ECLIPS

„**E**uropean **C**lassification and **L**abelling **I**nspections of **P**reparations, including **S**afety Data Sheets“

FINAL REPORT

June 2004

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1. INTRODUCTION

Classification and labelling as well as Safety Data Sheets of dangerous chemicals are the most important information sources for dangerous chemicals. For the general public the labelling is the only way to identify hazards posed by a dangerous product to human health and the environment. Safety Data Sheets (SDSs) are intended for professional users and only sound SDSs can ensure the safe handling of dangerous chemicals for workers at their work places and provide information about the necessary measures in case of an accident.

The objective of Directive 1999/45/EC ("Dangerous Preparations Directive", DPD) is to approximate laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, which consequently leads to a minimisation of risks at handling. The appropriate classification is the heart of the sound management of chemicals in general. The European chemicals industry manufactures and uses a large number of different chemical products. 90% to 95% of all chemicals on the European market are preparations, i.e. mixtures of chemical substances.

The Member States had to implement Dir. 1999/45/EC until 30th July 2002, including the new provisions referring to preparations which are dangerous for the environment. The provisions demanded by the DPD are strongly influenced by the Dangerous Substances Directive and the Directive related to the Safety Data Sheets (SDS). The latest amendments of these three Directives all have the same deadline for implementation into national legislation.

As agreed at the CLEEN (**C**hemical **L**egislation **E**uropean **E**nforcement **N**etwork) Conference in Vienna, Austria, in September 2001, an enforcement project should be started after the implementation period of the new Dangerous Preparations Directive. The control activities performed during the ECLIPS project intended to focus on the compliance of the recent changes of the provisions for preparations dealing with classification and labelling as well as Safety Data Sheets. Enforcement has been performed in all participating EU countries and in some at the time accessing countries.

CLEEN is a network of chemical inspectorates that coordinates and improves the enforcement of EU chemicals legislation. It is basically a forum for information exchange and it performs in collaboration with the Member States enforcement projects. As enforcement is the responsibility of the Member States, the co-operation of the national chemicals inspectorates in the European Economic Area is absolutely necessary in view of the rules of the single market and the EU-wide economy. The aim is to consolidate and intensify such co-operation so that compliance with chemical legislation can be improved for the protection of man and the environment.

1.1 Legislative background

Dangerous Preparations Directive (DPD)
This new Dangerous Preparations Directive (Dir. 1999/45/EC) has replaced 88/379/EEC from 30 July 2002 for the majority of preparations, and from 30 July 2004 for plant protection products and biocides. 1999/45/EC extends the scope of the Dangerous Preparations Directive to include for the first time pesticides and a requirement to classify and label preparations for environmental hazards. Directive 2001/60/EC has adapted to technical progress for the first time Directive 1999/45/EC.

Dangerous Substances Directive (DSD)
Directive 2001/59/EC, the Dangerous Substances Directive, is the 28th adaptation to technical progress of Directive 67/548/EEC. This Directive is also concerned in the field of preparations mainly regarding the revision of the text of R-phrase R40 to refer to carcinogenic, category 3, substances and the introduction of a new R-phrase R68 for mutagenic, category 3, substances.

Safety Data Sheets Directive (SDS Directive)
European legislation requires producers of dangerous chemicals to set up an information system in the form of Safety Data Sheets (SDSs) in order to enable industrial and professional users to take the measures necessary to ensure the protection of health, safety and the environment at the workplace. Directive 91/155/EEC sets out the requirements for the information which should be included in a SDS relating to dangerous preparations in implementation of Art. 14 of the DPD and to dangerous substances in implementation of Art. 27 of Directive 67/548/EEC. Directive 2001/58/EC amending for the second time Directive 91/155/EEC extends the obligation to provide SDSs to certain preparations not classified as dangerous.

1.2 Goals

One of the main objectives of the ECLIPS project was to assess the compliance with the chemicals legislation and to develop a harmonised European enforcement of the DPD and the SDS Directive. As important as the former objective was to ensure the safety of employees handling dangerous preparations and the protection of consumers of chemical products as well as of the environment.

The following goals of this project were considered to be most important:

- Reduction of risks to man and environment by achieving high quality Safety Data Sheets and an appropriate classification and labelling of preparations containing dangerous substances.
- Exchange of information and experience between Member States to avoid differences in the way the Directives are enforced.
- Finding enforcement strategies for each country which are suitable for its national situation.
- Equal market conditions and competitiveness of enterprises.
- Correct labelling of dangerous preparations as a tool to attract attention of the users (workers and general public) in order to influence the buying decision.

Special ECLIPS focus
Although all three Directives mentioned above (DPD, DSD, SDS Directive) are concerned in the field of classification and labelling (C&L) and SDS, this project focuses on Directive 1999/45/EC because most of the chemicals on the market are preparations. Regarding the inspected products main focus was laid on preparations covered by new provisions, i.e.: preparations classified as dangerous for the environment and/or as **C**arcinogenic, **M**utagenic and/or toxic for **R**eproduction (CMR) as well as on preparations containing substances with sensitising properties or substances assigned a R67 (Vapours may cause drowsiness and dizziness). In order to keep the results comparable it was decided to focus on several product groups, i.e. paints and varnishes, cleaning agents (e.g. solvent based), detergents, preparations to be used during (re-)construction of buildings and photo chemicals.

1.3 Project description

The ECLIPS project was adopted at the CLEEN Conference in September 2001 in Vienna. The following countries participated in the project: Austria, Belgium, Finland, Greece, Germany, Ireland, Latvia, Norway, Poland, Slovenia, Spain and Sweden (Annex I). A working group was built up by four leading countries, consisting of Austria, Germany, Spain and Sweden and in the initial phase also supported by The Netherlands.

The project set-up was divided into three phases:

Preparation phase

This phase consisted of three steps linked with the CLEEN Interim Meeting in February 2002 in Valencia and the Third CLEEN Conference in September 2002 (Copenhagen). As this project covers a wide focus it was necessary to select some items and to be specific.

First step

- clarifying participation (Candidate Countries were also invited to participate as far as their national legislation was in place)
- initiation of contacts between involved authorities in the Member States to gather national experiences concerning enforcement of the Directive
- definition of main focus: products which are used both professionally and by consumers and which are dangerous to the environment since labelling of preparations is completely new for this dangerous property
- integration of human health aspects referring to the modified criteria for C&L, new rules for application of labelling elements (e.g. R67) and to modified risk-phrases (R68)
- target of inspections: labelling and SDS
- investigation of preparations consisting of substances easy to control (e.g. substances in Annex I of 67/548/EEC)
- groups of products containing a high percentage of preparations dangerous to the environment
- clarification about how many inspections and where they will be performed
- clarification and interpretation of technical guidelines

- development of stepwise ECLIPS working methods, including preparation steps and all working steps for inspectors concerning company visits and follow up
- working out features which could be used to enforce the Directive, e.g. Annex I of Directive 67/548/EEC in electronic form or some software for calculation methods

In the Interim Meeting the above mentioned preparation steps concerning strategies and methods of the enforcement were discussed and a list of product groups were selected.

Second Stepp

A Guidance Manual (Annex II) together with working methods and the elaboration of tools were set up until the End of 2002 in order to train the inspectors properly. A questionnaire has been developed in order to collect the results in a harmonised way. At the CLEEN Conference in September 2002 (Copenhagen) agreement was reached on the working methods and on the operational phase.

Third step

- distribution of all information to national authorities
- training on European level for participating countries
- training of the national inspectors in order to get familiar with the technical guidelines, the working methods and the report forms
- providing information about the project to trade associations and companies
- public relation activities to raise public awareness

Operation phase

The companies were chosen by the national authorities and inspections were carried out following the Guidance Manual. The inspections were performed during winter 2003, ending in late January 2004.
Inspections included:

- control of classification and labelling of preparations
- control of Safety Data Sheets
- support and information for the companies

During this phase first results and problems were presented and discussed at the 4th CLEEN Conference in Brussels in 2003.

Reporting phase

The results of the more than 1500 inspected products were compiled and afterwards analysed. Difficulties turned out during the analysis of this huge amount of data, e.g. with definition of the severity code of faults and to which extent to go in-depth into the results. The final report was drafted by the member states of the ECLIPS working group and the tasks were distributed to the Working Group.

Time Table

The project was performed according to the following schedule:

- *Preparation phase until December 2002*
- *Task force meeting during preparation phase in February/March 2002 (Valencia)*
- *CLEEN Conference in September 2002 (Copenhagen)*
- *ECLIPS training for participating countries in November 2002 (Stockholm)*
- *Start of the operation phase (company inspections) in January 2003, inspections until End of 2003*
- *CLEEN Conference in October 2003 (Brussels)*
- *Reporting phase during the second half of 2004 and the Final Report is foreseen to be published in June 2004*

	01/Q3	01/Q4	02/Q1	02/Q2	02/Q3	02/Q4	03/Q1	03/Q2	03/Q3	03/Q4	04/Q1	04/Q2
Preparation 1st step												
Preparation 2nd step												
Preparation 3rd step												
Operational phase												
Reporting												

Project management

At the beginning the project management was in the hands of consultants with the following tasks:

- planning of the project
- drawing up of proposals, including information and suggestions from project participants
- organise and design the meetings concerning feed-back and information provided by the participating countries

During spring 2003 the consultants had to be displaced due to cancelling of the financial support. A small group of Member States consisting of Austria, Germany, Spain and Sweden took over the tasks of the consultants and additionally supported and supervised the work in kind of a task force. This group takes on the responsibility for this final report.

2. ENFORCEMENT RESULTS

2.1 Participating Countries

Tables below show the number of inspected products in the participating countries. The difference in numbers of inspected products per country reflects itself in the results of this report. As an example Germanys results (491 inspected products) influence the results much more than the Norwegian results (19 inspected products). It may be possible that some of the products could have been inspected from more than one regional inspectorate. That is a thing one shall be aware of – the quantity and quality of inspections in each country or each region or even for each inspector varies.

Country	Nr of inspected products
Norway	19
Greece	38
Latvia	44
Slovenia	44
Ireland	49
Belgium	52
Sweden	54
Austria	116
Poland	206
Finland	222
Spain	279
Germany	491
Total no of inspected products	1579

Table 1: Number of inspected products per country

Even the operation phase was before the accession of the new MSs three of them took part in the whole project.

The Netherlands
The Netherlands (The Dutch Inspectorate for Food and Goods and the Inspectorate for Housing, Spatial Planning and the Environment) has also done some inspections in this field in 2003. Unfortunately the concerned Directives have not been implemented in their national legislation during the operation phase, therefore the controls were not similar to the method in the ECLIPS-Guidance Manual but had partly the same intention. The Inspectorate for Food and Goods investigated 116 samples of different kinds of chemicals for consumer uses. The Inspectorate for Housing, Spatial Planning and the Environment has visited 19 companies and controlled 67 different kinds of chemicals for industrial uses.

2.2 Company and preparation data

Fig. 1 gives a picture on what branches were inspected.

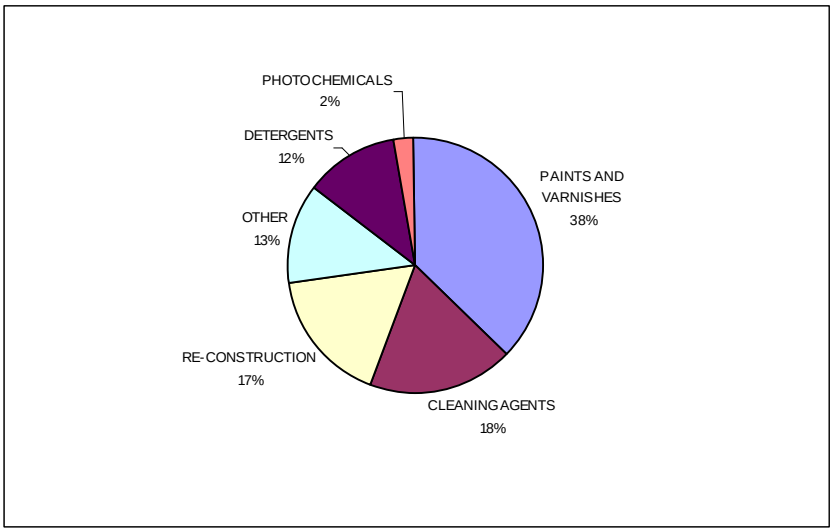

Figure 1: Inspected branches in the project (% of nr of inspected products)

Table 2 shows what kind of companies have been inspected and their exact numbers. Table 2 is divided into two parts: the first part shows the number of inspected products for all participating countries except Germany, whereas the second part shows the number of inspected companies in Germany.
This differentiation is due to different kind of reporting in Germany.

No of products (all countries except Germany):

Category	**Number of products**
Chemical Industry	591
Trade company	123
Retail trade	351
Total	1065

Certified management system	
ISO 14000/ EMAS etc.	207
ISO 9000	285
NO	542
Total	1034

Trade org.	
No	599
Yes	489
Total	1088

Size of company	
<10	304
>100	232
10-100	551
Total	1087

No of companies (German result):

Number of company
109
16
5
135

91
45
136

91
45
136

Table 2: Number of inspected companies (Germany) and products, size of companies and certified management system

2.3 Results in general

The results on the quality of classification and labelling and Safety Data Sheets are taken from the questionnaire. Most of the figures and tables deal with the deficiencies for different endpoints. No discrimination has been made between severe or minor deficiencies. If this discrimination had been made then there would be considerable differences in interpretation between the MSs and possibly also within one country. One should bare that in mind when reading the results.
Examples of deficiencies for each inspected endpoint are listed in Annex III.

Severity
Sweden has statistics of the degree of deficiencies over the last 10 years.

Deficiencies /seriousness	Example of deficiencies
10 % severe	Example: severe are such deficiencies that are also reported to the police. This is the case if the toxic symbol and/or the corresponding R- and S-phrases are missing or when the sensitising warning is missing (R42, 43). C product not classified.
50 % middle	Example: Other R-/S-phrases missing. Xn instead of Xi, def in SDS
20 % minor	Not totally correct R-phrases, wrong names headings in SDS
20 % no deficiencies	

Table 3: Example from Sweden about severity of deficiencies

Germany also gave an idea about the severity of deficiencies. From the German result the following picture can be drawn:
Severe: 23,3 %
Middle: 17,2 %
Minor: 58,8 %

Products with no error
An overall view is given in Table 4 below. The deficiencies in Figures 2 and 3 are summing up to about 20 – 40 % for each inspected endpoint. However, each product can have more than one deficient endpoint. When making an overall view of the quality of the information the figures are different: Only 22 % of all products showed no deficiency, 31 % of all SDS were correct and only 40 % of all C&L were OK.

	% OK
C & L	40 %
SDS	31 %
All endpoints	22 %

Table 4: Percentage of inspected products without deficiencies

2.4 Deficiencies in classification and labelling

An overall picture of the quality of the C&L is shown in Figures 2 and 3. The deficiencies in C&L for all endpoints are around 20 – 35 %. Note though that it is for each endpoint. The percentage of a label without any deficiencies is around 31 % (Figure 3). The special ECLIPS focus about the news in the legislation shows that the

additional sensitising phrase that shall be put on the label "*Contains (name of sensitising substance). May produce an allergic reaction*" is named "Sens<1%" in Table 4. This phrase is missing on 50% of the products. The environmental classification and the new phrase R67 "*Vapours may cause drowsiness and dizziness*" show the same range of deficiencies as all the other end-points which have been in force for a longer time if compared to Fig. 2.

A more exact descriptions of each endpoint can be found in Annex III.

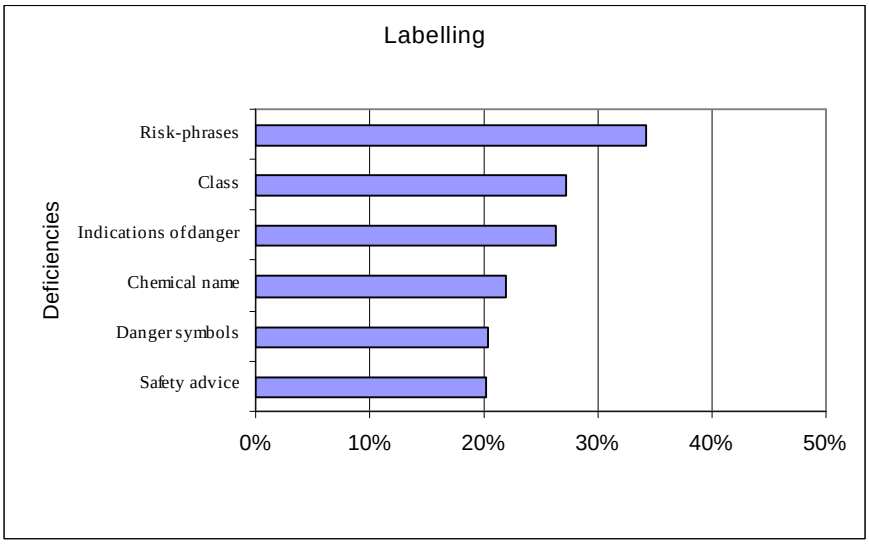

Figure 2: Deficiencies in labelling for all endpoints

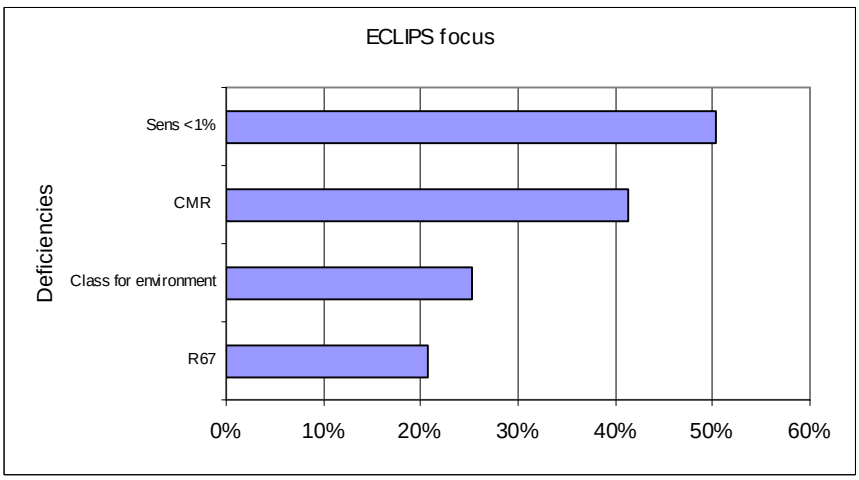

Figure 3: Deficiencies in labelling for the special ECLIPS focus

2.5 Deficiencies in Safety Data Sheets

The deficiencies for the SDS give approximately the same picture as for C&L. The deficiencies for different headings vary between 20 – 40 %. A quite better result is shown concerning the availability of SDS (only 6 % deficiencies for distribution and availability). As can be seen in Fig. 4 the deficiencies of the "classification-headings" (2, 3 and 15) have most deficiencies. An explanation for these deficiencies can be that heading 11 and 12 are quite complicated ones according to the corresponding legislation. The same applies for headings 2, 3 and 15.

A more exact descriptions of each endpoint can be found in Annex III.

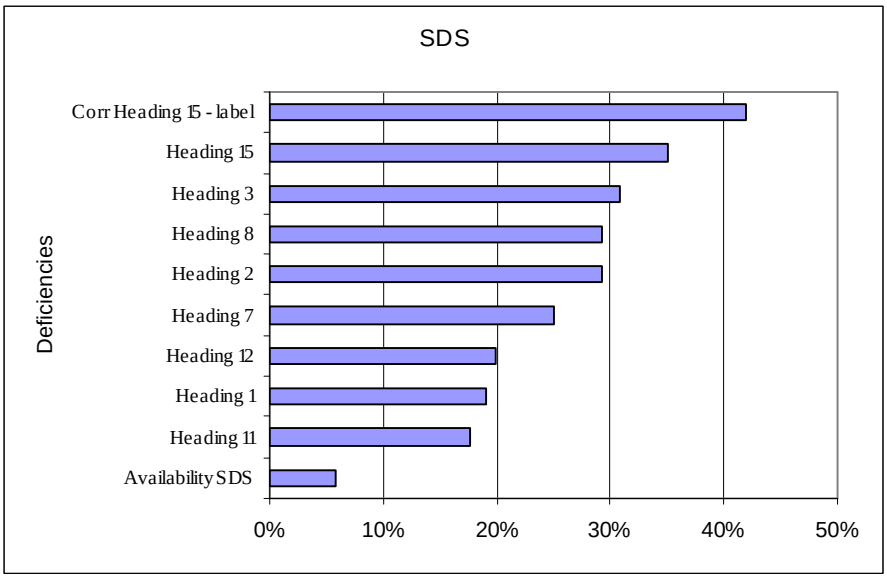

Figure 4: Deficiencies in Safety Data Sheets

2.6 Correlation between characteristics of the companies and results in C&L and SDS of preparations

In the project also information was collected about the companies to be able to see whether the size of the company or an existing environment certified management system makes any difference in the quality of C&L and SDS. For these comparisons the following deficiencies have been picked out: R-phrases, danger symbol, indication of danger and SDS heading 15.
Figures 5 and 6 show a clear correlation concerning the deficiencies: the bigger the size (no of employees) of a company the better the quality of the data. The same thing may be said about the implementation of certified environment management systems. Companies that have implemented the ISO 14 000 system* have less deficiencies in data than others. In Figure 7 you can see that mostly the bigger companies have implemented ISO 14000. This gives an indication that better quality of C&L and SDS depends on the size of the companies, since bigger companies also achieve to implement certified management systems.

* Note that when ISO 14000 is mentioned it means that also other equal system can have been used such as EMAS.

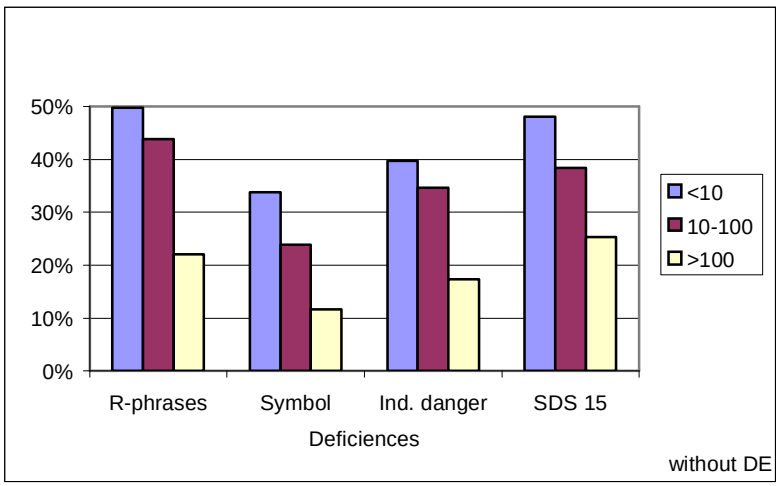

Figure 5: Selected deficiencies compared to different size of company

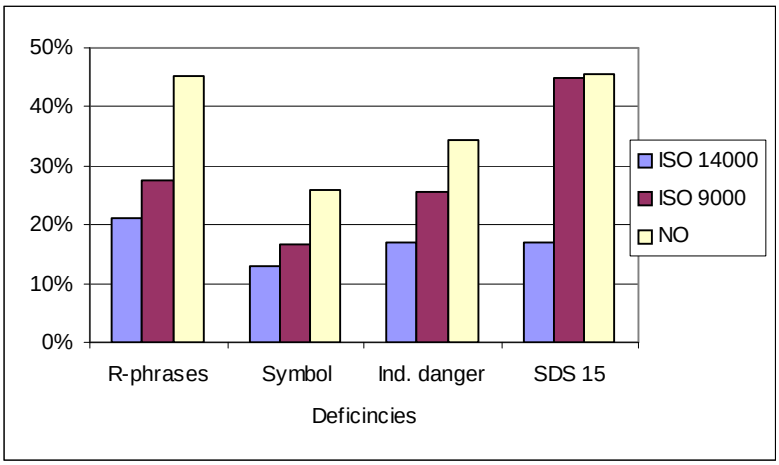

Figure 6: Selected deficiencies compared to the implementation of a certified management system

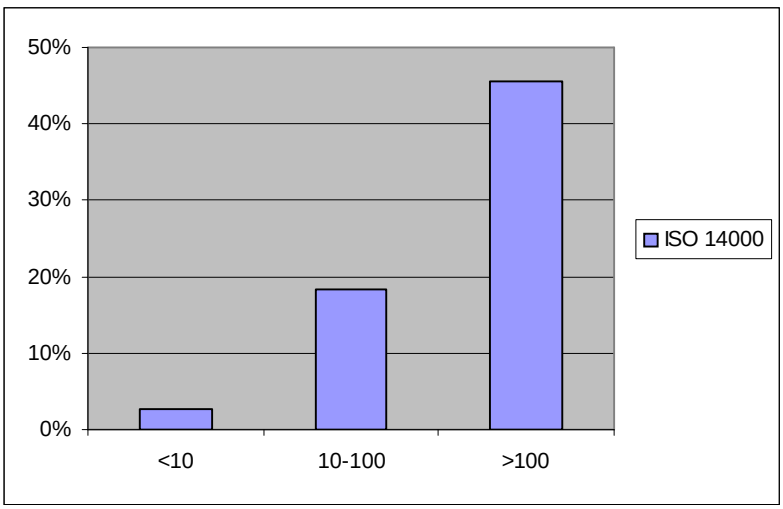

Figure 7: Companies that are ISO 14000 certified compared to company size

Some other parameters are less obvious, however, there is still a correlation. Data from companies that are members in trade organisations have a slightly better quality than data from others. On the other hand those companies that are members still have deficiencies around 20 – 40 %. There is still work to do for the trade organisations.

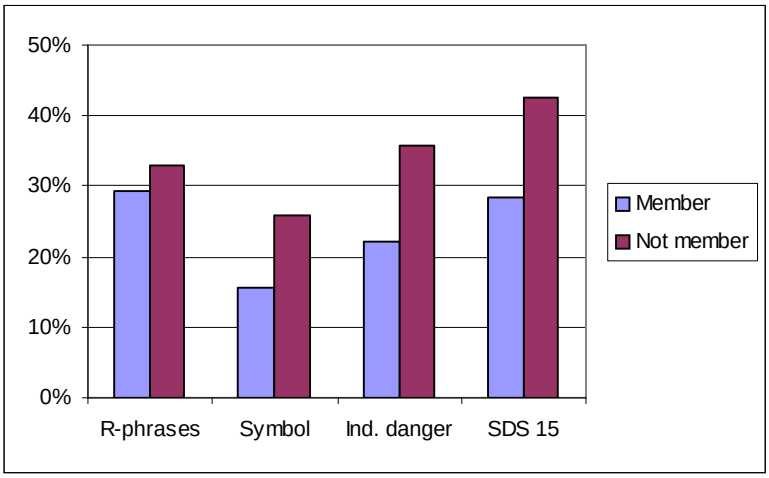

Figure 8: Selected deficiencies compared to membership in trade organisations

In the questionnaire the opinion of each inspector about the knowledge of the concerned legislation in the companies was asked for. The knowledge could either be in the company itself, hired (consultants) or missing. These results are subjective but they still indicate that the quality of C&L and SDS is better with knowledge – which might not come as a surprise. However, even in those companies with knowledge (hired or in company) the deficiencies summed up to 20 – 30 %.

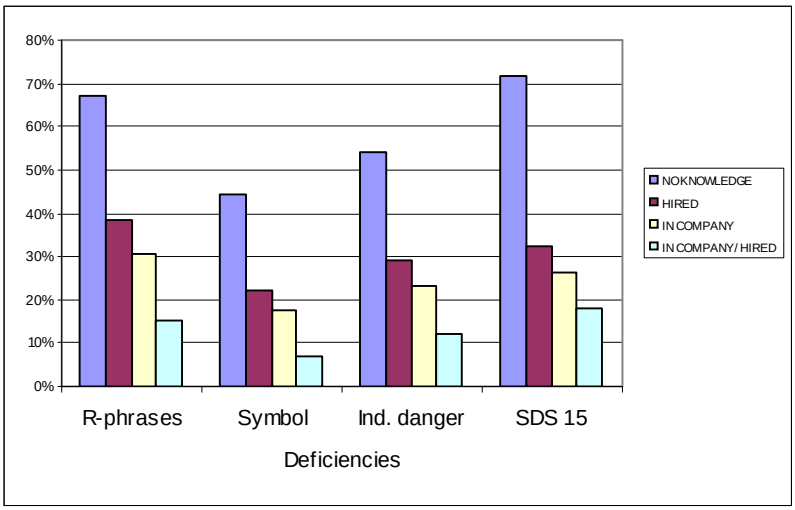

Figure 9 . Selected deficiencies compared to knowledge of the legislation in company

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

3.1.1 In relation to project aims

- **Co-ordinated enforcement of provisions of Dir. 1999/45/EC (1st ATP: Dir. 2001/60/EC) and Dir. 91/155/EC (2nd amendment: Dir. 2001/58/EC).**

The inspections have focused on the new aspects included in both Directives. In Dir. 1999/45/EC: N-classified preparations, containing sensitizers over 0,1%, containing R67 substances, CMR classified preparations, non dangerous preparations containing dangerous substances for professional use. In Dir. 2001/58/EC: new information required on different headings, SDS for non dangerous preparations.

In many countries, the ECLIPS Project has stimulated the enforcement activities in an extent which could not have been achieved without it.

1. On the whole, all countries have improved their level of information on the enforcement and compliance of the Directives, in their own countries and in relation to other EEA countries.

2. The Provisions of the mentioned regulations have been enforced, by all participating countries, in a co-ordinated way.

- **Harmonization of the working method among the participating countries.**

The working method developed is based on enforcement tools specifically developed for the Project: Guidance Manual and Inspections Report Forms [Questionnaire 1, Q1 (Company information) and Questionnaire 2, Q2 (The inspected products)], to perform the inspections on the same issues and to get results that can be statistically treated.

Many national enforcement tools have been made available in English to all participants: leaflets, Guides on C&L and SDS, check lists, etc.

3. Harmonization of inspections by means of using the same working method among all project participants has been accomplished, and common problems in the implementation of the Directives have therefore been identified.

A compilation of FAQs, Frequently Asked Questions, (regarding the legislation applied to preparations and SDS with straightforward answers) have been done during the development of the Project (see Annex IV) as a more specific contribution to the harmonization of technical criteria.

4. The sharing of experiences before mentioned will lead to more effective and efficient future enforcement activities on these issues.

- **Assessment of the grade of compliance of Dir. 1999/45/EC (1st ATP) and of Dir. 91/155/EC (2nd amendment) by the industry.**

5. The grade of compliance of both Directives in the inspected companies has been assessed (see Enforcement results and Chapter 3). The main conclusions are highlighted in item 3.1.2 below.

6. A better understanding of the actual scenario in Europe, regarding the compliance of both Directives, has been achieved by the participating countries.

- **Improvement of companies compliance and of the enforcement tools.**

Follow up actions based on the results of chemical preparations inspections have been made in almost every case.

The methodology used in enforcement has been revised and some gaps have been identified, like the need to define beforehand the "deficiencies" to be taken into account in the inspections, in order to concentrate the assessment on "serious deficiencies" and therefore, minimize the influence of personal assessment criteria in the final results of the Project.

7. Improved grade of awareness of the preparations and SDS legislation in industry has been achieved, and also improved tools for enforcement, as direct results from the development of the ECLIPS Project.

3.1.2. In relation to enforcement results

A complete overview of the enforcement results is shown in Chapter 2.

1. The present grade of implementation of Dir. 1999/45/EC (1st ATP) is still deficient in a significant percentage (60 %).
The preparations inspected have serious deficiencies related to the information contained in the label, e. g.: R-phrases missing, danger symbols and indication of danger missing or wrong. Also deficiencies related to S-phrases and the chemical names of the substances that contribute to certain dangerous properties.

2. The present grade of implementation of Dir. 91/155/EEC (2nd Amendment) is still deficient in a significant percentage (69 %).
The preparations inspected have serious deficiencies related to the information contained in the Safety Data Sheet in relation to the legislated content of headings 2, 3, 7, 8, 11, 12 and 15, and also and most important, in relation to the consistency of the information in heading 15 and the label.

3.1.3. In relation to the enforceability of the Preparations Directive

1. Some relevant issues have been identified as being problematic in the enforcement of the obligations of Dir. 1999/45/EC (1st ATP).

Many of these issues have been compiled in Annex V *as* "Interpretation Questions, IQs"*, that should be of further clarification, in a way that could be useful for all parties, including possible amendments of the Directives implied.*

Some of the main issues of concern are hereafter shortly described:

- Different treatments of R67 phrase in the Dangerous Preparations Directive and in the Dangerous Substances Directive (DSD) including its 28th ATP.
- Danger symbols in outer packages or unique packages for N-classified substances: criteria for application of transport symbol nr 9 or orange-black symbol.
- Labelling of preparations delivered in bulk.
- pH (and alkaline reserve) as determining factors for classification and labelling of dangerous preparations.
- Self-classified substances with different classifications depending on the manufacturer: a problem that makes extremely difficult enforcement and competitiveness among companies.

2. Annex I of the Dir. 67/548/EEC has proven to be the most relevant tool for the inspectorate in the enforcement of the classification, labelling and SDS of dangerous preparations.

3.1.4 In relation to the enforceability of the Safety Data Sheets Directive

1. Some relevant issues have been identified as being problematic in the enforcement of the obligations of Dir. 91/155/EC (2nd amendment).

Many of these issues have been compiled in Annex V as "Interpretation Questions, IQs", that should be subject of further clarification, in a way that could be useful for all parties, including possible amendments of the Directives implied.

Some of the problems are hereafter shortly described:

- SDS of substances with carcinogenic ingredients (Notes P, K, ...) or preparations that contain substances with carcinogenic ingredients: Information required in Heading 2.
- The importance of having a national emergency telephone number in Heading 1.

- Specific contents and more precise wording that can be demanded in several Headings of the SDS of a preparation, e.g. Headings 3, 11 and 12.

2. The enforcement of Directive 91/155/EC (2nd amendment) presents difficulties related to the fact that under some headings it is not very clear what information is mandatory. Assessment under some headings concludes about: poor quality / good quality information, but that is it. More accuracy in the definition of the contents of some Headings depending on the type of preparation is needed.

3. The expression "proportionate information" related to the contents of SDSs of non-classified preparations for professional users has to be developed in the SDS Directive.

3.2. Recommendations

3.2.1. To the European Commission:

Ø Annex I of Dir. 67/548/EEC

The Annex I future status is of great importance in order to assure and enforce the quality of the information contained in labels and Safety Data Sheets of dangerous substances and preparations.

It should be taken into account that Annex I has become a clear and powerful tool to harmonize and enforce the "hazards information" provided to final users by the mentioned information systems, not only regarding CMR and sensitising properties but also others as important as very toxic, toxic and dangerous for the environment properties.

Annex I should keep its actual mandatory status in the forthcoming legislation, as the main tool for companies and enforcers regarding the harmonization of the classification and labelling of chemical compounds.

Ø Manual of Decisions concerning Dir. 1999/45/EC (and its 1st ATP) and Dir. 91/155/EEC (and its 2nd amendment).

The development of the ECLIPS Project has brought up the need to have a "Guidance Document" or a "Manual of Decisions" concerning specific matters related to the implementation and application of the Directives, as it is reflected in Annex V, of "Interpretation Questions".

It should be a "living document", elaborated by the MSs and the European Commission, to be regularly modified or updated, not judicially binding, but to ensure

a common understanding of enforcement issues and therefore a more coherent approach to the implementation of the legislation among countries, and also, in certain aspects, among industry.

3.2.2. To EU Member States/EEA countries

- **Ø Follow up actions: future CLEEN projects focusing on both Directives**

Due to the obtained results regarding the grade of compliance with both Directives and the experience and improvements obtained in the used working method, it seems necessary for the CLEEN network to develop future projects involving as many EEA countries as possible, to assess the situation regarding the chemical products information systems (*), on a co-operation and co-ordination basis.

(*) Specially, taking into account the main role assigned to the SDS as the tool to materialise the information flow down the supply chain, in the forthcoming EU chemicals legislation REACH [Registration, Evaluation, Authorization (Restriction) of Chemicals].

3.2.3. To industry

- **Ø Grade of compliance**

The grade of compliance with of the Dangerous Preparations and the SDS Directives of the chemical industry must be improved.

- **Ø Small and Medium Enterprises (SMEs)**

The awareness of small size enterprises of human and environmental risks posed by chemical products should be raised.

Bigger efforts from the trade associations towards small enterprises, especially an enhanced involvement in supplying information, training and assessment regarding the chemicals legislation should be made.

The consideration of all hazardous properties of chemical products will be of special importance under REACH, where no harmonized classification is, in principle, foreseen for many endpoints.

Annex I: List of participants

Member State	Participant	Institution
Austria	Witzani Helmut	Umweltbundesamt
	Cladrowa Sabine	Umweltbundesamt
Burgenland	Aigner Rudolf	Burgenländische Landesregierung
	Gross Gerhard	Burgenländische Landesregierung
Kärnten	Malicha Rosemarie	Kärntner Landesregierung
	Kampl Eva Maria	Kärntner Landesregierung
Niederösterreich	Mittendorfer Walter	Amt der NÖ Landesregierung, Chemikalienkontrolle
	Hofmarcher Karl Michael	Amt der NÖ Landesregierung, Chemikalienkontrolle
Oberösterreich	Schiefer Dieter	Amt der Oö. Landesregierung, Abt. Umwelt- u. Anlagentechnik
	Bauer Günter	Amt der Oö. Landesregierung, Abt. Umwelt- u. Anlagentechnik
	Nöhbauer Franz	Amt der Oö. Landesregierung, Abt. Umwelt- u. Anlagentechnik
Salzburg	Kaufmann Rudolf	Salzburger Landesregierung
Steiermark	Stessel Helmut	Steiermärkische Landesregierung
	Friedrich Tamara	Steiermärkische Landesregierung
	Hofer Peter	Steiermärkische Landesregierung
Tirol	Glieber Barbara	Amt der Tiroler Landesregierung
	Wieser Josef	Amt der Tiroler Landesregierung
Vorarlberg	Anwander Eugen	Environmental Institute of the State of Vorarlberg
	Rinderer Martin	Environmental Institute of the State of Vorarlberg
Wien	Götz Heinz	Magistrat der Stadt Wien - MA 36
Belgium	Leynen Michel	Federal Public Service Health, Food Chain Safety and Environment, Environment Directorate-General
	Maasen Katrien	Federal Public Service Health, Food Chain Safety and Environment, Environment Directorate-General
	Klemans Willem	Federal Public Service Health, Food Chain Safety and Environment, Environment Directorate-General
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	Procureur Fabrice	Federal Public Service Health, Food Chain Safety and Environment, Environment Directorate-General
Finland	Ekman Annette	National Product Control Agency for Welfare and Health, Chemicals Department
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	Kemilänen Birgit	Finnish Environment Institute

	Leinonen Riitta	Finnish Environment Institute
	Kirjavainen Hannu	Municipality of Kuopio
	Salovaara Marjatta	Municipality of Tampere
	Hietala Tuula	Municipality of Valkeakoski
	Keskitalo Pentti	Municipality of Ylöjärvi
	Alho Pekka	Municipality of Uusikaupunki
	Aliharju Jaana	Municipality of Pori
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	Virtanen Teemu	Municipality of Lahti
	Forsbacka Anna	Municipality of Helsinki
	Syrjälä Vesa	Municipality of Helsinki
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	Juopperi Saara	Municipality of Vantaa
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	Hautalahti Pirkko	Municipality of Anjalankoski
	Kulmalahti Alexandra	Municipality of Padasjoki
	Hänninen Tapani	Municipality of Kerava
	Mikkanen Virpi	Municipality of Hanko
	Keisteri Liisa	Municipality of Espoo
	Österberg Timo	Occupational Safety and Health Inspectorate of Turku and Pori
	Smal Kari	Occupational Safety and Health Inspectorate of Oulu
	Salo Jaana	Occupational Safety and Health Inspectorate of Uusimaa
	Sahamies Tuula	Occupational Safety and Health Inspectorate of Uusimaa
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	Böhrer Gerald	Gewerbeaufsichtsamt Augsburg
	Weinig Klaus	Gewerbeaufsichtsamt Würzburg

	Siglmüller Franz	Gewerbeaufsichtsamt München-Land
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	Schmid Barbara	Regierungspräsidium Kassel
	Günther	Regierungspräsidium Kassel
	Weber	Regierungspräsidium Gießen
	Flocke	Regierungspräsidium Darmstadt
	Schmid	Regierungspräsidium Darmstadt
	Herber	Regierungspräsidium Gießen
	Hock Stefanie	Regierungspräsidium Darmstadt
	Frensch	Regierungspräsidium Darmstadt
	Linke Burghard	Regierungspräsidium Kassel
	Wölfinger	Regierungspräsidium Kassel
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	Christ Gabi	Health & Safety Authority
	Feehan Margaret	Health & Safety Authority
	Mc Mickan Sinead	Health & Safety Authority
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	Fossnes Tone Line	Norwegian Pollution Control Authority
	Nygreen Beryl	Norwegian Pollution Control Authority
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	Molina García Laura	DAP Granada
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	Gata Diez Jaime Angel	DAP Jaén
	Gómez Jiménez Lourdes	Delegación Salud Jaén
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	Lopez Torres Miguel Angel	DAP Jaén Nordeste
	Marrón Moreno Milagrosa	DAP Jaén
	Ollero Palma Mª Jesús	DAP Jaén Sur
	Padilla Weigand Regina	DAP Jaén
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	Villalba Dedoya Diego	DAP Málaga
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	Martín Vallejo Elena	DAP Sevilla
	Méndez Moreno Mercedes	DAP Sevilla Norte
	Núñez Castaín Concha	Delegación Salud Sevilla
	Palma Morgado Daniel	DAP Sevilla
	Paz Castro Francisco	DAP Sevilla Este
	Pérez Torres Mª Eugenia	DAP Sevilla
	Vázquez García Rosa	DAP Sevilla Norte
Comunidad Autònoma de Castilla – La Mancha		
Coordinator Toledo	Marcial Gómez Orrios	Consejería de Sanidad
Albacete	Navarro Honrubia Carlos	Técnico Superior Delegación Provincial
Ciudad Real	Torres Manrique Felicia	Jefa de Sección de Sanidad Ambiental
Guadalajara	Pedredo Dombriz Isabel	Técnico Superior Delegación Provincia
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Comunidad Autònoma de Castilla - Leòn		
Coordinator Valladolid	Enrique Estrada Vélez	Consejería de Sanidad y Bienestar Social
Palencia	Arangüena Fanego Marta	Servicio Territorial Sanidad y Bienestar Social
Valladolid	Úbeda Blanco Cristina	Servicio de Sanidad Ambiental/ Agencia de Protección de la Salud y Seguridad Alimentaria
Comunidad Autònoma de Madrid		
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Madrid	De Paz Collantes Concepción	TSSP Área I - ISP
	Redondo Sobrado Rosario	TSSP Área II – ISP
	Zamora Soler María	TSSP Área II – ISP
	De Bernardo Alonso Pilar	TSSP Área III – ISP

	Carrillo Pulido Isabel	TSSP Área V – ISP
	Turrero Pontiel Estrella	TSSP Área VI – ISP
	Merino Carretero María Luz	TSSP Área VIII – ISP
	Álvaro Gómez Beatriz	TSSP Área VIII – ISP
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Coordinator Murcia	Juan Ignacio Sánchez Gelabert	Consejería de Sanidad y Consumo
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	Buenestado Castillo Claudio	Inspector Farmacéutico de Salud
Comunidad Autònoma de Navarra		
Pamplona	José María Barricarte Gurrea	Consejería de Salud
Comunidad Autònoma de la Rioja		
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Comunidad Autònoma Generalidad Valencia		
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Guipúzcoa	Santa Marina Rodríguez Loreto	Técnico de Salud Pública
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	Rumar Karin	Swedish Chemicals Inspectorate

Annex II: Guidance manual

Guidance Manual ECLIPS

European **C**lassification and **L**abelling **I**nspections of **P**reparations, including **S**afety Data Sheets

December, 2002

This guidance manual has been elaborated prior to the operation phase. Please take note that some information may meanwhile be outdated.

Content

1. General aspects of ECLIPS

1.1 Introduction

The Chemical Legislation European Enforcement Network (CLEEN) is a forum for information exchange. The general aims of CLEEN are to:

- Facilitate better compliance
- Provide feed back to the commission about execution of enforcement programs, sensitivity to fraud, enforceability and field experiences and changes in the market.
- Share experience and knowledge: Best practices
- Exchange and coordinate information between the members of the network
- Ensure that companies are equally dealt with across the EU

To reach these aims, CLEEN enables projects on specific matters (see figure 1). The project European Classification and Labelling Inspections of Preparations, including Safety Data Sheets (ECLIPS) is the CLEEN-project that is planned for the 2002-2003. The ECLIPS project focuses on the enforcement of the European legislation on classification and labelling of chemical products and on Safety Data Sheets.

Figure 1. Project cycles CLEEN-projects

This guidance manual is for all members of CLEEN that are involved or interested in the ECLIPS project. This manual describes the enforcement project which is carried out by (almost all) members of CLEEN. Further more the manual gives an overview of all relevant information and enforcement tools concerning ECLIPS.

The manual is a product of the cooperation of the CLEEN members and based on intensive information exchange. During the CLEEN Conference in Vienna (September 2001) the first project proposal was discussed. In the interim meting in Valencia (February 2002) the project outlines where defined. As a result of this interim meeting the first draft guidance manual of ECLIPS was drawn and discussed within CLEEN during the annual conference held in Copenhagen (September 2002). As a result the final version of the Guidance Manual was sent to all CLEEN members in (November 2002).

1.2 Legislation

The European chemicals industry manufactures and uses a large number of different chemical products. 90% to 95% of all chemicals on the European market are preparations, i.e. mixtures of chemical substances. To achieve al

high level of protection of human health and the environment from chemicals, harmonized community rules are made for the classification, packaging and labelling of dangerous chemical substances and preparations (see textbox 1).

Text box 1. Overview European Legislation

▫ Dangerous Preparations	2001/60/EC 1999/45/EC 88/379/EEC
▫ Dangerous Substances	2001/59/EC 67/548/EEC
▫ Safety Data sheets	2001/58/EC 93/112/EC 91/155/EEC

The ECLIPS project focuses on the enforcement of the recent changes in European legislation on classification and labelling of preparations and SDS:

1. *Dangerous Preparations Directive*
   This new Dangerous Preparations Directive (Dir. 1999/45/EC) will replace 88/379/EEC from 30 July 2002 for the majority of preparations, and from 30 July 2004 for plant protection products and biocides. 1999/45/EC extends the scope of the dangerous preparations directive to include for the first time pesticides and a requirement to classify and label preparations for environmental hazards. Directive 2001/60/EC has recently adapted to technical progress for the first time Directive 1999/45/EC.
2. *Safety Data Sheets*[1]
   European legislation requires producers of dangerous chemicals to provide industrial and professional users with detailed health, safety and environmental information and advice about their chemical products in the form of safety data sheets. Directive 91/155/EEC, as amended by Directives 93/112/EC and 2001/58/EC, sets out the requirements for the information which should be included in a SDS.

A summary of the most important changes in this legislation is given in textbox

Text box 2. Important changes in EU legislation concerning the ECLIPS project

- *Labelling of preparations with regard to danger for the environment*
  Criteria of danger for the environment will apply also to preparations. Until now, this rule has applied to substances only. Danger symbol and risk phrases must be used on the label of the packaging.
- *More products will have safety data sheets*
  Safety data sheets must be provided for preparations classified as dangerous for the environment and substances classified as dangerous for the environment must be stated in the labelling. This is already the case for products hazardous to health.

  Professional users of chemical products will have the right to require safety data sheets for certain products which are not classified as dangerous. This applies for example if the product contains low concentrations of a substance classified as dangerous to health or the environment (1% or more). The user will be notified of this right by information on the packaging label.
- *Sensitising substances will have to be stated in the labelling*
  Substances giving rise to sensitisation must be indicated on the label of the packaging, also when included in such low concentrations (0.1% or more) not the

[1] Even though this project focuses on the Dangerous Preparations Directive, the provisions of the Dangerous Substances Directive are taken into account (in particular the 28th ATP (Dir. 2001/59/EC)).

require the entire product to be classified as sensitising.

[Source: www.kemi.se/classificationandlabelling]

1.3 Objectives and goals of ECLIPS

The objectives of the ECLIPS-project are:

1. To assure a harmonized European enforcement of the Dangerous Preparations Directive (Dir. 1999/45/EC).
2. To show the necessity of appropriate classification and labelling as well as complete and correct safety data sheets (SDS) for dangerous preparations (Dir. 2001/58/EC).
3. To focus on chemicals classified as dangerous for the environment (Dir. 2001/60/EC) and also inspect products classified as carcinogenic, mutagenic and/or toxic for reproduction (CMR) (Dir. 2001/58/EC).

The goals to of the ECLIPS-project are:

- Reducing the risks to human health and environment by establishing a standard for safety data sheets and the appropriate classification and labelling of preparations containing dangerous substances.
- Exchanging information and sharing experiences between the CLEEN members in order to avoid differences in the way the directive is enforced.
- Finding enforcement strategies for each country which are suited for its national situations.
- Ensuring that companies are equally dealt with across the EU.
- Enforcing correct labelling of preparations containing dangerous substances as a means to provide reliable information for the end users and consumers.

2. ECLIPS project activities

To achieve the goals and objectives of the ECLIPS project, an Enforcement project will be carried out by CLEEN. This is supported by an active information exchange between the CLEEN members.

2.1 Enforcement project (see chapter 3 and 4 of this Guidance Manual)

The operational goal of the enforcement project is to inspect companies and their handling and labelling of preparations containing dangerous substances. These inspections will lead to an improved insight in (1) the level of compliance and (2) the problems for companies in complying to this legislation.
The results of these inspections will generate conclusions about the following aspects:

- Are the available guidelines and tools for inspection sufficient or can they be improved?
- Are there any recommendations to the EU which can lead to an improvement of the directives and their enforceability?
- Are the companies compliant with the legislation?

In chapter 3 the project plan for this enforcement project is worked out. Chapter 4 works out a check list for the actual inspections.

2.2 Information exchange (see chapter 5 of this Guidance Manual)

The goal of information exchange is support the Enforcement project and to facilitate the harmonization of the way the directive is enforced. Given the nature of the Directive, this information exchange will focus on the following aspects:

- To identify the relevant knowledge and the instruments available at the members of the CLEEN Network.
- To facilitate that this information is scrutinized by the Working Group and subsequently made available to all members of the Network.

This information exchange will provide support for all members of the Network to set up and implement enforcement strategies which are suited for its national situations.

2.3 Working Group and Participating Countries

Working Group
The project activities are coordinated by the ECLIPS Working Group.

Table 1. Members ECLIPS Working Group (leading countries)

Nr	Name	Country	E-mail
1	Mr Gerhard Zucht	Germany	zucht.gerhard@baua.bund.de
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4	Ms. Carla Speel-Zuiderwijk	Netherlands	carla.speel-zuiderwijk@minvrom.nl
5	Ms Karin Rumar	Sweden	karin.rumar@kemi.se
6	Mr. Peter Bex	CLEEN Secretary	eclips@cleen-europe.org

Participating Countries
In the table below the participating countries for the ECLPIS Project are listed. These countries will visit at least 10 companies (and inspect 5 chemical products/preparations). The observing countries will not do inspections, but if they have access to relevant data, they will provide this information to the Working Group.

Table 2. Participating and observing countries Enforcement project

Participating countries	Observing countries
- Austria (working group) - Belgium - Finland - Germany (working group) - Greece - Ireland - Netherlands (working group) - Spain (working group) - Sweden (working group) - Denmark - France - Norway - Slovenia	- Italy - Luxembourg - Portugal - United Kingdom - Switzerland - Slovakia - Czech Republic

3. Enforcement Project ECLIPS

3.1 Introduction

In this chapter the Enforcement Project ECLIPS is described in more detail. Paragraph 3.2 describes the scope of the project (which products and what the elements to be inspected). In table 3 and 4 the information that is collected during the inspections is summarised. The forms to be filled in by the inspectors can be found in annex II and III of this guidance manual. In table 5 of this paragraph is a first impression of the subjects to report on in the final report. In paragraph 3.3 the out line of the project is summarised and in paragraph 3.4 the ECLIPS project planning is worked out in detail.

A general overview of the ECLIPS project is presented in the figure below.

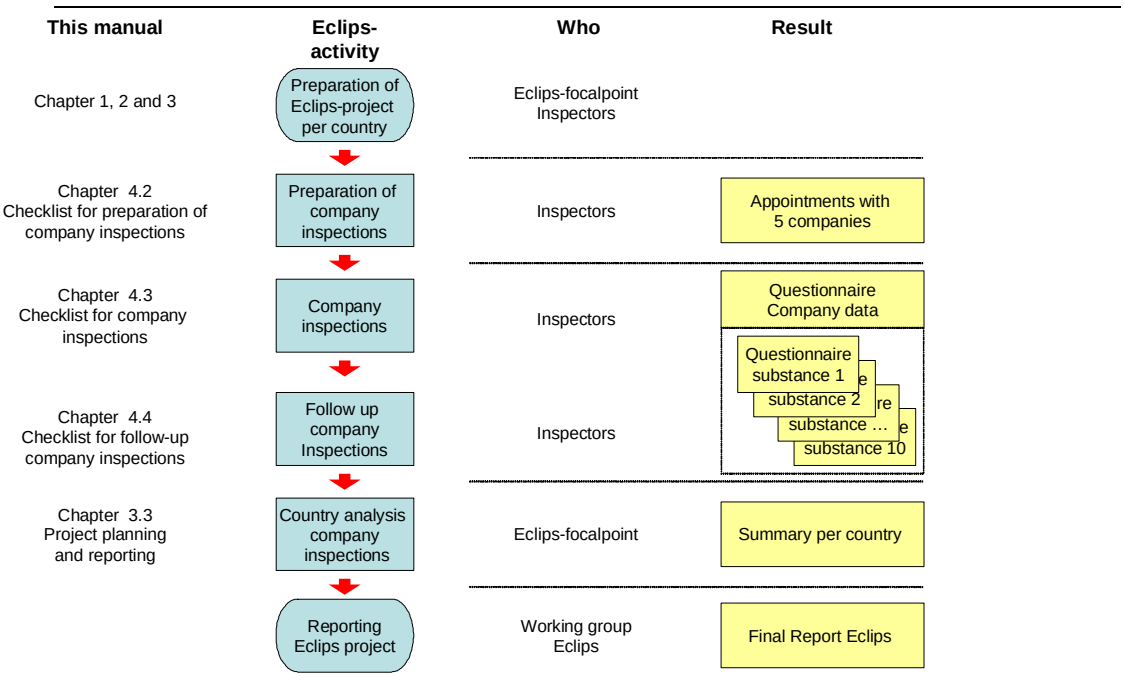

Figure 2. Overview ECLIPS project and the parts of the Guidance Manual

3.2 Scope of the Enforcement Project

Products
The Enforcement Project focuses on several groups of preparations containing dangerous substances:

- Paints and varnishes
- Cleaning agents (e.g. organic solvent-based)
- Detergents
- Preparations to be used during (re-)construction of buildings
- Photo chemicals.

Within these product groups, there will be a focus on dangerous preparations consisting of substances that are:

- Dangerous for the environment
- CMR (carcinogenic, mutagenic and toxic for reproduction)
- Sensitizers
- R67

Questionnaire for ECLIPS-inspections

During the Copenhagen conference in September 2002, consensus was reached about the questionnaire that will be used for the inspections. The structure of this questionnaire is given in the table below. It was agreed to evaluate this questionnaire after the first round of inspections during the interim meeting in March 2003 in Vienna. In the annex II and III the questionnaire forms described in more detail.

Table 3. Questionnaire 1. Company information

Nr	Company data	Description
1	Size of the company	Number of employees
2	Category	Chemical industry, Trading company, Retail company
3	Membership professional organisation	Companies are members of professional organisations (national and international). These organisations generally claim that their members comply with relevant legislation.
4	Knowledge in company or hired	The knowledge necessary to ensure compliance with the legislation can be either in the company or can be provided by hiring professional services.
5	ISO 9001 or ISO 14001	ISO standards ensure that the management system of a company satisfies certain requirements. This can have an influence on the capability of a company to comply with relevant legislation.
6	Supply chain	Check if SDS is “travelling along” with the preparation

Table 4. Questionnaire 2. The inspected products

		Dangerous Preparations Directive	ok	defective	irrelevant	
Nr	**Labelling**					**Notes**
1	Trade name or designation	Art. 10, 2.1.				
2	Chemical name of the substances	Art. 10, 2.3.				
3	Name, full address, telephone number	Art. 10, 2.2.				
4	Danger symbols	Art. 10, 2.4.				
5	Classification	Art. 4-7 Ann. I, 67/548/EC				
6	Indications of danger	Art. 10, 2.4.				
7	Risk-phrases	Art. 10, 2.5.				
8	Safety advice	Art. 10, 2.6.				
9	Nominal quantity	Art. 10, 2.7.				
10	**CMR** phrase and labelling	*)				
11	Class & labelling of prep. hazardous for environment	Art. 10. Annex III				
Nr	**Presentation of the label**					**Notes**
12	Is the symbol correct (colour, shape etc)?	Art. 10, 2.4. Art 11				
13	Is the label easily removable from the package ?	Art 11				
14	Is the label clean and readable ?	Art 11				
Nr	**Special provisions under annex V B, C**					**Notes**
15	Paint and varnishes containing lead	Ann. V B 1.1.				
16	Adhesives containing cyanoacrylates	Ann. V B 2.1.				
17	Isocyanates	Ann. V B 3.				
18	Epoxy constituents	Ann. V B 4.				

19	Active chlorine >1%	Ann. V B 5.				
20	Contains cadmium (brazing/soldering)	Ann. V B 6.				
21	Contains substances not yet tested completely	Ann. V B 8.				
22	Contains **sensitising** substances but not classified	Ann. V B 9.				
23	Contains HHC >5%	Ann. V B 10.				
24	Contains a substance assigned phrase **R67**	Ann. V B 11.				
25	Cements and cement preparations containing chromium (VI)	Ann. V B 12.				
26	Not intended for the general public	Ann. V C 1.				
Nr	**Safety data sheet**					**Notes**
27	Availability SDS					
28	Heading 1 Identification product/company					
29	Heading 2 Substances					
30	Heading 3 Danger					
31	Heading 7 follow up					
32	Heading 8 follow up					
33	Heading 11 volontary					
34	Heading 12 volontary					
35	Heading 15					
36	Correspondence Heading 15 - label					

* According to Dir. 67/548/EEC and Dir. 1999/45/EC (and if possible to check if the preparation or substance inspected is under the CMR list of Directive 76/769/EEC and the use category of that preparation or substance)

Analysis and Findings

Based on the results of the inspections, three categories of findings can be formulated. The table below gives in general the findings that might come available after the inspections and an analysis of the filled in questionnaires. This contents of this table will be discussed, together with the outlines of the final report, during the interim meting in Vienna (March 2003).

Table 5. Findings (in general)

Finding	Description
What is the situation regarding the compliance with the inspected elements of the directives?	The information collected during the inspections will provide insight into the compliance situation per country. The exact way of reporting the results of the inspections is not clear jet. This discussion can take place on the basis of the first round of inspections during the interim meeting in Vienna (March 2003).
Should the questionnaire, checklist or instruments for the inspections be improved?	The questionnaire, checklist or instruments (SDS guidelines etc.) are based on the interpretation of the directives. After the first round of inspections their practical usability will be evaluated, possibly resulting in hints and instructions if some parts of the questionnaire or checklist are easily misunderstood.
Are there recommendations for the EC regarding e.g. the enforceability of the directives?	After the second round of inspections, possible improvements of the directives can be identified and communicated to the EC.

3.3 The project outline

Project phases

The Enforcement Project ECLIPS follows an approach in phases in where information is distributed, discussed, (if necessary) changed and adapted. The project consists of the following phases:

Table 6. Project outlines

Nr		Working Group	Participating Countries
1	Finalize Guidance Manual ECLIPS	Distribute draft guidance manual for comment from the participating countries Discuss the received comments from the CLEEN network and finalize draft guidance manual (including check list and questionnaire)	Evaluate Guidance Manual and check list and sent comments and additions to the Working Group
2	Start of inspections (see chapter 4 Working method inspections)	Summarise interim results from countries who did inspection in the period January - March 2003.	Inspections of 10 companies and 5 chemical products / preparations
3	Preparation of the interim report	Discuss interim results and guidance manual (including check list and questionnaire). Communicate results interim meeting to the participating countries and the CLEEN network.	
4	Ongoing inspections (see chapter 4 Working method inspections)		Inspections of 10 companies and 5 chemical products / preparations
5	Preparation of the draft report	Prepare a draft report for the Enforcement Project ECLIPS. Prepare the ECLIPS part of the CLEEN conference in September/October 2002.	
6	Discussion of the draft report		Participation in CLEEN Conference 2003
7	Finalization of the ECLIPS report	Prepare final report and formulate recommendations to the EC	

Inspections
All participating countries agreed that for the Joint Enforcement Project ECLIPS at least 10 companies are inspected and that a minimum of 5 chemical products / preparations per company are checked.

If for some reason a company has less than the 5 products / preparations (or chemical product groups) as an exception less product are allowed.

3.4 Project planning and reporting

Planning
The timetable focuses on the agreed aim of CLEEN and that is to finalise at least one joint enforcement project per year. For the ECLIPS project it is therefore necessary to have all information available before the next CLEEN conference in September/October 2003. This conference can than be used to finalise the enforcement project, optimising the helpdesk and agree on follow up (e.g. recommendations to the EC). Figure 3 gives a detailed planning of the ECLIPS project.

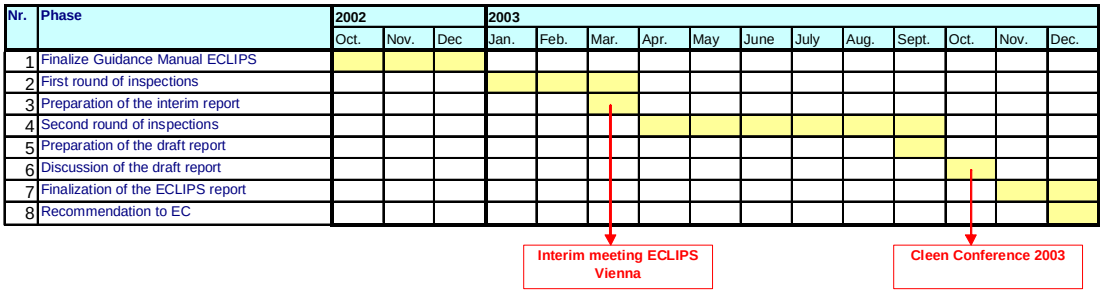

Figure 3. Project planning

Reporting
All questionnaires (see annex) are filled in by the inspector and sent to the ECLIPS focal point. The focal point summarises the results in an agreed reporting format (this is worked out during the interim meeting in Vienna) and send it to the CLEEN Secretariat. All summaries are send to the CLEEN secretariat before 15 September (eclips@cleen-europe.org). The CLEEN secretariat draws up an interim report and the final report. The out lines of the final report will be discussed during the meeting on march 28th and 29th in Vienna.

4. Checklist and points of attention

4.1 Introduction

The checklist for the inspections can be divided in the steps of the inspection:

Step	Activity
1. Preparation of the inspection	a) Select companies to be inspected b) Announce inspection and make appointments c) Inform other relevant authorities d) Carry out desk research e) Prepare inspection
2. Inspection of the company	a) Introduction b) Select preparations to be inspected c) Ask for copies of labels and SDS d) Ask for composition of the preparations and take samples (only if necessary) e) Check compliance f) Inform company about preliminary results and follow-up
3. Follow up of the inspection (the points d, e, f, and g, are only relevant if important additional information is received some time after the inspection)	a) Check analysis of the samples taken during the inspection b) Confirm findings of the inspection to the company c) Watch the deadlines of follow-up actions d) Check later received information on composition e) Check later received labels and SDS

	f) Confirm the findings of later received information g) Carry out second inspection (if necessary) h) Inform other relevant inspectorates and organisations i) Report results on individual companies to the focal point j) Focal Point summarizes country results for CLEEN-secretary.

In the next paragraphs the checklists are described in more detail.

4.2 Checklist - for preparation of inspections

a.	**Select companies to be inspected**
	Select companies that produce, import or trade products within the scope of the ECLIPS-project: - paints and varnishes; - cleaning agents (e.g. organic solvent-based); - detergents. - preparations to be used during (re-)construction of buildings - photo chemicals Make sure the selected products are not for the companies own use, the have to sell the products.
	***Hints & Tips***
	Sources that could be uses for the selection of companies: - Internal databases/ former inspections - Yellow pages, i.e. internet - Chamber of commerce - Trade organizations - Registers (e.g. Nordic Countries) - Customs - Other authorities / Other Member States

b.	**Announce inspection and make appointments**
	- Inform the company about inspection and make an appointment for the visit. - Ask the company to have a actual list of products sold today available at the visit (both to professional user and consumers) - Ask the company also to have available labels, SDS and compositions. If the company has many products ask for a selection of products. - Confirm the appointments in an announcement letter.
	***Hints & Tips***
	- Depending of national legislation; ask for amounts of products sold last year.

c.	**Inform other relevant authorities**
	- Check for other relevant legislation for company - Inform other involved authorities and ask for relevant information or cooperation.
	***Hints & Tips***

	- Combined inspections are recommended if useful or necessary (depending on national legislation)

d.	**Carry out desk research**
	- Check for results of former inspections - Collect general information about the company
	***Hints & Tips***
	- If available check product information from the register (e.g. Nordic countries)

e.	**Prepare inspection**
	Collect everything needed for the visit: - Tools and legislation - Information for the company - Instruments to take samples
	***Hints & Tips***
	Other tools that can be used during the visit: - Camera to take photographs - Laptop including e.g. o Annex I (Dir. 67/548/CEE including 28th TPA, Dir. 2001/59/CE) o Databases o Calculation program

4.3 Checklist - for inspection of the company

a.	**Introduction**
	Inform the company about: - purpose of the visit - procedure (work and time visit, follow up) - possible consequences in case of non-compliance (sanctions)
	***Hints & Tips***
	- Mention CLEEN-network / ECLIPS-project if appropriate

b.	**Select preparations to be inspected**
	- Check the list of sold products - Select 5 preparations (if possible), that will be checked, taking into account the criteria: ECLIPS focus: o Dangerous for the environment o CMR (Carcinogenic, mutagenic and toxic for the reproduction) o Sensitizers o R67 (vapours may cause drowsiness and dizziness) General criteria: o Diversity in classification o Quantity of the products sold; focus on high volumes o Diversity in use

	***Hints & Tips***
	Substances on Annex I (Dir. 67/548/CEE including 28th TPA, Dir. 2001/59/CE) are easier to prosecute.

c.	**Ask for copies of labels and SDS**
	- Ask the company to provide copies of the labels and SDS for the selected preparations. - If not available, notice non-compliance, and set deadline for company.
	***Hints & Tips***
	- The term for the deadline depends on the national legislation. - Take the origin of the product into account when setting the term. - SDS and information on composition from third countries might be a problem.

d.	**Ask for composition of the preparations and take samples**
	Ask the company for detailed information on the composition of the product. If composition is not available; - ask company to request the supplier to send composition-information direct to inspectorate If there are doubts on the composition; - take a sample to verify the composition (very seldom necessary - focus on correct information instead).
	***Hints & Tips***
	If confidentiality of the composition is a problem; ask the company to contact their supplier to send information direct to the inspectorate.

e.	**Check compliance**
	Check the classification and the presence and quality of the label and fill in the ECLIPS-questionnaire.
	***Hints & Tips***
	See questionnaire

f.	**Inform company about preliminary results and follow-up**
	Inform company about: - the findings - possible follow-up actions
	***Hints & Tips***
	Make appointments about: - Term to be compliant (second inspection?) - Labels and SDS to be provided - Other information if necessary

4.4 Checklist - for follow up of the inspection

a.	**Check analysis of the samples taken during the inspection**
	Compare the classification and information on the label and SDS with the outcome of the calculation or test-results
	***Hints & Tips***
	See also remarks from the ECLIPS helpdesk when interpreting legislation on classification and make use of the FAQ-database.

b.	**Confirm findings of the inspection to the company**
	Confirm to the company by letter* : - the results of the visit - in case of violations; o confirm a penalty (depending of violations) o the term to be compliant - follow-up actions; o labels and SDS to be provided o other information if necessary * In some countries only a letter is written when violations are found.
	***Hints & Tips***
	Depending on different national procedures an inspection report might be send.

c.	**Watch the deadlines of follow-up actions**
	If the requested information is not received from the company in time, contact company and set deadline.
	***Hints & Tips***
	The term for the deadline depends on the national legislation and procedures.

d.	**Check later received information on composition**
	Compare the classification and information on the label and SDS with the outcome of the calculation results
	***Hints & Tips***
	See also remarks from the ECLIPS helpdesk when interpreting legislation on classification.

e.	**Check later received labels and SDS**
	Checking the quality of the labels and SDS

	***Hints & Tips***
	Use and fill in the ECLIPS-questionnaire

f.	**Confirm the findings of later received information**
	Confirm to the company by letter* : - the results of the checks on later received information - in case of violations; o confirm a penalty (depending of violations) o the term to be compliant - follow-up actions * In some countries only a letter is written when violations are found.
	***Hints & Tips***

g.	**Carry out second inspection (if necessary)**
	If agreed during the first visit, or when the outcome of alter received information is non-complying, carry out second inspection.
	***Hints & Tips***

h.	**Inform other relevant inspectorates and organisations**
	Inform inspectorates about result of inspections and follow-up actions In case of an important violation started in another country; contact your national focal point. The national focal point might contact the focal point in the other country about the violation.
	***Hints & Tips***
	If available; the ALERT-system might be used to notify other Member States

i.	**Sent questionnaire of companies to the Focal Point**
	Report results to your by sending the filled in questionnaires to the national Focal Point
	***Hints & Tips***
	Use the questionnaire

j.	**Focal Point summarizes country results for CLEEN-secretary**
	Focal Points send the collected results to the secretariat using the reporting format
	***Hints & Tips***
	Use the reporting format

5. Information exchange

5.1 Quick Reference Guide ECLIPS

Scope
Several countries developed tools, instruments and guidelines to implement the EU legislation and support enforcement on classification, labelling and safety data sheets. The ECLIPS-project wants to make this information available for CLEEN members.

Quick Reference Guide ECLIPS
The table below gives an overview of all available information (up date till September 2002) and the responsible contact person. All members can request this information via this person.

Table 7. Quick Reference Guide ECLIPS

Nr	Title	Content	Contact
1	Basic Guide on Labelling and Safety Data Sheets	Gives an overview of the relevant legislation and its implementation	Mr. Fransico Vargas Marcos (fvargas@msc.es) Ms Rosario Alonso-Fernandez (ralonso@msc.es)
2	CD-rom with all relevant legislation	All original legislation concerning classification, labelling and SDS. Includes an overview of all relevant changes.	Mr. Gerhard Zucht (zucht.gerhard@baua.bund.de)
3	The art of making Safety Data Sheets	Brochure for companies on SDS (made by industry)	Ms. Karin Rumar karin.rumar@kemi.se
4	The art of reading Safety Data Sheets	Brochure for companies on SDS (made by industry)	Ms. Karin Rumar karin.rumar@kemi.se
5	Presentation ECLIPS-conference	Overview of the ECLIPS-project, relevant legislation and discussion points	Mr. Peter Bex ECLIPS@cleen-europe.org Or website: www.cleen-europe.org
6	Presentation changes in classification, labelling and SDS legislation.	Highlights the most important changes in the legislation concerning ECLIPS	Ms. Angeliki Tsatzou gxk-environment@ath.forthnet.gr
7	CHIP Guide for idiots	Explanation of all relevant legislation.	Mr. Robert Warner Bob.Warner@hse.gsi.gov.uk
8	Power-point presentation of training in C&L and SDS	Slides from training-course in Stockholm 2002 about classification and labelling and safety data sheets	Ms. Karin Rumar karin.rumar@kemi.se
9	FAQ database	Frequently Asked Questions database	Mr. Peter Bex peter.bex@siraconsulting.nl ECLIPS@cleen-europe.org
10.	Training course safety data sheets	Full training documentation of training programme inspectorate Netherlands	Ms. Carla Speel-Zuiderwijk carla.speel-zuiderwijk@minvrom.nl
11.	Classification of Petroleum Substances as Dangerous to the Evironment	CONCAWE's recommendations on classification of petroleum substances	Mr. Peter Bex peter.bex@siraconsulting.nl ECLIPS@cleen-europe.org

Procedures
The CLEEN secretary is responsible for updating the Quick Reference Guide ECLIPS[2], to do so the following procedure is developed:

[2] At this moment the CLEEN Secretariat looking for possibilities to make this information available via the CLEEN website. Due to file sizes of these documents enabling this information via internet is at this moment not possible.

1. New tools that come available and might be interesting to share with the CLEEN members can be sent to the ECLIPS working group.
2. The ECLIPS working group decides if this information is useful and not in violation with earlier made agreements on implementation of the EU legislation. The ECLIPS working group informs the CLEEN secretary and the person how suggested the new tool on their decision.
3. If the new tool is suitable for other countries the secretary will update the Quick Reference Guide ECLIPS. By email all ECLIPS contact persons and CLEEN focal points will receive the updated Quick Reference Guide and the document.

5.2 Helpdesk

Scope

The task of the helpdesk is to help inspectors with inspections and enforcement problems concerning classification, labelling and SDS. The helpdesk is also used to identify general problems with the implementation of the EU legislation and differences in enforcement per country.

Helpdesk

The helpdesk is consists of:

1. *A ECLIPS Focal Point per country*: The ECLIPS Focal Point per country coordinates all questions from inspectors. If questions arise frequently or if differences in implementation (may) occur the question is sent to the ECLIPS-helpdesk (see annex 3 for overview of ECLIPS Focal Points per country).
2. *The ECLIPS Working Group*: The ECLIPS Working Group discusses the questions and if necessary provides an answer. All relevant questions (including the appropriate answer) are sent to the CLEEN Secretariat.
3. *CLEEN Secretariat*. The CLEEN Secretariat is responsible for the Frequently Asked Questions Overview. All new questions and issues are collected and made available in a database. If relevant some issues might be discussed with all CLEEN members, the CLEEN Secretariat will then coordinate and facilitate an email discussion.

Procedures

If any technical questions (steps in inspections, enforcement problems and solutions, etc.) arise in carrying out the inspections, please ask the ECLIPS Focal Point in your country.

If necessary the ECLIPS Focal Point sets out the question at the ECLIPS-helpdesk. The answer from the ECLIPS-helpdesk is sent to the respondent and the ECLIPS-secretariat. The ECLIPS Focal Point distributes the answer to the inspector(s) in his/her country. The ECLIPS-helpdesks updates the FAQ-overview and sends out an email to all ECLIPS participants and CLEEN-focal points.

[2] At this moment the CLEEN Secretariat looking for possibilities to make this information available via the CLEEN website. Due to file sizes of these documents enabling this information via internet is at this moment not possible.

Country	ECLIPS Focal Points	Phone number	Email
Austria*	Helmut Witzani	+43 (1) 31 304 5620	witzani@ubavie.gv.at
Belgium	Paul Cuypers	+32 2 553 7964	paul.cuypers@lin.vlaanderen.be
Denmark	Birte Borglum	+45 (32) 66 02 97	BB@MST.DK

Finland	Annette Ekman	+358 9 3967 2771	annette.ekman@sttv.fi
France	Dominique Brunet		Dominique-s.brunet@drt.travail.gouv.fr
Germany*	Gerhard Zucht	+49 (0) 231 9071 517	zucht.gerhard@baua.bund.de
Greece	Angeliki Tsatsou	+30 (10) 6479450	gxk-environment@ath.forthnet.gr
Ireland	Caroline Walsh		caroline_walsh@hsa.ie
Netherlands*	Carla Speel	+31 (0)10 22 44 474	carla.speel-zuiderwijk@minvrom.nl
Norway	Maren Wikheim	+47 (22) 573 586	maren.wikheim@sft.no
Spain*	Rosario Alonso	+34 91 596 2001	ralonso@msc.es
Sweden*	Karin Rumar	+46 8 783 1252	karin.rumar@kemi.se
Slovenia	Ivan Stefelj		

Appendix to the Guidance Manual ECLIPS

Explanation to Questionnaire I (Company Information)

Nr	Company data
B1	Fill in the number of employees
B2	Select one of the following categories (1) Chemical industry, (2) Trading company, (3) Retail company
B3	Fill in Yes if the companies is a members of professional organisations (national and international). These organisations generally claim that their members comply with relevant legislation.
B4	The knowledge necessary to ensure compliance with the legislation can be either in the company or can be provided by hiring professional services. If the company has no
B5	ISO standards ensure that the management system of a company satisfies certain requirements. This can have an influence on the capability of a company to comply with relevant legislation. Please fill in certified standards of the company.
B6	Check if SDS is “travelling along” with the preparation, please describe the position of the company in the product chain.
B7	Please describe any other relevant information about the company or the inspected products

Explanations to Questionnaire II (The inspected products)

Please fill in if the described element is in compliance. Only if is filled in “no”, please motivate this under notes. Below an explanation is given of the different subjects.

Nr	LABELLING	
1	Trade name or designation	Is this information provided on the label?
2	Chemical name of the substances	Is this information provided on the label? No, what is wrong about it?
3	Name, full address, telephone number	Is this information complete provided on the label? No, what is missing?
4	Danger symbols	Are the right symbols on the label? No, which ones are missing or wrong and why?
5	Classification	Is the product classified correctly? If not what is wrong
6	Indications of danger	Does the product have the correct indication of danger? If not what is wrong?
7	Risk-phrases	Are the risk-phrases correct? If not what is wrong
8	Safety advice	Are the correct safety-phrases mentioned on the label? If not what is wrong about is?
9	Nominal quantity	Is the normal quantity mentioned on the label?
10	**CMR** phrase and labelling	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
11	Contains elements **hazardous for environment**	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
Nr	**Presentation of the label**	
12	Is the colour of the symbols orange ?	Fill in Yes or No
13	Is the label easily removable from the package ?	Fill in Yes or No
14	Is the label clean and readable ?	Fill in Yes or No
Nr	**Special provisions under annex V B, C**	
15	Paint and varnishes containing lead	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
16	Adhesives containing cyanoacrylates	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
17	Isocyanates	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
18	Epoxy constituents	If relevant, please check if labelling is correct. If not please describe what is wrong about it.

19	Active chlorine >1%	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
20	Contains cadmium (brazing/soldering)	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
21	Contains substances not yet tested completely	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
22	Contains **sensitising** substances but not classified	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
23	Contains HHC >5%	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
24	Contains a substance assigned phrase **R67**	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
25	Cements and cement preparations containing chromium (VI)	If relevant, please check if labelling is correct. If not please describe what is wrong about it.
26	Not intended for the general public	If relevant, please check if labelling is correct. If not please describe what is wrong about it.

Nr	Safety data sheet	Chapters
27	Availability	Is the safety data sheet easily assessable (guideline: within 10 minutes the right SDS can be handed over)?
28	Heading 1 Identification product/company	Is any of the required information missing? If so please indicate which.
29	Heading 2 Substances	Are chemical names, concentration and classification (for the substances) given? If not what is missing
30	Heading 3 Danger	
31	Heading 7 follow up	
32	Heading 8 follow up	
33	Heading 11 volontary	
34	Heading 12 volontary	
35	Heading 15	
36	Correspondence Heading 15 - label	Does the labelling and heading 15 correspond? If not what is wrong?

Annex III Examples of deficiencies for different endpoints

The comments given in the column “Examples of deficiencies” in this Table have been made by the inspectors after their inspections.

Nr	LABELLING	Examples of deficiencies
2	Chemical name of the substances	Incomplete name, substances name missing
4	Danger symbols	Wrong or missing symbol, wrong shape or colour
5	Classification	Could be wrong or missing symbol, R-phrases, indication of danger etc.
6	Indications of danger	Wrong or missing. Quite often linked with symbol - when the symbol is missing the indication of danger is also missing.
7	Risk-phrases	Wrong or missing R-phrases
8	Safety advice	Wrong or missing S-phrases
10	**CMR** phrase and labelling	CMR R-phrases missing
11	Contains elements **hazardous for environment**	Wrong environmental classification such as wrong R-phrases, symbol missing
Nr	**Special provisions under annex V B, C**	
22	Contains **sensitising** substances but not classified	Special phrase missing: “Contains (name of sensitising substance). May produce an allergic reaction”
24	Contains a substance assigned phrase **R67**	R67 phrase missing: “Vapours may cause drowsiness and dizziness”

Nr	Safety data sheet / Headings	
27	Availability of SDS	Missing or not delivered
29	Heading 2 Substances	Substances missing, wrong classification for substances, incorrect chemical name, concentration of substances missing.
30	Heading 3 Danger	Wrong classification, R-phrases missing, poor info
31	Heading 7 follow up	Too limited info, irrelevant instructions, specific uses missing, handling info missing.
32	Heading 8 follow up	Very generic- NO OELV´s, Respiratory protection equipment should be announced more specified, Insufficient type of protection equipment, personal protection measures missing
33	Heading 11 voluntary	Only data given – summary and symptoms description missing, too limited; LD 50 does not tell enough to the user. Sensitizers info missing.
34	Heading 12 voluntary	Data and effects missing, Conclusion missing
35	Heading 15	Wrong classification, R- and S-phrases missing.
36	Correspondence Heading 15 - label	Different classification, R- or S-phrases is given in label compared to heading 15.

Annex IV:
Frequently Asked Questions (FAQs) of the ECLIPS Project

1. Introduction

Annex IV gives an overview of **Frequently Asked Questions (FAQs) (paragraph 2)** about classification, labelling and Safety Data Sheets.

The questions are focussed on the interpretation of following EU Directives:

- Classification & labelling:
  - 67/548/EEC Dangerous Substances Directive, DSD, (2001/59/EC, 28th ATP). 92/32/EEC latest consolidated version.
  - 1999/45/EC Dangerous Preparations Directive, DPD, (2001/60/EC, 1st ATP).
- Safety Data Sheets (SDS):
  - 91/155/EC (2001/58/EC, 2nd amendment).

The FAQs are a co-production of the ECLIPS working group and the countries participant in the CLEEN-network. The FAQs list was started during an ECLIPS Training in Stockholm, November 2002.

They will contribute to clarify certain aspects of the Directives both for the inspectorate and the industry and also to harmonize criteria within the EEA countries, so that the same basic approach is made to comply the legislation about preparations and Safety Data Sheets.

2. FAQs: Classification & labelling and Safety Data Sheets

Directive 1999/45/EC	Frequently Asked Questions
28th ATP, Annex VI, Chapter 3.2.8 2001/60/EC Annex , point 11	**FAQ 1** **Must a preparation be classified as dangerous to be assigned the risk phrase R 67?** **Answer:** No, for preparations that fulfil the criteria for R67 (≥ 15%), R67 shall be assigned irrespectively if the preparation is classified as dangerous or not. For substances however, R67 is an additional risk phrase that only shall be assigned to substances classified as dangerous. This difference between the substance and prep. directives should be lifted to the commission.
Annex II Part A 1.1.2.	**FAQ 2** **Regarding Health Classification by the conventional method when it comes to preparations with substances classified as very toxic, toxic or harmful in lower individual concentrations than the limits specified in Annex I or the corresponding Tables, when applying the general formula of the summatory, the legislation does not say if it is possible or not to add percentages of weight of substances that hold different routes of exposure. It also does not say if you add percentages, with what R- phrases should the preparation be classified for its acute effects on health.** **Nevertheless, for other summatories of acute effects on health, such as Irritants, different routes of exposure are not added.** **For instance: Preparation A** **3% Substance 1 (T+ with R26)** **4% Substance 2 (T+ with R27)** **Answer:** Different exposures routes can be added and the classification of the product should be T+. Nothing in the Directive is in conflict with that. In. 1.1.2. in Annex II, part A it says "each very toxic substance"; there is no specification about the route of exposure. Below Table 1 of Part B it says "the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification". **This has to be clarified in the Directive or in some other way by the Commission.**

Directive 1999/45/EC	Frequently Asked Questions
Article 10,5	**FAQ 3** **How to cope with Article 10,5 in the DPD? For example, is it allowed to mention "biodegradable" on the label of a preparation that is classified as irritant?** **Answer:** This kind of "non-information" should not exist on the label. Only the dangerous properties shall be written on the label. Information should not be contradictory, for example: if the product is classified as N and it says on the label that it is environmentally friendly. However if the product is classified as biodegradable (if reference is made to OECD guideline), it could be mentioned on the product but not on the danger label.
DSD	**FAQ 4** **Classification of preparations with one (or more) component that is also a preparation (for example; *Trade Name X*). Shall classification be done on the basis of** **a) the dangerous substances in the product? or** **b) the component (*Trade Name X*) classification?** **Answer:** Classification shall be done on basis of dangerous substances present in the product. [Alternative a)]
	FAQ 5 **Who is responsible for the labelling: e.g. the producer or a store who is selling a preparation?** **Answer:** Anyone who places a product on the market has a responsibility. The producers or importers have the complete *knowledge* and responsibility for correct classification, labelling and safety data sheets, which the stores can not have. If distributors re-label the products with their company name and address, they should be held responsible for the label. Anyone down the supply chain who modifies the information systems putting their company as the only responsible in labels or SDS, should in fact be responsible for possible deficiencies in those systems along with the producers/importers.
Article 10,2.3	**FAQ 6** **Should the names of R65-substances be mentioned on labels of R65-classified preparations (except if the product is placed on the market in aerosol container/fitted spray container)** **Answer:** They should be mentioned. There is an exception in Art. 10, 2.3.3 and 2.3.5 that says that if there are many names, some could be excluded (but that is in general and not only for R65-classified products)

Directive 1999/45/EC	Frequently Asked Questions
DSD Annex I	**FAQ 7** **Substances that have note H, are at the moment only classified for cancer R45, and/or for R65 effects in Annex I.** **Is it correct that for all other effects/properties, the company has to do a "self-classification" according to the criteria in the Directive?** **Answer:** Yes. Many of these kind of products should be classified also for their acute toxicological effects and for being dangerous for the environment Note: (CONCAWE has a list of substances which are self-classified for environmental effects and other health effects too: www.concawe.org).
DSD Article 24	**FAQ 8** **Dimensions of the symbols are usually too small in inspected products. What minimum size should we demand?** **Answer:** The "dangerous part" of the label should only contain the "danger" information and the symbol should cover at least 1/10 of this area. Other information should not be included in this area. The minimum dimensions of this area are established regarding the package capacity, in Annex VI of the DSD. .
DSD Annex I	**FAQ 9** **Danger for the Environment is a danger category not taken into account in the individual concentration limits in Annex I substances.** **Is the interpretation then that the Tables in Directive 1999/45/CE shall always be followed to use the calculation method?** **Answer:** Yes, according to criteria and tables in Annex III in the 1999/45/EC. In the 29th ATP this will be corrected.
DSD Annex I (class. list) Article 12,2	**FAQ 10** **How would metal lead be classified, which is not included under lead substances in Annex I? The product is a solder paste which contains lead powder.** **Answer:** This kind of product should be classified in the same way as other lead substances. Metal lead (powder) causes health problems when heated up and therefore the assumption in Article 12,2 shall not apply.
Article 5	**FAQ 11** **Labelling of preparations concerning their physico-chemical properties, for example flammability. When companies refuse to perform assays, and there are e.g. flammable components of the preparations, shall we look at the worst-case possibility, and demand classification in one of these categories?** **Answer:** Yes. The classification should be based on the worst case consideration until the company proves the opposite.

Directive 1999/45/EC	Frequently Asked Questions
2001/59/EC (28th ATP), Annex VI, Chapter 4	**FAQ 12** **Labelling of CMR substances and preparations. It says: "...and it shall be assigned the symbol T (for instance) and the risk phrase ...45 (for example)." But it says nothing about the indication of danger.** **For the rest of categories, it says: "...and it shall be assigned the symbol Xn (for instance), the indication of danger "Harmful" and the risk phrase ...42 (for example)."** **Answer:** It can not be demanded according to the directive. It is deliberately written so for the CMR-effects. Some countries have implemented the Directive at this point in a different way and demand it in their national legislation.
Article 10,1.1(b)	**FAQ 13** **Requirements in labelling of a NDP (Non Dangerous Preparation) covered by the Directive 45/1999/EC** **Answer:** Concerning labelling: The NDP can only be commercialized when the label contains: a) The commercial name of the preparation b) Name, complete address and telephone number of the person/company responsible of its placing in the EU market c) Special provisions specified in parts B and C of Annex V of the DPD.

2001/58/EC SDS- directive, unless other directive is given	Frequently Asked Questions
Heading 2 Article 3,3 (the table) 1999/45/EC	**FAQ 14** **According to the table in Article 3.3 in DPD the limit for sensitising properties is 1%. But in Annex V there is a limit specification for 0,1% limit for sensitising products? At which concentration must sensitising substances be mentioned under Heading 2?** **Answer:** Under Heading 2 the limit for sensitising substances should be 0,1%. In Heading 2 in the SDS Directive it says literally that dangerous substances in the preparation should be indicated along with its concentrations or concentration ranges, if they are present in concentrations above those expressed in art 3.3 of DPD, unless lower limits are established in Annex I of the DSD, or Annex II; III or V of the DPD. For sensitizing substances the 0,1% limit established in Annex V is enough to inform on the label about the danger of allergic reactions. Heading 2 has to give information on the hazards with which the components of the prep may contribute to the dangerous properties of the preparation.
Heading 2 DSD	**FAQ 15** **Coal and oil derivatives, with notes J, K, L, M, N, P, Q and R.** **If the company can show (e.g. data from analysis) that the substance complies with the content of these different notes, this information (the content in the carcinogenicity marker or if it is less than the limit ststed in the Notes) should be clearly stated in the SDS.** **If not, by omission, substances with these notes should be classified as carcinogenic?** **Answer:** Companies should put this information under Heading 2. Otherwise, the product should in fact be classified as carcinogenic, by omission, because these Notes mean the possibility of **an exemption** from the general classification as carcinogens these products already have in Annex I of the DSD. Note: See CONCAWE´s criteria in www.concawe.org
Heading 15	**FAQ 16** **Is it necessary to include the names of the substances that should be mentioned on the label under Heading 15?** **Answer:** Yes. All the "danger information" that is mandatory on the label, also should be under Heading 15.
General	**FAQ 17** **Can one safety data sheet be used for several different preparations?** **Answer:** No, not if they differ in classification. Only if they are very similar in formulation, for instance different colours (nuances) and the components that make the difference in the similar formulations do not modify the dangerous properties of the preparation.

2001/58/EC SDS- directive, unless other directive is given	Frequently Asked Questions
1991/155/EC Article 1,2	**FAQ 18** **When a SDS is updated with new information there is a 12 month rule (an updated SDS shall be sent to all customers that have bought the product within the last 12 month). Shall the company distribute new SDS for every little change in the SDS or are only important changes valid for the 12-month rule?** **Answer:** Distribution of updated SDS are only necessary when there are important changes in the SDS, that concerns the information on the dangerous properties and precautionary measures, e.g. new classifications or relevant , more detailed information in the different Headings.
Heading 1 1.3	**FAQ 19** **Does a national company name has to be put under heading 1?** **Answer:** Yes, if possible (if there is a national supplier or a supplier with an address in the country)
Heading 1 1.4	**FAQ 20** **Is a national emergency telephone number demanded?** **Answer:** There should be a national emergency telephone number. Support for that can be found in Article. 17 of DPD. If we consider what is the sense of an emergency number (mainly help to urgent medical assistance or also proper assistance in an accident affecting the environment) a national emergency nº is the only reasonable option.
Heading 2	**FAQ 21** **Concentration ranges under Heading 2, that crosses classification limits. How to look at it?. For example: A Xi classified substance is given the interval 10-30% and the classification limit is 20%?** **Answer:** We can recommend companies not to cross a classification limit when setting concentration intervals. If the concentration rate crosses such a limit, the higher limit should be used for the classification (worst case), unless the company prefers to change the SDS information based on the real concentration of the component in the product.
Heading 2 2.2 (ii)	**FAQ 22** **Is there no limit for substances with workplace exposure limits for preparations classified as dangerous, regarding Heading 2?** **Answer:** According to Heading 2.2 there is no limit.

2001/58/EC SDS- directive, unless other directive is given	Frequently Asked Questions
Heading 11	**FAQ 23** **Heading 11 can be interpreted differently. What kind of information shall be given under this heading?** **Answer:** A description on what effects and symptoms are produced by the product (both substances and preparations) is very important. This information is sometimes missing or put under heading 3 instead of under heading 11 (the most important parts from heading 11 can be put under heading 3). Only information on data is not enough. To give only the R-phrases is not sufficient.
Heading 11	**FAQ 24** **A product which contains a lead substance, but the dangerous properties of lead is missing under this heading (only R-phrases given). How to look at this lack?** **Answer:** That is not enough. Special symptoms caused by lead have to be mentioned.
General	**FAQ 25** **Requirements in SDS of a NDP (Non Dangerous Preparation) covered by the Directive 1999/45/EC** Concerning SDS: - If the NDP contains > or = 1% for non gaseous preparations and > or = 0,2% for gaseous preparations of at least: one dangerous substance or a substance with EU exposure limits at workplace, an SDS with "proportionate information" should be made and delivered at request. - If the NDP is only affected by the Annex V of the DPD and contains a percentage of a dangerous substance or a substance with EU exposure limits at workplace, smaller than those described above, no SDS will be required.

Annex V: Interpretation Questions (IQs) of the ECLIPS project

1 Introduction

Annex V gives an overview of **Interpretation Questions (IQs) (paragraph 2)** about classification, labelling and Safety Data Sheets.

The questions are focussed on the interpretation of following EU Directives:

- Classification & labelling:
  - 67/548/EEC Dangerous Substances Directive, DSD, (2001/59/EC, 28th ATP). 92/32/EEC latest consolidated version.
  - 1999/45/EC Dangerous Preparations Directive, DPD, (2001/60/EC, 1st ATP1).
- Safety Data Sheets (SDS):
  - 91/155/EC (2001/58/EC, 2nd amendment).

Interpretation Questions, IQs, are a co-production of the ECLIPS working group and the countries participant in the CLEEN-network. The IQs list was started during an ECLIPS Training in Stockholm, November 2002. IQs have not reached a quorum, therefore to read Chapter 3 on “Conclusions and Recommendations” is suggested.

2 IQs : Classification & labelling and Safety Data Sheets

Directive 1999/45/EC	Interpretation Questions
General	**Interpretation Question 1** **Articles or chemical products, is Directive 1999/45/EC applicable?** **Examples:** **- plastic master batches with e.g. lead chromates (used as colorant)** **- pens (markers), ink cartridges** **Answer:** No consensus. Need of clarification.
General	**Interpretation Question 2** **How are multi language labels to be made and inspected?** **Answer:** The information of each single language should not be spread out. One language should be put together on the label to make it easy to read. Multi language labels can only be accepted if the product has the same classification in all languages. Additionally, it must be assured that the information on the label is readable Need to have a harmonized answer in a Technical Document.
Annex II	**Interpretation Question 3** **How shall this non-gaseous product be classified? The product contains:** **Substance A: 0,5 % T+; R27** **Substance B: 15 % T; R25** **Substance C: 30 % Xn; R20** **Answer:** **T+; R27?** 0,5 % table limit < 1% **No**, go to next level **T; R24, 25?** 0,5/1 + 15/25 = 1,1 **Yes** **Xn R20?** 30% table limit > 25% The product shall be classified as; T;R24/25, R20 The procedure under Annex II, Part A of Dir. 1999/45/EC ("Procedure for evaluation of health hazards") foresees that the evaluation has to proceed "stepwise as follows". In practise it means that it is necessary to start with the most dangerous category "very toxic" going down to "harmful" and to check step by step if the peparation - depending on the substances contained - will be very toxic, toxic or harmful, in this order. **This has to be clarified in the Directive or in some other way by the Commission**

Directive 1999/45/EC	Interpretation Questions
General	**Interpretation Question 4** **Washing powders shall often be classified as Irritant (Xi) with Xi-classified substances over 20%. The industry often refers to the AISE guidelines, when Xi classification and labelling is not done. How should these products be classified?** **Answer:** The products should be classified and labelled as Irritants, according to the conventional method or testing according to criteria given in Annex VI in the Directive 67/548/EC. Briefly speaking, the AISE-guidelines say that instead of the "conventional (=calculation) method", which is usually applied to evaluate the skin and eye irritation potential, for detergents and cleaning products specific classification and risk-evaluation methods (Human Patch Test, Low Volume Eye Test) should be conducted on the preparation itself. As far as we know, there is no such scientific proof of the fact that the calculation method (which does not entail the use of animals!) and the methods referred to in Directive 67/548/EEC, are not suited to evaluate the skin and eye irritation caused by detergents and cleaning products. Moreover, according to our knowledge no scientific proof is existing of chemical antagonisms in the preparation, which would justify a correction of the results achieved from the calculation method. This means that according to EU-Chemicals legislation most detergents have to be classified as being "Irritant". Need to have a harmonized answer in a Technical Document.
Article 11 6. b)	**Interpretation Question 5** **In Article 11, 6. b) there is an assumption that says that the transport symbol is enough for labelling. Does this mean that CMR-, Xi- or N-products do not need to be labelled with the danger symbol?** **Answer:** It is very unclear in the directive how to label CMR and Xi classified pre-parations regarding transport of dangerous goods legislation, as there are no transport symbols related to these categories. If preparations are packaged in an outer and an inner packaging, it is sufficient to label the outer packaging according to the transport label. The inner packaging(s) have to be labelled with all labelling elements according to Directive 1999/45/EC, including all relevant danger symbols. If a preparation has only one packaging for transport, this packaging has to show as danger symbols only those relevants for transport, but in case of N-classified products, the criteria should be that the orange and black N-symbol has to be put on the label unless the product is only classified for the environment (or as Xi or CMR also), in which case the transport symbol nr 9 has to be on the label, because it includes "Environmental hazards". In the case of a product requiring only CMR or Xi labelling, on the (single) packaging in addition to the transport information, also the product name, dangerous ingredients, the person being responsible for putting the preparation on the market, as well as R-phrases and S-phrases for all dangerous properties have to appear. Should there be an obligation to keep orange and black symbols on label, specially for CMRs preparation? **Could this be clarified in the Directive?**

Directive 1999/45/EC	Interpretation Questions
Article 12 3(a)	**Interpretation Question 6** **How shall preparations delivered in bulk (containers, tankers, tank wagons etc) be labelled?** **Answer:** For bulk transportation of chemical products, if the recipient (cistern, tanks, wagon...) is only a transport element, which means, it contains the preparation only during the transportation of the goods, DGT (Dangerous Goods Transport) legislation should be applied in labelling, and SDS should be delivered to the final destiny. If the recipient is also the final package of the preparation, which means, it is left at final destiny to contain the product, then this packaging should be labelled according to the DGT legislation and the Directive 1999/45/CE, and SDS should be delivered to final destiny. Need to have a harmonized answer in a Technical Document.
DSD Annex VI 3.2.5	**Interpretation Question 7** **Is the pH a determining factor for classification and labelling?** **Answer:** If the pH is < 2 or > 11.5 the product should be classified as corrosive unless an in vitro test (as described in the criteria) proves otherwise. But what happens when there are Annex I substances and the calculation method based on individual concentration limits established either in Annex I or in Calculation Tables gives an Irritant classification while pH gives Corrosive? Taking into account Annex I is mandatory. Need to have a harmonized answer in a Technical Document.
	Interpretation Question 8 **How should inspectors deal with the same substance with different labelling (self classification)?** **Answer** This is always a problem. It could be the case that different companys classify one substance differently, and that it is OK according to the legislation. Some substances might the authorities have more knowledge about them or good arguments for a different classification, but it is always a case by case situation. Need to have a harmonized answer in a Technical Document.

Directive 1999/45/EC	Interpretation Questions
DPD Article 10	**Interpretation Question 9** **Chemical names of dangerous substances in preps labels that contribute to classify the preparation, present below their individual concentration limits** In article 10,2.3 it is stated that for T+, T, Xn, C preparations (acute toxic effects) the names of the T+, T, Xn, C substances that are present above their lowest individual concentration limits (limit Xn or Xi), should be given in the label. What names should be stated in the case that a preparation is classified as T+, T, Xn, C (acute toxic effects) by application of the formulas stated in Annex II, Part A of the Directive, used when T+, T, Xn, C substances are present below their lowest individual concentration limits? Proposal: All names of T+, T, Xn, C substances that contribute to the classification of the prep as T+, T, Xn, C should be given, even if they are below their Xn, Xi limits. Should be stated in the Directive 1999/45/EC
2001/58/EC SDS- Directive	Interpretation Questions
Article 1 1 (a)	**Interpretation Question 10** **SDS on request of professional users. Are there differences depending on where in the supply chain or different kind of stores? Must a store give the SDS at once or is there a time limit?** **Answer:** All agreed on that the store does not have to actively hand over a SDS, without being asked. But no consensus was reached about the time limit. Need to have a harmonized answer in a Technical Document.
DPD Article 14 2.4	**Interpretation Question 11** **SDS supplied electronically? What does electronically mean?. Must it be an active sending by e-mail from the company or is it enough to have the SDS on a homepage?.** **Answer:** Yes, the SDS may be supplied electronically, provided that the receiver accepts it. It is not enough to have SDS on the homepage. It is the responsibility of the companies to actively give the SDS to the customer and that is the only way to ensure that the customer gets the correct SDS. Need to have a harmonized answer in a Technical Document.
Heading 12	**Interpretation Question 12** **What information shall be given under this heading?** **Answer:** Conclusions are very important, and should be given. It should also be clear if the given data is for the whole product (only tox) or for certain substances. **The text in the directive is hard to interpret.**

Directive 1999/45/EC	Interpretation Questions
Heading 2	**Interpretation Question 13** **SDS of preparations made from substances or other preparations with CMR ingredients (Notes P, K,...): Information on Heading 2.** **When a preparation contains a substance which is classified on the basis of its content of a CMR ingredient, subject of a specific Note in the DSD (e.g.: Note P or K), the preparation´s classification is unclear.** **If the substance is petroleum oil present in a preparation in a 10% w/w and contains 1% of bencene, therefore classified with R45, following the general rule of the calculation method, the preparation would also be classified with R45. This can lead to a situation where preparations containing more and more diluted petroleum or carbon derivatives with almost no content of the carcinogen, are still classified as carcinogenic products.** **Answer:** The approach should be to classify the preparation on the basis of its final content of the CMR ingredient. In these cases, then, companies should always specify the CMR ingredient´s maximum content in the final preparation (or in the substance, ingredient of the preparation) in Heading 2 of the SDS, as it is essential information on the dangerous components of this preparation, and determines its classification, whether it is over the limits established in the Notes of Annex I of DSD, or not. Needs to be specifically included in the SDS Directive
Article 1 1(b)	**Interpretation Question 14** **In SDS of non dangerous preparations delivered at request for professional users, what is the meaning of "proportionate information"?** Answer: The contents of such expression should be specifically included in the SDS Directive

Annex VI Glossary

C

C&L	**C**lassification and **I**abelling
CLEEN	**C**hemical **L**egislation **E**uropean **E**nforcement **N**etwork
CMR	**C**arcinogenic, **M**utagenic and/or toxic for **R**eproduction

D

DE	Germany
DG ENTER	Directorate General Enterprise
DG ENV	Directorate General Environment
DPD	**D**angerous **P**reparations **D**irective
DSD	**D**angerous **S**ubstances **D**irective
Dir	**D**irective

E

EC	**European Commission**
ECLIPS	**E**uropean **C**lassification and **L**abelling **I**nspections of **P**reparations, including **S**afety Data Sheets
EEA	**European Economic Area**
EU	**European Union**

F

FAQs	**F**requently **A**sked **Q**uestions

G

GM	ECLIPS **G**uidance **M**anual

I

IQs	**I**nterpretation **Q**uestions

M

MSs	**M**ember **S**tates

Q

Q1	Questionnaire 1: Company information (Report form) of the GM
Q2	Questionnaire 2: The inspected products (Report form) of the GM

R

R67	Vapours may cause drowsiness and dizziness

S

SDSs	Safety Data Sheets