
SOLID ENFORCEMENT OF NEW SUBSTANCES IN EUROPE (SENSE)

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SUMMARY

The second European enforcement project on EU directives 92/32 EEC and 67/548 EEC (notification of new chemicals) was carried out in 1996 and 1997. In total about two thousand substances were checked at 100 companies all over Europe. Most common trespassing of the directives occurred in the field of Safety Data Sheets (lacking or incorrect over 30%), labeling, and classification. Various measures have been taken. Only 5% of the new chemicals were not notified which is an improvement compared to the first enforcement project which had a rate of 37%. However, incorrect labeling remains a problem.

1 INTRODUCTION

The objective of the European Union's (EU) effort to harmonize notification procedures for new substances (EU directives 92/32/EEC and 67/548/EEC) is to obtain reliable data about new chemical substances before they are placed on the market (as a substance or in a preparation). This enables Member States to evaluate the associated risk of the notified substance on the public and the environment and, if necessary, to consider measures for risk reduction. In practice, there appeared to be substantial differences in the way the Directive was enforced in Member States. For this reason, a European enforcement project on the Notification of New Substances: NONS was carried out, starting in January 1995 and ending in June 1996. All Member States (except Luxembourg) and Norway participated in the project; Italy participated as an observer.

To further strengthen and expand the European enforcement network, a second enforcement project has been carried out, focusing again on Directive 92/32/EEC. The same countries participated as in NONS. The project, called SENSE (Solid Enforcement of New Substances in Europe) started in September 1996 and ended in December 1997.

2 OUTCOME: SUBSTANCES CHECKED

In total, 1,905 substances were checked at 100 companies within the framework of the SENSE project. Of the total number of 1,905 substances checked, 1,805 (95%) could be identified. Finally, 100 substances (5%) could not be identified.

Of the 1,905 substances checked, 1,572 (83%) were existing and 233 (12%) were new and therefore were required to be notified. Only 11 of these 233 new substances (5%) were not notified.

The classification and labeling of dangerous substances was checked as well. Of the 1,805 substances checked and identified, 513 (28%) were on Annex 1. Of these 513 substances, 386 (75%) were correctly classified and 295 (58%) were correctly labeled.

For 1,252 of the 1,905 substances checked (66%), material safety data sheets were available. A check of these data sheets showed that 80% (1,004 of these 1,252) were correct.

There were 38 samples taken of substances checked within the framework of the SENSE Project. Only 14 of these samples have been analyzed; 12 of them (86%) are in correspondence with the information provided by the company.

3 OUTCOME : COMPANIES INSPECTED

The SENSE Project found that 32 of the 100 companies inspected (32%) were not working according to Directive 92/32/EEC. The violations included:

- marketing new, not notified substances;
- marketing quantities of new, notified substances not according to the notification;
- no or incorrect, labeling and safety data sheets; and/or
- no or insufficient internal control.

More than 600 requests for information and 200 warnings were sent to the inspected companies. These mainly concerned the identification of chemical substances and the improvement of company records, classification and labeling, and safety data sheets. As a result of the follow up actions, the number of substances that could not be identified decreased by 569 (from 669 directly after the company inspection to 100 after follow up). This is 30% of all the 1,905 substances checked. In 8 cases, the production/import of a substance was forbidden. Two such selected substances were notified by a sole representative. Because more importers in more Member States were involved, these inspections gave the opportunity to gain experience with coordinated enforcement actions on a European scale. The inspections made clear that most of the companies inspected did not even know that they were covered by a sole representative.

4 CONCLUSIONS

A comparison of the results of the SENSE project with those of the NONS project leads to the conclusion that the compliance with Directive 92/32/EEC by companies seems to have improved. Despite the apparent improvement, it can be concluded that compliance by companies should still further improve in order to further reduce the risks for public health and the environment. Besides, the SENSE project made clear that companies can still not always provide the controlling authorities with the data necessary to establish the chemical identity of substances.

However, most of the companies inspected were very cooperative and endorsed the project goals (as was the case in the NONS project).

Thanks to the experiences gained with company inspections in the NONS project, inspectors were more familiar with the enforcement of Directive 92/32/EEC. This resulted in a more efficient and effective way of working in the SENSE project.

The SENSE project has certainly consolidated and strengthened the existing European NONS network. New inspectors were trained and information was exchanged in a large number of bilateral contacts.

5 RECOMMENDATIONS

5.1 To companies

The SENSE project made clear that, as in the NONS project, the identification of chemical substances is often difficult and time consuming. Safety of employees and customers would be greater and inspections could be more efficient and effective if substances were adequately labeled and if companies would have an adequate recording system, enabling them to identify what they supply. In particular, the classification and labeling of dyestuffs needs and is an area which capable of improvement.

5.2 To Inspectorates

With regard to future inspections of companies a balance should be found between 'fast checks' and 'in-depth checks.' Inspections can be more efficient if inspectors are supported by technical facilities, such as a computerized version of European Inventory of Existing Chemical Substances/European List of New Chemical Substances that can be used 'on the site.'

Working on a project-basis proved to be successful. To emphasize the advantages and results of the project approach, a leaflet will be drafted and disseminated in which the NONS and SENSE experiences will be summarized (project approached, results and reasons for success).

There is a need for an 'on going' European enforcement structure for new substances. Collaboration with any initiatives on existing substances is considered to be fruitful. Some Member States consider that, ultimately, there should be a common network for all chemicals. However, in the meantime, to ensure a clear focus for the enforcement networks, separate identities should be retained for any new and existing substances. In view of the success of the NONS and SENSE projects, the existing substances network should be encouraged to adopt similar approaches.

The participants of the SENSE Project agreed to hold a further meeting of the network immediately after the first meeting of the existing substances Project. A proposal is now being prepared. This first meeting will probably take place in March 1998.

5.3 To the European Commission

One of the recommendations of the NONS project was that consideration be given to clarifying the need for a requirement in national legislation in future amendments to relevant EU Directives. This is important to allow legal steps to be taken against companies who do not provide data necessary to identify chemical substances. This recommendation still stands after the results of the SENSE project. The 'ongoing' European enforcement structure on new substances should be supported by the European Commission (directly and through IMPEL - The Implementation and Enforcement of Environmental Law network), thus ensuing a coordinated approach and enlarging the 'status' of the European network.

In view of its interest in the environmental aspects of this work, IMPEL will be informed of the outcome of the SENSE project and any further initiatives. It is also recommended that IMPEL consider adopting similar project approaches for any enforcement initiatives on environmental legislation that fall within their purview.

