Ann. Ist. Super. Sanità, vol. 30, n. 4 (1994), pp. 367-372

Implications of Council regulation 793/93 on the evaluation and control of existing substances

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Summary. - The European Union (EU) programme on existing substances makes provision for the delivery by industry of data on substances produced or imported above certain quantities which will be used by the Commission to facilitate selection of priority lists of substances for which risk assessments will be carried out. The substances comprise three subsets of the existing substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) according to the respective deadlines for delivery of the data. The risk assessments are performed by the member states according to a commission regulation 1488/94 supported by guidance documents, may require further data delivery or performance of tests by industry and must conclude that the substance is either of no concern, of concern and risk reduction measures are appropriate, or require further data or testing to arrive at one of the other conclusions. The EU programme on existing chemicals is coordinated with the related OECD programme which will allow chemicals evaluated under regulation 793/93 to constitute an EU contribution to OECD and to largely allow the community to avoid investing unnecessary resources in substances being evaluated by non-EC countries.

Key words: risk assessment, existing substances.

Riassunto *(Implicazioni del regolamento del Consiglio 793/93 sulla valutazione e controllo delle sostanze esistenti).* - Il programma dell'Unione Europea (UE) sulla valutazione e il controllo delle sostanze esistenti, in base al regolamento del Consiglio 793/93, prevede la fornitura di dati sulle sostanze commerciali prodotte o importate al di sopra di determinate quantità. I dati saranno quindi utilizzati dalla commissione per la selezione delle sostanze la cui valutazione del rischio sia ritenuta prioritaria. Le sostanze interessate dal regolamento costituiscono tre classi delle sostanze elencate nell'Inventario europeo delle sostanze chimiche esistenti (European Inventory of Existing Commercial Chemical Substances, EINECS) e definite dalla data entro la quale devono essere fornite le informazioni. La valutazione del rischio è eseguita dai paesi membri in base al regolamento 1488/94 della commissione ed alla documentazione guida, ma potrebbe richiedere ulteriori dati o l'effettuazione di saggi da parte dall'industria. La valutazione deve portare a una conclusione sull'esistenza, o meno, di rischi, sull'adeguatezza, o meno, delle misure di controllo, ovvero sulla necessità di ulteriori dati o prove per giungere a una conclusione. Il programma dell'UE è coordinato con quello dell'OCSE nel senso che le sostanze valutate in base al regolamento 793/93 costituiscono un contributo dell'UE al programma OCSE il che permette alla Comunità di evitare inutili investimenti nello studio di sostanze già valutate in paesi extracomunitari.

Parole chiave: valutazione dei rischi, sostanze esistenti.

Introduction

The European Union Programme on Existing Substances per Council regulation 793/93 on the evaluation and control of the risk of existing substances was adopted by Council on 23 March 1993 and came into force on 4 June 1993.

The regulation provides for the delivery by industry of data on substances produced or imported above certain quantities. This data will be used by the Commission to facilitate the selection of priority lists of substances for which risk assessments will be carried out by rapporteurs in the member states.

This paper outlines how the regulation is being implemented, describing the successive activities and the roles of the parties involved, as shown in Fig. 1.

Data. Collection and delivery

Substances

The substances covered by the regulation and for which data must be delivered comprise three subsets of the existing substances listed in European Inventory of Existing Commercial Chemical Substances (EINECS) according to the deadlines for delivery of the data.

- HPV (high production volume) substances produced (or imported) in more than 1000 tonnes per annum and which are listed in annex I of regulation 793/93. Data for this set of substances must be delivered by 4 June 1994.

- HPV substances other than those listed in annex I, yet listed in EINECS for which data must be delivered by 4 June 1995.

- LPV (low production volume) substances produced or imported in 10-1000 tonnes/annum and listed in EINECS for which data must be delivered between 4 June 1996 - 4 June 1998.

Data. Structure and software

Basic data on production volumes and uses, physical-chemical properties, toxicological and ecotoxicological effects as well as environmental fate, shall be delivered by companies who produce or manufacture the substances covered by the regulation. The data must be delivered on diskette in one of four specific formats using a special software package, named Harmonised Electronic Data Set (Hedset) developed by the Commission and available in the nine EU languages from the EU offices in the member states (annex V of the regulation).

The diskettes are delivered to the European Chemicals Bureau at the Commission's Joint Research Centre at ISPRA, Italy, where they are stored in a database called European Chemicals Information Database (Euclid), based on a structure replicating that of Hedset and supported by software facilitating data searches in the nine languages of the EU.

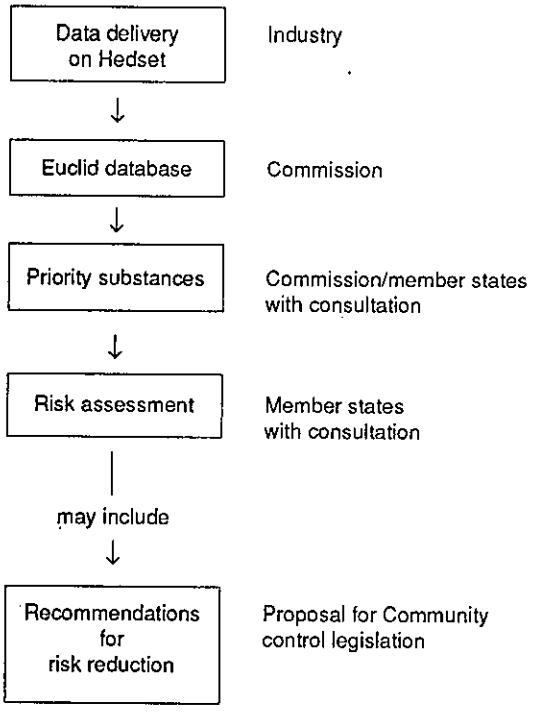

Fig. 1. - Council regulation 793/93/EEC on the evaluation and control of the risks of existing substances. Adopted by European Council: 23 March 1993. Entered into force: 4 June 1993.

Hedset and Euclid have been accepted by OECD as software tools for data collection and management in their existing chemicals programme with which the EU Programme is coordinated.

Liability to deliver data falls on those companies which produced or imported the substance in the quantity described at least once in the three years preceding the adoption of the regulation or in the year following adoption, i.e. during the period 23 March 1990 - 23 March 1994. The substance related data may be submitted by one company on behalf of others who must however and in all cases deliver the company-related part of the data.

Data. Access and dissemination

Access to all data stored in Euclid will be, given the commercially sensitive nature of some of the data, restricted to persons "habilités aux secrets" of the Commission and the competent authorities of the member states. A separate version of Euclid excluding this sensitive data which will still include all the scientific and technical data will also be made generally available.

The dissemination medium foreseen is that of CD-ROM. This data can be incorporated in existing data structures or utilized as supplied. It is necessary to have an Oracle licence in order to use the Euclid software, which will be made available separately. The Euclid software is essential where the user intends to exploit fully the searching permutations facilitated by the Euclid structure. Where only basic document (dataset) retrieval or other simple queries are envisaged, this can be realised using the Hedset software or other software which operates in a DOS environment. The Commission also envisages to publish a version of the non-confidential data on a CD incorporating such a basic retrieval software.

Selection of priority lists

The objective of collecting data on Hedset is to facilitate the selection of priority substances. This will be based on an automated preanalysis of the data and will also take into consideration both work being carried out in other fora or under other pieces of EU legislation and previous work of such programmes or legislation.

First list

Given the deadlines imposed by the regulation it was necessary to distinguish between the first priority list which must be published by 4 June 1994 (the date by which data must be delivered for annex I HPV substances) and later lists. As the first list could not be based on analysis of data arriving to a deadline by which the list is published, it was prepared in an *ad hoc* fashion by considering national proposals in the light of work in other programmes.

Ranking of substances according to the IPS priority setting method

The member states have considered the use of a computerized model (the IPS priority setting method) to rank chemicals according to relative risk comprising scores for physical-chemical properties, human health and ecotoxicological effects and environmental fate based on an analysis of the data submitted on Hedset pursuant to articles 3 and 4 of regulation 793/93.

As it is clear that a ranking produced by any model is certain to be based on assumptions and approximations and the relative subjectivity of weighting factors, a ranking on its own cannot constitute an adequate evaluation of risk to man and the environment and thus a model cannot be the only tool used in selection of priorities.

Priority setting. Considerations

The role of the ranking produced by the IPS method in the overall scheme of selecting priority chemicals for evaluation per regulation 793/93 is illustrated in Fig. 2.

The factors which should be considered in deriving the priority list from the ranking emanate from the policy outlined in article 8 of the regulation:

- the effects of the substances on man or the environment;
- the exposure of man or the environment to the substance;
- the lack of data on the effects of the substance on man and the environment;
- work carried out in other international fora;
- other EU legislation and/or programmes relating to dangerous substances.

The first two factors, the effects and the exposure are considered by the IPS method. The lack of data on these factors is also considered by the IPS method as data gaps are filled with conservative default values based on risk phrases per directive 67/548/EEC. Work already carried out in international fora and under other legislative programmes is however not considered by the IPS method.

An existing risk assessment report on a substance arising from work in other fora could either:

- lead to its being set-aside if that report indicates that the substance is of low concern, in which case the ranking is likely to be low; or
- lead to its being adopted as a candidate for a fast-track review where the report recommends risk reduction or indicates that the substance is of concern.

These principles apply to reports generated pursuant to other EU legislation as well as other international programmes.

Where a substance is currently being evaluated under a similar programme or legislation, it would be advisable to set it aside regardless of its ranking until such time as the evaluation in the other programme is complete.

This policy is based on the principle of avoiding duplication of work already carried out and by setting priorities in concert with other similar and ongoing programmes.

It is clear that the EU programme must be coordinated in particular with the OECD programme where concertation will allow chemicals evaluated under regulation 793/93 to constitute an EU contribution to OECD and to largely allow the community to avoid investing unecessary resources in substances being evaluated by non-EU countries.

Priority list. Components

In considering these factors, priority lists comprise three components:

- substances which a preliminary analysis (using the IPS model) indicates to be of concern (high ranking);
- substances for which few data are available and for which the ranking is high due to default and/or acceptable quantitative structure activity relationship (QSAR) values;
- substances which are already the subject of a report produced in another forum indicating that the substance is of concern.

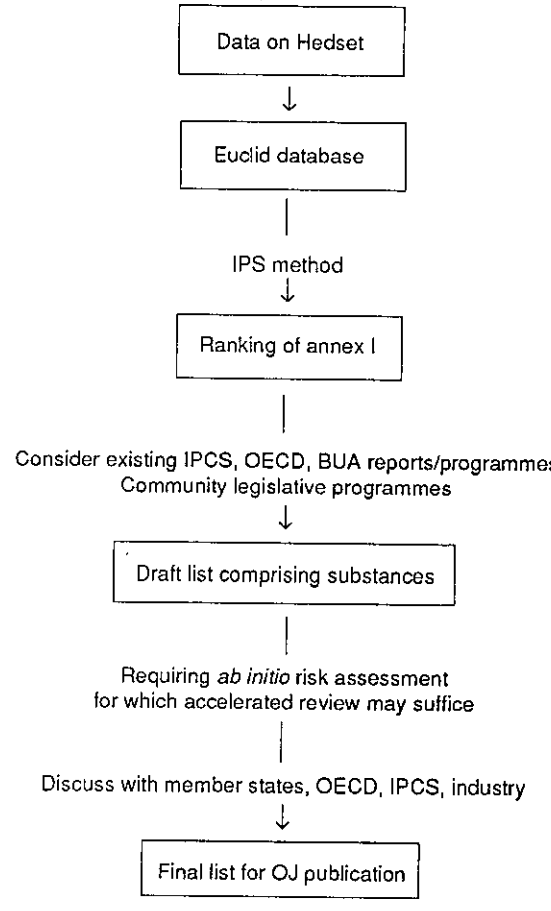

Fig. 2. - Priority setting - Overall scheme.

Components 1 and 2 comprise substances for which a full *ab initio* risk-assessment must be carried out whereas component 3 comprises those for which an accelerated review of an existing report might be sufficient.

Consultation

As the post-ranking considerations comprise a political element, the derivation of the final list will involve consultation with colleagues;

- in member states concerning national priorities, who may utilize product registers and other data in their consideration of the proposal;
- in other Commission services concerning other programmes carried out under other EU legislative actions;
- in other international programmes concerning current and future programmes;
- in industry through the chemical industry association, prior to adoption by the member states.

As the draft list will have been systematically derived any proposed modifications will be expected to be justifiable on the basis of scientific argument.

Risk assessment

Existing substances placed on a priority list are subject to an evaluation of risk based on a regulation which follows in principle that already adopted for new substances, i.e. directive 93/67/EEC. The regulation will be supported by more detailed guidance documents which indicate how the assessment should be performed. These guidance documents are based on similar existing documents for new substances.

Member state rapporteur

Each substance selected as being of priority is formally assigned to a rapporteur in one of the competent authorities of the member states who shall evaluate the data available in Euclid for that substance as well as available data per annex VII A of directive 67/548/EEC. The responsibility for delivering such data falls on those companies who submitted data on Hedset for that substance. The annex VII data comprises detailed reports, whereas the Euclid data, while covering basically the same elements, is of a summary nature.

Further data and testing

The rapporteur shall draft a risk assessment report for consideration by the member states and where appropriate request formally further delivery of data and/or testing. Any further testing shall be carried out according to good laboratory practice as laid down in directives 87/18/EEC and 86/609/EEC and shall, where possible, avoid or limit use of animals. Although in principle further testing should be carried out by all companies, such testing, where necessary, should be carried out by only one company on behalf of all.

Whilst the rapporteur prepares a draft assessment and proposes further data delivery and testing, actual decisions are taken by a committee of member states which finally adopts the report which is then published (see Fig. 3). Decisions are taken by majority voting as laid down in article 148(2) of the Treaty of Rome (establishing the European Communities). Provisions exist for resolving a situation where the committee fails to adopt such proposals.

The risk assessment procedure is also subject to specific deadlines. Further data and results of further testing on a priority substance must be delivered to the rapporteur within 6 and 12 months, respectively, of the request made by the committee.

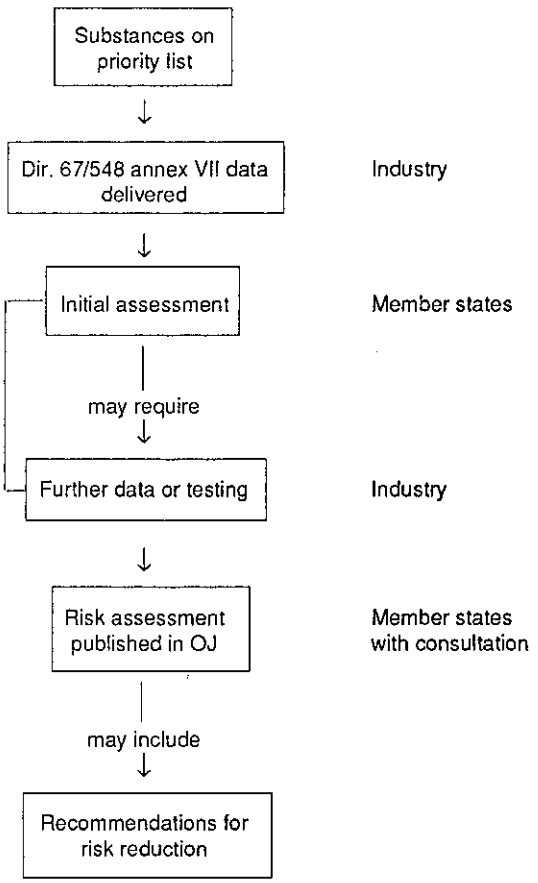

Fig. 3. - Risk assessment.

Risk assessment conclusions

The risk assessment must conclude that the substance is:

- of no concern, or there is no need for further information or testing or risk reduction measures beyond those already being applied;
- of concern and risk reduction measures are appropriate or;
- requires further data/testing to arrive at one of the other conclusions.

The risk reduction measures recommended may be taken up as the basis of proposals for EU measures in the framework of Council directive 76/769/EEC relating to restrictions on marketing and use of certain dangerous substances and preparations and other relevant EU instruments. The Commission is currently exploring non-traditional approaches to implementation of risk reduction recommendations.

Relationship to other programmes

Per article 8.2 of regulation 793/93 priority substances shall be selected considering, *inter alia*, work done and programmes in other fora.

In order to avoid duplication of efforts regarding future work and to go as far as possible in mutually recognizing existing work done in other fora, interaction between the EU programme and other programmes will be necessary at the various stages in the process, from defining priorities through to accepting risk assessments for those substances selected as priority, as shown in Fig. 4.

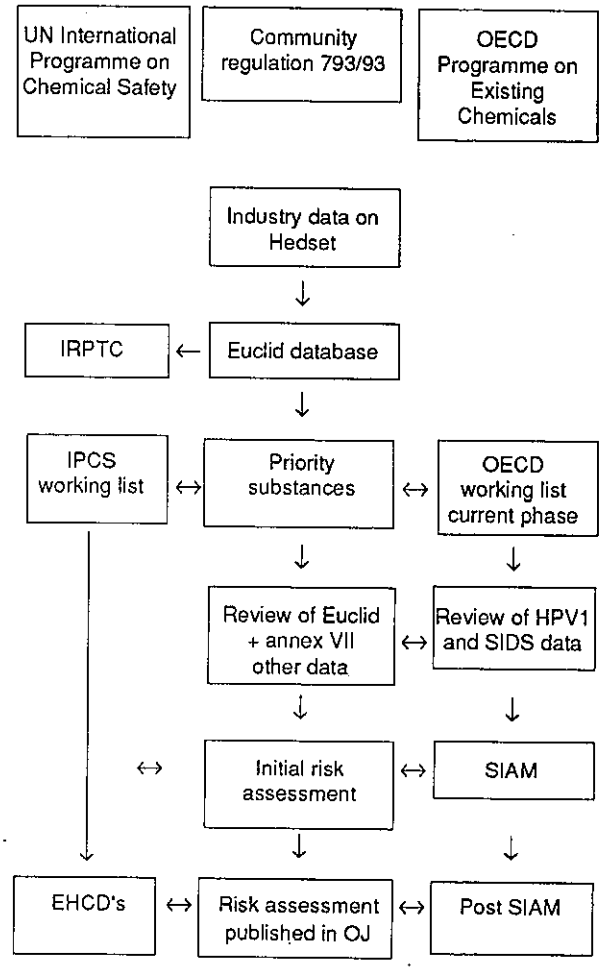

Fig. 4. - Relation of regulation 793/93 to other international programmes on existing chemicals. Equivalent stages where consultation should occur.

Priority setting

At the priority setting stage, it is necessary to consider both previous and future work carried out under other programmes. Existing reports may indicate that substances are of concern. Risk assessment per regulation 793/93 could consist of an accelerated review and if necessary revision of an existing report to ensure that:

- the report is concerned with risk and not just hazard;
- exposure assessment is appropriate to the EU and;
- modification is necessary in the light of data only available in Euclid.

Future programmes shall be concerted such that work embarked upon in respective programmes is mutually complementary.

Risk assessment

It is essential that future assessments are carried out in respective programmes on the basis of very similar, if not identical, principles as laid down in the risk assessment regulation and supported by guidance documents, such that reports from one programme may be recognized in the other. Risk assessment per regulation 793/93 could without difficulty be presented at OECD as an EU contribution.

Reports at OECD from non-EU countries could only be adopted at EU level by placing them on a priority list and carrying out an accelerated review as outlined above.

Having coordinated priority setting and harmonized principles and practices of risk assessment it is necessary to create a mechanism facilitating the uptake, recognition, adoption or utilization of risk assessment reports by the EU programme from these other fora.

Other programmes

The OECD existing chemicals programme is now entering its fourth phase for which candidate substances have been selected and for which the first EU priority list is considered as an EU contribution. In preparation of the

first EU priority list, substances for which OECD assessments are available were not considered except as candidates for accelerated review.

Prior to preparation of a draft risk assessment it is necessary to ascertain whether the data available are sufficient in content and quality. In this evaluation of data, EU Euclid datasets supplemented by annex VII data corresponds to, but may go well beyond, that of the SIDS dossier at OECD. As no formal procedure is required by the regulation for evaluation of data, datasets will be submitted to OECD for data review under OECD's SIDS procedure only where under art. 9.3 the committee decides that further testing in respect of missing annex VII data is not required.

The relationship to IPCS is generally analogous to that with OECD. Existing environmental health criteria (EHC) documents may have an impact on priority setting by reinforcing a ranking suggesting a substance is of no concern or of concern. These IPCS reports on substances of concern may be utilized in accelerated reviewing of priority substances.

Regarding future work, IPCS will have an opportunity to comment on draft priority lists and risk assessments before formal adoption by the art. 15 committee. Published risk assessments will be available to IPCS as input to EHC documents, though here it is recognised that EHC documents may be more detailed than the risk assessment reports are likely to be.

Given that IRPTC already has a role in disseminating SIDS data (now being prepared in Hedset format) for OECD, this programme could also be a vehicle for disseminating the Euclid data to non-OECD countries. While utilisation of Euclid data is maximized by using the Euclid software based on Oracle, it is recognised that many of IRPTC's users may prefer the "low-cost" option of using Euclid data in a DOS environment.

Existing reports generated in national programmes will be considered in drawing up priority lists in the same way as OECD and IPCS reports and may facilitate accelerated reviews of priority substances. This applies to national programmes both within and outside the EU. To the extent that non-EU national programmes are purely domestic, i.e. not presented at OECD, consultation shall take place to coordinate selection of future priorities to avoid overlap similar to concertation with OECD and IPCS discussed above.

Submitted on invitation.
Accepted on 12 September 1994.