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## **A EUROPEAN ENFORCEMENT PROJECT ON THE NOTIFICATION OF NEW SUBSTANCES (NONS); A COOPERATIVE PROJECT OF 14 EUROPEAN COUNTRIES**

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### **SUMMARY**

An impression on the set up and progress of the European inspection project on the notification of new substances (NONS) is given. Fourteen European countries have participated in this ongoing project and inspected approximately 100 companies. The preliminary results show some serious problems with enforcing this regulation. These problems will be reported to the European Commission and might lead to revision of European legislation. Besides this, the set up of this project has already proven to be very successful and can serve as a blueprint for other European inspection projects.

### **1 NOTIFICATION OF NEW SUBSTANCES, DIRECTIVE 67/548/EEG**

#### **1.1 European legislation on new substances**

In Europe many chemical substances are produced and imported. These chemicals may expose man and the environment to unknown risks. To prevent the placing on the market of new substances without reliable information on the dangerous properties the European Union adopted in 1979 the Dangerous Substances Directive and improved this in 1992 (92/32/EEC)<sup>1</sup>

By introducing a harmonized notification procedure since 1983 new chemical substances must be notified before placing on the market. The submitted information enables assessment by the various EU-member states of the dangerous properties of the chemical substance and is used to provide essential information for users in classification, labelling, packaging and safety data sheets.

#### **1.2 Enforcement activities**

The success of the above described risk assessment relies not only on the chemical substances regulation implemented in the national legislation of the affected European countries, but also on the monitoring of compliance with this regulation. New chemical substances which have been placed on the market without proper notification lack adequate information. These substances could be on the market without proper classification, labelling and packaging, and without proper information in safety data sheets. These "no-notified" substances could present a serious danger to man and the environment, not only in one member state but potentially in all European Countries.

As most Member States were not yet actively enforcing this regulation, the EU started in 1991 a project to develop a guidance manual to assist enforcement authorities in starting up enforcement activities in this area. The manual was developed by a European working group. It is based on practical experience within Member States in the selection and preparation of

inspections of companies that are manufacturing, selling, or importing new chemical substances. In October 1993, the manual was accepted by the Member States. A European inspection project seemed to be a useful continuation of the cooperation between member states on the enforcement of this regulation.

## **2 THE “NOTIFICATION OF NEW SUBSTANCES” (NONS) PROJECT**

The Dutch Main Department of Enforcement Environmental Legislation of the Inspectorate for the Environment took the initiative to coordinate an enforcement project on this area; The realization of this project takes place in cooperation with the EU-subgroup on Control Measures under the Chairmanship of the United Kingdom.

### **2.1 Aim of the project**

The main aim of the NONS-project is to foster a greater degree of compliance of companies with regard to the notification of new substances. A second aim is to monitor the occurrence of hazardous dyestuffs. This information can be useful for policy decisions. Moreover, the cooperation of the participating countries might be an example for other European enforcement projects.

### **2.2 Set up of the project**

A Dutch proposal for a European inspection project was put forward during a meeting of the competent authorities for the implementation of directive 92/32/EEC, (Brussels, 17 and 18 January 1995). The proposal was given a positive reception. The competent authorities of most of the EU member states and of Norway were interested in participating in the project. The European Commission (DG XI), also present at the conference, stressed the importance of the interchange of information and sharing of enforcement experience and welcomed the initiative of an inspection project.

For the organization of the project the Dutch Inspectorate contracted an experienced consultancy. The first action was to send a ‘request for participation’ accompanied by a proposal for a project plan, to all European Member States and to Norway. According to the project proposal, participation in the project requires attending three workshops and carrying out a certain number of company inspections. The response was overwhelming. The following countries indicated that they were interested and are now actually participating in the inspection project: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom.

The project includes three phases: the preparation phase, the operational phase, and the reporting phase. Each phase ends with a conference. Subjects of those conferences are subsequently: 1) preparation and working method; 2) problems and preliminary results and 3) the final report and future cooperation. Participants are committed to inspect a number of companies and to take (if necessary) some samples for analyses.

During the first conference in Leiden (the Netherlands) on May 15-17, 1995 enforcement and policy authorities from 14 European countries reached agreement on the project program. This meant that those countries would visit between 70 and 100 importers and producers of dyestuffs during 1995 and in the beginning of 1996. The dyestuff industry was selected because a desk study had shown that this sector is the most innovative in developing new chemical substances and it is well known that certain groups of dyestuffs have hazardous properties. The conference met at the end of the preparation phase and at the beginning of the operational phase.

A company inspection means: checking whether imported or produced substances (which can be part of a preparation) are in the European inventory of existing chemical substances (EINECS)<sup>2</sup>. In order to check this, one needs to know the chemical constitution of the product or the CAS-<sup>3</sup> and/or EINECS-numbers of all ingredients. During the conference participants agreed that minimal 25 dyestuffs would be checked per company.

### 2.3 Results so far

By now the project is in the operational phase. The first results of the project are emerging. Most countries have selected companies by using all different kind of sources, like custom agencies, product registers, and handbooks. Company visits are carried out and for problems related to those visits, a help-desk in the Netherlands is available. Participants are kept informed about each others activities by means of newsletters.

Company visits lead often to demanding problems, which require energy and creative solutions from the inspector. A problem, for instance, is the lack of knowledge of the regulation especially by importers of dyestuffs. Part of the companies are not aware of their obligations and know only the performance of a product rather than their chemical constitution.

In addition, suppliers of visited companies are not very keen to provide information about the chemical identity of a product. They are not familiar with the EINECS and, according to some of the visited companies, suppliers in Eastern Asiatic countries do not always know themselves the chemical constitution of a dyestuff. Hopefully producers, especially in those countries, will become more conscious of European obligations and the need to register chemical names and potential hazards of their products.

By means of sample analyses supplied information on the chemical constitution of a product is checked. In too many cases it happens that the given information is proven to be wrong. The credibility of other supplied information by the company is therefore questionable.

## 3 AN EXAMPLE FOR OTHER EUROPEAN PROJECTS

### 3.1 Positive results

Positive results so far are; increased cooperation between participating countries, sharing of knowledge and improved control methods by discussing results and using each other's capacities. Probably all participants underwrite the preliminary conclusion that the enforcement in every participating country improved during this NONS-project and is stimulated by new ideas about enforcement methods.

Another result of this project might be a strong signal to policy-makers and the European Commission concerning problems in enforcing this directive. This may lead to a modification of some essential regulations. By now major differences are seen in, for instance, national legislation concerning the registration of the chemical constitution of products by companies.

### 3.2 A Blueprint

It is evident that European directives will be executed much more effectively when enforcement is realized in all Member States, instead of absence of enforcement in all or some member states. For participating countries which were not yet actively enforcing this regulation, gaining experience might be an impulse for maintaining an appropriate enforcement level on this area. On the other hand countries which already have an enforcement history on this area learn to look critically to their enforcement methods and to sharpen them.

On several related areas the progress and results of the NONS-project are followed with interest. For instance, the Existing Substances Regulation might be the next European Enforcement project to be started in this area. For this regulation one might expect enforcement barriers on international level, as its effectuation asks already a lot of cooperation between member states on policy level.

### 3.3 Conclusion

Being aware of the promising progress of this project and the enthusiastic participation of the fourteen countries, one might conclude that a project like this is very valuable and might serve as a blueprint for other European projects.

## REFERENCES

1. European Directive 92/32/EEC is the 7th Amendment of Directive 67/548/EEC on classification, packaging and labelling of dangerous substances, European Commission, 27 June 1967.
2. European Publication C 146A, European inventory of existing chemical substances (EINECS); 15 June 1990, Brussels; this inventory was made during the eighties and is meant to make a distinction between 'new' and 'existing' chemical substances.
3. The CAS-register (chemical abstract service) is a kind of chemical library. Every substance which has been published is given a reference number in order to facilitate literature searches. Substances in EINECS are numbered and cross-linked with their CAS-number. So having a CAS-number might be an entrance to check whether a substance is in EINECS.