by application of paragraph 2;
 - (i) analytical methods if requested in accordance with Annex VII or VIII which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans;
 - (j) the fact that testing on vertebrate animals has been carried out.
2. The following information shall be considered as confidential, even if no declaration in accordance with Article 115 paragraph 2 is made:
- (a) details of the full composition of a preparation;
 - (b) the precise use, function or application of a substance or preparation;
 - (c) the precise tonnage of the substance or preparation manufactured or placed on the market;
 - (d) links between a manufacturer or importer and his downstream users.
3. All other information shall be accessible in accordance with Article 115.

Article 117
Cooperation with third countries and international organisations

Notwithstanding Articles 115 and 116, information received by the Agency under this Regulation may be disclosed to any government or body of a third country or an international organisation in accordance with an agreement concluded between the Community and the third party concerned under Regulation 304/2003/EC or under Article 181a (3) of the EC Treaty, provided that:

- the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation, and
- the third party protects the confidential information as mutually agreed.

TITLE XII

COMPETENT AUTHORITIES

Article 118

Appointment of competent authorities

Member States shall appoint the competent authority or competent authorities responsible for performing the tasks allotted to competent authorities under this Regulation and for co-operating with the European Commission and the Agency in the implementation of this Regulation. Member States shall place adequate resources at the disposal of the competent authorities to enable them to fulfil their tasks under this Regulation in a timely manner.

Article 119

Co-operation between competent authorities

The competent authorities shall co-operate with each other in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States all the necessary and useful support to this end.

Article 120

Public Communication of Information on Risks of Substances

Member State competent authorities shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment.

Article 121

Other responsibilities of the competent authorities

The competent authorities shall provide advice to manufacturers, importers, downstream users and any other interested parties on their responsibilities and obligations under this Regulation, in addition to the operational guidance documents provided by the Agency under Article 73 (2) (f).

TITLE XIV ENFORCEMENT

Article 122 Tasks of the Member States

Member States shall maintain a system of official controls and other activities as appropriate to the circumstances.

Article 123 Sanctions for non-compliance

1. The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of the present Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than eighteen months after entry into force of the present Regulation and shall notify it without delay of any subsequent amendment affecting them.
2. In cases where the provisions of the Member States require a fine, the amount of the fine shall be determined according to the gravity and duration of the infringement, the extent of damage to environment and human health and any aggravating or attenuating circumstances, such as consideration of animal welfare, as appropriate. It shall be set at a level, which ensures that it has a deterrent effect.

Article 124 Report

Member States shall submit a report to the Agency by 1 July each year on the results of the official checks, the monitoring carried out, fines set and the other measures taken pursuant to Articles 122 and 123 during the previous calendar year. The Agency shall make these reports available to the Commission.

TITLE XV

TRANSITIONAL AND FINAL PROVISIONS

Article 125

Free movement clause

Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a preparation or in an article, falling within the scope of this Regulation, which complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation..

Article 126

Safeguard Clause

1. Where a Member State has justifiable grounds for believing that a substance, on its own, in a preparation or in an article, although satisfying the requirements of this Regulation, constitutes a risk to human health or the environment, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based.
2. The Commission shall take a decision in accordance with the procedure referred to in Article 130 (2) within 90 days from receipt of the information from the Member State. This decision shall either
 - a) authorise the provisional measure for a time period defined in the decision, or
 - b) require the Member State to revoke the provisional measure.
3. If in the case of paragraph 2 a) the provisional measure taken by the Member State consists of a restriction on the placing on the market or use of a substance, that Member State shall initiate a Community restrictions procedure by submitting to the Agency a Dossier, in accordance with Annex XIV within 3 months from the date of the Commission decision.
4. In the case of paragraph 2 a), the Commission shall consider whether the present Regulation needs to be adapted.

Article 127

Motivation of decisions

The Competent Authorities, the Agency and the Commission shall state the reasons for all decisions they take under this Regulation.

Article 128
Amendments to the Annexes

The Annexes may be amended in accordance with the procedure referred to in Article 130 (3).

Article 129
Implementing legislation

Legislation for the efficient implementation of this Regulation may be adopted in accordance with the procedure referred to in Article 130 (3).

Article 130
Committee procedure

1. The Commission shall be assisted by a Committee composed of representatives of the Member States and chaired by the representative of the Commission.
2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.
3. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.
4. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 131
Transitional measures regarding the Agency

1. The Commission shall fulfil the functions of the Agency during the period following the entry into force of this Regulation until these functions are transferred to the Agency as provided for in paragraph 3. In particular the Commission may appoint personnel and conclude contracts on behalf of the Agency, thereby using the budget foreseen for the latter. This includes the appointment of a person who fulfils the functions of the Executive Director until an Executive Director is appointed by the Management Board of the Agency in accordance with Article 80.
2. Within 18 months of the entry into force of the present Regulation, the Executive Director of the Agency shall notify the Commission stating that the Agency is ready to assume its functions under this Regulation.
3. Within two months of receipt of the notification from the Executive Director of the Agency or within 18 months of the entry into force of this Regulation, whichever is the earlier, the Commission shall transfer these functions to the Agency.

Article 132
Transitional measures regarding restrictions

Within 18 months of the entry into force of this Regulation, the Commission shall, if necessary, prepare a draft amendment to Annex XVI in accordance with:

- (a) any risk evaluation and recommended strategy for limiting risks that has been adopted at Community level in accordance with Article 11 of Council Regulation (EEC) No 793/93 but for which Community measures to limit those risks have not yet been taken or;
- (b) any proposal it has adopted to introduce restrictions under Directive 76/769/EEC.

Article 133
Review

- 1. Twelve years after the Regulation comes into force, the Commission shall carry out a review with a view to the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. On the basis of this review, the Commission may, in accordance with the procedure referred to in Article 130 (3), extend this obligation.
- 2. As soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after having published a report on
 - the risks posed by polymers in comparison with other substances and
 - the need, if any, of registering certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of health and the environment on the other,the Commission may adapt Articles 14 and 37 in accordance with Article 130 (3).
- 3. The report on the experience acquired with the operation of the present Regulation referred to in Article 114 (3) shall include a review of the requirements related to registration of substances manufactured or imported only in quantities starting at 1 tonne but less than 10 tonnes per year per manufacturer or importer.

Based on this review, the Commission may, in accordance with the procedure referred to in Article 130 (3), modify the information requirements specified in Annex V for substances manufactured or imported in quantities of 1 tonne or more up to 10 tonnes per year per manufacturer or importer, taking into account the latest developments, for example in relation to alternative testing and (quantitative) structure-activity relationships ((Q)SARs).

Article 134
Repeal

1. Directives 76/769/EEC, 79/663/EEC, 82/806/EEC, 82/828/EEC, 83/264/EEC, 83/478/EEC, 85/467/EEC, 85/610/EEC, 89/677/EEC, 89/678/EEC, 91/155/EEC, 91/157/EEC, 91/173/EEC, 91/338/EEC, 91/339/EEC, 91/659/EEC, 93/112/EEC, 94/27/EC, 94/48/EC, 94/60/EC, 96/55/EC, 97/10/EC, 97/16/EC, 97/56/EC, 97/64/EC, 98/101/EC, 1999/43/EC, 1999/51/EC, 1999/77/EC, 2001/41/EC, 2001/90/EC, 2001/91/EC, 2001/58/EC, 2002/45/EC, 2002/61/EC, 2002/62/EC, 2003/02/EC, 2003/03/EC, 2003/11/EC, 93/67/EEC, 93/105/EC and 2000/21/EC and Regulations (EEC) No 793/93 and (EC) 1488/94 are hereby repealed. References to these regulations and directives shall be construed as references to this Regulation.
2. Article 4 and Annexes I and II of Regulation (EC) {on Persistent Organic Pollutants} are hereby repealed. In Article 15 (1) of Regulation (EC) {on Persistent Organic Pollutants} the words "Annex I, II" shall be deleted.
3. Article 14 of Directive 1999/45/EC is hereby repealed.

Article 135
Entry into Force and Application

1. This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.
2. Titles II and XII shall apply from the 60th day following the entry into force of the Regulation.
3. Articles 81 and 82 shall apply from the day falling one year after the entry into force of the Regulation.
4. Articles 66 to 70 shall apply from the day falling 18 months after the entry into force of the Regulation.
5. Articles 44 to 46 shall apply from the day falling 2 years after the entry into force of the Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

For the European Parliament
The President
[...]

For the Council
The President
[...]