FINAL REPORT
OF
THE SLIM PHASE IV TEAM
ON
DANGEROUS SUBSTANCES
(Directive 67/548/EEC)
Table of Contents

1. EXECUTIVE SUMMARY
   ............................................................................................................. 3

2. INTRODUCTION
   ............................................................................................................. 4
   2.1. The SLIM exercise .................................................................................... 4
   2.2. Objectives and history of Directive 67/548/EEC ........................................ 4
   2.3. Strategic considerations ............................................................................. 6

3. ISSUES FOR THE SLIM EXERCISE ............................................................ 8
   3.1. Structure of the Directive .......................................................................... 8
   3.2. Objectives, scope and definitions ............................................................... 9
   3.3. Classification, packaging and labelling of dangerous substances .......... 10
   3.4. Notification of new substances ................................................................ 14
   3.5. Other issues ............................................................................................. 20

4. LIST OF RECOMMENDATIONS ................................................................ 23

5. ANNEXES ...................................................................................................... 29
   5.1. Composition of the SLIM team on dangerous substances ................. 29
   5.2. Calendar and content of meetings ............................................................ 31
   5.3. List of written contributions .................................................................... 32
1. EXECUTIVE SUMMARY

The SLIM Group has concluded that the underlying principles of the Dangerous Substances Directive (DSD) remain a sound basis for chemicals management. The DSD provides an important platform for a wide range of down-stream EU legislation. However, many provisions of the Directive and its accompanying requirements are in serious need of modernisation, rationalisation and simplification. There is an urgent need to introduce greater clarity, speed and efficiency in the operation of the Directive. At the same time, high standards of protection for man and the environment must be ensured. To achieve these goals alongside the EU’s broader policy objectives the group has developed a set of 48 recommendations which aim to:

– Rationalise the structure of the Directive, separating matters of policy and technical detail through an examination of the different elements and their legal form to make the legislation more transparent and easier to use, transpose and update;

– Introduce speedier processes for classifying substances making better use of available data;

– Improve the comprehensibility and usefulness of labels through the rationalisation of labelling provisions to eliminate redundant requirements and provide the necessary information to the user;

– Ensure that the provisions for research and development, and criteria for notification of polymers do not stifle innovation and scientific development;

– Simplify the notification requirements for intermediates reflecting the limited exposure of man and the environment; and introduce modifications in the notification system for low volume substances;

– Re-allocate responsibilities between the Commission, the Competent Authorities and the notifier, and streamline working procedures to enhance efficiency and make more effective use of resources and expertise;

– Ensure better access to information for users and the public;

– Reduce unnecessary animal testing through more effective mechanisms to encourage data sharing.

Parallel to this analysis the European Commission is undertaking a broader review of EU chemicals legislation. Therefore proposed changes must take account of the implications of the wider review as well as the consequences for inter-related instruments.

At the same time, work at international level to develop a Globally Harmonised System (GHS) for the classification and labelling of chemicals has made significant progress. The recommendations reflect the importance of incorporating these wider global developments within the EU legal system.

The Records of the deliberations of the SLIM Group have been made available to all Competent Authorities and other stakeholders. All comments received have been considered by the Group.
2. INTRODUCTION

2.1. The SLIM exercise

SLIM is an exercise organised by the Commission, which is aimed at improving the enforcement and effectiveness of legislation related to the Single Market. Taking into account the requests made by the Member States, the European Parliament, the Economic and Social Committee and business representatives, it was agreed that the Phase IV of SLIM should cover the following sectors: company law, pre-packaging and dangerous substances (Directive 67/548/EEC, Dangerous Substances Directive).

The exercise on dangerous substances focused on Directive 67/548/EEC. This Directive has been amended 9 times and its annexes have been adapted to technical progress 25 times in order to take into account the continuous increase of scientific and technical knowledge. This has increased the complexity of the Directive.

In addition, the Directive is intimately linked to other pieces of Community chemical legislation, such as Directive 93/67/EEC describing the principles of risk assessment, Directive 76/769/EEC on the restrictions on the marketing and use of certain dangerous substances and preparations, Directive 90/394/EEC on the protection of workers from carcinogens or the new Dangerous Preparations Directive.

The operation of SLIM is based on small teams composed of participants of up to five Member States and an equal number of users of legislation. For the team on dangerous substances, DG XI provided the Secretariat. Experts from Denmark, France, the Netherlands, Portugal, the United Kingdom, 2 industrial organisations (CEFIC and UNICE), 1 Trade Union organisation (TUTB), 1 organisation for consumer protection (BEUC) and 1 non-governmental organisation (WWF)1 were invited to participate. Mr Stuffmann, a former Commission Head of Unit, now counsellor to Commissioner Wulf-Mathies, chaired the team meetings. Participants from other Directorates-General of the Commission were present at the meetings as observers. Other Member States and organisations were involved in the work of the team by submitting their written contributions, according to the Guidelines provided by DG XV.

Each SLIM team has to prepare a report with recommendations on simplifying legislation in the sector concerned. The outcome of Phase IV of SLIM will be included in an overall report addressed to the Council and to the European Parliament with respect to the 3 sectors covered by Phase IV.

2.2. Objectives and history of Directive 67/548/EEC

The legislation examined in the area of chemicals is Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the

1 WWF did not attend any meeting of the SLIM team on dangerous substances but contributed in writing.
classification, packaging and labelling of dangerous substances. The Directive is based on article 95 of the Treaty and has been amended 9 times; its annexes have been adapted to technical progress 25 times in order to take account of the continuous increase of scientific and technical knowledge in the field of dangerous (chemical) substances.

The Dangerous Substances Directive is an important single market Directive. Its key objectives are to ensure the operation of the European single market in chemicals and to provide high standards of human health and environmental protection. The scope for this report is taken to be the totality of the Directive including:

- its articles and annexes;
- its transposition in Member States; and
- its associated operational and administrative procedures.

From 1967 the Directive introduced harmonised provisions on the classification of dangerous substances into (now) fifteen classes of danger, on packaging of dangerous substances, and on labelling of dangerous substances in informing the users about the nature of danger(s) of the substance and about the safety measures to apply during handling and use. The Directive included a list of substances classified as dangerous in Annex I, symbols and indications of danger to identify one or more of the fifteen classes of danger in Annex II, nature of special risk phrases and safety phrases in Annexes III and IV.

The intrinsic properties of a substance, namely its physico-chemical properties, environmental fate properties and its toxicity towards human health and the environment, have to be evaluated in order to determine the symbols of danger and other indications that have to be put on the label. Annex V contains testing methods to determine the potentially dangerous properties of substances, and Annex VI provides detailed criteria on the proper choice of the class of danger and how to assign the danger symbols, R(isk)- and S(afety)-phrases to a tested substance. Several Annexes are also applicable to dangerous preparations, which fall under the new Dangerous Preparations Directive. Every company placing a substance on the market must ensure that the substance is classified and labelled according to the provisions of Directive 67/548/EEC.

For a range of about 4800 dangerous substances, classification and labelling have been agreed on a Community level and are listed in Annex I of the Directive. Substances which are not dangerous according to the Directive do not require classification.

Since 1981 with the sixth Amendment the Directive requires that any substance which is placed on the Community market, and which has never been on the market before, is notified by the manufacturer or the importer to a national Competent Authority. This substance is called a “new” substance. A detailed notification file has to be submitted to the Authority, which includes among others the description of the intrinsic physico-chemical, toxicological and ecotoxicological properties of the substance. On the basis of the intrinsic properties found in these substances, specific symbols of danger and other indications have to be put on the label. When the file is in compliance with the Directive, the substance may be marketed 60 days after submission to the Competent Authority, otherwise the Authority will request further data to complete the file. Once the notification file is accepted the substance may be marketed in all 15 Member States (mutual recognition of the notification file in all Member States and free circulation of the chemical in the Internal Market).
For every “new” substance a risk assessment is prepared by the Competent Authority. It evaluates the risks that a dangerous substance may pose to human health and the environment. The conclusion of an assessment can be chosen among four possibilities. They range from “no further information about the dangers of the substance” is needed to immediate “recommendations for risk reduction”. Such a recommendation could require the restriction of the marketing and use of the substance in accordance with Directive 76/769/EEC. Until today 8 “new” substances have been restricted.

Since 1981 about 2400 “new” substances have passed this pre-marketing notification system. Before that date substances could be placed on the market without being notified. They are called “existing substances”. There are more than 100000 (one hundred thousand) “existing substances”, published in 1990 in a list called EINECS (European Inventory of Existing Commercial chemical Substances). New notified substances are listed in ELINCS (European List of Notified Chemical Substances) to be published yearly.

2.3. Strategic considerations

Significantly the Directive provides an important platform for a wide range of downstream EU legislation. Its classification criteria and approach to hazard identification form the basis for chemicals management in the EU, impacting upon the operation of several other Directives and EC Regulations on the supply and use of chemicals and on the assessment and control of risks from chemical substances. The principles of the Directive have also underpinned the EU’s approach to discussions in international fora under the programme for the Global Harmonisation of Classification and Labelling of Chemicals arising from the Rio Summit. The working group recognised from the outset that any proposals for change arising from its review had therefore to take account of the Directive’s key objectives; its inter-relationship with other pieces of Community legislation and with global considerations.

In parallel with the work of the SLIM project team the European Commission is undertaking a broader Review of EU chemicals legislation which includes the Dangerous Substances Directive. The strategic perspective of the broader Review would necessarily impact on the DSD and the recommendations arising from SLIM. It was therefore important that the team’s recommendations were informed by these strategic considerations and able to complement the wider review process.

In order to anchor to these strategic concerns, at the outset the team established a set of overarching principles which could encompass the SLIM objectives and provide a comprehensive framework for discussions:

- to maintain high standards of protection for human health and the environment;
- to maintain harmonisation in order to eliminate barriers to trade;
- to avoid unnecessary administrative burdens;
- to ensure transparency;
- to respond to developments from the ongoing global harmonisation activities of classification and labelling systems;
- to foster sustainability and encourage scientific development and innovation;
• to streamline and improve the operation and effectiveness of the Directive;
• to ensure consistency with other pieces of Community legislation; and
• to ensure that the objectives of the SLIM IV review of the Directive are relevant to and consistent with the wider EU Chemicals Policy.
3. ISSUES FOR THE SLIM EXERCISE


_analysis_

The present structure of Directive 67/548/EEC is based on the working practice of classification and labelling (C&L) of new and existing substances according to their intrinsic dangerous properties, notification of new substances prior to marketing, of hazard characterisation and risk assessment of new substances, and, when appropriate, on recommendations for risk reduction measures. The working practice of the Directive requires complex, time-consuming, and resource-intensive procedures. Some provisions of the Directive are difficult to understand because they are based on implicit expert knowledge, or need a clearer drafting.

Another aspect that complicates the understanding of the provisions is the sometimes confusing structure of the Directive. Missing clarity makes it difficult for the beginner to overview the manifold rules which are laid down, and the trained user may overlook provisions which could be important for an actual problem.

A clear structure is even more important because the Directive is embedded in a well-developed network of provisions on chemical substances. Provisions of the Directive are used by other Directives, such as the new Dangerous Preparations Directive or Directive 76/769/EEC on the restrictions on the marketing and use of certain dangerous substances and preparations; or pointed to other Directives, such as Directive 93/67/EEC describing the principles of risk assessment or Directive 91/155/EEC on Safety Data Sheets, both vital for the practical operation of the Dangerous Substances Directive.

The provisions for C&L of preparations are dealt with in the new Dangerous Preparations Directive. However, Annex VI of the Dangerous Substances Directive providing criteria on the proper choice of the class of danger and how to assign the danger symbols, R- and S- phrases does not restrict the application of the criteria to only substances.

C&L of substances and notification of new substances are closely linked, especially with regard to testing of substances and hazard characterisation based on test results. C&L of preparations are mainly based on using an alternative methodology.

_recommendations_

1. The legal basis and form of instruments most appropriate for delivery of objectives for classification, packaging and labelling and for notification provisions within Member States need to be examined within the context of wider EU Chemicals Policy.

2. The wording of the Directive should be updated to incorporate the current philosophy and principles that underpin sound chemical management in a holistic manner.
3. The architecture of the Directive should be rationalised to ensure that only matters of policy and principle are incorporated in the main text and that technical detail is dealt with through annexes.

4. The advantages and disadvantages of splitting the provisions for C&L and notification into two different legal instruments combining the provisions for C&L of dangerous substances and preparations in the same instrument and setting up a Regulation for C&L provisions or at least for those Annexes dealing with C&L (Annexes I to VI and IX) should be examined. These proposals should take into account the implication of the Directive in other pieces of related EU legislation.

5. The SLIM team stressed the need to publish a codified version of the Dangerous Substances Directive taking on board the recommendations presented in this report.

3.2. Objectives, scope and definitions

Analysis

Article 1(1) does not state the objective of the Directive, but lists only several elements without clarification. The objectives and the different elements of the Directive remain unclear. The application of the exemptions included in Article 1(2) pose practical problems because the scope of the different Directives mentioned is not clearly delimited. Clear definitions of certain items such as waste or recycled products are also needed.

The definitions in Article 2(1) give rise to problems of interpretation. There are different definitions of "placing on the market" in several pieces of EU legislation. The notification and labelling requirements of dangerous substances in articles, i.e. specific containers, are unclear because articles are not defined in the Directive. The provisions for "sole representative" can trigger multiple notifications in some specific cases, e.g. re-import of an EU manufactured substance. These provisions lead to unnecessary administrative burden for EU manufacturers.

Recommendations

6. Article 1(1) of the Directive should be reviewed in order to bring the objectives into line with the current practice and to clarify the different elements.

7. The continued applicability of exemptions detailed in Article 1(2) should be re-examined taking into account developments within global harmonisation and the wider review of EU Chemical Policy.

8. The definitions used in the Directive and in particular those for "placing on the market" and "sole representative" should be re-examined as should the possibility of introducing a definition for "articles", "waste" in relation to recycled products.
9. In order to facilitate the updating of the definitions of dangerous substances and preparations included in Article 2(2), the possible incorporation of the technical and scientific details of those definitions in an Annex of the Directive should be explored.

### 3.3. Classification, packaging and labelling of dangerous substances

#### 3.3.1. Classification, including globally harmonised classification

- **Implementation of the Globally Harmonised System**

  **Analysis**

  International work to develop a Globally Harmonised System (GHS) for the classification and labelling of chemicals as proposed at the Rio Summit is being carried forward in OECD, ILO and UN fora and is supported by all Member States. The principles and criteria of Directive 67/548/EEC has been used as the basis of developing the EU’s position in these international discussions. The possible implementation mechanism for the GHS is still being developed. Agreements already reached in these international fora may have important implications for Directive 67/548/EEC and related EU legislation which need to be taken into account.

  **Recommendation**

  10. The Commission should take into account the work on a Globally Harmonised System (GHS) for the classification and labelling of chemicals developed in the OECD, ILO and other UN fora, and should evaluate the impact of the GHS on Directive 67/548/EEC and other related pieces of EU legislation.

- **Potency in Classification and Labelling (C&L)**

  **Analysis**

  Some endpoints on human health, e.g. sensitisation, carcinogenicity, mutagenicity and reproductive toxicity, do not take into account the “biological mode of action” and/or the factor "potency" for C&L purposes, i.e. the magnitude, with respect to dose, of the carcinogenic activity of a chemical. It is difficult to progress the principle of “biological mode of action” and/or “potency” under the current scientific knowledge without clear definitions and criteria.
**Recommendation**

11. With respect to classification criteria, it should be recognised that some endpoints on human health (e.g. sensitisation, carcinogenicity, mutagenicity and reproductive toxicity) should take into account the need to consider "potency" and/or the "biological mode of action" for C&L purposes.


**Analysis**

Annex VI contains a lot of complex technical information, which is difficult to handle for companies with little experience in classification. The system of assigning R- and S-phrases has become extremely complicated. A fundamental revision of its practical arrangements should be considered to clarify the provisions. The fact that Annex VI deals with both substances and preparations also confuses small companies.

**Recommendation**

12. Annex VI should be critically reviewed in order to make it more understandable, taking into account its application to substances and preparations.

- **Non-classified substances**

**Analysis**

There are problems derived from non-classified substances. Since the classification of substances is based on available data, a non-classified substance means that either the substance does not present any hazard or that there is not any available data on it.

**Recommendation**

13. Possible solutions for the problem of how to tackle non-classified substances in the absence of data should be explored.

- **Improvement of transparency**

**Analysis**

The accessibility and availability of information to the general public concerning the classification of substances is unsatisfactory at present. The C&L activities carried out by the Commission (European Chemicals Bureau, ECB) such as the records of the meetings on C&L and the rationale for C&L proposals of substances are not published.
Recommendation

14. The accessibility and availability of information to the general public about classification of substances should be improved, taking into account the Århus Convention on access to information, public participation in decision-making and access to justice in environmental matters, 23-25 June 1998. Options such as the publication on Internet of relevant information about the C&L activities carried out by the COM (ECB), the access to key data on the properties of substances and the publication of provisional C&L of substances in progress solely intended for information should be considered.

3.3.2. Hazard communication: labelling and safety data sheets

- Simplification and improvement of labelling

Analysis

The labelling provisions in the Directive are quite complex and unclear. The Articles of the Directive that deal with labelling, particularly Articles 23 and 24, have an excessive technical content. The current format of the label contains redundant information, which hinders comprehensibility and usefulness.

Recommendations

15. The labelling provisions in the Directive and the content of the label should be reviewed in order to improve the comprehensibility and usefulness and to eliminate redundant information. The revision should take into account available relevant studies on this subject.

16. The technical information included in the Articles dealing with labelling should be separated and transferred to an Annex of the Directive.

- Temporary storage

Analysis

The importation of dangerous substances into the EU immediately triggers labelling, even without intended marketing in the country of import. Later, the substances have to be re-labelled according to the particular requirements of the destination country within the European Economic Area (EEA), e.g. the specific language.
Recommendation

17. The labelling requirements for substances imported into the EU and stored before distribution should be reviewed in order to improve the efficiency and to avoid unnecessary burdens but ensuring that adequate information is provided to allow persons to take necessary measures to protect the health and safety of man and the environment during storage.

3.3.3. Annex I: structure and procedure for implementation

• **Structure and format of Annex I**

**Analysis**

The current use of existing data on classification and labelling (C&L) is not satisfactory. In particular, the information on the IUCLID database (International Uniform Chemical Information Database) is not sufficiently used and the introduction of updated data in Annex I is a lengthy process.

**Recommendations**

18. Mechanisms should be explored to make better use of existing data on classification and labelling (C&L), in particular the data available on the IUCLID database (International Uniform Chemical Information Database), and to speed up the incorporation of this data into Annex I to Directive 67/548/EEC.

19. Annex I or the database containing detailed information of substances listed in Annex I should include the "age" of the C&L data, such as reflected by the date of the meeting of the Commission Working Groups "Classification and Labelling" at which the C&L data was recommended, or the date of adoption of the C&L data by the Commission.

• **The implementation of Annex I**

**Analysis**

The implementation of Annex I differs between Member States. The publication of Annex I and its implementation at Member State is currently a lengthy process.

**Recommendations**

20. The publication of Annex I and its implementation at Member State level should be streamlined with a view to make it more user-friendly.

21. Possibilities to ease the linguistic versions of the chemical names of the substances should also be considered.
• **The working procedure for updating Annex I**

*Analysis*

The current procedure to include classified substances in Annex I is a lengthy process. Subsequently Annex I has to be used for C&L regardless of the availability of more recent data on the substances which would modify C&L. Therefore there is a need to facilitate the incorporation of updated C&L proposals into Annex I in order that the information about C&L can be made available for the users more speedily.

*Recommendation*

22. Procedures to speed up the incorporation of C&L proposals into Annex I should be explored, with a view to make the C&L data more speedily available for use. The integrity of the current system and the confidence between the Member States should be maintained.

3.4. **Notification of new substances**

3.4.1. **The scheme for the notification of new substances**

*Analysis*

In general the system for the notification of new substances is sound. However, there is a need to increase flexibility in order to ensure that innovation and the development of new substances are not stifled, while retaining the current high level of protection for human health and the environment.

The principle of the system of notification is the submission of minimum sets of data that guarantee the safety of new substances. This is a preventive approach that provides control over the substances prior to placing them on the market. When the quantity of the substance placed on the market reaches certain tonnage levels, the amount of data to submit increases accordingly.

However, there is a need to find a right balance between notification requirements to ensure safety and appropriate exemptions to encourage the development of new and safer substances which could replace existing substances with more toxic properties.

The OECD initiated the development of a programme with the aim to harmonising notification requirements in order to share notification and assessment information effectively with a minimal additional regulatory requirements. The Directive does not enable flexibility in the notification procedure for notifications submitted and accepted elsewhere.
**Recommendations**

23. Possibilities to decrease the number of notifications such as covering a group of similar substances, e.g. salts of a substance, under a single notification should be considered, on the basis of scientific justification and the experience gained with existing substances.

24. It is recommended to consider the introduction of a limited administrative procedure for notifications of substances already notified and accepted under other recognised notification systems. Possibilities such as flexibility in time period and in recognition of assessments should be explored.

**3.4.2. Specific requirements**

- **Scientific Research & Development (R&D) and Process-Orientated Research & Development (PORD)**

  **Analysis**

  The Directive includes notification exemptions for R&D and PORD, namely a quantity threshold of 100-kg for scientific R&D and a period of 1-year for PORD (susceptible of extension to a second year under justification). However, the testing and developing of substances used for the synthesis of products such as pharmaceuticals and pesticides needs to be carried out at higher quantities or for more prolonged periods but the Directive does not allow much flexibility in the application of the exemptions.

  **Recommendation**

  25. The provisions for research and development exemptions should be reviewed with a view to introducing more flexibility concerning the quantity threshold for scientific research and development (R&D) and the time period limit for process-oriented R&D (PORD).

- **Polymers**

  **Analysis**

  The criteria for the notification of polymers including the reduced test package are complicated and unclear. Nevertheless, there is a need for sufficient scientific evidence to substantiate any modification of the criteria.
**Recommendation**

26. The criteria that determine whether a polymer constitutes a new substance should be revised provided that the criteria are based on sufficient scientific evidence. Particular consideration should be given to examining the testing requirements for polymers; they should be made more proportionate.

- **Intermediates**

**Analysis**

Intermediates are substances used in the processing of other products. If intermediates are processed in more than one manufacturing plant, they are placed on the market and subject to the general notification requirements included in the Directive. Since marketed intermediates are only handled by professional staff on a controlled number of sites, the exposure of man and the environment is limited. A reduced test set could be sufficient without lowering the level of protection of human health and the environment. In addition, intermediates isolated on the manufacturing site for further processing need a special consideration because these substances are not placed on the market.

**Recommendations**

27. The notification requirements for intermediates placed on the market should be examined in order to make them more adapted to their limited exposure of man and the environment, but to keep them proportionate with respect to the volumes concerned and the safety requirements during normal handling and use of these intermediates.

28. An area to be considered in addition are site limited, isolated intermediates, which do not fall within the scope of the present Directive. It is recommended to explore options in order to ensure that adequate information for worker protection, environment protection and emergency response is available on site.

- **The system of reduced notification**

**Analysis**

The Directive includes a reduced notification procedure for substances placed on the market in quantities of less than 1 tonne per annum per manufacturer. The competent authorities find it difficult to obtain clear results in risk assessment and risk management due to the limited data included in the reduced notifications.
Recommendation

29. The reduced notification requirements for substances placed on the market in quantities of less than 1 tonne per annum and manufacturer should be reviewed. Replacement of the current notification requirements by responsible record keeping in industry combined with a monitoring and safeguard role of the competent authorities should be explored.

3.4.3. Working procedures, duties and responsibilities

- The administrative procedure for notification

Analysis

The efficiency of the current working procedure for the notification of new substances is not optimal. The provisions of the Directive laying down the duties of the Commission including the European Chemicals Bureau (ECB), the competent authorities and the notifier, as well as the requirements of the notification procedure, are unclear.

Recommendations

30. Possible options to improve the current working procedures for the notification of new substances should be explored. Areas where the centralisation of information management could enhance the efficiency of the notification system should be identified.

31. Priority should be given to an independent review of all aspects of the notification procedures including the administration and the balance of responsibility between the Commission, the competent authorities and the notifier. The review should identify options to make the role of the parties more transparent; the process more efficient; and the use of expert resource more effective.

32. Flexibility should be given to the competent authority to handle the approval period for re-notifications (notifications submitted a second time after having brought the dossier into conformity with the requirements of the Directive) in appropriate time frames even shorter than 60 days.

33. The notifier should be informed of the outcome of the notification process and should be consulted in the case of diverging conclusions.
• **The Sole Representative facility**

*Analysis*

The Sole Representative facility has proved to be very effective in reducing the administrative burden by limiting repeated notifications. However EU manufacturers and non-EU companies not being the original manufacturers of imported new substances cannot use this facility, which is restricted to non-EU manufacturers only.

*Recommendation*

34. The extension of the Sole Representative facility to EU manufacturers and to non-EU companies not being the original manufacturers of the imported new substance in question should be explored in order to avoid unnecessary multiple notifications.

• **Data sharing**

*Analysis*

The provisions for data sharing included in the Directive allow companies to share test data on new substances in order to avoid repeated tests on animals. However the Directive does not oblige the notifier to share data and therefore some companies are reluctant to share their test data with rivals because of commercial reasons. The positions within the EU Member States are not harmonised: Austria and Germany are currently the only Member States with obligatory schemes for data sharing.

*Recommendation*

35. More effective mechanisms to promote the sharing of data should be developed in order to avoid repetition of animal testing in accordance with existing EU provisions on animal protection. The harmonisation of Member States' positions should be considered. Effective mechanisms to facilitate the exchange of information and to preserve the rights of the "first notifier", i.e. the company that provides the data, will have to be developed.

• **Notification requirements for substances solely intended for export**

*Analysis*

The Directive restricts the notification procedure to new substances placed on the EU market. Therefore those substances manufactured in the EU solely intended for export to third countries are exempted from notification. However, Regulation (EEC) 2455/92 on export and import of certain dangerous chemicals states that all exported chemicals should be classified and labelled according to the EU requirements and listed substances should be notified to the importing countries.
36. The possible obligation to notify new substances manufactured within the EU, solely intended for export to third countries should be explored, if the substance has not been notified under any other recognised system. Requirements should be consistent with Regulation (EEC) 2455/92 on export and import of certain dangerous chemicals and the Rotterdam Convention on the Prior Informed Consent procedure (PIC).

3.4.4. Testing methods

Analysis

The current transposition of the testing methods developed at OECD level into EU legislation is too lengthy. The notification requirements included in the Directive are not appropriate for the notification of enzymes. In particular, the testing methods from Annex V are not suitable for these substances.

Recommendations

37. The Commission should explore ways to speed up the transposition of OECD Test Guidelines into testing methods for Directive 67/548/EEC.

38. Particular areas for which more appropriate testing methods should be developed, such as for the evaluation of enzymes, should be explored.

3.4.5. Risk assessment of new substances

Analysis

The Directive places the responsibility to carry out risk assessments (RA) for notified substances on the competent authorities. However, because of the explicit knowledge on use and exposure, the notifier is better placed to provide more realistic and specific RA than the competent authorities, who would normally only perform generic RA based on default values.

Recommendations

39. The notifier of a new substance should take responsibility for the preparation of the initial risk assessment. The adequacy of technical guidance and available software to support this should be addressed as a matter of priority. This change should be without prejudice to the competent authorities’ right to request additional information as part of their review of the risk assessment.

40. The requirement concerning the preparation of the risk assessment should be proportionate. In this respect consideration should be given to the need to establish appropriate triggers, such as tonnage levels or hazard.
41. The accessibility and availability of information to the public about risk assessment should be improved. Options such as the publication of risk assessment and the setting-up of a centralised database containing risk assessment should be explored while adequately protecting confidential data of the notifier.

42. The decision criteria for additional testing of notification levels 1 and 2 should be harmonised. The results of the risk assessment performed with information at base-set level should be taken into account, rather than performing all tests of Annex VIII.

3.4.6. Confidentiality of data

Analysis

According to the Directive, information related to the notification about chemical identity, marketed quantities and use of the substance can be kept confidential. Since the disclosure of confidential information about marketed quantities and use of the substance can present problems for industry, there is a need to find a proper balance between commercial interest and transparency.

Recommendation

43. Mechanisms to make available to the public meaningful generic information about risk assessment on substances while taking into account confidentiality and preserving the rights of the first notifier should be explored. The wording of Article 9 on the 10-year rule for substances already notified should be reviewed to make it clearer.

3.5. Other issues

3.5.1. Compliance

Analysis

The enforcement of legislation falls under the responsibility of the Member States. Since enforcement is not the responsibility of the competent authorities but of national inspection bodies, the enforcement actions carried out in the Member States are not always sufficiently co-ordinated. The complexity of legislation poses problems of understanding and compliance to small companies.

Recommendation

44. Effective compliance with the Directive in Member States should be encouraged. Consideration should be given to regular networks for Trans-boundary co-operation on inspection activities and the better use of existing networks of enforcement.
45. In the short term a consolidated version of the Directive should be prepared in order to make it easier to use and assist compliance.

3.5.2. Frequency of Adaptation to Technical Progress (ATP)

Analysis

The Directive is regularly adapted to technical progress taking into account the latest scientific and technical development. There is a need for a quick introduction of these adaptations into the Directive.

Recommendation

46. An examination should be undertaken of the impact of the frequency of adaptations on industry and the Member State authorities. The outcome of this examination should be used to balance the need to introduce scientific and technical changes rapidly with the need to reduce unnecessary burdens.

3.5.3. Advertisement

Analysis

Article 26 (advertisement) of the Directive is inconsistent with the corresponding Article of the new Dangerous Preparations Directive.

Recommendation

47. Article 26 on advertisement should be reviewed in order to make it consistent with the corresponding Article of the new Dangerous Preparations Directive.
3.5.4. Reporting

Analysis

The three-year frequency of the preparation of the report on the implementation of the Directive in the Member States is too short. Some Member States evaluate the implementation of the Directive every 5 years.

Recommendation

48. The frequency of the preparation of the report on the implementation of the Directive in the Member States should be reviewed.
4. **LIST OF RECOMMENDATIONS**

**Structure of the Directive**

1. The legal basis and form of instruments most appropriate for delivery of objectives for classification, packaging and labelling and for notification provisions within Member States need to be examined within the context of wider EU Chemical Policy.

2. The wording of the Directive should be updated to incorporate the current philosophy and principles that underpin sound chemical management in a holistic manner.

3. The architecture of the Directive should be rationalised to ensure that only matters of policy and principle are incorporated in the main text and that technical detail is dealt with through annexes.

4. The advantages and disadvantages of splitting the provisions for C&L and notification into two different legal instruments combining the provisions for C&L of dangerous substances and preparations in the same instrument and setting up a Regulation for C&L provisions or at least for those Annexes dealing with C&L (Annexes I to VI and IX) should be examined. These proposals should take into account the implication of the Directive in other pieces of related EU legislation.

5. The SLIM team stressed the need to publish a codified version of the Dangerous Substances Directive taking on board the recommendations presented in this report.

**Objectives, scope and definitions**

6. Article 1(1) of the Directive should be reviewed in order to bring the objectives into line with the current practice and to clarify the different elements.

7. The continued applicability of exemptions detailed in Article 1(2) should be re-examined taking into account developments within global harmonisation and the wider review of EU Chemical Policy.

8. The definitions used in the Directive and in particular those for "placing on the market" and "sole representative" should be re-examined as should the possibility of introducing a definition for "articles", "waste" in relation to recycled products.

9. In order to facilitate the updating of the definitions of dangerous substances and preparations included in Article 2(2), the possible incorporation of the technical and scientific details of those definitions in an Annex of the Directive should be explored.
Classification, packaging and labelling of dangerous substances

Classification, including globally harmonised classification

10. The Commission should take into account the work on a Globally Harmonised System (GHS) for the classification and labelling of chemicals developed in the OECD, ILO and other UN fora, and should evaluate the impact of the GHS on Directive 67/548/EEC and other related pieces of EU legislation.

11. With respect to classification criteria, it should be recognised that some endpoints on human health (e.g. sensitisation, carcinogenicity, mutagenicity and reproductive toxicity) should take into account the need to consider "potency" and/or the “biological mode of action” for C&L purposes.

12. Annex VI should be critically reviewed in order to make it more understandable, taking into account its application to substances and preparations.

13. Possible solutions for the problem of how to tackle non-classified substances in the absence of data should be explored.

14. The accessibility and availability of information to the general public about classification of substances should be improved, taking into account the Århus Convention on access to information, public participation in decision-making and access to justice in environmental matters, 23-25 June 1998. Options such as the publication on Internet of relevant information about the C&L activities carried out by the COM (ECB), the access to key data on the properties of substances and the publication of provisional C&L of substances in progress solely intended for information should be considered.

Hazard communication: labelling and safety data sheets

15. The labelling provisions in the Directive and the content of the label should be reviewed in order to improve the comprehensibility and usefulness and to eliminate redundant information. The revision should take into account available relevant studies on this subject.

16. The technical information included in the Articles dealing with labelling should be separated and transferred to an Annex of the Directive.

17. The labelling requirements for substances imported into the EU and stored before distribution should be reviewed in order to improve the efficiency and to avoid unnecessary burdens but ensuring that adequate information is provided to allow persons to take necessary measures to protect the health and safety of man and the environment during storage.
Annex I: structure and procedure for implementation

18. Mechanisms should be explored to make better use of existing data on classification and labelling (C&L), in particular the data available on the IUCLID database (International Uniform Chemical Information Database), and to speed up the incorporation of this data into Annex I to Directive 67/548/EEC.

19. Annex I or the database containing detailed information of substances listed in Annex I should include the "age" of the C&L data, such as reflected by the date of the meeting of the Commission Working Groups "Classification and Labelling" at which the C&L data was recommended, or the date of adoption of the C&L data by the Commission.

20. The publication of Annex I and its implementation at Member State level should be streamlined with a view to make it more user-friendly.

21. Possibilities to ease the linguistic versions of the chemical names of the substances should also be considered.

22. Procedures to speed up the incorporation of C&L proposals into Annex I should be explored, with a view to make the C&L data more speedily available for use. The integrity of the current system and the confidence between the Member States should be maintained.

Notification of new substances

The scheme for the notification of new substances

23. Possibilities to decrease the number of notifications such as covering a group of similar substances, e.g. salts of a substance, under a single notification should be considered, on the basis of scientific justification and the experience gained with existing substances.

24. It is recommended to consider the introduction of a limited administrative procedure for notifications of substances already notified and accepted under other recognised notification systems. Possibilities such as flexibility in time period and in recognition of assessments should be explored.

Specific requirements

25. The provisions for research and development exemptions should be reviewed with a view to introducing more flexibility concerning the quantity threshold for scientific research and development (R&D) and the time period limit for process-oriented R&D (PORD).

26. The criteria that determine whether a polymer constitutes a new substance should be revised provided that the criteria are based on sufficient scientific evidence.
Particular consideration should be given to examining the testing requirements for polymers; they should be made more proportionate.

27. The notification requirements for intermediates placed on the market should be examined in order to make them more adapted to their limited exposure of man and the environment, but to keep them proportionate with respect to the volumes concerned and the safety requirements during normal handling and use of these intermediates.

28. An area to be considered in addition are site limited, isolated intermediates, which do not fall within the scope of the present Directive. It is recommended to explore options in order to ensure that adequate information for worker protection, environment protection and emergency response is available on site.

29. The reduced notification requirements for substances placed on the market in quantities of less than 1 tonne per annum and manufacturer should be reviewed. Replacement of the current notification requirements by responsible record keeping in industry combined with a monitoring and safeguard role of the competent authorities should be explored.

**Working procedures, duties and responsibilities**

30. Possible options to improve the current working procedures for the notification of new substances should be explored. Areas where the centralisation of information management could enhance the efficiency of the notification system should be identified.

31. Priority should be given to an independent review of all aspects of the notification procedures including the administration and the balance of responsibility between the Commission, the competent authorities and the notifier. The review should identify options to make the role of the parties more transparent; the process more efficient; and the use of expert resource more effective.

32. Flexibility should be given to the competent authority to handle the approval period for re-notifications (notifications submitted a second time after having brought the dossier into conformity with the requirements of the Directive) in appropriate time frames even shorter than 60 days.

33. The notifier should be informed of the outcome of the notification process and should be consulted in the case of diverging conclusions.

34. The extension of the Sole Representative facility to EU manufacturers and to non-EU companies not being the original manufacturers of the imported new substance in question should be explored in order to avoid unnecessary multiple notifications.
More effective mechanisms to promote the sharing of data should be developed in order to avoid repetition of animal testing in accordance with existing EU provisions on animal protection. The harmonisation of Member States’ positions should be considered. Effective mechanisms to facilitate the exchange of information and to preserve the rights of the "first notifier", i.e. the company that provides the data, will have to be developed.

The possible obligation to notify new substances manufactured within the EU, solely intended for export to third countries should be explored, if the substance has not been notified under any other recognised system. Requirements should be consistent with Regulation (EEC) 2455/92 on export and import of certain dangerous chemicals and the Rotterdam Convention on the Prior Informed Consent procedure (PIC).

Testing methods

The Commission should explore ways to speed up the transposition of OECD Test Guidelines into testing methods for Directive 67/548/EEC.

Particular areas for which more appropriate testing methods should be developed, such as for the evaluation of enzymes, should be explored.

Risk assessment of new substances

The notifier of a new substance should take responsibility for the preparation of the initial risk assessment. The adequacy of technical guidance and available software to support this should be addressed as a matter of priority. This change should be without prejudice to the competent authorities’ right to request additional information as part of their review of the risk assessment.

The requirement concerning the preparation of the risk assessment should be proportionate. In this respect consideration should be given to the need to establish appropriate triggers, such as tonnage levels or hazard.

The accessibility and availability of information to the public about risk assessment should be improved. Options such as the publication of risk assessment and the setting-up of a centralised database containing risk assessment should be explored while adequately protecting confidential data of the notifier.

The decision criteria for additional testing of notification levels 1 and 2 should be harmonised. The results of the risk assessment performed with information at base-set level should be taken into account, rather than performing all tests of Annex VIII.
Confidentiality of data

43. Mechanisms to make available to the public meaningful generic information about risk assessment on substances while taking into account confidentiality and preserving the rights of the first notifier should be explored. The wording of Article 9 on the 10-year rule for substances already notified should be reviewed to make it clearer.

Other issues

Compliance

44. Effective compliance with the Directive in Member States should be encouraged. Consideration should be given to regular networks for Trans-boundary co-operation on inspection activities and the better use of existing networks of enforcement.

45. In the short term a consolidated version of the Directive should be prepared in order to make it easier to use and assist compliance.

Frequency of Adaptation to Technical Progress (ATP)

46. An examination should be undertaken of the impact of the frequency of adaptations on industry and the Member State authorities. The outcome of this examination should be used to balance the need to introduce scientific and technical changes rapidly with the need to reduce unnecessary burdens.

Advertisement

47. Article 26 on advertisement should be reviewed in order to make it consistent with the corresponding Article of the new Dangerous Preparations Directive.

Reporting

48. The frequency of the preparation of the report on the implementation of the Directive in the Member States should be reviewed.
5. **ANNEXES**

5.1. **Composition of the SLIM team on dangerous substances**

<table>
<thead>
<tr>
<th>Chair</th>
<th>DG XI</th>
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</table>
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Fax: +32-2-224 05 61  
E-mail: kgrodzki@etuc.org |
## 5.2. Calendar and content of meetings

<table>
<thead>
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<th>Meeting</th>
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<th>Articles</th>
</tr>
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<tbody>
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<td>(22/01/99)</td>
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<td></td>
<td>- Definitions</td>
</tr>
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<td>2&lt;sup&gt;nd&lt;/sup&gt; meeting</td>
<td>(19/02/99)</td>
<td>Articles</td>
</tr>
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<td>- Classification</td>
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<td>- Labelling</td>
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<td>3&lt;sup&gt;rd&lt;/sup&gt; meeting</td>
<td>(10-11/03/99)</td>
<td>Articles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Notification of new substances</td>
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<td></td>
<td>- Pending issues of 2nd meeting</td>
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<td>4&lt;sup&gt;th&lt;/sup&gt; meeting</td>
<td>(08-09/04/99)</td>
<td>Articles</td>
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<td></td>
<td></td>
<td>- Other issues</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Other general issues</td>
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<td>5&lt;sup&gt;th&lt;/sup&gt; meeting</td>
<td>(06/05/99)</td>
<td>- 1&lt;sup&gt;st&lt;/sup&gt; draft of the report containing recommendations</td>
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<td>6&lt;sup&gt;th&lt;/sup&gt; meeting</td>
<td>(27-28/05/99)</td>
<td>- Adoption of the report containing recommendations</td>
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### 5.3. List of written contributions

<table>
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<th>DATE</th>
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<tr>
<td>10/09/98</td>
<td>• UK position paper on dangerous substances - Dir. 67/548/EEC</td>
<td>UK</td>
</tr>
<tr>
<td>12/02/99</td>
<td>• SLIM Prov. Rec. 1st</td>
<td>A</td>
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<td>12/02/99</td>
<td>• Comments on draft summary record of 1st meeting and strategy of the meetings &lt;br&gt; • NL view on the Dangerous Substances Directive 67/548/EEC</td>
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<td>16/02/99</td>
<td>• Draft Summary Record of 1st meeting and approach to future meetings</td>
<td>UK</td>
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<td>16/02/99</td>
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<td>17/02/99</td>
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<td>18/02/99</td>
<td>• SLIM 2nd Meeting</td>
<td>A</td>
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<td>18/02/99</td>
<td>• SLIM Phase IV - Dangerous Substances. Spanish comments about 1st meeting</td>
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<td>23/02/99</td>
<td>• An SME View on the EU Chemical Legislation and the SLIM Process</td>
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<td>03/03/99</td>
<td>• Nota della delegazione italiana</td>
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<td>05/03/99</td>
<td>• Draft summary record and recommendations of the 2nd meeting, and agenda of the 3rd meeting</td>
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<td>08/03/99</td>
<td>• SLIM IV: Notification issues</td>
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<td>09/03/99</td>
<td>• Draft Summary Record of 2nd meeting and provisional recommendations</td>
<td>UK</td>
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<td>• DK response on French proposal on predicted non acutely toxic substances (aquatic organisms) and biodegradability</td>
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