CLEEN
Chemical Legislation European Enforcement Network

EuroDeter

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Inspection and law enforcement were conducted under the regulatory framework existing during the EuroDeter inspection campaign (2012 - 2013).

Contents

Abstract

CLEEN conceived, planned, coordinated and evaluated an enforcement project focussing on detergents placed on the market and their compliance with the legal obligations which they are subject to:

- Regulation (EC) No. 648/2004 (the Detergents Regulation, 'DETER')
- Directive 1999/45/EC (the Dangerous Preparations Directive, 'DPD')
- Directive 98/8/EC (the Biocidal Products Directive, 'BPD')

The project is called EuroDeter. It was managed during 2012 – 2014.

In total 12 countries participated in the project executing very complex inspections and reported about their findings in 319 companies, thereby screening 907 detergents.

This report gives an overview of the most striking observations.

Almost 70 % of the detergents screened during the inspection campaign are non-compliant with at least one of the cited legislations.

This report gives also some elementary recommendations to remedy the present situation.

Summary

1.1. Introduction

CLEEN conceived, planned, coordinated and evaluated an enforcement project focusing on detergents placed on the market and their compliance with the legal obligations they are subject to:

- Regulation (EC) No. 648/2004 (the Detergents Regulation, 'DETER')
- Directive 1999/45/EC (the Dangerous Preparations Directive, 'DPD')
- Directive 98/8/EC (the Biocidal Products Directive, 'BPD')

The project is called EuroDeter and the Manual was developed and distributed by the working group (Belgium and Spain) among participating countries in December 2011. It was managed during 2012 – 2014 following the usual CLEEN project phases. The EuroDeter Final Report draft was released in the 15th CLEEN Conference in Utrecht, The Netherlands, in September 2014 for discussion.

In total 12 countries: Belgium (BE), Estonia (EE), Finland (FI), Germany (DE), Ireland (IE), Latvia (LV), Lithuania (LT), Poland (PL), Slovenia (SI), Spain (ES), Sweden (SE) and Switzerland (CH) have participated in the Project, completing detailed inspections.

The Project Report aims to provide an insight into the degree of compliance with DETER in Europe by the industrial sector involved in the manufacture and placing on the market of detergents and/or surfactants depending on their specific purpose: for the general public, industrial or institutional sectors, or both. It also aims at enforcing compliance with related legislation, such as BPD and DPD.

1.2. Number of inspections

In total 907 products were examined in 319 companies. The number of products and companies inspected per country varies widely. On average 20 companies were inspected per participating country and more than 50 products were inspected per country.

1.3. Companies description

The examined companies are considered according to their size, role and knowledge of the DETER and whether or not they are affiliated to a professional association.

The Report concludes that most of the inspected companies are small and medium enterprises (92%), the majority being micro companies (1 to 9 workers).

The results show that over 80% of inspected companies have roles as formulators or packagers working for their own account ("DUs") or distributors ("D") (creating or changing the labels). Therefore, they are responsible for ensuring compliance with the information requirements set out under DETER, especially with regards to labelling.

1.4. Products description

The most common profile (99%) of the inspected products is a mixture placed on the market as detergent under DETER, used either by the general public or by professional users for institutional or industrial purposes (50%/50%)

1.5. Project findings

The Project findings have been related to the three legislative provisions mentioned in the introduction above.

1.5.1. Enforcement of DETER

The placing on the market of detergents is subject to different labelling or packaging provisions (Article 11, Annex VII parts A and B of DETER) and others (DPD, BPD, the CLP Regulation ((EC) No. 1272/2008)). For general public use, a detergent requires specific labelling as determined by DETER informing consumers about the presence of possible allergens such as fragrances and preservation agents, and requires compulsory information to be provided on the internet (list of all ingredients in the product as per Annex D of DETER). For detergents intended for the industrial/institutional sector, i.e. not available to the general public, those specific requirements do not have to be fulfilled on the label or on a website if the information is provided by means of a technical data sheet, safety data sheet or in a similar manner.

The highest non-compliance rate was found regarding the obligation to "list the allergenic substances" on the label. More than 40% of the inspected products did not include, where applicable, all mandatory allergenic fragrances on the label or packaging.

The second highest non-compliance rate was found in the obligation to "list the preservation agents" contained in the mixture: over 30% of the inspected products lack that information, where applicable, on the labelling or packaging of the detergent.

With regard to the "web site address related to the list of ingredients (LI)" (Annex VII D of DETER), the Report results show that in almost 30% of the inspected detergents for the general public, the website address is not mentioned on the label/packaging. The highest level of non-compliance related to this obligation was that the LI is not available on the website address included on the label for 46% of the examined products.

Results on “laundry detergents for the general public” requirements (Annex VII B of DETER) show that less than 70% of products inspected bear the information on standard washing machines loads on the label.

The label has to provide “indications of use and/or special precautionary measures to be taken, if required” (Article 11.3 of DETER). 85% of inspected products are compliant with this obligation. However, DETER does not provide clear details or guidance on what indications of use or measures should be mentioned and how they could be included on the label.

For medical professionals, detailed information on the composition of the detergent is provided via the “ingredient data sheet, IDS” (Article 9.3 of DETER). The IDS content is prepared according to Annex VII C of DETER. For 23% of the inspected products, no IDS was available. For 14% of inspected products, the IDS was not made available for inspectors. 26% of the IDSs were not in conformity with the requirements listed in Annex VII C.

Article 9 of DETER and associated Annexes require that surfactants used in detergent products are biodegradable. So, information concerning the “biodegradability” tests is required. More than 97% if the surfactants in the checked detergents were found to be biodegradable, compliant with the criteria of DETER

1.5.2. Link to the Biocidal Products Directive 98/8/EC (BPD)

Certain requirements under BPD are linked to Article 3 of DETER. 6% of the inspected detergents had a biocidal claim. Product type 2 (Private area and public health area disinfectants and other biocidal products) was the most often found product type. In addition, many detergents contain an in-can preservative (biocidal product type 6) for controlling microbial deterioration to ensure the shelf life of a product. 65% of the inspected detergents contained a PT6 active substance. Of them, 13% have proven to be illegal, formaldehyde being the most frequently active substance used in this scenario.

1.5.3. Link to the Dangerous Preparations Directive 1999/45/EC (DPD)

The majority of detergents in the market are mixtures classified as dangerous (DPD obligations or the CLP Regulation (EC) No. 1272/2008). 65% of the inspected products were classified as hazardous of which 9% were in accordance with the CLP Regulation with regard to labelling.

For detergents classified according to the DPD, more than 80% of them were classified as corrosive/irritant.

Non-compliance with specific DPD labelling requirements was found in 20 to 30% of inspections regarding: lack of danger symbols and indications of danger, risk-phrases (R-sentences), safety advices (S-phrases), chemical names of the dangerous

substances in the mixture, information on sensitizing properties and special packaging requirements for dangerous mixtures handed to the general public. The findings are similar with those of CLEEN's ECLIPS Project in 2003 – 2004.

Special attention was given to detergents classified as sensitizing (R42 and/or R43), or those which contained sensitizing substances without being classified (DPD Annex V phrase). 91 of the inspected products were subject to labelling obligations regarding sensitizers, from which 50% failed to mention all information required on the label.

1.5.4. Overall compliance

With regard to the findings from the EuroDeter project as carried out in 12 countries, it was found that more than 2 out of 3 products are non-compliant with at least one of the relevant legislations (DETER, DPD and BPD).

1.5.5. Legal actions

Inspectors took measures in almost all cases of non-compliance.
The legal actions taken were as follows: 48% by written advice, 38% by order, 9% by verbal advice, 3% others. There were relatively few actions such as fines, enjoinment and criminal complaint taken by inspectors during this project.

1.6. Conclusions and recommendations

1.6.1. Conclusions

Twelve countries (EU plus Switzerland) were involved in the development and operation of the EuroDeter inspection project under the CLEEN umbrella. Detergents were inspected and their level of compliance with the major provisions to be applied (DETER, DPD, BPD) were checked.

With regard to DETER, the results show that the Regulation meets its goals concerning environmental protection (detergents biodegradability). Unfortunately the results are not so favourable with regard to protection of health, especially when one looks at the compliance levels with the provisions which aim to protect the general public by providing sufficient information on potential allergens present in the commercial mixtures, either on the label or on the internet.

Downstream users and distributors (creating or changing the label) responsible for labelling and placing detergents on the market in compliance with DETER and DPD, do not comply with the requirements to provide information about allergens (fragrances and in-can preservatives) present in the mixtures (DETER). The findings of the project show that frequently LIs cannot be found on the Internet, and also that the special packaging requirements in the DPD/CLP, intended to protect vulnerable population (sensitized persons, children and blind persons) are not met.

Most of the inspected companies are SMEs, specifically micro companies (formulators, packagers, distributors) with incomplete knowledge of the provisions. So, the legal framework may be too complex to be correctly understood and interpreted.

Companies and inspectorates believe that it is a challenge to comply with the three pieces of different legislation: DETER, DPD and BPD, as all of them regulate similar aspects, for instance, how to include the contents of the mixture on the label or other means, however, there is little consistency between the labelling requirements.

1.6.2. Recommendations

As a potential resolution, it is proposed that the cited legal framework is simplified so that with a minimum of provisions, maximal protection of the consumer and the environment is ensured, as well negligible internal and external safety risks taking into account that from June 1st 2015, a new classification and labelling methodology will enter into force raising the level of health and environmental protection, especially with regard to the information on hazardous substances and their presence in the mixtures.

Special attention should be drawn to lack of compliance in packaging in regard to vulnerable population, as these same requirements are included in CLP, so that results obtained in EURODETER can give an insight into the level of compliance regarding this aspect of the regulation.

Awareness raising initiatives via information campaigns can also be seen as productive enforcement actions, specially directed towards small and micro size companies.

CLEEN invites the European Commission, the International Association for Soaps, Detergents and Maintenance Products, and all other relevant public and non-public stakeholders to acknowledge the findings of CLEEN's EuroDeter project and use them for fruitful discussions in regard to future activities related to the EU legislation on detergents and the protection of health and the environment.
The CLEEN members ask the Commission to take account of the findings and consider streamlining the Detergents Regulation in order to ease the legislative burden currently placed on SMEs with an aim to ensure consistency between the labelling provisions required under CLP/DPD, the requirements of Annex II of REACH in relation to SDSs and the labelling and information requirements in the Detergents Regulation.

1 Introduction

Many detergents are known to cause allergies due to the sensitizing properties of some of their components. Their widespread use in households can be a health risk, especially for vulnerable individuals like children, persons with poor health or other naturally sensitive persons.

The large quantities of detergents used and the possible low biodegradability of surfactants they contain, constitute a potential environmental risk, because of the ensuing menace of surface and marine waters' pollution. Detergents are introduced into the environment mainly via sewage. Surfactants used should be biodegradable and meet acceptable or existing standards for biodegradability. The use of those surfactants that are unacceptably harmful, should be restricted or even banned.

The European legislator has created a regulatory framework to reduce cited risks to an acceptable level. It is up to the Member States to enforce these safeguarding provisions.

Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (DETER) harmonizes the rules for placing on the market of detergents, including surfactants. With regard to human health protection, it focuses on the allergic reaction to exposure to certain chemicals like potent sensitizers contained in detergents formulations, mainly fragrance substances and preservation agents. To keep consumers informed on the chemical nature of the components of the commercial mixtures, DETER obliges manufacturers to offer on-line information about the ingredients used, aside from labelling obligations. Medical personnel should be able to obtain information directly from the manufacturer or from a specific public body designated by the Member State, about the ingredients of a mixture, to establish a link if it is the case, between exposure and patients' allergic or other responses.

The environmental protection requirements in DETER deal with the concept of biodegradability and are applicable only to surfactants and detergents containing surfactants. Formerly, the governing legislation addressed only primary biodegradability (PB) and anionic and non-ionic surfactants. DETER though extends the requirements to all surfactants. It emphasizes ultimate aerobic biodegradability taking the potential toxicity of persistent metabolites into account. This means paying attention to the capacity of surfactants or detergents containing surfactants for total oxidation to carbon dioxide, water and mineral salts (mineralization). Ultimate aerobic biodegradability should be evaluated by one of the test methods listed in the Annex III of DETER.

The Biocidal Products Directive 98/8/EC (BPD) requests Member States to regulate the placing on the market of biocidal products. As stated in DETER, detergents and surfactants for detergents shall comply where relevant, with the BPD. Preservation

agents used in detergents are biocides belonging to Product-type 6. Hence, they have to comply with the BPD as well.

As most detergents placed on the market are mixtures, they must currently comply with the obligations set out in Directive 1999/45/EC (DPD) regulating the classification, packaging and labelling of dangerous preparations (until 31st May 2015) or with Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP). CLP harmonises the rules on classification, labelling and packaging for hazardous substances and mixtures and obliges suppliers to classify, label and package substances and mixtures placed on the market accordingly

CLEEN's EuroDeter project aims at assessing the presence of certain chemicals (fragrances, enzymes, preservation agents i.e. biocidal products type PT6) in detergent formulations as well as compliance with the requirements on relevant information management. Compliance with cited instruments has been included in this project.

The primary goal of the EuroDeter Project is to contribute to the implementation of DETER by inspection and enforcement. Prior to 2012, there had not been a widespread harmonized enforcement initiative throughout the European Economic Area (EEA) focussing on this Regulation. Also, the compliance with the Biocidal Products Directive was investigated by paying attention to the preservation agents present in the detergents formulations. The compliance with the labelling and packaging obligations for mixtures as imposed by the Dangerous Preparations Directive was also checked.

The EuroDeter project aims at contributing to harmonized enforcement of the detergents legislation and promoting good cooperation between enforcement authorities, nationally and internationally.

At the 11th CLEEN (Chemicals Legislation European Enforcement Network) Conference in Sucevita (Romania) in 2010, it was agreed that an Enforcement Project focusing on Regulation (EC) No 648/2004, on detergents, should be prepared and carried out. At the presentation of this new project, several countries showed their interest to participate and the EuroDeter working group (Spain & Belgium) was established.

This working group developed a practical and understandable Project Manual and a consistent harmonized Questionnaire to collect the results. A first draft was presented at the 12th CLEEN Conference, in Larnaca (Cyprus), in September 2011 and national commitments to participate in the Project were obtained.

In December 2011 the final documents to perform the inspections (Project Manual & Questionnaire) were adopted and distributed only among the participating inspectors. The preparation phase ended in the first quarter of 2012 with the development of an excel tool to collect final results.

The operational phase took place in 2012-2013 and a presentation of preliminary impressions of the findings was given at the 14th CLEEN Conference in London, in September 2013.

This report aims at presenting the main results of the EuroDeter project which was carried out in 12 countries. It provides an insight into the degree of compliance with DETER in Europe by the industrial sector involved in the manufacture and placing on the market of detergents, cleaners and/or surfactants. It also aims at looking at the compliance with related legislation, such as BPD and DPD.

2 Project Findings

2.1 Number of inspections

12 countries of the CLEEN network participated in the EuroDeter project. The participating countries were Belgium (BE), Estonia (EE), Finland (FI), Germany (DE), Ireland (IE), Latvia (LV), Lithuania (LT), Poland (PL), Slovenia (SI), Spain (ES), Sweden (SE) and Switzerland (CH).

They are presented in following table together with the number of inspected companies and products per country.

Country	Inspected Companies	Inspected Products
BE	28	90
CH	27	54
DE	8	8
EE	11	33
ES	117	352
FI	9	42
IE	10	25
LT	10	31
LV	23	95
PL	21	56
SE	38	104
SI	17	17

Table 1: Participating countries and number of companies and products inspected

The degree of participation in this project is 39% of the CLEEN network (12 participants out of 31 members of CLEEN).

In total, inspection findings regarding 319 companies were reported. The number of companies inspected per country varies widely. On average, about 20 companies were inspected per participating country.

In total, findings on 907 products were reported. Like the inspected companies, also the number of products inspected per country varies widely. On average, more than 50 products were examined per participating country, and 3 products per inspected company.

Total number of inspected …	**in the EURODETER Project**
Companies	**319**
Products	**907**

Table 2: Number of inspected companies and products

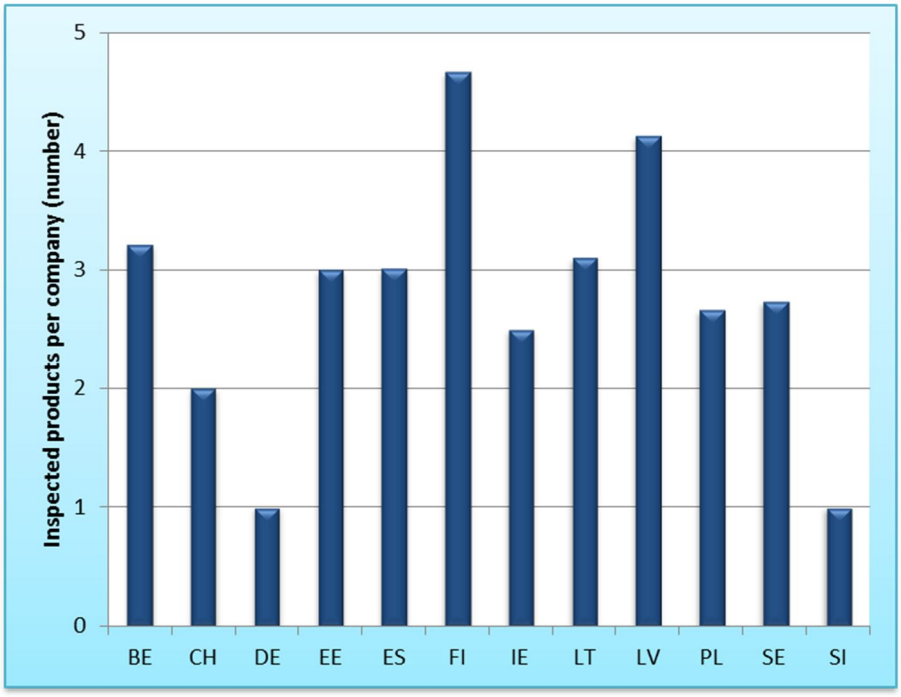

Figure 1: Average number of inspected products per company per participating country

2.2 Companies' description

2.2.1 Companies' size

Article 2 of Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises states:

> 1. The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.
>
> 2. Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million.
>
> 3. Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million

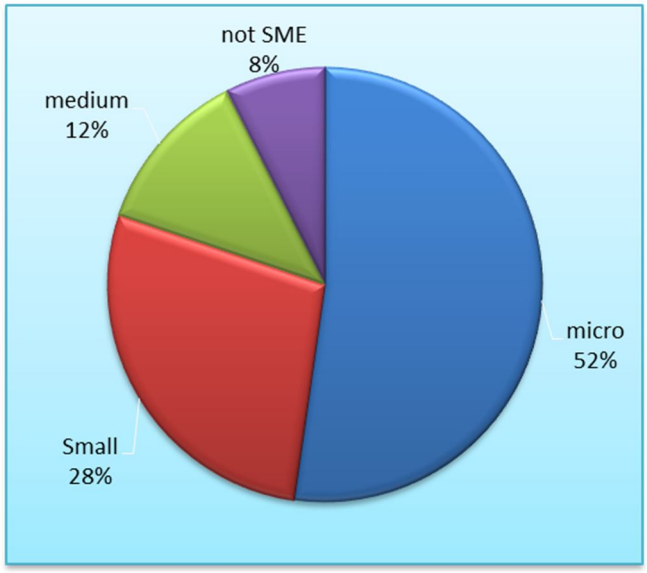

Figure 2: Overview of the company size of the inspected companies

The data in the reports of the participating countries show that most of the inspected companies are SMEs (92%). The majority of the inspected companies are micro companies (1 to 9 workers).

2.2.2 Companies' role

The inspected companies can assume one role or different roles simultaneously.

The roles have been classified as follows: Manufacturer *of a surfactant* (M), Importer *of a surfactant or detergent* (I), Formulators or Packagers *working for their own account* (DU), Distributors (*creating or changing the labels*) (D) and End users (DU (end user)) .

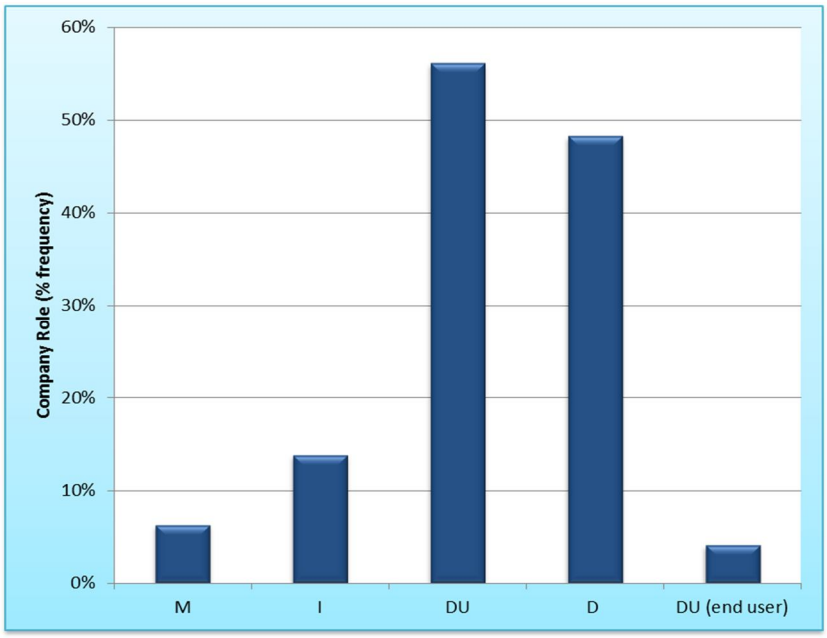

Figure 3: Role of the inspected companies

DETER defines as ‘Manufacturer’ the natural or legal person responsible for placing a detergent or a surfactant for a detergent on the market; in particular, a producer, an importer, a packager working for his own account, or any person changing the characteristics of a detergent or of a surfactant for a detergent, or creating or changing the labelling thereof. Those companies who are manufacturers, as defined by DETER, must comply with the labelling, packaging and information requirements set out in the Regulation.
Distributors (D) who create or change the labelling of a detergent product are included in this definition, and, along with the formulators and packagers (DU), accounted for over 80% of inspected companies.

Over 96% of the inspected companies corresponded to the definition of Manufacturer.

End users do not have any duties regarding labelling or provision of information under DETER. They accounted for just 4% of the inspected companies.

2.2.3 Companies’ knowledge of DETER / affiliation to a professional association

The inspectors reported their appreciation of the knowledge inspected companies had about DETER. They queried also whether or not the company was affiliated to a professional stakeholder association.

In approximately one third of the inspected companies, companies’ knowledge about DETER was reported to be at least, incomplete.

A majority of companies (62%) declared not to be associated to any professional stakeholder association.

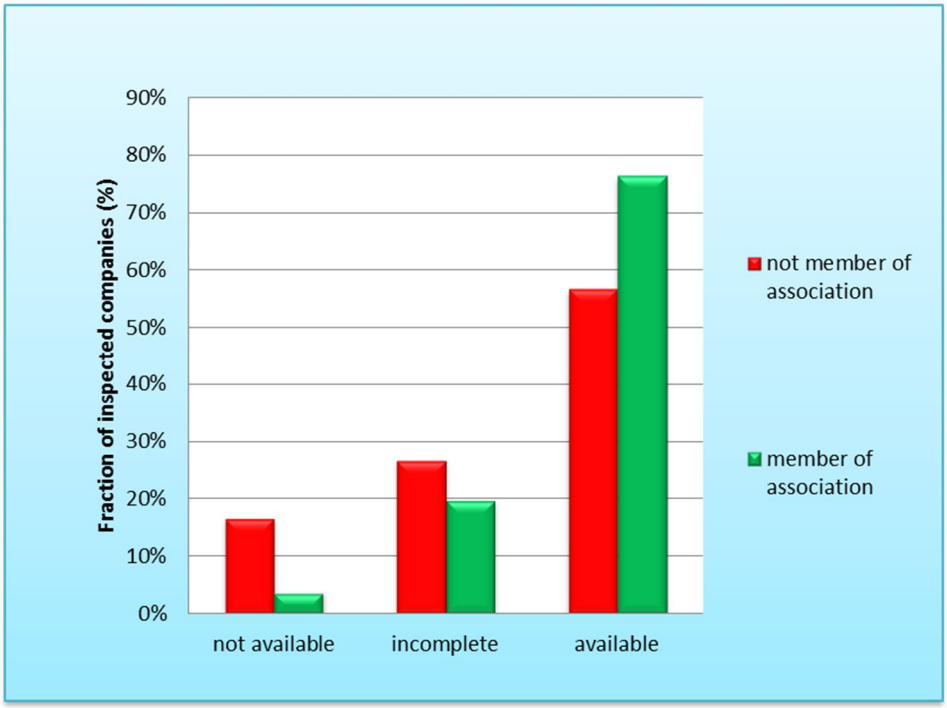

Figure 4.1: Knowledge of DETER in relation to the membership of an association

Figure 4.1 shows that companies affiliated with a professional association have, in general, a better knowledge of DETER's provisions than companies that are not affiliated to a professional association.

All inspected companies that are "not-SME" have sufficient knowledge of DETER. This is not the case for the smaller companies, e.g. micro-size companies where 49% of them show incomplete or no available knowledge of DETER's provisions.

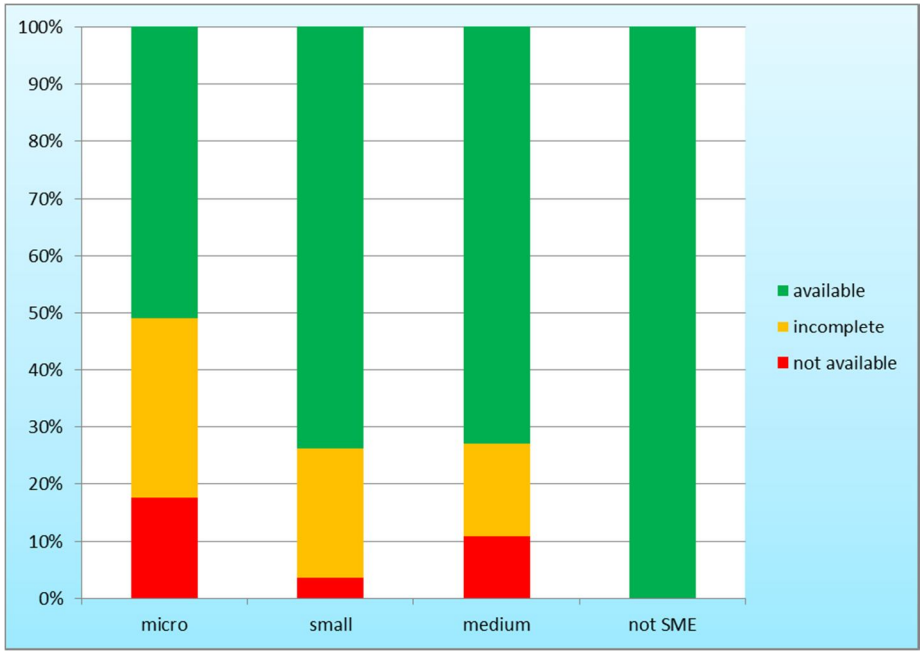

Figure 4.2: Knowledge of DETER in relation to company size

2.2.4 Summary and comments on companies' description

The majority of the inspected companies are "manufacturers" under DETER (formulators, packagers or distributors creating or changing the labelling), micro-size SMEs (1 to 9 workers), with incomplete or no knowledge of the DETER.

Hence, these companies, who may not be high up in the supply chain, are responsible for disseminating information necessary to protect vulnerable persons, to the general public. In addition, they often are not aware of the total number of, and nature of, the ingredients present in the mixture or their specific percentages in it. They usually rely on the Safety Data Sheet (SDS) supplied to them as the only source of information about the substances in the mixture.

2.3 Products Description

2.3.1 Type of users

The reported inspection findings show that the sample size of the inspected products destined for the general public as well as the sample size of inspected products for industrial / institutional use was comparable.
Together they account for over 90% of the inspected products.
Products destined both for the general public as for industrial / institutional users were a non-negligible minority (9%).

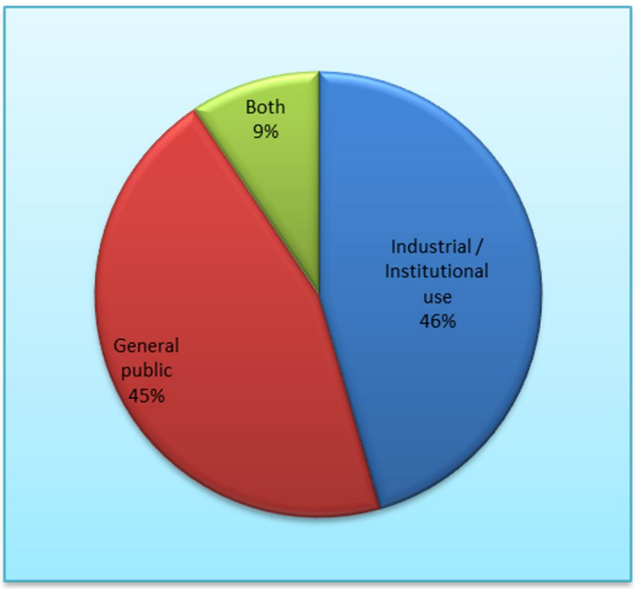

Figure 5: Destination of the inspected products

2.3.2 Type of products

Almost all detergent products inspected were **mixtures** (99% of the checked products).

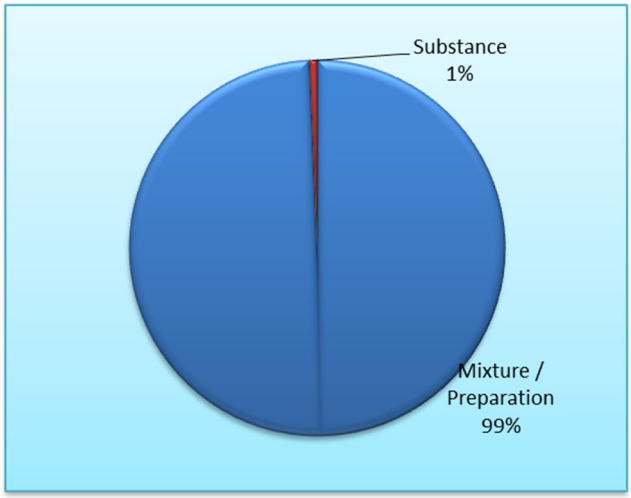

Figure 6: Distribution of the inspected products amongst substances and mixtures

2.3.3 Summary on products description

The most common profile of the inspected products (>90%) is a mixture placed on the market as a detergent under DETER, used either by the general public or by professional users for institutional or industrial purposes (50%/50%).

2.4 Project findings: Enforcement of Regulation (EC) No. 648/2004 (DETER)

2.4.1 Additional information on the label of detergents

The placing on the market of detergents is subject to different labelling provisions (without prejudice to other legislation like e.g. DPD, CLP) in DETER.

Specific labelling requirements have been introduced in the Regulation to inform consumers about the presence of possible allergenic substances such as fragrances and preservation agents in detergents.

For detergent products for the general public, it is compulsory to list certain components (e.g. phosphates, non-ionic surfactants, soap, …) as listed in Annex VII, A of DETER on the label in decreasing order of concentration as well as the address of a website where consumers can obtain the complete list of the detergents ingredients.

For detergents intended to be used in the industrial/institutional sector, and not made available to the general public, the abovementioned requirements do not have to be

fulfilled if equivalent information is provided by means of technical data sheets, safety data sheets, or in a similar appropriate manner.

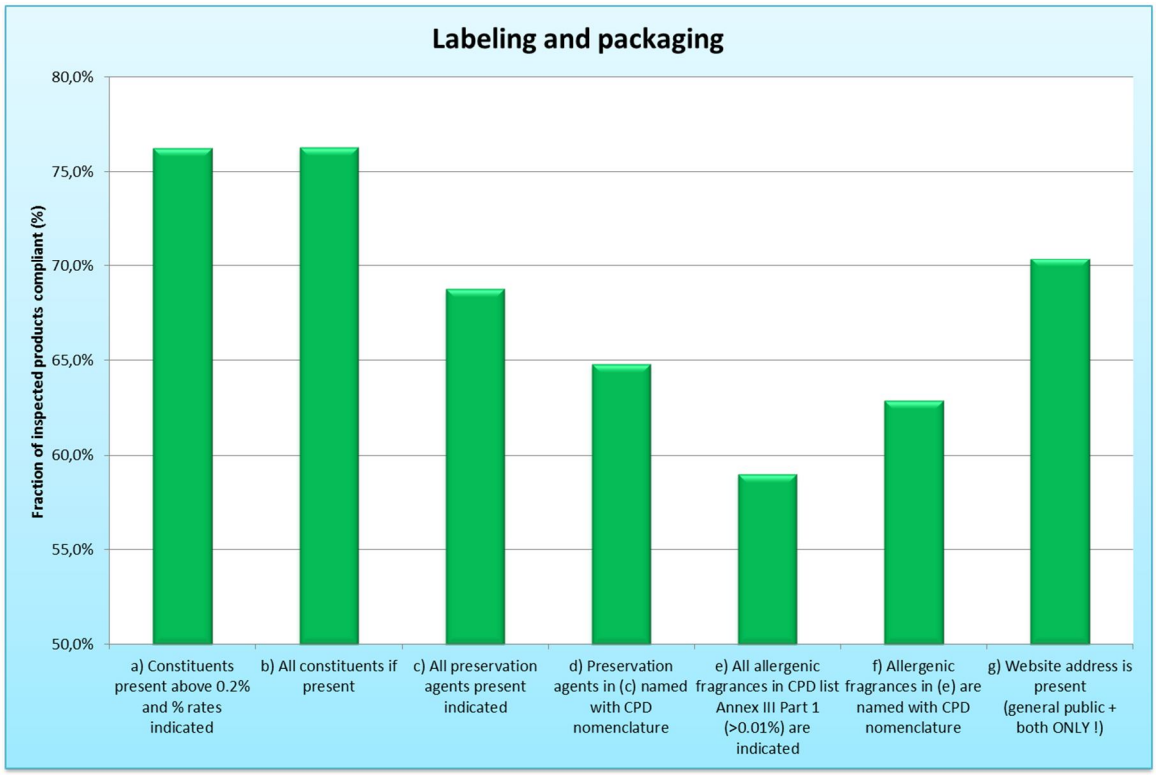

Figure 7: Compliance rate with labelling requirements from Annex VII, parts A and D of Regulation 648/2004/EC

Figure 7 shows an overview of the compliance rate of these specific labelling requirements.

<u>Allergenic fragrances and preservation agents</u>

The highest non-compliance rate is found in the obligation to list the allergenic fragrances on the label: more than 40 % of the inspected products do not include on the label or packaging all the mandatory allergenic fragrances present in the inspected product.

Similarly, the second highest non-compliance rate is found in the obligation to list the preservation agents contained in the detergent product: over 30% of the inspected products lack information about the preservation agents on the label or packaging, that are present in the detergent.

Web site address related to list of ingredients

DETER requires that the legal person responsible for placing a detergent product on the market provides the general public with the list of ingredients (LI) present in the detergent via the internet.

The website address must be mentioned on the detergent label.

In almost 30% of the inspected detergents for the general public, this website address is not mentioned on the label/packaging.

Information for the general public

General information about the product and the details of the party responsible for placing the detergent product on the market for the general public must be printed on the label or packaging (Art. 11(2)) i.e. a) Name/Trade name/Trademark of product b) Company details (name, address and telephone number) and c) address, e-mail address (where available) and telephone number from which the ingredient data sheet (IDS) can be obtained.

While information contained in a) and b) is also mandatory in other legislations, such as the DPD, BPD or CLP Regulation, c) is a specific requirement only included in DETER.

Figure 8 represents the compliance rate with these requirements. While compliance is high (>90%) for the general information concerning a) and b), the full contact details where the IDS can be obtained, i.e. an ingredient data sheet with detailed specifications of the ingredients and specified weight ranges destined for medical personnel, are **missing in 23% of the inspected products.**

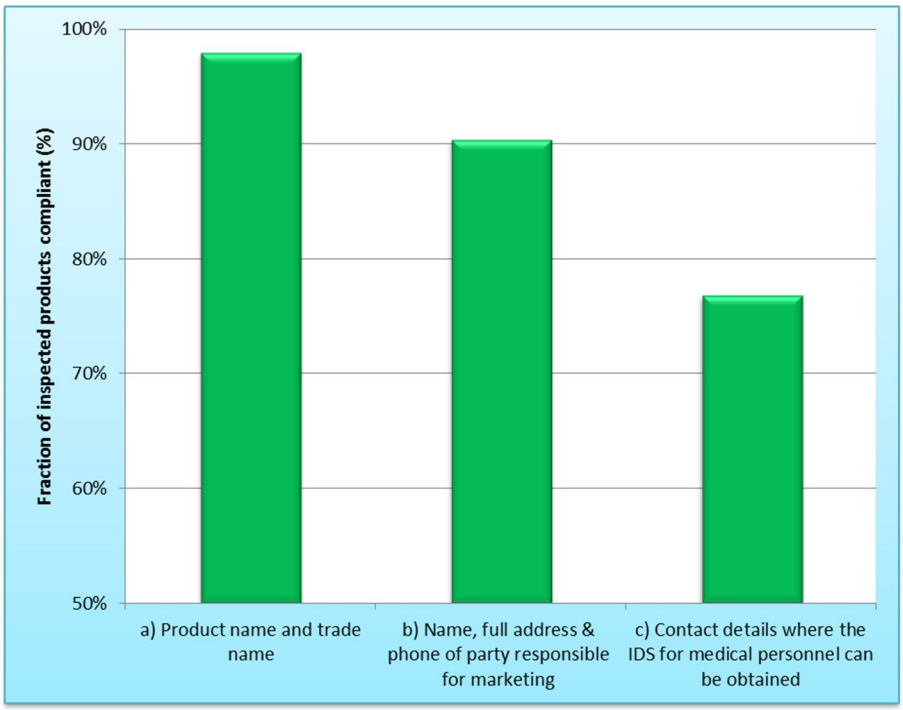

Figure 8: Compliance rate of the specific requirements for detergents for the general public (according to article 11.2 of DETER)

Laundry detergents for general public

The packaging of detergents for the general public, intended to be used as laundry detergents, shall bear additional supplementary information (as per Annex VII B):

- The recommended quantities and/or dosage instructions expressed in millilitres or grams suited for a standard washing machine load, for soft, medium and hard water hardness classes and making provision for one or two cycle washing processes;
- For heavy-duty detergents, the number of standard washing machine loads of "normally soiled" fabrics, and, for detergents for delicate fabrics, the number of standard washing machine loads of lightly-soiled fabrics, that can be washed with the contents of the package using water of medium hardness, corresponding to 2,5 milimoles CaCO3/l;
- The capacity of any measuring cup, if provided, shall be indicated in millilitres or grams, and markings shall be provided to indicate the dose of detergent appropriate for a standard washing machine load for soft, medium and hard water hardness classes.

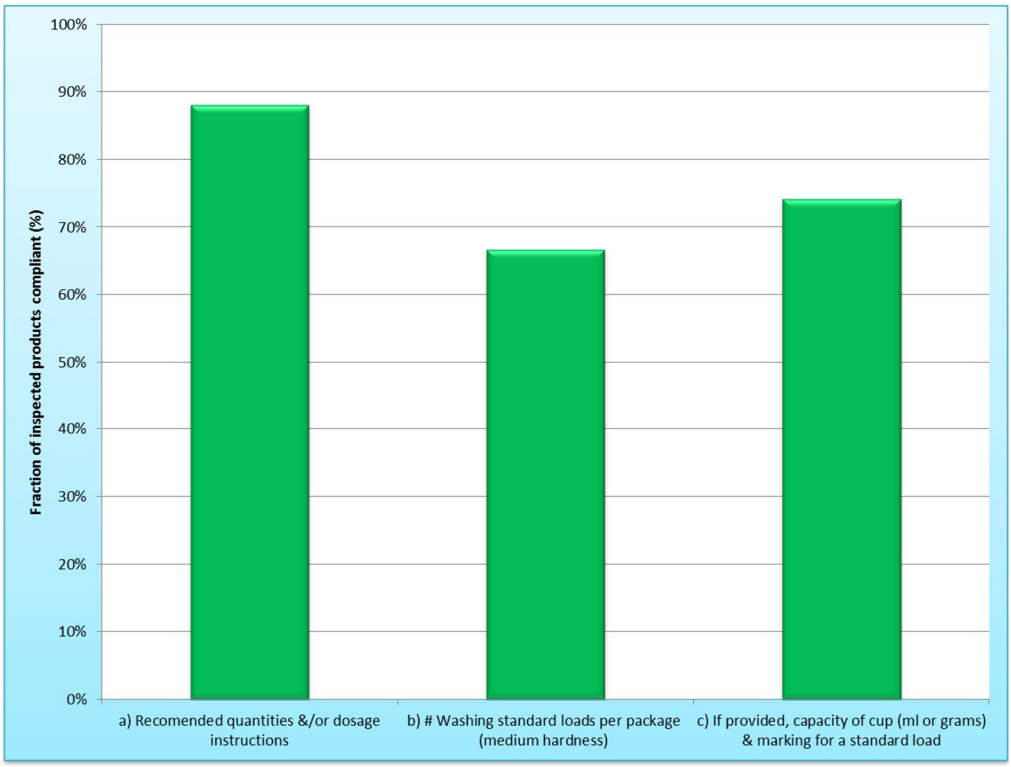

Figure 9: Compliance rate of the specific requirements for laundry detergents sold to the general public (according to annex VII B of DETER)

The results show that less than 70% of the inspected laundry detergents, where obligatory, bear the information on standard washing machine loads on the label.

Dosage instructions or recommended quantities information accompany almost 90% of the inspected detergents.

Indications of use

The package shall also indicate “Indications of use” and special precautionary measures to be taken, if required (Article 11(3) of DETER).

DETER does not provide details on what is considered to represent 'instructions for use and special precautions', to be indicated on detergents label.

However it could possibly be considered that 'instructions for use and special precautions' for the given detergent are different from other legal statements such as S-phrases from DPD or similar phrases coming from other pieces of the chemicals legislation.

The possible exemptions following the “if required” specification in DETER, remain unclear. Therefore, no distinction was made between “non-compliant” and “not required” in the questionnaire.

At least 85% of the inspected products are compliant with this obligation (Article 11(3) of DETER).

15% of the total number of inspected products did not contain **any** indications of use and/or special precautionary measures, however, as there is currently no guidance on what is and is not required under Art. 11(3), no conclusions can be drawn regarding compliance with this requirement.

2.4.2 List of Ingredients (LI)

Project findings show that

- the website address is available on the label where compulsory in 70% of inspected products
- the LI was not available at the website address mentioned on the label for 46% of the inspected products.

This LI must be provided according to the requirements set out in Annex VII, D of DETER.

29% of the checked LIs – published on a website or not - are not compliant with the instructions laid down in Annex VII D of DETER.

Figure 10 is an overview of the reported shortcomings in the checked Lists of ingredients (58 reports). It shows how often a shortcoming appears.

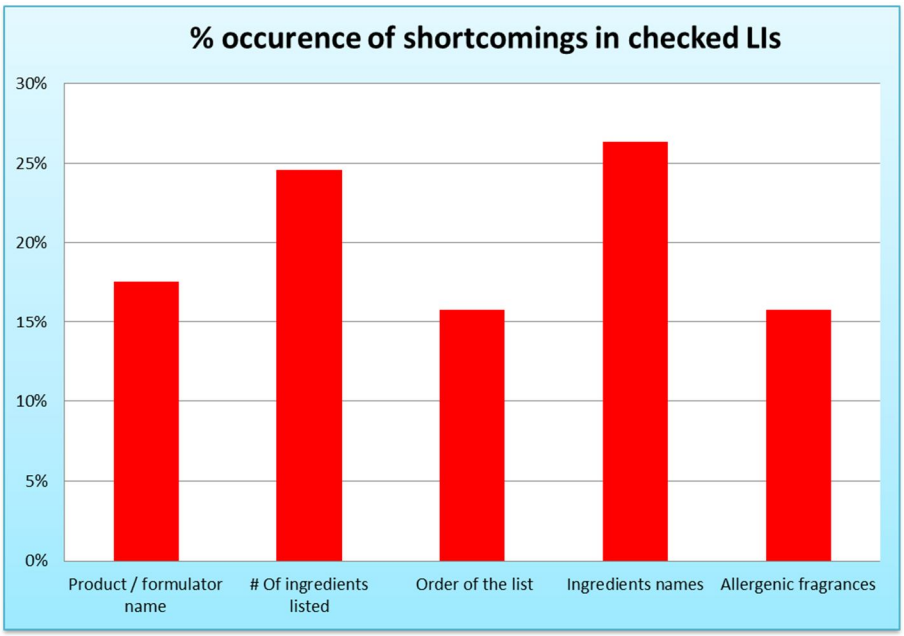

Figure 10: Shortcomings in LIs

Non-compliances related to the information on the list of ingredients are for instance the publication of the wrong ingredients or incorrect chemical names, (26% non-compliance), incomplete listing of the ingredients of which the detergent is composed (25% non-compliance).

It has not been verified whether the LI is available or not, when the label does not mention a website address.

According to DETER, the website should also include a link to the Commission Pharmacos website or to any other suitable website that provides a table of correspondence between INCI names, European Pharmacopoeia names, and CAS numbers. In 56% of the cases where a LI is published, no link to the Pharmacos website (or alternative) was found.

2.4.3 Ingredient data sheet (IDS)

Those responsible for the labelling and packaging of detergent products ("Manufacturers") must also ensure that an Ingredient Data Sheet containing the name of the detergent, the name of the manufacturer and a list of all of the ingredients in the detergent is made available for medical personnel (as per Art. 9(3) of DETER) upon request, so that they can determine whether there is a causal link or not between a patient's allergy or specific symptomatology and a substance present in the detergent.
In additionally, Member States (MS) may request on a national basis, that the IDS is provided by the manufacturer to a specific public body, to which the MS has assigned the task of providing the information to medical personnel.

For 23% of the inspected products, an IDS is not available.

The IDS content has to fulfil the obligations as set out in Annex VII C of DETER (the Ingredient Data Sheet shall list the name of the detergent and of the manufacturer, and all ingredients shall be listed in order of decreasing abundance by weight in the weight ranges specified).

Figure 11 presents an overview of the compliance rate with this obligation.

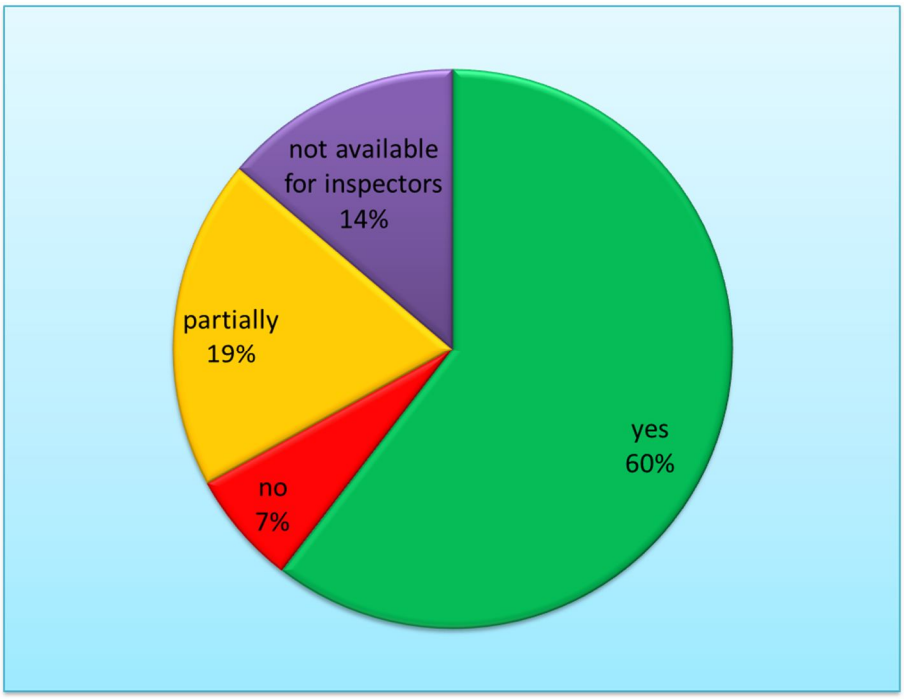

Figure 11: Compliance of the IDS content with annex VII C of DETER

For 14% of the inspected products, the IDS was not made available for inspectors. 26% of the Ingredient Data Sheets checked were not in conformity with the requirements set out in Annex VII C of the regulation.

2.4.4 Biodegradability

DETER (Article 9 and Annexes to the Regulation) requires that the surfactants used in detergent products are biodegradable. As figure 12 shows, the necessary information concerning the biodegradability tests is not always available at the premises of the legal person responsible for the placing on the market. If studies are available at all, then for less than 40% of the studies there is sufficient proof that the legal person can benefit from the property rights of the test results.

Over 97% of the surfactants in the checked detergents were biodegradable compliant with the criteria of the DETER.

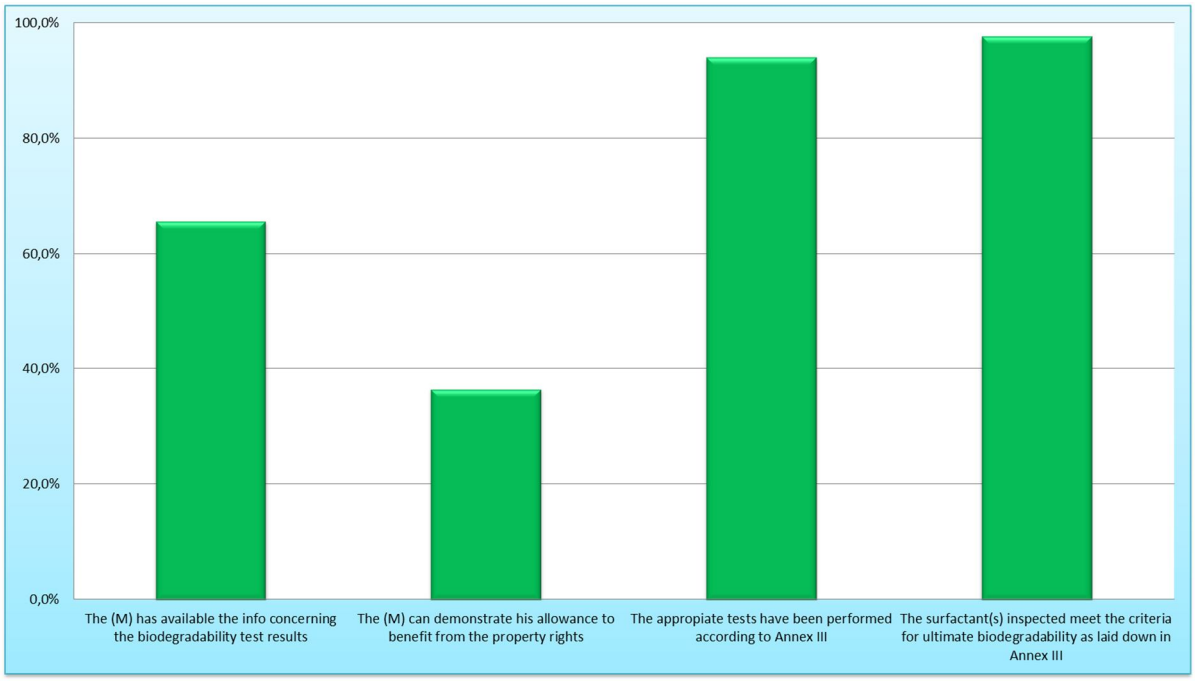

Figure 12: Fraction of checked detergents compliant with DETER with regard to biodegradability of its surfactants

2.5 Project findings: Link to the Biocidal Products Directive 98/8/EC (BPD)

As stated in Article 3 of DETER, detergents and surfactants used in detergents shall comply with the provisions of the detergents regulation, and, where relevant, with BPD.

Of the inspected detergents, only 6% had a biocidal claim. Product type 2 ('Private area and public health area disinfectants and other biocidal products') is by far the most often encountered product type. No further investigation was performed on the compliance of these products with BPD.

On the other hand, many detergents contain in-can preservatives. These preservatives are biocidal products of product type 6 (PT6) and used for the preservation of manufactured products, other than foodstuffs or feeding stuffs, in cans, tanks or other closed containers by control of microbial deterioration to ensure their shelf life.

The project investigated the presence of these in-can preservatives, and checked whether the active substances have a legal status in the EU market.

For the inspected detergents, 65% contain an in-can preservative with at least one active substance, as such or as a mixture. The analysis of the present PT6 substances showed that **up to 13% of these substances are illegal.**

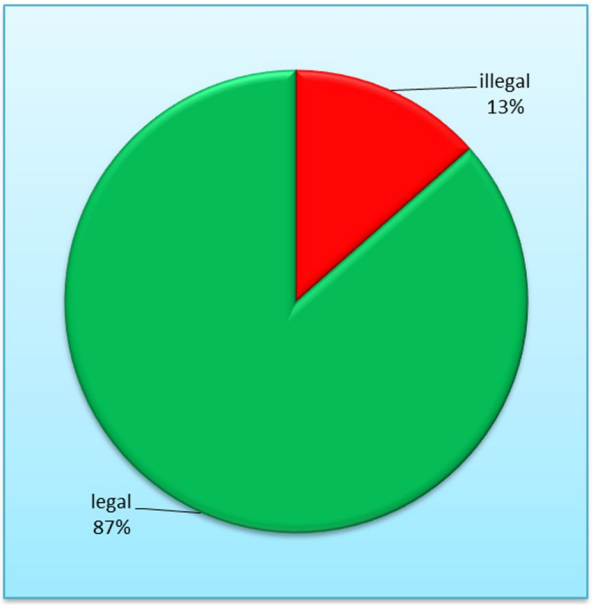

Figure 13: Legality of in-can preservatives in the inspected detergents

The most frequent banned in-can preservative found in the checked products was formaldehyde (CAS 50-00-0) (cfr. Commission Decision 2010/675/EU). Other illegal PT6 substances detected were e.g. 1,3-bis(hydroxymethyl)urea (CAS 140-95-4) (cfr. Commission Decision 2008/809/EC), sodium benzoate (CAS 532-32-1) (cfr. Commission Decision 2008/809/EC) and quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides (CAS 63449-41-2).

2.6 Project findings: Link to the Dangerous Preparations Directive 1999/45/EC (DPD)

The majority of the detergents placed on the market are mixtures classified as hazardous/dangerous and therefore have to fulfil the labelling and packaging obligations laid down in the Dangerous Preparations Directive (1999/45/EC) or in the CLP Regulation ((EC) No. 1272 of 2008).

65% of the inspected products were classified as hazardous. In 9% of the cases of the classified detergents, the CLP Regulation was implemented to label the product accordingly. No further investigation was initiated on the compliance of the detergent with the CLP Regulation.

Where the DPD was used to classify and label the detergent, the category corrosive /irritant represents more than 80% of the inspected hazard categories.

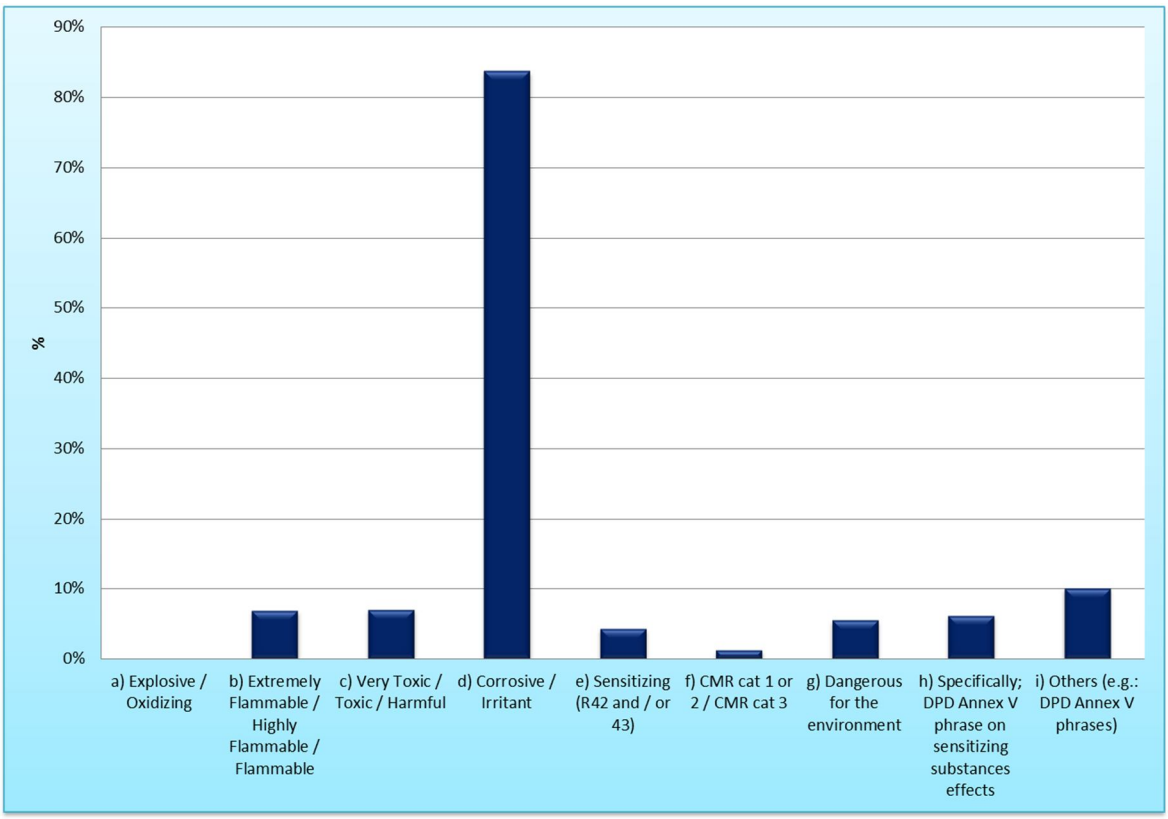

Figure 14: Occurrence of a classification or of a DPD hazard statement in checked detergents

Figure 15 gives an overview of the compliance of the checked detergents with specific DPD obligations.

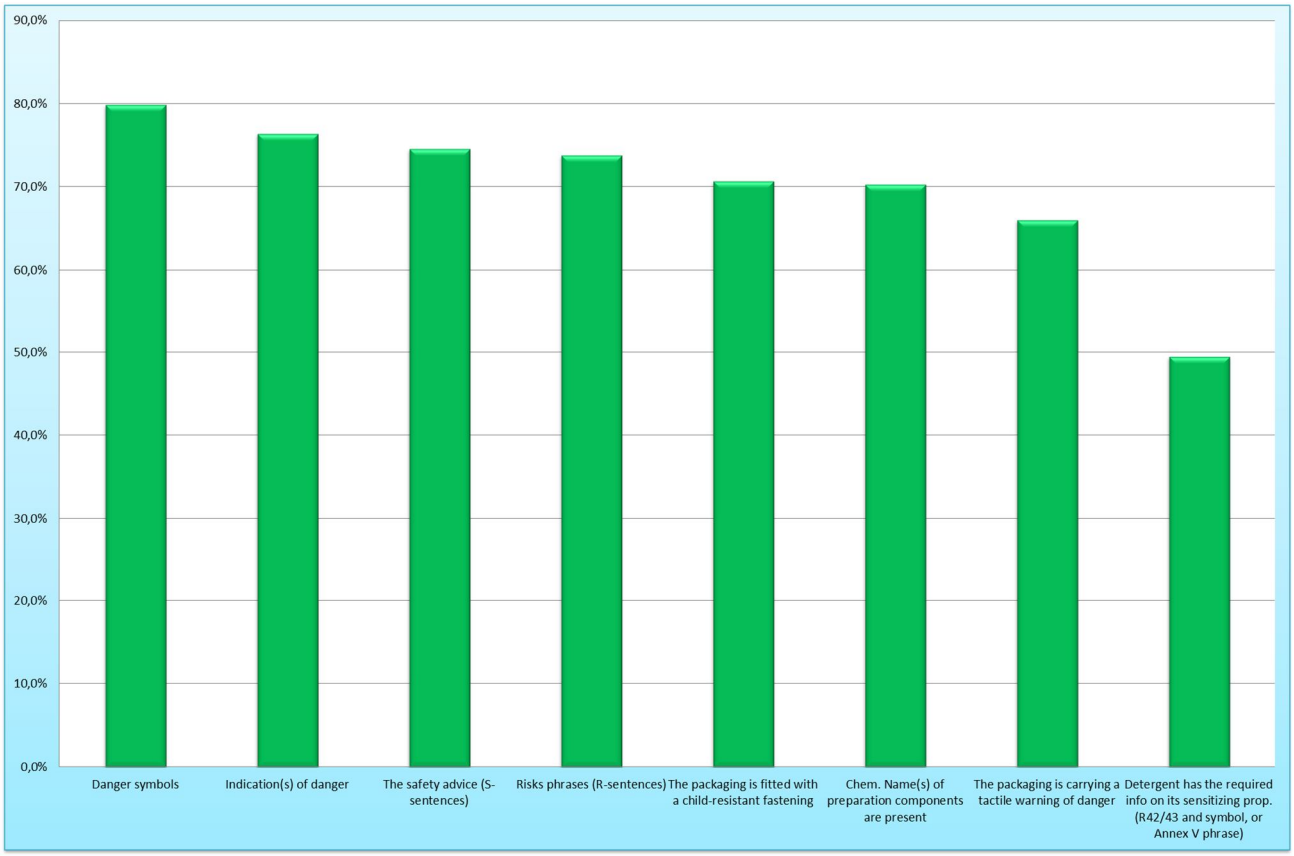

Figure 15: Fraction of checked detergents compliant with specific DPD requirements

Non-compliance with specific DPD labelling requirements is found in 20 to 30% of the checked detergents, in particular with regard to a lack of the following information:

- Danger symbols and indications of danger,
- Risk-phrases (R-sentences),
- Safety advices (S-phrases),
- Chemical names of the dangerous substances in the mixture,
- Information on sensitizing properties
- Special packaging requirements for dangerous mixtures handed to the general public.

The findings are similar with those of CLEEN's ECLIPS-Project in 2003-2004.

Special attention was given to detergents classified as sensitizing (R42 and/or R43), or those which contained sensitizing substances without being classified (Annex V phrase).

In total, 91 of the inspected detergents were subject to labelling obligations regarding sensitizing aspects, of which 50% failed to mention all the required information on the label.

The inspectors investigated also the packaging itself. DPD requires that certain products classified as hazardous are supplied in appropriate containers, for example having a child-resistant cap or a tactile danger warning, when supplied to the public.

The project shows a rather high non-compliance rate for these two safety measures: 17 out of 50 checked relevant products (= 34%) did not carry a tactile danger warning, and 12 out of 41 checked relevant products (= 29%) did not have a child resistant fastening as required. The number of checked products is low, since these obligations are limited only to certain categories of classified products sold to the general public.

It is remarkable to see a low degree of compliance of the inspected products with the legal requirements of the DPD given that these requirements have been mandatory for a considerable length of time.

2.7 Overall compliance and legal actions

Looking at the complete set of inspected products, over two thirds are non-compliant with at least one of the relevant legislations (DETER, DPD, BPD).

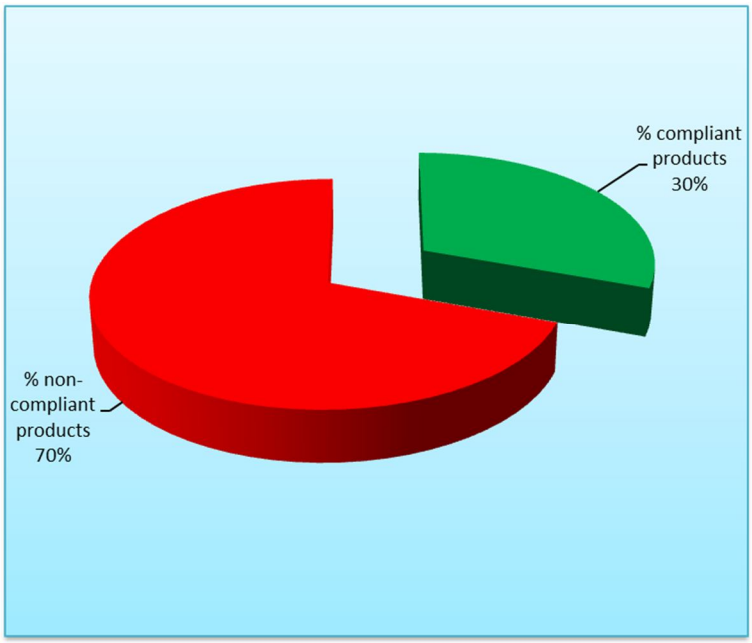

Figure 16.1: Compliance of inspected detergents with DETER and DPD and BPD

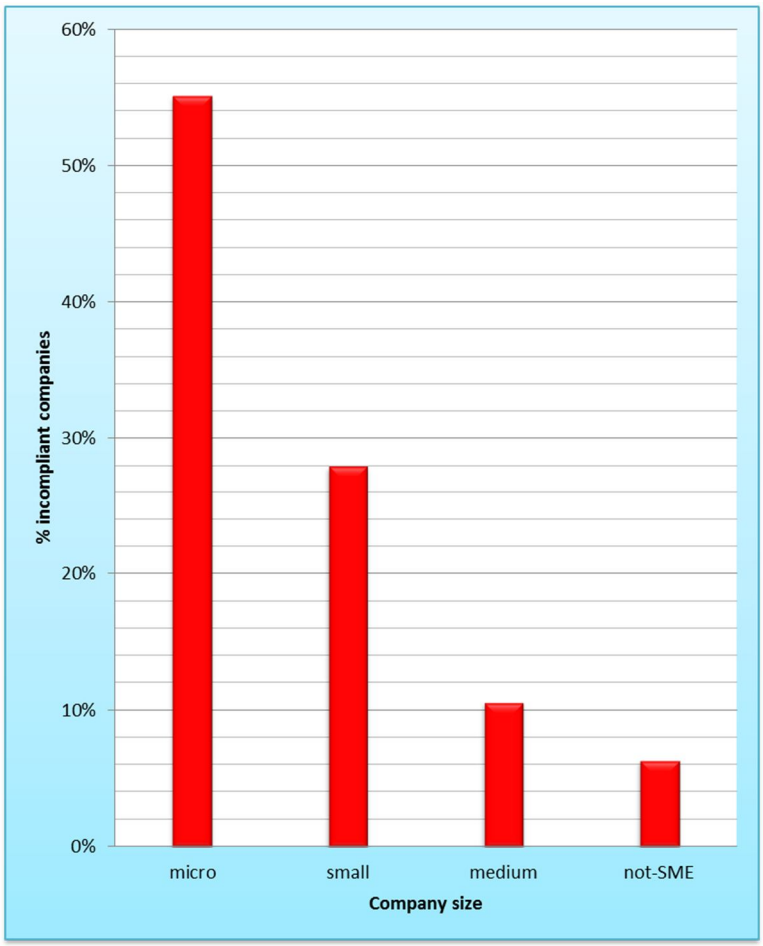

Figure 16.2: Incompliance vs company size

A total of 244 inspected companies (76 %) were found to be non-compliant for at least one of their detergents. Of those, the inspectors mentioned their size for all but eight companies. We see in figure 16.2 that 55% of the non-compliant companies are micro sized, almost 30% are small sized, almost 11% medium sized and around 6% not-SME sized. The non-complaint company is typically micro sized.

Figure 16.3 shows that the knowledge of DETER a company has does not seem to be related to its compliance behavior.

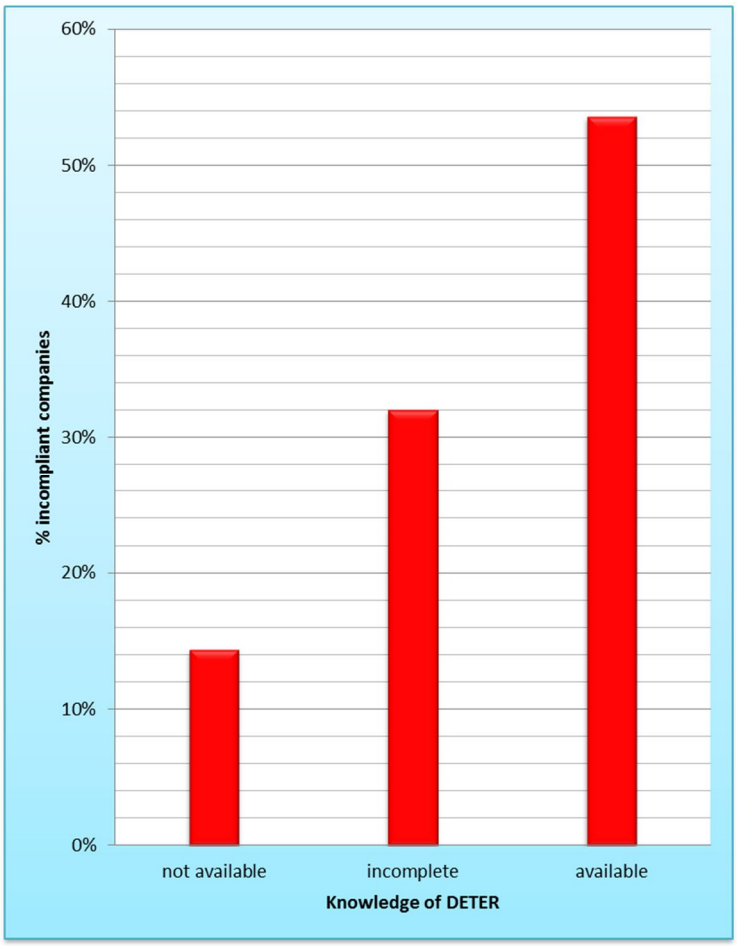

Figure 16.3: Link between available knowledge of DETER and compliance

We see in figure 16.4 that almost 2 thirds of the non-compliant companies are not affiliated to a professional association.

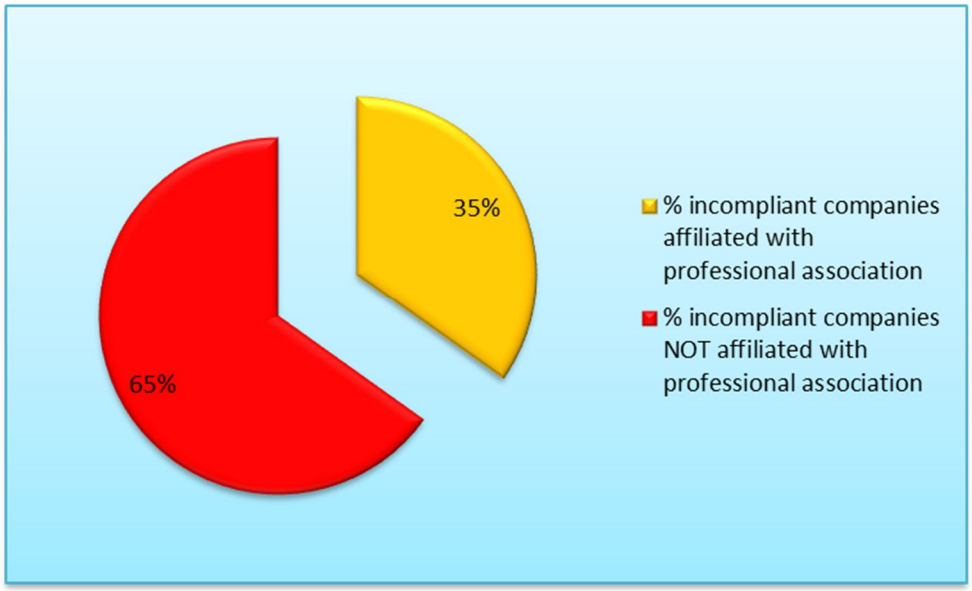

Figure 16.4: Influence of being affiliated to a professional association

The inspectors have imposed measures for almost all non-compliant products.

The most common measures taken were providing written advice, or in more severe cases serving an order, whereby a company is urged to take action and account for the action taken within a certain period of time. More radical legal actions like reporting to the public prosecutor, commanding immediate action or sanctioning were seldom applied.

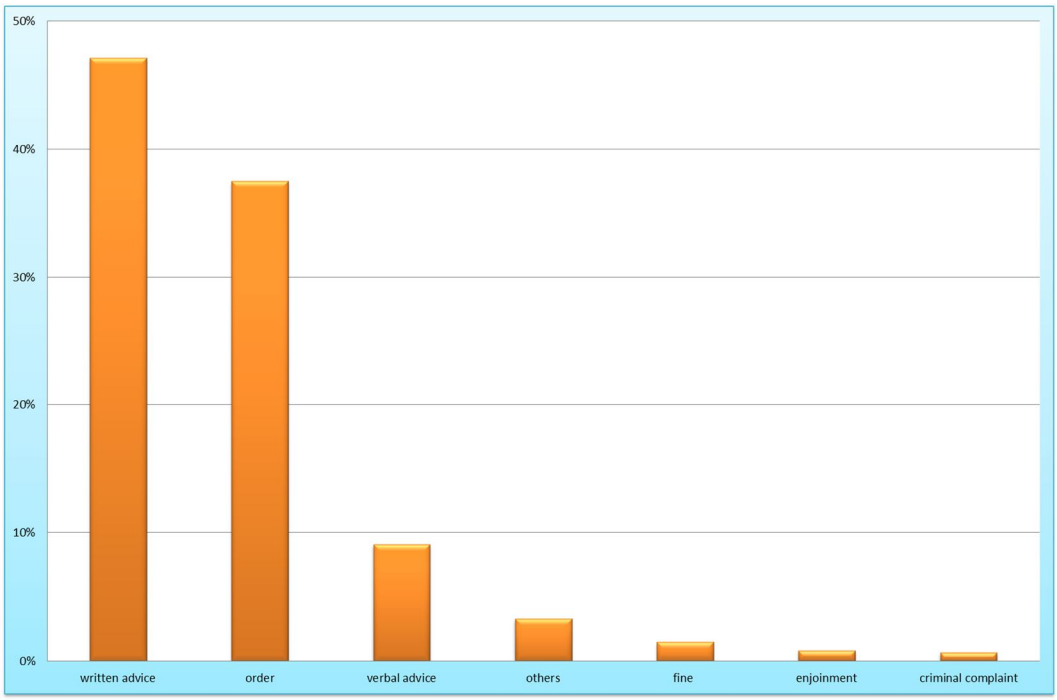

Figure 17: Occurrence of issuing measures per non-compliant detergent

3 Conclusions & considerations

Within a number of Member States in the European Union and in Switzerland, an inspection campaign has been executed focussing on the compliance with legal obligations imposed on the placing of detergent products on the market. In 12 countries a small sample of commercially available detergents was screened as well as the compliance levels of the companies responsible for their supply, mostly SMEs.

It is rather the exception than the rule that a detergent is compliant with all three of the relevant legislations (the Detergents Regulation, the Dangerous Preparations Directive, the Biocidal Products Directive). Non-compliance is observed in almost 70% of the inspected products. A non-compliant product was found in three out of four inspected companies.

This report lists the most frequently observed shortcomings in compliance of marketed detergents with the three cited legislations.

3.1 Most significant findings in DETER

- Missing information on the label about allergenic fragrances (over 40 % of checked detergents where applicable) and also about preservation agents (over 30%).
- The LI (list of ingredients) is not published on a website in almost 1 out of 2 checked detergents for general public.
- The IDS (ingredient data sheet) for medical personnel is missing in almost 1 out of 4 checked detergents (23%).
- Used surfactants in the formulations are biodegradable, meeting the criteria for ultimate biodegradability as laid down in Annex III.

3.2 Most significant findings in BPD

- Banned in-can preservatives are still used in detergents (up to 13%),formaldehyde being the active substance most frequently used in these cases.

3.3 Most significant findings in DPD

- There has been no improvement of the compliance level with labelling requirements since the CLEEN's ECLIPS project which was carried out in 2003-2004: comparable to the ECLIPS project findings[1], there is still between 20 and 30 % deficiencies in label information.

[1] http://www.cleen-europe.eu/projects/ECLIPS.html

- Concerns relating to the current packaging conditions for detergent mixtures offered to the general public, specifically:

    - Tactile warning of danger for blind persons ➔ 17 out of 50 relevant products non-compliant (34% non-compliance)
    - Child-resistant fastening ➔12 out of 41 relevant products non-compliant (29% non-compliance)

3.4 Other significant findings

The overall results show that affiliation to a professional stakeholder association enhances knowledge of the chemical legislation applicable to detergents.

All inspected companies that are “not-SMEs” have sufficient knowledge of DETER. This is not the case for the smaller companies, e.g. micro-size companies where 49% of them show incomplete or no available knowledge of DETER’s provisions.

3.5 Some considerations in relation to the findings

According to the findings of this project, there is an indication that companies were not aware of the specific requirements of DETER and it is likely that the legal framework is too complex to allow companies to fully comply.

Checking compliance with 3 legislations at the same time was also felt as a challenge by the participating Competent Authorities.

DETER, CLP, DPD and REACH impose for example more or less similar information requirements differently. The table below compares these different information requirements regarding the ingredients in the mixture.

Mixtures in CLP/DPD: label	Chemical names of hazardous substances / No percentages are required on the label
Mixtures in DETER: label	Certain components, hazardous or not, and their percentage ranges: > 30%, 15-30%, 5-15%, <5% Preservation agents (regardless of conc) using INCI name Allergenic fragrances (> 0.01%) listed in Annex III of Cosmetics Directive by their INCI name
LI on web page (DETER)	INCI name, if not: European Pharmacopean name, if not: Chemical name.
SDS (REACH)	Chemical names of hazardous substances present over certain concentration limits established by REACH (and CLP).
IDS in DETER mixtures	All ingredients: (Chemical names, CAS nº, INCI name, European Pharmacopean name) in the following percentage ranges: > 10%, 1-10%, 0,1-1%, <0,1%.

Art. 45 in CLP mixtures	Chemical names of all ingredients and chemical composition of the mixture to be delivered to a specific national public body.

Comparing the SDS requirements and DETER's obligations, it should be remarked that how the constituents are named in both pieces of legislation, is not consistent.
In the SDS the chemical name and CAS or EC number is required (or equivalent) whereas in the Detergent Regulation, the generic name only is required e.g. non-ionic surfactant.
It is then difficult as an enforcer to establish whether a substance named in the SDS is a surfactant or not, and if so, whether it is anionic, cationic, non-ionic or amphoteric. Consistency in naming requirements should be looked at, if the provisions as set out in the Detergent Regulations are to remain.

In general, these information provisions as mentioned in the table should be streamlined.

4 Recommendations

As a potential resolution, it is proposed that the cited legal framework is simplified so that with a minimum of provisions, maximal protection of the consumer and the environment is ensured, as well negligible internal and external safety risks.

CLEEN suggests that the Commission takes account of the findings and considers streamlining the Detergents Regulation in order to ease the legislative burden currently placed on SMEs, with an aim to ensure consistency between the labelling provisions required under CLP/DPD, the requirements of Annex II of REACH in relation to SDSs and the labelling and information requirements in the Detergents Regulation.

Special attention should be drawn to the lack of compliance with regard to packaging of hazardous detergent products for the vulnerable population. This can be seen as an indication that, in the framework of the enforcement of CLP, analogous non-compliances could be encountered in broader fields.

Provisions aiming at better wording for the “Instructions of use” could be built into DETER, in order to be sure that all detergents placed on the market bear unambiguous instructions of use or special precautions on the label.

The high degree of non-compliance observed and the inherent real risks can be seen as a motivation for continuation of the market surveillance exercise which is CLEEN’s EuroDeter project, and its expansion to countries that did not participate in the project.

Awareness raising initiatives on the requirements of the Detergents Regulation in particular via information campaigns, especially directed towards small and micro-sized companies, can also be seen as productive enforcement actions.

CLEEN invites the European Commission, the International Association for Soaps, Detergents and Maintenance Products, and all other relevant public and non-public stakeholders to acknowledge the findings of CLEEN’s EuroDeter project and use them for future activities related to the improvement of the EU legislation on detergents and the protection of humans health and the environment.

5 Annexes

5.1 Annex I: Glossary

BE: Belgium
BPD: Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market
CAS/CAS Registry Number: unique numerical identifier assigned by Chemical Abstracts Service to every chemical substance described in the open scientific literature
CH: Switzerland
CLEEN: Chemical Legislation European Enforcement Network
CLP: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
CMR: Carcinogenic, Mutagenic and Reprotoxic
CPD: Council Directive (76/768/EEC) of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products
D: Distributor
DE: Germany
DETER: Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
DPD: Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations
DU: Downstream User
EC: European Commission
EE: Estonia
EEA: European Economic Area
ES: Spain
EuroDeter: CLEEN's enforcement project on on detergents
FI: Finland
I: Importer
IDS: Ingredient Data Sheet
IE: Ireland
INCI: International Nomenclature of Cosmetic Ingredients
LI: List of Ingredients
LT: Lithuania
LV: Latvia
M: Manufacturer
PL: Poland
PT: Product Type
SE: Sweden
SI: Slovenia
SME: Small and Medium Enterprise

5.2 Annex II: EuroDeter Project Manual (adopted December 2011)

Project Manual
EuroDeter

Final Version 1.6

07-12-2011

WG members:

Rosario Alonso Fernández (ES)
Paul Cuypers (BE)
Michel Leynen (BE)
María Tarancón Estrada (ES)

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APPENDICES LIST

1. PREFACE

On 7th and 8th September 2010, at the 11th CLEEN (Chemicals Legislation European Enforcement Network) Conference in Sucevita (Romania), it was agreed that an Enforcement Project focusing on Regulation (EC) No 648/2004, on detergents, should be prepared and carried out. At the presentation of this new project, at Sucevita, several countries showed their interest to participate, so the **EuroDeter** working group (Spain & Belgium) was set.

Thenceforth, the development of tools for making the inspections, with special dedication to a Project Manual, that would be practical and understandable, and a consistent harmonized Questionnaire to collect the results, has been an on-going process within the WG. At the 12th CLEEN Conference, in Larnaca (Cyprus), 19th and 20th September 2011 the first draft of the Project Manual and Questionnaire were distributed and national commitments to participate in the Project were obtained. The WG received comments from NL, LV, LT, SE and CH, that have been taken into account for this final version (v1.6). In December 2011 the final documents to perform the inspections (Project Manual & Questionnaire) are adopted and distributed only among the inspectors. The preparation phase ends in the first quarter of 2012 with the development of an excel tool to collect final results.

The operational phase is foreseen to be running along 2012 and the presentation of final results will be given, presumably, at the 14th CLEEN Conference, in 2013.

The EuroDeter Project aims to provide an insight into the degree of compliance with the detergents legislation in Europe by the industrial sector involved in the manufacture and placing in the market of detergents, cleaners and/or surfactants. It also aims to look at the compliance of related legislation, such as the Biocidal Products Directive (BPD) in the particular case of this type of products or the Dangerous Preparations Directive (DPD), in the case formulations/mixtures/preparations are being inspected.

2. PROJECT DESCRIPTION

Detergents are products containing surfactants and/or soaps. They are intended for washing and cleaning processes, and have become an essential commodity in our daily lives. By safely and effectively removing dirt particles, stains and other contaminants, they help us to maintain appropriate hygienic conditions at home, workplaces and public spaces, thus contributing to a high level of health protection. They can be supplied in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and are widely used for household, institutional or industrial purposes.

Many detergents are known to cause allergies due to sensitizing properties of some of their components. Their widespread use in households could be a *health risk*, especially for vulnerable individuals like children, already sensitized persons or other naturally sensible persons.

Excessive use of laundry detergents is also a major concern. The large quantities of detergents used and the low biodegradability of many surfactants are an *environmental risk* because of the inherent high potential for surface and marine waters' pollution. Detergents are introduced into the environment mainly via sewage. Surfactants used should meet standards for biodegradability. Those that do not comply should be restricted or even banned.

2.1. Regulation (EC) No 648/2004: Objectives and scope

Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (DETER) harmonizes the rules for placing on the market of detergents, including surfactants. Its scope (Art. 1) concerns:

- Biodegradability of surfactants in detergents.
- Restrictions or bans on surfactants on grounds of biodegradability.
- Additional labelling of detergents, including fragrance allergens and preservation agents.
- Information manufacturers must hold at the disposal of the Member States Competent Authorities and medical personnel.

This Regulation has as main objective to achieve the free movement of detergents and surfactants for detergents in the internal market while ensuring a high degree of protection of the environment and human health.

The Regulation **widens the concept of detergents** to include other **cleaning products**, even if they do not have surfactants or soaps in their formulation, such as:

- "Auxiliary washing mixture"
- "Laundry fabric-softener"
- "Cleaning mixture"
- "Other cleaning and washing mixtures"

Regulation (EC) No 648/2004 has been amended four times:

Table 1. Amendments

Commission Regulation (EC) Nº 907/2006 of 20 June 2006	Annexes III and VII
Regulation (EC) Nº 1336/2008 of the European Parliament and of the Council of 16 December 2008	Introducing the term "mixture/s"
Regulation (EC) Nº 219/2009 of the European Parliament and of the Council of 11 March 2009	Commission competence to modify Annexes….
Commission Regulation (EC) Nº 551/2009 of 25 June 2009	Annexes V and VI

Consolidated version *(27_06_2009)* of DETER available in the following European Commisssion´s (DG Enterprise) web link:
http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/detergents/index_en.htm

Table 2. The Annexes of Regulation (EC) No 648/2004

ANNEX I - Standards of accreditation, good laboratory practice and animal protection concerning the laboratories that are competent and authorised to provide the necessary service for checking compliance of detergents
In the abovementioned web page, there is available a list of List of approved laboratories in accordance with Art. 8 of Regulation 648/2004
ANNEX II - Primary biodegradability test methods for surfactants in detergents
Primary biodegradability is measured by the determination in biodegraded liquors of the remaining level of parent surfactants. This Annex begins with a list of the test-methods common to all classes of surfactants, and then lists the analytical test procedures specific to each class of surfactant.
ANNEX III - Ultimate biodegradability (mineralisation) test methods for surfactants in detergents
The reference method for laboratory testing of surfactant ultimate biodegradability in this Regulation is based on the EN ISO standard 14593: 1999 (CO2 headspace test). This Annex lists the test methods that can be used and the criteria for mineralisation for each of them in terms of percentages and days.

ANNEX IV - Complementary risk assessment for surfactants in detergents
ANNEX V - List of surfactants that have obtained a derogation
Only the entry "*Alcohols, Guerbet, C16-20, ethoxylated, n-butyl ether (7-8EO)*, CAS: 147993-59-7" has obtained a derogation until 2019. It may be used for bottle-cleaning, metal cleaning and cleaning-in-place.
ANNEX VI - List of banned or restricted detergent surfactants
No banned or restricted surfactant has yet been included
ANNEX VII - Labelling and Ingredient Data Sheet
Labelling provisions, Ingredient Data Sheet and Publication of the list of ingredients
ANNEX VIII - Test methods and analytical methods
Simulation of municipal sewage treatment: improved conditions in EN ISO 11733

2.2. Definitions

Some definitions set out in Art. 2 are as follows:

Related to products

- **'Detergent'** means any substance or mixture containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes.

Other products to be considered as detergents are:

- **'Auxiliary washing mixture'**: intended for soaking (pre-washing), rinsing or bleaching clothes, household linen, etc.
- **'Laundry fabric-softener'**, intended to modify the feel of fabrics in processes which are to complement the washing of fabrics;
- **'Cleaning mixture'**, intended for domestic all purposes cleaners and/or other cleaning of surfaces (e.g.materials, products, machinery, mechanical appliances, means of transport and associated equipment, instruments, apparatus, etc.);
- **'Other cleaning and washing mixtures'**, intended for any other washing and cleaning processes.

- **Surfactant** means any organic substance and/or mixture used in detergents, which has surface-active properties, and which consists of one or more hydrophilic and one or more hydrophobic group of such a nature and a size that is capable of reducing the surface tension of water and of forming, spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces.

- **‘Ingredient’** (Annex VII.C) means any chemical substance, of synthetic or natural origin, intentionally included in the composition of a detergent.

  For the purpose of Annex VII of DETER, a **perfume**, an **essential oil**, or a **colouring agent** shall be considered to be a **single ingredient** and none of the substances that they contain shall be listed, with the exception of those allergenic fragrance substances that appear on the list of substances in Annex III, Part 1 to Directive 76/768/EEC on Cosmetic Products Directive **(CPD)** if the total concentration of the allergenic fragrance substance in the detergent exceeds the limit mentioned in section A.

Related to actions

- ‘**Washing’** means the cleaning of laundry, fabrics, dishes and other hard surfaces.

- **‘Cleaning’** has the meaning defined by EN ISO 862**: “**The act of bringing the phenomenon of detergency into effect”.
  “**Detergency; detergence**” defined by EN ISO 862: “The process by which soil is dislodged from the substrate and brought into a state of solution or dispersion. In its usual sense, detergency has the effect of cleaning surfaces. It is the result of the action of several physico-chemical phenomena”.

- **‘Placing on the market’** means introducing onto the Community market, thereby making available to third parties, whether in exchange for payment or not. Import into the Community customs territory shall be deemed to be placing on the market.

Related to Biodegradability

- **‘Primary biodegradation’ (PB)** means the structural change (transformation) of a surfactant by micro-organisms resulting in the loss of its surface-active properties due to the degradation of the parent substance and consequential loss of the surface-active property as measured by test methods listed in Annex II.

- **‘Ultimate aerobic biodegradation’ (UAB)** means the level of biodegradation achieved when the surfactant is totally used by micro-organisms in the presence of oxygen resulting in its breakdown to carbon dioxide, water and mineral salts of any other elements present (mineralisation), as measured by test methods listed in Annex III, and new microbial cellular constituents (biomass).

Related to target companies

- **‘Manufacturer’** means the natural or legal person responsible for placing a detergent or a surfactant for a detergent on the market; in particular, a producer, an importer, a packager working for his own account, or any person changing the characteristics of a detergent or of a surfactant for a detergent, or creating or changing the labelling thereof, shall be deemed to be a manufacturer.

  A distributor who does not change the characteristics, labelling or packaging of a detergent, or of a surfactant for a detergent, shall not be deemed to be a manufacturer, except where he acts as an importer.

2.3. Human health protection information requirements in Reg 648/2004

With regard to human health protection, the Regulation focuses on the allergic reaction to exposure to certain chemicals like powerful sensitizers contained in detergents formulations, mainly fragrance substances and preservation agents.

This project aims at assessing the presence in detergent formulations of the aforementioned chemicals [fragrances, enzymes, preservation agents (biocidal products type, PT6)], as well as the compliance with the requirements on relevant information management. Compliance with the BPD (Directive 98/8/EC) is included as well (Art. 3 DETER).

To keep consumers informed on the chemical nature of the components of the commercial mixtures, the DETER imposes that manufacturers offer on-line information about the ingredients used, aside from labelling obligations. Medical personnel should be able to obtain information directly from the manufacturer or from a specific public body designated by the Member State, about the ingredients of a mixture, to establish a link if it is the case, between exposure and patients' allergic responses.

The specific measures described by this Regulation in order to protect human health are summarized in the following:

a) Additional labelling and packaging requirements for detergents

Ref: Annex VII.A and art. 11.3 (instructions for use)

.

- **Specific constituents when present above 0.2%**

The following weight percentage ranges should be used to indicate the content of the constituents listed below: less than 5%; 5% or over but less than 15%; 15% or over but less than 30%, 30% and more.

This is applied for: phosphates, phosphonates, anionic surfactants, cationic surfactants, amphoteric surfactants, non-ionic surfactants, oxygen-based bleaching agents, chlorine-based bleaching agents, EDTA and salts thereof, NTA (nitrilotriacetic acid) and salts thereof, phenols and halogenated phenols, paradichlorobenzene, aromatic hydrocarbons, aliphatic hydrocarbons, halogenated hydrocarbons, soap, zeolites, and polycarboxylates.

- **Specific constituents, always, if present**

If added, enzymes, disinfectants, optical brighteners and perfumes shall be listed, irrespective of their concentration.

- **Allergenic fragrances**

Single fragrant components of a perfume are called fragrances; specific scents of certain perfumes are created by combining different fragrances.

DETER, contains two separate obligations in relation to fragrances and perfumes detailed in Annex VII.A, regarding information on the label:

1. An obligation to list **perfumes** as a **generic ingredient** if any fragrance has been added at all;
2. An obligation to additionally declare as separate ingredients **specific allergenic fragrances** annexed to the **CPD** (Directive 76/768/EEC, as amended, in **Annex III, Part 1**) if any have been added to the product **exceeding 0.01% by weight**.

This means that only if **fragrances that are not restricted under the CPD, Annex III part 1, are added** to a detergent, the label must state that the product contains "perfumes", but need not specify the particular fragrance or fragrances added.

If any **fragrances** used in the detergent **are restricted under the CPD**, **Annex III part 1,** in addition they have to be declared as separate ingredients, using the nomenclature established in this Directive.

The newest consolidated version *(03_06_2011*) of the CPD can be found in Eur-lex: http://eur-lex.europa.eu/RECH_consolidated.do

Searching for allergenic fragrances in part 1 of Annex III is not always an easy task, as it may happen that CAS numbers are not provided in the Annex for all the substances included.

It is also necessary to bear in mind that all the amendments of the CPD should be considered.

Also, when perfumes are added to a detergent, knowing the composition of the perfume in order to detect possible allergens, might not be an easy task for inspectors.

Perfume´s SDS or related information should in all cases be inspected and, if necessary, information should be obtained from the provider of the perfume.

There is a comprehensive list of fragrances used in consumer goods, of over 3.000 ingredients, with their CAS numbers, available at IFRA´s web page (International Fragrance Association): http://www.ifraorg.org/en-us/Ingredients_2

A list of the most commonly reported consumer goods allergens, with the reference to their entries in Annex III, part I of the CPD, and the INCI (International Nomenclature Cosmetic Ingredient) name, has been elaborated, in order to facilitate inspections:

Table 3.

Non exhaustive list of most commonly used allergenic fragrances listed in Annex III, part 1 of the CPD with the entry number

CAS Numbers	List of common allergenic fragrances	INCI Nomenclatura	Entry Annex III part 1 Cosmetic Directive
List of most frequently reported allergenic fragrances (well recognized contact allergens)[(1)]			
122-40-7	Amyl cinnamal	AMYL CINNAMAL	67
100-51-6	Benzyl alcohol	BENZYL ALCOHOL	45
104-54-1	Cinnamyl alcohol	CINNAMYL ALCOHOL	69
5392-40-5	Citral	CITRAL	70
97-53-0	Eugenol	EUGENOL	71
107-75-5	Hydroxycitronellal	HYDROXYCITRONELLAL	72
97-54-1	Isoeugenol	ISOEUGENOL	73
101-85-9	Amylcinnamyl alcohol	AMYLCINNAMYL ALCOHOL	74
118-58-1	Benzyl salicylate	BENZYL SALICYLATE	75
104-55-2	Cinnamal	CINNAMAL	76
91-64-5	Coumarin	COUMARIN	77
106-24-1	Geraniol	GERANIOL	78
31906-04-4	4-(4-Hydroxy-4-methylpentyl)-3-cyclohexenecarboxaldehyde (HMPCC)	HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE	79
List with frequently reported allergenic fragrances (less documented as consumer allergens)[(1)]			
105-13-5	Anisyl alcohol	ANISE ALCOHOL	80
103-41-3	Benzyl cinnamat	BENZYL CINNAMATE	81
4602-84-0	Farnesol	FARNESOL	82
80-54-6	2-(4-*tert*-Butylbenzyl)-propionaldehyde (Lilial)	BUTYLPHENYL METHYLPROPIONAL	83
78-70-6	Linalool	LINALOOL	84
120-51-4	Benzyl benzoate	BENZYL BENZOATE	85
106-22-9	Citronellol	CITRONELLOL	86
101-86-0	Hexyl cinnam-aldehyde	HEXYL CINNAMAL	87
5989-27-5	D-Limonene	LIMONENE	88

111-12-6	Methyl heptin carbonate (methyl 2-octynoate)	METHYL 2-OCTYNOATE	89
127-51-5	3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	ALPHA-ISOMETHYL IONONE	90
90028-68-5	Oak moss extract	EVERNIA PRUNASTRI EXTRACT	91
90028-67-4	Treemoss extract	EVERNIA FURFURACEA	92
81-15-2	Musk xylene		96
81-14-1	Musk ketone		97
1506-02-1 21145-77-7	Acetyl hexamethyl tetralin (AHTN) or 6-Acetyl-1,1,2,4,4,7-hexamethyltetraline); CAS No 1506-02-1/ 1-(5,6,7,8-Tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (Tonalide) CAS No 21145-77-7		182

(1) RIVM Report 320025001/2008: "Allergens in Consumer products"

- **Preservation agents**

Preservation agents are biocides belonging to Product-type 6 (PT6): **In-can preservatives.**

They are products used for the preservation of manufactured products, other than foodstuffs or feeding stuffs, in containers, by the control of microbial deterioration to ensure their shelf life, regulated by the Directive 98/8/EC of the European Parliament and of the Council, of 16 February 1998, concerning the placing of biocidal products on the market (BPD).

The enforcement of these biocides under the BPD will be detailed in Chapter 2.5

Regulation (EC) No 648/2004 (DETER) contains two obligations in relation to preservation agents (In-can preservatives), detailed in Annex VII.A, regarding information on the label:

1. **If added, preservation agents have to be declared as separate ingredients**
2. Common nomenclature established in the CPD should be used where possible.

Preservation agents should be looked into the CPD only for the sake of the nomenclature used. Otherwise, when detected in a detergent, inspectors should enforce compliance with the BPD and Regulation (EC) Nº 1451/2007, which repealed Regulation (EC) No 2032/2003, and entered into force on the 31st of December 2007.

Searching for preservatives (preservation agents) in the CPD is not always an easy task, as CAS numbers are not always provided in the Annexes.

It is also necessary to bear in mind that all the amendments of the CPD should be considered.

- **Web site address**

The web site address, from which the list of ingredients mentioned in section D of Annex VII can be obtained.

Detergents for industrial or institutional uses

If the detergent inspected is intended to be used in the industrial or institutional sector, and not made available to members of the general public, it has to be taken into account that the abovementioned requirements can be provided by means of technical data sheets, SDSs or in a similar appropriate manner.

Therefore, the former information can be excluded from the label and obtained from the documents described.

- **Instructions for use**

The packaging (or label) shall indicate instructions for use and special precautions, if needed. As this aspect is not developed in the annexes, it has been kept at a very general level in the questionnaire.

(See APPENDIX 4: *Instructions for filling in and explanations regarding the questionnaire)*

b) Additional labelling and packaging requirements and dosage information for detergents sold to the general public.

Labelling: Art. 11.2 and 11.4; Dosage information: Annex VII, B.

Special requirements for labels of detergents sold to the general public are listed:

-	Name and trade name of the product
-	Name or trade name or trademark and full address and telephone number of the party responsible for placing the detergent on the market
-	Address, email address (where available) and telephone number where the Ingredient Data Sheet for medical personnel can be obtained

Special requirements on dosage information for **laundry detergents** sold to the general public are listed:

- Recommended quantities and/or dosage instructions expressed in millilitres or grams appropriate to a standard washing machine load, for 3 water hardness levels and making provision for one or two cycle washing processes.
- Number of standard washing machine loads that can be washed with the contents of the package, using water of medium hardness.
- If provided, capacity of any measuring cup shall be indicated in millilitres or grams, and markings to indicate the dose of a standard washing machine load for 3 water hardness levels.

c) Ingredient Data Sheet (IDS)

Ref: Annex VII.C and Art. 9.3

Responsible legal or natural person

The person responsible of placing in the market detergents (mixtures), named in Regulation 648/2004 "manufacturer" (See Chapter 2.2 of this Manual), **has to develop an IDS for each of the mixtures placed in the market**, in order to make it available to any medical personnel upon request, without delay and free of charge.

In DETER, a packager working for his own account or any person changing the label of the mixture, shall be deemed to be a "manufacturer", therefore responsible of the IDS of the commercialized detergent.

Additionally, Member States (MS) may request **on national basis**, that the IDS is provided by the formulator to a specific public body, to which the MS has assigned the task of providing the information to medical personnel.

Confidential Information

The information contained in the IDS shall be kept confidential.

This confidentiality requirement affects **the recipients**: The public body, if there is one assigned and the medical personnel. The information shall be used only for medical purposes.

Table 4. Contents of the IDS

Contents of the IDS	Remarks
Name of the detergent	
Name of the manufacturer	
All ingredients[(1)] and for each of them: ▪ The common chemical name or IUPAC name ▪ The European Pharmacopoeia name ▪ The INCI name, where available ▪ CAS number ▪ The weight percentage range, as described on the right, in which it is added	- In order of decreasing abundance by weight - Sub-divided into the described weight percentage ranges: - 10 % or more, - 1 % or over, but less than 10%, - 0,1 % or over, but less than 1%, less than 0,1 %. - Impurities shall not be considered to be ingredients.
(1): Definition in Annex VII.C. and in Chapter 2.2. of this Guidance-Manual	

d) Publication of the List of Ingredients (LI)

Ref: Annex VII.D

The List of Ingredients is a less detailed version of the IDS, that must be placed in the public domain (on a website).

The following information of the IDS can be avoided:

- CAS number
- The weight percentage range, as described on the right, in which it is added

Table 5. Contents of the List of Ingredients

Contents of the LI	Remarks
Name of the detergent	
Name of the manufacturer	
All ingredients[(1)] and for each of them: ▪ The INCI name If not available: ▪ The European Pharmacopoeia name If not available: ▪ The common chemical name or IUPAC name	- Impurities shall not be considered to be ingredients. - The required name correspondence is established in the CosIng Data Base of the EC, at http://ec.europa.eu/consumers/cosmetics/cosing/
(1): Definition in Annex VII.C. and in Chapter 2.2. of this Guidance-Manual	

The **characteristics** of the web site should be inspected to enforce compliance:

Table 6. Characteristics of the web site

Characteristics of the web site	
Free access	The web site address can be obtained from the label of the inspected detergent. Access to the website shall not be subject to any restriction or condition
Kept up to date	Updated information on detergents composition
Link to the Commission Pharmacos website or a suitable web site providing a **correspondence between INCI names, European Pharmacopeia names and CAS numbers**	

We have to bear in mind that the obligation to publish the list of ingredients on a website does not apply to industrial or institutional detergents if they have a Safety Data Sheet or other appropriate documents in which this information is available.

FINAL NOTE OF CHAPTER 2.3: LABELS, IDS AND LIST OF INGREDIENTS INSPECTIONS FOR DETERGENTS

Verification of

a) and b) Additional labelling and packaging requirements for detergents concerning constituents
c) Ingredient Data Sheet (IDS)
d) List of Ingredients (LI)

To verify if the components of a detergent declared by the company are complete and if they fulfil the requirements of R (CE) nº 648/2004, the following documents should be **obtained** from the company and **compared**.
Consistency in the information offered should be found:

- **Label/package**
- **Safety Data Sheet**
- **Ingredient Data Sheet**
- Published **List of Ingredients** (if required)
- **Complete composition** of the inspected mixture
- Safety Data Sheet(s) of component(s)
- If appropriate, components chemical analysis.

2.4. Environmental protection requirements in Reg 648/2004

The environmental protection requirements in the Regulation 648/2004 deal with the concept of **biodegradability** and are applicable only to:

- Detergents containing surfactants
- Surfactants

In former legislation **only primary biodegradability (PB)** was addressed applicable only to anionic and non-ionic surfactants.

Present Regulation extends the requirements to cationic and non-ionic surfactants. It emphasizes **ultimate aerobic biodegradability (UAB)** taking the potential toxicity of persistent metabolites into account. This means paying attention to the capacity of surfactants or detergents containing surfactants for total oxidation to carbon dioxide, water and mineral salts (mineralization). UAB should be evaluated by one of the test methods listed in the Annex III of the Regulation. The level of UAB tested has to meet the criteria established in Annex III. A.

The criterion for ultimate biodegradability is 60% mineralisation within 28 days.

a) Laboratories competent to carry out the tests required

Ref: Annex I and Articles 7 and 8

The competence standards have to be proven by means of EN/ISO/IEC 17025, or the principles of GLP (except for cases in which GLP is mandatory).
Each Member State will verify the compliance of laboratories by means of accreditation bodies or GLP monitoring authorities with standards described in Annex I.

The Commission has published the list (2009/C 39/05; OJEU C39; 18.2.2009) of approved laboratories in the Official Journal at the following web site:

http://ec.europa.eu/enterprise/sectors/chemicals/files/docs/list_labs_detergents180209_en.pdf

b) Derogation

Ref: Articles 4, 5 and 6

In accordance with Article 4(2) derogation may be requested for **surfactants** in **detergents used in specific industrial or institutional sectors** that do not fulfil the criterion of Annex III of ultimate biodegradation within the stipulated period.

- What does derogation mean?

It is a special authorization granted by the Commission and published regularly in Annex V of DETER.

Derogations may allow, limit or severely restrict the placing on the market and the use of surfactants as ingredients in detergents and they may include a phase-out period.

- Which surfactants are subject of derogation?

Those that comply with the following conditions:

- Surfactants in detergents used in specific industrial or institutional sectors (professional use), meeting the criteria established in Article 6(1).

AND

- Failing to meet the ultimate biodegradation criteria (UAB).

AND

- Passing the primary biodegradability (PB) tests.

Methods for the testing of PB of surfactants in detergents are listed in Annex II of the Regulation.

If the level measured is lower than the one established in the Annex II, (at least 80%), derogation shall not be granted.

There is only one entry in Annex V: "*Alcohols, Guerbet, C16-20, ethoxylated, n-butyl ether (7-8EO)*, CAS: 147993-59-7" has obtained a derogation until 2019. It may be used for bottle-cleaning, metal cleaning and cleaning-in-place.

- What happens to surfactants that fail the PB test?

Surfactants of all types that fail to pass the PB tests, if used as ingredients in detergents, **should not be marketed in the EU**.

A list of detergents surfactants identified as not complying with the provisions of the Regulation 648/2004 is to be published in Annex VI.

No banned or restricted surfactants have yet been included in Annex VI

c) Information at the disposal of the Competent Authorities, CAs, of the MS
Ref: Article 9.1 and 2.

Companies placing on the market substances or mixtures covered by Regulation 648/2004, shall hold at disposal of Enforcement CAs:

Table 7. Information on the biodegradability testing

Information on the biodegradability testing	
Information on results of the tests in Annex III (UAB).	
For those surfactants that failed UAB tests: additional testing results.	- Technical file on results of tests in Annex II (PB) - Technical file on results of tests in Annex IV
Documentation on the testing carried out.	- To demonstrate compliance - If necessary, to demonstrate that they can benefit from the property rights concerning the tests results.

2.5. Enforcement and Borderline cases with Directive 98/8/EC

As stated in article 3(1) of the DETER, Detergents and Surfactants for detergents shall comply with the provisions of the Detergents Regulation, and, where relevant, with Directive 98/8/EC (BPD).

a) Disinfectants (Main Group 1: Product Types 1, 2, 3 or 4)

- Surfactants in detergents that are also active substances as disinfectants

The following applies according to Article 3(1) of the DETER: "Surfactants that are also active substances within the meaning of Directive 98/8/EC (BPD) and that **are used as disinfectants** are exempt from the provisions of Annexes II, III, IV and VIII of this Regulation."

Surfactants used as biocidal active substances (**disinfectants, MAIN GROUP 1**) are **exempted** of the **environmental requirements** of the DETER.

Provided, they are:

- Listed in Annex I or IA of the BPD
- Constituents of biocidal products authorised under the BPD or
- Constituents of biocidal products allowed under the transitional period of the BPD
- or subject to the Review Programme (Regulation 1451/2007).

In these cases:

- These specific surfactants are considered to be disinfectants
- Detergents in which these surfactants are ingredients are subject to the labelling provisions of the DETER, and specifically, the ones about disinfectants in Annex VII.A.
- Other surfactants also contained in the detergents shall not be exempted from the environmental provisions of the Detergents Regulation.

- Detergents/Cleaners with a biocidal claim as disinfectants

These products shall comply with both the provisions of the Detergents Regulation, and with Directive 98/8/EC (BPD).

b) In-can preservatives (Main Group 2: Product Type 6)

Preservation agents are biocides belonging to Product-type 6: **In-can preservatives.**

In case they are added to a detergent, compliance with the DETER has already been analyzed in Chapter 2.3.

Regarding compliance with the BPD, preservation agents are biocides that do not confer biocidal properties to the mixture in which they are ingredients.

Enforcement of these biocides should regard the following steps:

Table 8. Steps in the enforcement of "in-can" preservatives

Steps in the enforcement of "in-can" preservatives
1. Identification of potential "in-can" preservatives in the mixture
2. Verification of their presence in Annex II of Regulation (EC) No 1451/2007 for PT6 or in Annex I/IA of D 98/8/EC for PT6: *legal status* http://ec.europa.eu/environment/biocides/annexi_and_ia.htm http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_325/l_32520071211en00030065.pdf#page=37
3. Verification of their presence in a Non-Inclusion Decision for PT6 or in Annex II of R(EC) 1451/2007 for other PTs: *illegal status* http://ec.europa.eu/environment/biocides/non_inclusions.htm
4. In case the active substances bear an illegal status, confirmation of their "intended use" in the mixture should be obtained, at least, in cases where the substances may perform other possible roles in the formulation.

Identification may not be straight forward if the biocide PT6 used is itself a mixture: in this case SDS of the biocide will be necessary.

If the active substance does not have a legal status, its "intended use" in the mixture as a biocide PT6 should be confirmed.

Illegal active substances for PT6 should not be placed in the EU market, as such or in mixtures.

Together with this Project Manual **an Excel database** will be delivered to all participants, published on the internet by the French Ministry for Ecology, Sustainable development, Transport and Housing, **with the updated legal situation of all active substances** of the 23 biocidal product types in accordance with the EU Regulation (EC) No 1451/2007. (*See Chapter 8. Useful Links).*

2.6. Horizontal legislation

a) CLP Regulation

CLP Regulation is the new European Regulation on **C**lassification, **L**abelling and **P**ackaging of chemical substances and mixtures. The legislation introduces throughout the EU a new system for classifying and labelling chemicals, based on the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS).

CLP Regulation stands **for Regulation (EC) No 1272/2008** on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH). It came into force on 20 January 2009 and applies across the European Union.

The provisions of CLP will replace Council Directive 67/548/EEC (Dangerous Substances Directive, **DSD)** and Directive 1999/45/EC (Dangerous Preparations Directive, **DPD)** in a stepwise approach.

There are certain timelines for industry to classify and label their substances and mixtures in line with the CLP rules.

The obligations of a supplier of a substance or mixture depend upon his/her role under CLP.

The transition from the DSD/DPD directives to the CLP Regulation requires companies to plan certain steps.

For detergents and surfactants in detergents inspected, the common rule will be that surfactants C&L, as substances, will be adapted to CLP since 1st of December, 2010 and mixtures will generally still be classified and labelled, until June the 15th, 2015, according to DSD and DPD.

Nevertheless, it shall be taken into account that the responsible party could also classify and label mixtures according to CLP already now.

b) REACH Regulation

REACH is the Regulation for **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

It entered into force on 1st June 2007 to streamline and improve the former legislative framework on chemicals of the European Union (EU). REACH places greater responsibility on industry to manage the risks that chemicals may pose to the health and the environment.

In principle REACH applies to all chemicals: not only chemicals used in industrial processes but also in our day-to-day life, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances.

All manufacturers and importers of chemicals must identify and manage risks linked to the substances they manufacture and market. For substances produced or imported in quantities of 1 tonne or more per year per company, manufacturers and importers need to demonstrate that they have appropriately done so by means of a **registration** dossier, which shall be submitted to the Agency.

REACH also foresees an **authorisation** system aiming to ensure that substances of very high concern are adequately controlled, and progressively substituted by safer substances or technologies or only used where there is an overall benefit for society of using the substance.

REACH can impose **restrictions** and prohibit or set conditions for the manufacture, placing on the market or use of certain dangerous substances or group of substances when unacceptable risks to humans or the environment have been identified, through the restriction process described in REACH. In its Annex XVII, there is a list of the restricted substances or mixtures, which are regularly updated.

Manufacturers and importers must provide their downstream users with the risk information they need to use the substance safely. This will be done via the Classification and Labelling system (C&L) and Safety Data Sheets (SDS), where needed.

In REACH, a manufacturer means any natural or legal person established within the Community who manufactures a substance within the Community.

It has to be taken into account that the meaning differs significantly from the meaning of "manufacturer" under the Detergents Regulation. *(see Chapter 2.2 Definitions)*

In the **Questionnaire**, **REACH nomenclature** and definitions have been used to characterize the companies' roles, as it is basic legislation for chemicals.

3. OBJECTIVES AND GOALS

The primary goal of this Project is to contribute to the implementation of the Regulation by inspection and enforcement, as well as to evaluate the level of compliance with the Regulation.

At present, enforcement of this Regulation has been initiated in some Member States, but there has not been a widespread harmonized enforcement initiative throughout the European Economic Area **(EEA).** No EU-wide results from inspections and enforcement are known.

Also the compliance of the Biocidal Products Legislation will be evaluated in relation with the preservation agents present in the detergents formulations, as a logical follow up of the EuroBiocides Project run under the CLEEN umbrella.

The EuroDeter project wishes to foster and enhance the level of compliance, by performing control activities and by taking administrative measures to withdraw products that could present a risk for human health or environment. The Project can contribute to harmonized enforcement of the detergents legislation and promote good cooperation with enforcement authorities, nationally and internationally.

4. TIMELINE OF THE PROJECT

This project was presented at the 11th CLEEN Conference in September 2010 in Sucevita, Romania. All Member States and CLEEN members were invited to participate in the project.

Project execution is divided into three phases:

4.1 Preparation phase (2011-2012)

- Presentation of the Project at the 11th CLEEN Conference
- Clarification of participation of countries until the 30th of November 2010
- Establishing a project lead group which elaborates a guidance manual describing the working method, an inspection check list, an enforcement data collecting tool
- Establishing national coordinators, **NC,** in each of the participating countries (see their responsibilities on "Chapter 7, Participating countries").
- Timeline for the NCs of participating countries for contributing to the EuroDeter Manual and Questionnaire: 31st October 2011
- Adopting and distributing Manual & Questionnaire by the WG: December 2011
- Developing an excel-tool to collect the participant countries final results.

4.2 Operational phase (2012)

- Providing training for inspectors on national level by national coordinators: first quarter 2012
- WG sending out the excel-tool for collecting the results: first quarter 2012
- Performance of on site and on line inspections: May to November 2012
- Sending of a progress-report questionnaire by the WG to all NC of participating countries (June 2012). Feedback to the WG by end July 2012
- WG presentation of the progress report: 13th CLEEN Conference (Sept. 2012)
- Collecting and processing results by the NC: December 2012 – end of January 2013

4.3 Reporting Phase (2013)

- Processing the results and drafting the global report by the WG: February – September 2013
- Presentation of the Final Report at the 14th CLEEN Conference (September 2013)
- Publication of Final Report (December 2013).

- Preparation phase: until first quarter of 2012
- Operational phase: until end of 2012
- Reporting phase: until end of January 2013 with optional WG meeting
- Presentation and adoption of the Final Report: 14th CLEEN Conference (2013)

At national level, all results concerning enforcement, inspection of the companies, websites inspections and laboratory analysis evaluation are sent to the national coordinators. The national coordinators compile the results and send them via the enforcement data collecting tool to the project lead group.

The project lead group will draft a presentation containing interim results that will be presented and discussed in the plenary CLEEN meeting scheduled in 2012 (13th CLEEN Conference).

A draft final report will be discussed at the 14th CLEEN Conference, and the last version could be published at the end of 2013 and spread the results as usually.

5. WORKING METHOD FOR INSPECTIONS

A proposal for a harmonized working method to perform the inspections based on a step-by-step approach is included in the **Appendix 2** of this Project Manual.

5.1. Inspections Questionnaires: Q1, Q2 and Q3

- **Q1: General Company Information** to be fulfilled one per company inspected and

- **Q2: Product Information** to be fulfilled one per product

Specific **Instructions for filling in and explanations** regarding both questionnaires are included in the **Appendix 4** of this Project Manual.
See also **Table 9** in this Manual.

- **Q3: EURODETER Project General Comments**

To be fulfilled by the EAs (Enforcement Authorities), one per EA, and all Q3s produced whithin a participating country finally compiled by the NC of the Project into **one Q3 per country**.

Q2 Questionnaire is structured in the following sections:

Table 9. Where to look for product information

Where to look for information	Q2: Product Information
	A. Product General Information
LABEL Composition	B. Additional Labelling and packaging requirements for detergents
	1. General content indications on the label
	2. Indications on use
	3. Requirements in detergents for the general public
	4. Dosage information in laundry detergents for the general public
IDS	C. Ingredient Data Sheet (IDS)
website	D. Publication of the List of Ingredients
Composition	E. Biocides Legislation (PT 6)
LABEL -PACKAGE Composition	F. Preparations Directive: Classification & Labelling & Packaging
Test Verification	G. Biodegradability of surfactants
	H. Inspection Follow-up: Non-compliances identification/Measures to take

5.2 Number of inspections of companies and products

At the 12th CLEEN Conference, it was proposed and accepted that a minimum of **10 companies** should be inspected per participating country and minimum of **3 products** when possible, per company inspected.

Data collecting Excel tool

Results obtained in the Questionnaires Q1 and Q2 will be compiled in an Excel tool developed by the WG.

One Excel tool with all the collected data from the Questionnaires will be produced per participating country with the results of all inspections performed at a national level in the Eurodeter Project.

6. PROJECT MANAGEMENT

From the 11th CLEEN Conference (Sucevita, September 2010) Belgium and Spain are responsible for the management of the EuroDeter project, coordinating the overall project activities: preparing the Guidance- Manual, presenting it at the 12th CLEEN Conference (Larnaca, September 2011) and launching it in 2011.

6.1. Tasks of the Project Management:

- Elaboration of the Guidance-Manual describing the working method, including inspection Questionnaires and distribution by December 2011.
- Developing and sending to NCs an enforcement data collecting tool
- Preparation of a progress-report questionnaire to all NC of participating countries by June 2012 and presentation of results to the 13th CLEEN Conference.
- Compiling the results in the Excel tool from the NCs, and analyzing the data.
- Preparing the Final report with the results of the Project.

6.2. Members of the Project Management and Working Group

Spain **Rosario Alonso Fernández** Deputy Directorate General for Environmental and Occupational Health, Directorate General for Public Health. Ministry of Health, Social Policy and Equality, Madrid.
Spain **Maria Tarancón Estrada** Environmental Health Department. Directorate General of Public Health. Regional Department of Public Health of Andalucia, Sevilla.
Belgium **Michel Leynen** Federal Public Service Health. Food Chain Safety and Environment. DG Environment Enviroment Inspection, Brussels.
Belgium **Paul Cuypers** Flemish Government. Department Environment, Nature and Energy Environment Inspection Section, Brussels.

7. PARTICIPATING COUNTRIES

For the time being, 13 countries are participating: Belgium (BE), Estonia (EE), Finland (FI), Greece (GR), Ireland (IE), Latvia (LV), Lithuania (LT), Poland (PL), Serbia (RS), Slovenia (SI), Spain (ES), Sweden (SE) and Switzerland (CH). They should commit to support the project by allocating the necessary resources for the national preparation and operational phase of the project. Their national coordinators should be involved in the operational phase of the project.

7.1. National Coordinator tasks

The coordinator's function is to assure that the project is carried out in his/her country according to the agreed Manual.

Duties are:

- Informing involved authorities and trade organizations about the project
- If necessary, translate the manual, questionnaire and tools of the project to the national language
- To establish information exchange with involved inspectors, provide them with information and explanatory material the project and organise their training
- To facilitate communication between the involved national enforcement authorities and to help clarifying arising questions concerning the practical project implementation
- To collect submitted, filled in questionnaires (Q1 and Q2) from the national inspectors and **compile national data in the Project Excel tool**, summing up the results of the questionnaires submitted by inspectors.
- To prepare **one Questionnaire Q3** with a summary of the most significant Comments made by the inspectorate.
- Checking and assurance of data quality in order to get reliable results

7.2. Participating countries and national coordinators/contact persons

Table 10. Countries and national coordinators/contact persons participating in the Project:

Country	Name	E-mail
Belgium (BE)	Paul Cuypers (FP, WG)	paul.cuypers@lne.vlaanderen.be
	Michel Leynen (NC, WG)	michel.leynen@milieu.belgie.be
Estonia (EE)	Natali Promet (FP, NC)	Natali.Promet@terviseamet.ee
Finland (FI)	Birgit Kemiläinen (NC)	Birgit.kemilainen@tukes.fi
	Anna Forsbacka	anna.forsbacka@tukes.fi
Greece (GR)	Sophia Antoniadou (NC)	industrial@gcsl.gr
Ireland (IE)	Sinead MacMickan (FP)	sinead_mcmickan@hsa.ie
Latvia (LV)	Sintija Elferte (NC)	Sintija.Elferte@vi.gov.lv
	Kristīne Kazerovska	Kristine.Kazerovska@vi.gov.lv

Lithuania (LT)	Skirmantė Ambrazienė (NC)	s.ambraziene@vnmpi.lt
Poland (PL)	Aleksandra Moczulak (NC)	A.Moczulak@gis.gov.pl
Serbia (RS)	Jelena Mijatovic (NC)	jelena.mijatovic@shema.gov.rs
Slovenia (SI)	Vesna Novak (FP)	vesna.novak@gov.si
	Mr. Krapež (NC)	
Spain (ES)	Rosario Alonso Fernández (NC, WG)	ralonso@mspsi.es
	María Tarancón Estrada (WG)	maria.tarancon@juntadeandalucia.es
Sweden (SE)	Hadil Karim (NC)	Hadil.Karim@kemi.se
	Mona J. Åkerstörm (NC)	Mona.J-Akerstrom@kemi.se
Switzerland (CH)	Nadine Grisel (NC)	nadine.grisel@bag.admin.ch

FP: CLEEN focal point
NC: National coordinator for EuroDeter
WG: EuroDeter working group

8. USEFUL LINKS

8.1. Web DG ENTERPRISE, DETERGENTS
http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/detergents/index_en.htm

8.2.- Detergents consolidated version (27.06.2009)http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0648:20090627:en:PDF

8.3.- Cleaning – Detergency Definitions – Vocabulary – Trilingual version/ EN ISO 862, August 1995 (Ref. No. ISO 862: 1995 E)/ ISBN 0 580 201139

8.4.- List of approved laboratories in accordance with Art. 8 of DETER
http://ec.europa.eu/enterprise/sectors/chemicals/files/docs/list_labs_detergents180209_en.pdf

8.5.- CPD newest consolidated version (03.06.2011)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0768:20110603:EN:PDF
http://eur-lex.europa.eu/RECH_consolidated.do

8.6.- IFRA (International Fragrance Association)
http://www.ifraorg.org/en-us/Ingredients_2

8.7.- RIVM Report 320025001/2008: “Allergens in Consumer products”
http://www.rivm.nl/bibliotheek/rapporten/320025001.pdf

8.8.- Web site with a database of ingredients mentioned in Annex VII(D) of DETER:
http://ec.europa.eu/consumers/cosmetics/cosing/

CosIng Manual (version 12.03.2009):
http://ec.europa.eu/consumers/cosmetics/cosing/layout/CosIng_Manual.pdf

8.9.- Verification of the “in-can” preservatives presence in Annex II of Regulation (EC) No 1451/2007 for PT6 or in Annex I/IA of Directive 98/8/EC for PT6: *legal status*
http://ec.europa.eu/environment/biocides/annexi_and_ia.htm
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_325/l_32520071211en00030065.pdf#page=37

8.10.- Verification of “in-can” preservatives presence in a Non-Inclusion Decision for PT6 or in Annex II of Regulation (EC) No 1451/2007: *illegal status*
http://ec.europa.eu/environment/biocides/non_inclusions.htm

8.11.- Updated chart with the legal situation of all active substances of the 23 biocidal product types in accordance with the EU Regulation (EC) No 1451/2007 available on the Webpage of the French Ministry for Ecology, Sustainable development, Transport and Housing:
http://www.developpement-durable.gouv.fr/La-reglementation-biocide.html
(last updated 23.11.2011)

APPENDIX 1: List of the European Community Legal acts mentioned in the Manual or the Questionnaire

Subject	Directive / Regulation
Detergents	- Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents **(DETER)** - Last consolidated version 27.06.2009
Detergents, Annexes III and VII	Commission Reg (EC) No 907/2006 of 20 June 2006, amending DETER in order to adapt Annexes III and VII
Detergents, introducing the term "mixture/s"	Reg (EC) No 1336/2008 of the European Parliament and of the Council of 16 December 2008, amending DETER in order to adapt it to Reg (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
Detergents, Commission competence to modify Annexes	Reg (EC) No 219/2009 of the European Parliament and the Council of 11 March 2009, adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny
Detergents, Annexes V and VI	Reg (EC) No 551/2009 of 25 June 2009, amending DETER in order to adapt Annexes V and VI thereto (surfactant derogation)
Cosmetic products	- Council Directive 76/768/EEC of 27 July 1976, on the approximation of the laws of the Member States relating to cosmetic products **(CPD)** - Last consolidated version 03.06.2011
Biocidal products	- Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998, concerning the placing of biocidal products on the market **(BPD)** - Last consolidated version 01.03.2011
Biocidal products	Commission Reg (EC) No 1451/2007 of 4 December 2007, on the second phase of the 10-year work programme referred to in Article 16(2) of BDP
Classification, Labelling and Packaging **(CLP)**	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, on CLP of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Reg (EC) No 1907/2006 (REACH Regulation)
Dangerous substances	Council Directive 67/548/EEC of 27 June 1967, on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. **(DSD)**

Dangerous preparations	- Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999, concerning the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. **(DPD)** - Last consolidated version 20.01.2009
Registration, Evaluation, Authorisation and Registration of Chemicals **(REACH)**	- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC - Last consolidated version 05.05.2011
Micro, small and medium-size enterprises **(MS&MSE)**	Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises

APPENDIX 2: Working Method

Step	Activities	Comments/hints
1	**Developing Information to involve enterprises, authorities, trade unions about the EURODETER Project** • Public awareness	**Who**: CAs, EAs **Where:** Internet, letters, others
2	**Company selection** • Selection of companies: A **minimum of 10 companies** to be inspected by country	**Information sources:** Internet, catalogues, national/local companies registries, inspectorate lists & experience, etc.
3	**Collection of information to be used within the visit and preparation of the visit:** • Collect information on the company • Check if all information required is available	**Information sources:** Internet, catalogues, national/local companies registries, inspectorate former reports/knowledge.
4	**Preparation of the company visit:** *If notified inspections:* ▪ Send a letter with information on the Project and the inspection. • Make an arrangement with the company • Contact adequate person • Confirm arrangement *If non-notified inspections:* • Control the selected companies, traders, etc. Contact adequate person	**Notified or non-notified inspections**
6	**Select products** (detergents or surfactants) to be inspected: • A minimum of **3 products** (when possible) **per company inspected** • Ask for a list of detergents/ surfactants the company is producing/ importing/ using/ selling and volume produced or used, if necessary. • Ask for the SDS (and composition if necessary) of detergents/surfactants of interest and type of user. • Select the products	**Selection criteria:** -high volume production, -product type (surfactants/mixtures), -user (general public, professional), -hazards (harmful, sensitizer, dangerous for the environment…) -presence of in-can preservatives, -biocidal claim
6	**Q1 Inspect Company (Note 6.1)**	**In the Instructions to fill**

	- Company data - Company type (REACH definitions) - Member of association - Company size	**up the Questionnaire Q1,** an explanation of company roles and prioritization criteria are included.
7	**Q2 Check selected detergents/surfactants** *Ask for:* - Label/package - Safety Data Sheet - Ingredient Data Sheet - Complete composition of the inspected mixture - If appropriate, chemical analysis of the detergents or its components. - Information on Biodegradability tests results - Excel file with legal status of active substances. *Also:* - Clasification & labelling requirements - In-can preservatives presence: id and %. - Legal status of active substances. - Biocidal claim advertisement - Surfactant Biodegradability information	**In the Instructions to fill up the Questionnaire** there is clarification on how to proceed with Q2.
8	**Q2 Check website** - List of Ingredients - Contents of List of Ingredients - Characteristics of the website	**if mandatory** for the product
9	**Further information/enforcement required** - First inspection results obtained done - Evaluate the need for further information/analysis necessary - Ask for further information/analysis - Information/analysis received - Evaluation of additional documentation	
10	**Results** **-** Final results obtained - Evaluation of non-compliances/violations - Knowledge of the company on the detergents legislation	
11	**Follow-up** **-** Are there detected non-compliances **-** Adoption of measures - Need for further inspections - Report to legal departments	

APPENDIX 3: Questionnaires Q1, Q2 and Q3

EURODETER CLEEN PROJECT

Q1 – General/Company Information

- **Q1- Section 1. General Information**

1.1 Country:

1.2 Inspection date:

Only for internal use

1.3 Inspectors:

- **Q1- Section 2. Company Information**

2.1 Company code:

Only for internal use **2.1.1** Company name: **2.1.2** Address (street, number): **2.1.3** City: **2.1.4** Postal/zip code **2.1.5** Telephone/Fax: **2.1.6** E-mail: **2.1.7** Web:	

- **2.2.** Company type: (multi optional).

☐ Surfactant Manufacturer (M)
☐ Surfactant/Detergent Importer (I)
☐ Detergents Formulator or Packager working for his/her account (DU)
☐ Distributor (D) (creating or changing the labelling)
☐ End user (DU)

- **2.3** Member of an association of the detergents/chemicals sector or other professional associations

☐yes ☐no ☐Other. If "yes" or "other", indicate which:_____

- **2.4**. Company size: Definition according to Comm Recommendation 2003/361/EC

☐ Micro ☐ Small ☐ Medium ☐ Not SME ☐ Not known

Micro: <10 employees and ≤2 million euro annual turnover
Small: <50 employees and ≤10 million euro annual turnover
Medium: <250 employees and ≤50 million euro annual turnover

- **2.5** Knowledge about the Detergents Regulations

☐ available (either internally or sourced out)
☐ incomplete
☐ not available

EURODETER CLEEN PROJECT

Q2 – Product Information *(one per product)*

- A. Product General Information

1. Company code:
(please note it must be identical to the one assigned in Q1- 2.1)
2. Product code:
3. Product name:

4. Type of user:
☐ General public ☐ Industrial/institutional use ☐ Both

5. Type of Product
☐ Substance ☐ Mixture/Preparation

6. The information systems (label, SDS) inspected for this product are in the official language(s) of the Member State
☐ Yes ☐ No ☐ Partially

B. Additional Labelling and packaging requirements for detergents

☐ checked
☐ not checked

1.	**General content indications on the label / package** **Reference:** Art. 11.3 and Annex VII, Section A of Regulation (CE) nº 648/2004		
	a	Constituents present above 0,2% by weight and their percentage ranges are indicated as in Annex VII Section A, if present **Notes:**	☐ yes ☐ no ☐ partially ☐ not relevant
	b	All the constituents: enzymes, disinfectants, optical brighteners, perfumes are listed, if present **Notes:**	☐ yes ☐ no ☐ partially ☐ not relevant
	c	All the preservation agents present in the detergent are indicated **Notes:**	☐ yes ☐ no ☐ partially ☐ not relevant
	d	The preservation agents indicated are named using the nomenclature established in the Directive 76/768/EEC **Notes:**	☐ yes ☐ no ☐ partially ☐ not relevant
	e	All the allergenic fragrances on the list of substances in Annex III, part 1 of D76/768/EEC, if present above 0,01% by weight, are indicated **Notes:**	☐ yes ☐ no ☐ partially ☐ not relevant
	f	The allergenic fragrances indicated are named using the nomenclature established in the Council Directive 76/768/EEC	☐ yes ☐ no ☐ partially ☐ not relevant

		Notes:	
	g	The web site address (from where the List of Ingredients mentioned in Section D of Annex VII can be obtained) is present **Notes:**	☐ yes ☐ no ☐ partially ☐ not relevant
	[(1)] In case the detergent is intended to be used in the industrial or institutional sector, and not made available to members of the general public, it has to be taken into account that the abovementioned requirements can be provided by means of technical data sheets, SDSs or in a similar appropriate manner. In these cases, this information should be obtained from the documents described.		
2.	**General indications on use** **Reference:** Art. 11.3 of Regulation (CE) nº 648/2004		
	a	Instructions for use **Notes:**	☐ yes ☐ no/not required
3.	**General requirements in detergents for sale to the general public** **Reference:** Art. 11.2 and Art. 11.4 of Regulation R(CE) nº 648/2004		☐ checked ☐ not checked
	a	Name and trade name of the product **Notes:**	☐ yes ☐ no ☐ partially
	b	Name or trade name or trademark and full address and telephone number of the party responsible for placing the detergent on the market **Notes:**	☐ yes ☐ no ☐ partially
	c	Address, email address (where available) and telephone number where the Ingredient Data Sheet for medical personnel can be obtained **Notes:**	☐ yes ☐ no ☐ partially
4.	**Dosage information in laundry detergents for sale to the general public** **Reference:** Annex VII, B of Regulation (CE) nº648/2004		☐ checked ☐ not checked
	a	Recommended quantities and/or dosage instructions **Notes:**	☐ yes ☐ no ☐ partially
	b	Number of standard washing machines loads that can be washed with the contents of the package (using water of medium hardness) **Notes:**	☐ yes ☐ no ☐ partially

	c	If provided, capacity of any measuring cup (millilitres or grams) and markings for a standard load as expressed in Annex VII B. **Notes:**	☐ yes ☐ no ☐ partially
C. Ingredient Data Sheet[2]: Information of the inspected mixture to be made available **Reference:** Art. 9.3 / Annex VII, C of Regulation (CE) nº 648/2004 ☐ checked ☐ not checked			
1.	There is an Ingredient Data Sheet **Notes:**		☐ yes ☐ no
2.	The Ingredient Data Sheet is directly made available for medical personnel, upon request **Notes:**		☐ yes ☐ no
3.	The Ingredient Data Sheet is available through a national specific public body **Notes:**		☐ yes ☐ no ☐ not regulated
4.	The contents of the Ingredient Data Sheet are according to Annex VII, Section C **Notes:**		☐ yes ☐ no ☐ partially ☐ not available for inspectors
	[2]: The **Ingredient Data Sheet** is only meant for medical personnel, to be made available at request, without delay and free of charge, directly from the company responsible for placing the mixture in the market and, in some countries, through a specific public body. The responsible party may not provide, in a particular situation, the IDS to inspectors or other inspected companies. In this case, last option in question 4 should be chosen.		
D. Publication of the list of ingredients[3] **Reference:** Annex VII, Section D of Regulation (CE) nº 648/2004 ☐ checked ☐ not checked			
1.	The list of Ingredients is published on a website **Notes:** Address of the website		☐ yes ☐ no ☐ not relevant
2.	The contents of the list of Ingredients are according to Annex VII, Section D **Notes:**		☐ yes ☐ no ☐ partially

3.	If “no” or “partially” was the choice in the former question, missing information has been found related to: ☐ Product/formulator Name; ☐ number of ingredients listed; ☐ Order of the list ☐ Ingredients names; ☐ Allergenic fragrances **Notes:** *(multioptional answer)*	☐ no missing information
4.	There is free access to the website (not subject of any restriction or condition) **Notes:** If “no” indicate why.	☐ yes ☐ no
5.	The website is kept up to date **Notes:** If “no” indicate why.	☐ yes ☐ no
6.	The website includes a link to the Commission Pharmacos website or a suitable web site providing a correspondence between INCI names, European Pharmacopeia names and CAS numbers	☐ yes ☐ no
	[3] This obligation does not apply to industrial or institutional detergents, or to surfactants for industrial or institutional detergents, for which equivalent information is provided by means of a technical data sheet or safety data sheet or in a similar appropriate manner.	

E. Link to the biocides legislation (Directive 1998/8/EC, BPD): legal status of the preservation agents in the mixture and/or biocidal claim of the mixture

☐ checked
☐ not checked

1.		The mixture contains “preservations agents”: biocidal active substances (PT 6) (as such or in a mixture)	☐ yes ☐ no
2.		If “yes” to the former question:	
	a	**Active substance 1** ☐ Included in Annex II of R (EC) 1451/2007 for PT6 or in Annex I/IA of D 98/8/EC for PT6 (*status: legal)* ☐ In a Non- inclusion Decision for PT6 or included in Annex II of R (EC) 1451/2007 but only for other PTs. *(status: illegal)* **Notes:**	**CAS n° AS 1:** **EC n° AS 1:**
	b	**Active substance 2** *(only in case there are more than one)* ☐ Included in Annex II of R (EC) 1451/2007 for PT6 or in Annex I/IA of D 98/8/EC for PT6 (*status: legal)* ☐ In a Non- inclusion Decision for PT6 or in Annex II of R (EC) 1451/2007 only for other PTs. *(status: illegal)* **Notes:**	**CAS n° AS 2:** **EC n° AS 2:**

	c	**<u>Active substance 3</u>** *(only in case there are more than two)* ☐ Included in Annex II of R (EC) 1451/2007 for PT6 or in Annex I/IA of D 98/8/EC for PT6 (*status: legal)* ☐ In a Non- inclusion Decision for PT6 or in Annex II of R (EC) 1451/2007 only for other PTs. *(status: illegal)* **Notes:**	**CAS nº AS 3:** **EC nº AS 3:**
3.	The inspected mixture has a biocidal claim		☐ yes ☐ no
4.	If "yes" to the former question, indicate Product/s Type/s		PT1: PT2:
F. Link to the Preparations Directive (D 1999/45/EC, DPD): Detergents Dangerous properties information on the label **Reference:** article 11.1 of Regulation (CE) nº 648/2004 ☐ checked ☐ not checked			
1.	The detergent classifies as dangerous or is subject to hazard or safety statements, according to DPD **Notes: If no**, please go to question 11 of this section. **If yes**, go on with the questions 2-10 of this section.		☐ yes ☐ no
2.	Classification of the detergent according to DPD: *(multioptional, in each line tick the most severe applying danger category)* a. ☐ Explosive; ☐ Oxidizing b. ☐ Extremely Flammable; ☐ Highly Flammable; ☐ Flammable c. ☐ Very Toxic; ☐ Toxic; ☐ Harmful; d. ☐ Corrosive; ☐ Irritant; e. ☐ Senzitizing (R42 and/or 43); f. ☐ CMR cat 1 or 2; ☐ CMR cat 3; g. ☐ Dangerous for the Environment If it doesn´t classify as dangerous, but demands other hazard/safety statements: (*multioptional)* h. ☐ Specifically, DPD Annex V phrase on sensitizing substances effects. ☐ Others (e.g: DPD Annex V phrases)		
3.	The detergent has the required information on the label/package on its sensitizing properties (R42/43 and symbol, or Annex V phrase) according to DPD. **Notes:**		☐ yes ☐ no ☐ not relevant
4.	Chemical name(s) of the components of the preparation are present on the label according to DPD **Notes:**		☐ yes ☐ no ☐ partially ☐ not relevant
5.	The danger symbol(s) are present on the label according to DPD **Notes:**		☐ yes ☐ no ☐ partially ☐ not relevant

6.	The indication(s) of danger are present on the label according to DPD **Notes:**	☐ yes ☐ no ☐ partially ☐ not relevant
7.	The risk phrases (R-sentences) are present on the label according to DPD **Notes:** ("not relevant": e.g. packages < 125mL)	☐ yes ☐ no ☐ partially ☐ not relevant
8.	The safety advice (S-sentences) are present on the label according to DPD **Notes:** ("not relevant": e.g. packages < 125mL)	☐ yes ☐ no ☐ partially ☐ not relevant
9.	The packaging is carrying a tactile warning of danger **Notes:** Only for products sold to the general public classified as T+, T, Xn, C, F+(R12), or F (R11).	☐ yes ☐ no ☐ not relevant
10.	The packaging is fitted with a child-resistant fastening **Notes:** Only for products sold to the general public classified as T+, T, Xn (R65) or C.	☐ yes ☐ no ☐ not relevant
11.	The detergent classifies as dangerous or is subject to hazard or safety statements according to the CLP-regulation (Reg nº 1272/2008)	☐ yes ☐ no
G. Biodegradability of the surfactants: obligations of the manufacturers of surfactants (M) and formulators (DU) of mixtures **Reference:** article 9 and Annex II, III and IV of Regulation (EC) 648/2004 ☐ checked ☐ not checked		
1.	The manufacturer/Formulator (DU) of the substance/mixture has available the information concerning the biodegradability test results of the surfactant(s) either produced or used in the detergent? **Notes:** *If "no", why?*	☐ yes ☐ no ☐ partially ☐ not checked
2.	The manufacturer can demonstrate that he is allowed to benefit from the property rights concerning the test results (other than those results already in the public domain) **Notes:**	☐ yes ☐ no ☐ not checked
3.	The appropriate tests on ultimate biodegradability for the surfactant inspected (or surfactant(s) in the detergent inspected) have been performed according to Annex III **Notes:**	☐ yes ☐ no ☐ not checked
4.	The surfactant(s) inspected (or surfactant(s) in the inspected detergent) meet the criteria for ultimate biodegradability as laid down in Annex III. **Notes:** *If "no", go to question 5* *If "yes" or "not checked", go to section **H***	☐ yes ☐ no ☐ not checked
5.	The surfactant(s) inspected (or surfactant(s) in the inspected detergent) meets the criteria of primary biodegradability as stipulated in Annex II **Notes:**	☐ yes ☐ no ☐ not checked

6.	The surfactant(s) inspected (or surfactant(s) in the inspected detergent) is being placed on the market at the time the inspection takes place **Notes:** *If "yes" , go to question 7* *If "no" or "not checked" go to section **H***	☐ yes ☐ no ☐ not checked
7.	A request for derogation has been made to the CA of the MS and to the EC for the surfactant inspected (or surfactant(s) in the detergent inspected) **Notes:** *If "yes", go to question 8* *If "no" or "not checked", go to section **H***	☐ yes ☐ no ☐ not checked
8.	The commission has granted a derogation for the surfactant inspected (or surfactant(s) in the detergent inspected)	☐ yes ☐ no ☐ not checked
H. Inspection Follow-up		
1.	Has non-compliance been determined for the product? ☐ No ☐ Yes, with regard to ☐ Regulation (EC) nº 648/2004 ☐ Directive 1998/8/EC ☐ Directive 1999/45/EC **Comments:**	
2.	Measures imposed to the company due to non-compliance(s) found in this product inspection. ☐ No measures ☐ Verbal advice ☐ Written advice ☐ Order ☐ Enjoinment ☐ Fine ☐ Criminal complaint / Handing over to public prosecutor's office ☐ Others (please, describe in comments) **Comments:**	

EURODETER CLEEN PROJECT

Q3 – EURODETER Project General Comments

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APPENDIX 4: Instructions for filling in and explanations regarding the questionnaires

General Issues

- Fill out all items of a given section, except in the cases indicated in these Instructions.
- Fill out all relevant sections, if possible.

Q1- General / Company Information.

- Fill out one questionnaire per company – the form is not for distribution to companies.
- Questions shaded in grey indicate that these are questions which are only for internal use of the enforcement authority and which will not be used for the final project report

- **Section 2**

2.1. Company code: Code assigned by the enforcement authority (not a NACE code) that allows EAs to identify the inspected companies.

2.2. Company type: REACH definitions have been used, and compatibility with the "manufacturer" definition in the DETER is explained.

- **Surfactant Manufacturer (M):** any natural or legal person established within the Community who manufactures a substance (surfactant) within the Community.
- **Importer (I):** any natural or legal person established within the Community who is responsible for import of surfactants or detergents.
- **Downstream User (DU)**: any person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities, specifically formulators or packagers of detergents.
- **Distributor (D):** any person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture. (specifically those creating or changing the labeling)

The specific underlined parts in the definition of M/I/DU/D, are referring to the "Manufacturer" definition in the DETER, and therefore the responsible person for placing the surfactants/detergents on the market. These companies are the main target in the selection of companies in the Project

- **End User (DU):** A downstream user using substances or preparations in an industrial or professional activity (e.g. not a consumer or a distributor) who **does not supply** it further downstream. *(Ref: ECHA Guidance for Downstream Users).*

2.5. Knowledge about the Detergents Regulation

"Available" refers to "enough knowledge to fulfil the requirements of the Regulation".
"Not available" refers to "no knowledge about the Regulation at all".
"Incomplete" refers to "some knowledge as to fulfil some of the requirements but not enough to do it properly". It might be better to answer it at the end of the inspection.

Q2- Product Information.

- Fill out one form per product – the form is not for distribution to companies.
- Q2 has 8 sections: A, B, C, D, E, F, G and H.

Sections bound to be filled up depending on **the type of product** inspected:

Sections		Surfactants	Detergents for General public	Detergents Ind / Inst use
Q2.A	General information	X	X	X
Q2.B	Additional L&P requirements		X	X
Q2.C	Ingredient data sheet		X	X
Q2.D	Publication list of ingredients		X	
Q2.E	Link to the BPD		X	X
Q2.F	Link to the DPD		X	X
Q2.G	Surfactant biodegradability	X	X	X
Q2.H	Inspection follow up	X	X	X

Characteristics of the Sections: mandatory/optional parts:

Section A	Mandatory for all inspected products
Sections B, C, D, E, F, G	These Sections all have at the beginning the options "checked" or "not checked" ("not checked" because it is **not required or not relevant** or for other reasons) - One of the two options has always to be ticked - When option "not checked" is chosen, none of the questions of that section should be answered.
Section B	Mandatory for all inspected detergents **Parts 1 and 2** are mandatory for all detergents. **Parts 3 and 4** are meant only for detergents sold to the general public. In these two parts the options "checked" or "not checked" are inserted at the beginning of each part, and as indicated above: - One of the two options has always to be ticked - When option "not checked" is chosen, none of the questions of that section should be answered.

Section A

A2. Product code
It is not an EAN code but an internal code assigned by inspectors that allows EAs to identify inspected products if it is decided not to work with product names.

A5. Type of product
When a doubt arises as to whether the inspected product is a substance or a preparation/ mixture, the company declaration should be taken into account.

Section B

Part 2. Indications for use
They should relate to specific indications for use of the inspected detergent.
The Detergents Regulation does not provide details on what is considered to represent 'instructions for use and special precautions', to be indicated on detergents label.

However it could be considered that ' instructions for use and special precautions' encompasses the information necessary to be followed for a safe and efficient use of the given detergent.

The possible exemptions following the “if required” specification in DETER, remain unclear.

Regulation N°648/2004 provides for the requirements on labelling and packaging of detergents, without prejudice of provisions of DPD and DSD, now also by CLP.
Consequently, legal statements such as S-phrases from DPD or similar in other pieces of the chemicals legislation should not be considered as fulfilling “Instructions on use and special precautions'” of DETER.
(this criteria has been given by the EC/Enterprise GD~~,~~ after a request on the subject)

Part 3. General requirements in detergents for sale to the general public
Only to be checked when inspecting detergents placed on the market for the general public.

Part 4. Dosage information in laundry detergents for sale to the general public
Only to be checked when inspecting detergents placed on the market for the general public, specifically for laundry.

Section C

C1. There is an Ingredient Data Sheet (IDS)
The question asks if the IDS exist: if the party responsible for placing the detergent on the market has prepared an IDS.

C2. The IDS, Is it directly available for medical personnel, from the party responsible for placing the detergent on the market, by previous request?.

C3. Is the IDS available through a national specific public body?
- If in the participating country, the IDS management is regulated through a national body and the national body is in possession of the inspected IDS, the answer would be “yes”.

- If in the participating country, the IDS management is regulated through a national body and the national body is NOT in possession of the inspected IDS, the answer would be “no”.

- If in the participating country, the IDS management is NOT regulated through a national body, the answer would be “not regulated”.

Section D

Inspection of the website: The contents are described in the Manual, Chapter 2.3, Section d)

D1. The list of Ingredients (LI) is published on a website

The question asks if there is a website in which the list, LI, is published, regardless the quality or quantity of the information on it.

"Not relevant" will be used in the case of industrial or institutional detergents for which equivalent information is provided by means of a technical data sheet or safety data sheet or in a similar appropriate manner.

In case "Not relevant" is the answer chosen in D1, the rest of the questions in the Section should not be answered.

D3. Description of possible missing information

In case the answer to previous question D.2. is "yes", please tick the box of "no missing information" on the right. (in order to get more reliable final results, when treated).

D6. Link to a suitable Commission website where names correspondence can be found.

Section E

Section E tackles two specific aspects of the BPD: legal status of active substances (PT 6) and biocidal claim of the inspected product.

E1 and E2. Link to the Biocides Legislation: legal status of the preservation agents.

E1 has to be always answered.

In case "No" is the answer chosen in E1, question E2 should not be answered.

E3 and E4. Link to the Biocides Legislation: biocidal claim of the inspected product.

E3 has to be always answered.

If the answer is "yes", E4 asks for identification of the product/s type/s (23 in Annex V of the BPD) for which the biocide is placed on the market.

Section F

F1 has to be always answered.

In case "No" is the answer chosen in F1, questions F2 to F10 should not be answered.

Section G

This Section, if checked, has 3 questions, **G4, G6** and **G7**, in which, depending on the answer, the rest of the questions of the Section should be skipped and go to the following Section.

Section H

Clarifications on some of the terms used in this Section:

Written advice: Communicating obligations or minor improvements to be taken by the company.
Order: The company has to account for measures taken to correct identified failures within a certain time.
Enjoinment: Prohibition to place on the market the product before the identified failures have been corrected.
Fine: The company has to pay a fee for offence of a provision

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APPENDIX 5: Glossary

Agency: European Chemicals Agency (ECHA)
AS: Biocidal active substance
BDP: Biocidal Products Directive
BE: Belgium
CA/s: Competent Authority/ties
CAS nº: Chemical Abstracts Service number
CH: Switzerland
C&L: Classification and Labelling system
CLEEN: Chemical Legislation European Enforcement Network
CLP: European Regulation on Classification, Labelling and Packaging of ~~chemicals~~ chemical substances and mixtures
CPD: Cosmetic Products Directive
D: Distributor (company type) Q1
DETER: European Regulation on detergents
DPD: Dangerous Preparations Directive
DU: Down stream user (company type) Q1. End user is included
EA/s: Enforcement Authority/ties
EC: European Commission
EC nº: European Community number
ECHA: European CHemicals Agency
EE: Estonia
EEA: European Economic Area
ES: Spain
EuroDeter: CLEEN inspection project on the European Regulation on detergents
FI: Finland
GR: Greece
I: Importer (company type) Q1
IE: Ireland
IDS: Ingredient Data Sheet
INCI: International Nomenclature Cosmetic Ingredient
IFRA: International Fragrance Association
LI: List of ingredients
LT: Lithuania
LV: Latvia
M: Surfactant manufacturer (company type) Q1
MS&MSE: Micro, small and medium-size enterprises
MSE: Medium size enterprise
MS: Member States
NC: National Coordinator

NL: The Netherlands

PB: Primary biodegradation

PL: Poland

Pt/PTs: Biocidal product type/s

PT1: Human hygiene biocidal products

PT2: Disinfectants

PT6: Product type 6 (In-can preservatives)

Q1: EuroDeter questionnaire on “general company inspected information”

Q2: EuroDeter questionnaire on “product information”

Q3: EuroDeter project general comments

REACH: Registration, Evaluation, Authorisation and Registration of CHemicals

Reg: Regulation

RIVM: Dutch National Institute for Public Health and the Environment

RS: Serbia

SDS: Safety Data Sheet

SI: Slovenia

SE: Sweden

UAB: Ultimate aerobic biodegradation

UN GHS: United Nation’s Globally Harmonised System of Classification and Labelling of Chemicals

WG: Working Group

5.3 Annex III: Project management team

Spain

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