# Session 10

# International Harmonisation in Pesticide Registration and Legislation

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| Chairman | Mr T E Tooby |
| Session Organiser | Ms D J Hussey |
| Papers | 10-1 to 10-4 |

# SHOULD WE REDUCE THE POLITICS OF REGISTRATION: BY HARMONISATION OR BY BETTER SCIENCE?

A. M. HOUGHTON

Bureau Européen de Recherches, Rue du Noyer, 262, 1040 Brussels, Belgium

## ABSTRACT

The recent epic GATT accord, encompassing for the very first time agriculture in world trade agreements heralds a new era in international relations. GATT brings a measure of harmonisation to 140 countries' trade law and customs conditions. Can and should such success be transferred to the arena of pesticide registration (the phytosanitary chapter of the GATT gives us further insight)?

This paper examines the power balance between industrialists' ambition, the pride of regulatory science, and the re-election tactics of politicians as exemplified by the progress towards European Union registration harmonisation. Suggestions are made as to how the respective interest groups might improve their contribution to the debate and begs the question as to whether, without such adjustment, the goal of harmonisation will bring net benefit to society.

## INTRODUCTION

The observations in this paper are drawn from two attitude surveys amongst registration administrations in Member States of the European Union (EU) (Houghton, 1992 and 1993) and a number of discussions of the findings with registration policy makers from outside the EU.

The goal of world harmonisation has attained renewed interest with the successful conclusion of the GATT Uruguay agreement. The attachment of the sanitary and phytosanitary clauses to the agricultural chapter, whatever their limitations prove in practice, is a major advance in world trade relations. This serves to underline one of the reasons for seeking world harmonisation in registration of pesticides, the enhancement of trade. Improvement to world trade is declared to bring benefits to world economic growth and employment. Another reason for seeking harmonisation is the anticipated improvement in the efficiency of use and allocation of resources. Unnecessary repetition of research should be avoided, as too, the repetition of applying resources of registration authority personnel to the review of dossiers. So with two powerful and economic wealth generating reasons for harmonisation, why does achievement seem so elusive? First we must examine the different routes of achieving harmonisation and then see what lessons can be learnt from current progress.

## HARMONISATION ROUTES

I would say that there are, broadly, three approaches to harmonisation being pursued in registration at the moment:

i) **scientific cooperation**;
iii) **equivalence;**
ii) **unification.**

### Scientific cooperation

This is very much the domain of FAO, OECD and certain scientific groups such as EPPO. They are fora for the exchange of views amongst experts that meet with the express purpose of developing common frameworks for addressing scientific design issues or scientific assessment issues. Essentially the work is limited to scientific methodology for research that goes into registration dossier preparation rather than the process of dossier approval itself. Nevertheless the work is very important and achieves a level of harmonisation.

### Equivalence

Equivalence is the concept engaged between Canada and the US in the 1989 bilateral trade agreement and perpetuated and extended by incorporation into the recent NAFTA agreement. The same term has then been applied to the sanitary and phyto-sanitary clauses of the GATT Uruguay round. The principle can be summarised as 'engaging different means but arriving at the same end result' (Fig. 1). Thus equivalence in the GATT context achieves a limited level of world harmonisation in that it brings 140 nations together in the affirmation that they wish to achieve the same broad end, but leaves much to work through in practice. Of particular note is the advised recourse to bilateral and multilateral consultations in order to progress real harmony. In short, important as GATT is as a first step, it is not world harmonisation.

Equivalence

14. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

15. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

**Figure 1 GATT clause on equivalence**

Unification

The third approach being pursued by the European Union is that of unification, ie bringing the independent registration procedures of the twelve Member States into a single mechanism. This is a much more ambitious objective yet, if achieved, will bring the most benefits of improved trade and improved resource allocation compared to the other two routes of scientific cooperation or equivalence.

To achieve unification there are three areas to address:

i) the rules;
ii) the resource;
iii) the structures.

An enormous amount of human effort has been spent on the first part, the unification of European Union rules through the Directive 91/414 EEC, the Regulation 92/3600 EEC, their annexes and, currently under discussion, procedural rules. The human resource of Member States is being harnessed for registration dossier handling but the resource is very unevenly distributed across Europe (Fig. 2). If we compare this resource with the assigned work load for reviewing the registration of the first 90 compounds (the EU Commission has asked different Member States to handle different dossiers for the EU level review) then we can observe how far we are from total integration (Fig. 3).

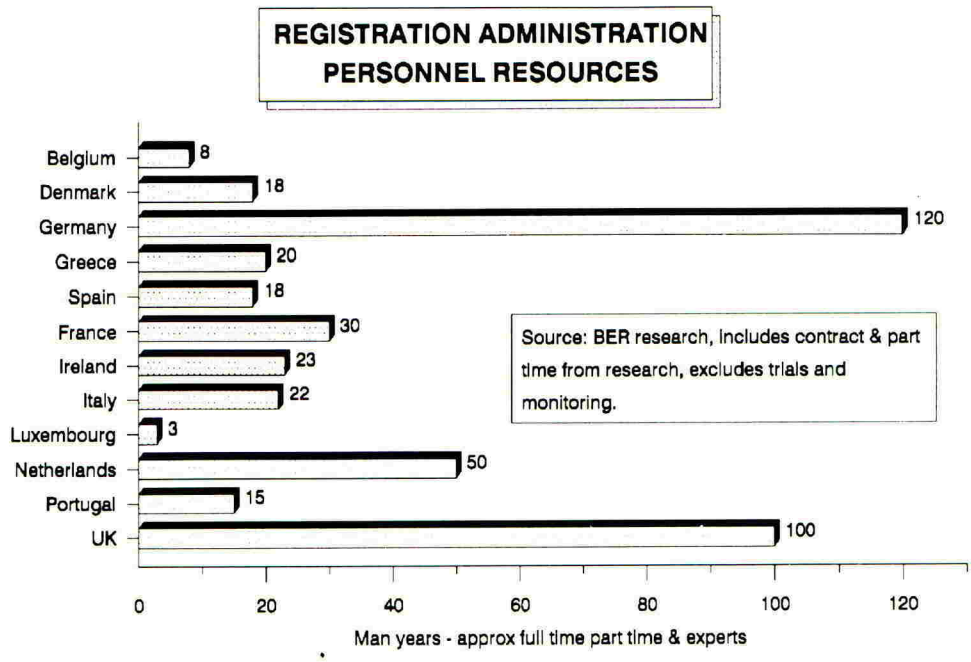


**Figure 2** **EU registration administration personnel resources**

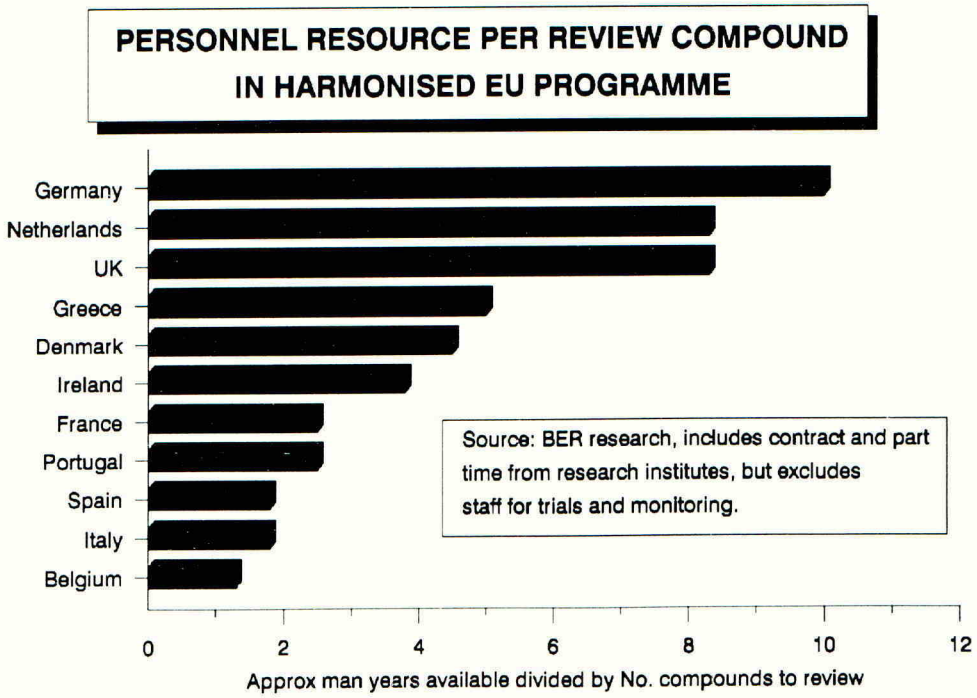


**Figure 3** **EU registration personnel and reviews**

When we consider the unification of structures across Europe we must first recognise the different Ministerial dependencies of administration in different Member States. Some are dependent on Ministries of Health, some Ministries of Agriculture, and others Ministries of Environment. Then in the administrative systems we have independent organisations, with different degrees of self financing targets. In some countries we have Institutes, Ministerial Departments or inter-Departmental Committee structures, (Table 1).

**Table 1. Administrative basis of national registration**

| | Lead organisation | | | | Decision process style | | |
|---|---|---|---|---|---|---|---|
| | Min of Agric | Min of Health | Min of Environment | Independent | Committee: but intra-ministerial only | Committee with external experts | Internal |
| BELGIUM | ✓ | | | | | ✓ | |
| DENMARK | | | ✓ | ✓ | | | ✓ |
| GERMANY | ✓ | | | semi- | | | ✓ mostly |
| GREECE | ✓ | | | | | ✓ only 1 of 2 countries to include chem industry | |
| SPAIN | ✓ | | | | | ✓ | |
| FRANCE | ✓ | | | | | ✓ only 1 of 2 countries to include chem industry | |
| IRELAND | ✓ | | | | | | ✓ |
| ITALY | (✓) | ✓ | | | ✓(1 Agric 1 Health) | | |
| LUXEMB'G | ✓ | | | | ✓ | | |
| NETHER-LANDS | ✓ | | | ✓ from 93 | | | ✓ from 93 |
| PORTUGAL | ✓ | | | semi- | | | ✓ |
| UK | ✓ | | | ✓ from 93 | | ✓ | |

Debates are also taking place outside Europe, for example, the Canadian government has said that it is committed to implement the results of the stakeholder's review which recommended the move away from inter-Departmental Committees to a self-financing agency.

Thus far in the EU we have not begun to move either to a unified single structure, nor to a EU wide concept of self-financing. Yet precedents are being established in the pharmaceutical and animal health product sectors. After a number of years of what might be considered interim arrangements, January 1st 1995 will usher in the new single centralised agency for product approval.

To summarise, the EU is moving towards unified rules but the other two aspects of harmonisation, unified resources and unified structures have yet to be considered.

## REGISTRATION APPROVAL - A SINGLE EVENT

There are basically two types of legislation harmonisation in the EU. Matters relating to economics or business have a tendency to be harmonised to the **lowest common denominator** (eg proposed law on EU cooperatives which have a particularly

important place in agricultural trade). By contrast matters that impinge upon public safety, such as pesticide registration, tend to be harmonised to the **highest standard**. This means that many Member States are faced with adopting more comprehensive and more detailed assessment programmes, and most often without the concomitant increase in resources.

The previous divergent approaches to pesticide registration by Member State, coupled with the legal and political challenge of trying to harmonise up rather than down, has meant that establishing the legal framework has been, and is still proving, an arduous task. This has been compounded by the drive by many scientists and administrators to move the legislation close to the boundary of scientific knowledge. Since the legislative framework had to be changed for reasons of harmonisation, the opportunity of change was siezed to push out the rules in areas where science is still relatively young, such as different aspects of environmental fate research and risk assessment.

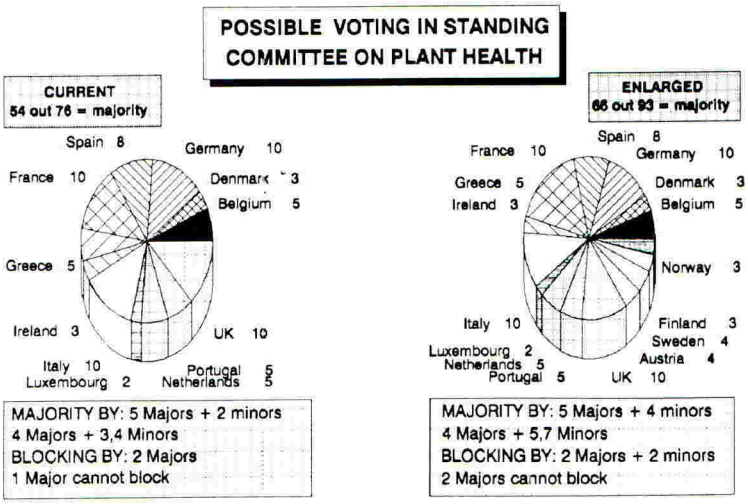


**Figure 4 The politics of voting on product approval**

The process of moving towards a harmonised approach in Europe has heightened the attention upon the single legislative event of either approval, or ten years later, re-registration. This has been true even before the new system has become fully operational. As the procedures get into gear for real product discussions in the ultimate decision making council, the Standing Committee on Plant Health, the political dimension will become even more significant (see voting impact of enlargement, Fig 4). The science to support a given product will never be black and white, interpretation and judgement will always play a role, and the more we add environmental fate assessment

to the dossiers, the more the imprecision will be accentuated. It is difficult to convey to an audience that does not participate in the daily workings of Brussels the purely political nature of the decision making, especially in relation to assembling qualified majority votes by country.

Thus the very act of harmonisation of the rules has focused attention on a single event at which a "yes" or "no" decision will be taken, and this, I contend will be aggravated as the real decisions on products move into gear. True, France and UK have different systems of provisional approval, which has been incorporated into the European system, but few other Member States seem likely to adopt the procedure in their own countries, even though the legislation would allow them to do so.

Implications

The implication of the increased pre-occupation with the single event decision process is that it reduces the perceived importance of monitoring of product use once approved. Indeed, the new system in the medium term increases the administrative workload to Member State administrations due to a number of factors:

i) the extra work in communicating between Member States and Brussels;
ii) the fact that harmonisation was upward, thereby adding new sections to dossiers in many countries;
iii) the formalising of a review programme, which was not present in such a rigorous way in a few Member States;
iv) the introduction of effectively a two tier system, with approval of actives and then formulations.

The Commission resource is very limited. At Member State level, I estimate that there are 430 man years of resource for handling dossiers which will only be increased by 1%. Yet the workload in the short term will increase by 25%. Thus it is clear that even the small amount of monitoring of products being carried out by some administrations will be under severe resource pressure and may even disappear, and there will probably not be any **increase** in monitoring activity.

Most experienced pesticide registration scientists will tell you that they learnt most about the effectiveness and safe use of the product in the first year of its full scale use. Some how we need to down weight the pre-occupation with the single procedural event and increase the importance given to the notion of continuous assessment.

## IMPROVEMENTS IN POLICY DIALOGUE

Not only in Europe, but also in North America and eventually the world, we should try to improve the quality of the debate. The GATT accord ought to represent a stimulus to the dialogue on policy. I would urge that the different parties to the exchange of views should lift their sights from the narrow tactical politics to the real strategic issues:

i) agrochemical companies should take a braver stance in relation to funding of

national administrative registration authorities, ie encourage the move to self-financing so that they can make demands on the centralisation of the resource, the unification of the structures and the increase of the proportion of weight given to monitored field use results, all of which will help de-politicize the registration process; (GIFAP on a world level and ECPA at the European level should get its own house in order to the point of being able to describe better the quantities of active ingredient use by crop);

ii) administration personnel, most of whom are scientists by training, should be less ambitious and put aside their aspirations for scientific peer recognition manifest in their tendency to frame legislation at the frontier of current knowledge. They should also focus their attention more on monitoring science even though there is less PhD material in this than in developing models;

iii) the 'green' lobbyists should curb their natural suspicious tendencies focused on product by product issues and examine how their extensive membership bases (albeit amateur) can receive training for monitoring data collection;

iv) farmer organisations should take a more active part in the policy development dialogue and might volunteer as to how on-farm recording could be improved in order that there could be more confidence in a notion of continuous assessment.

## CONCLUSION

The title of this paper, "Should we reduce the politics of registration: by harmonisation or by better science?" poses a question. In its current form, EU harmonisation is in severe danger of increasing the politics of registration approval of products. I fear too, that NAFTA in North America and GATT risks provoking a similar tendency in the world arena. Better science will, of course, always help, but not without some redirection of effort. Surely nobody would disagree that we 'should reduce the politics', however without some modification of objective, better science or harmonisation is not the answer.

The debate of the principal interested parties has an alarming tendency to concentrate on tactical issues and short term power politics. Not only do we need to raise the quality of the contributions in the way this paper suggests, but I believe we need to organise a world forum to deliberate upon registration strategy as an instrument of monitoring agrochemical use in a global context.

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# INTERNATIONAL HARMONIZATION IN BIOPESTICIDE REGISTRATION AND LEGISLATION

S.G. LISANSKY

CPL Scientific Limited, 43 Kingfisher Court, Hambridge Road, Newbury, Berskhire

## ABSTRACT

Pesticides, including biopesticides, require registration in virtually every country of the world. The purpose of legislation and the requirement for registration of biopesticides is to allow benefits (in this case, crop protection) to be obtained from these products while incurring the least possible risk of damage to humans, animals, plants or the environment. Assessing the benefits and measuring the risks incurs costs that are ultimately paid by the public. International harmonization, by providing a uniform set of rules, would help lower these costs without increasing the risks. Although progress is apparently being made towards achieving harmonization, differences in detail and in interpretation may undermine these efforts and continue to raise the costs of registering biopesticides. Higher costs deter the development of new biopesticides and are likely to increase our dependence on chemicals.

## INTRODUCTION

The term *biological pesticides* can include pheromones, insect and plant growth regulators, plant extracts, transgenic plants and macro-organisms as well as microorganisms. In this paper, *biopesticides* or *microbial pesticides* are products in which the active principle is a bacterium, fungus, virus, protozoan or nematode or an unmodified, unpurified biochemical product of a bacterium, fungus or virus which is intended to control insect or other pests, plant diseases or weeds. The EPA distinguishes biopesticides as: *Biochemical and microbial pesticides are generally distinguished from conventional pesticides by their unique modes of action, low use volume, target species specificity or natural occurrence. In addition, microbial pesticides are living entities capable of survival, growth, reproduction and infection.* Oddly, other products containing microorganisms for non-pesticidal agricultural uses do not require registration, although such microbes[1] present a hypothetical potential for harm similar to microbes destined to eliminate pests.

## LEGISLATION AND REGISTRATION

For all biopesticides, the safety of the active ingredient (AI) must be demonstrated. An AI can be formulated into intermediate products including a technical grade of active ingredient (TGAI) and other manufacturing-use products and finally into formulated end-use

[1] Examples include soil conditioners such as *Azotobacter*, fertilizers or plant growth promoters such as virtually all mycorhizal fungi, *Bacillus subtilis* or any of the plant growth-promoting rhizobacteria (PGPRs), silage additives like *Pediococcus*, animal growth promoters such as *Lactobacilli* and the like.

products. Most registration authorities require detailed investigation of the AI and somewhat less information about the final products.

To determine the requirements for legislation and registration for biopesticides, each country has had to address a number of problems including: specifying the nature of risk, deciding how to assess the dimensions of risk for biopesticides, deciding what methods to use and then carrying out a risk analysis; determining what type of scientific, technical or other data is required to address the risks; formulating legislation to ensure that the registration procedures minimize risk; deciding which experimental methods should be used to obtain the data for registration applications and specifying methods for validation of data; creating a mechanism for evaluating data submitted in registration applications and issuing registrations. In addition, each country has to decide whether it will adopt a policy of giving preference to biopesticides in the registration process. Fairly or not, biopesticides have been thought to be inherently more likely to be safe than synthetic chemicals.

## RISK

Assessing the risk posed by biopesticides requires knowledge of the biopesticide and its metabolites, the interactions between the biopesticide and its specific target and the environment into which the biopesticide will be introduced including the host range.

### The probability of harm

Biopesticides should pose a relatively low risk of harm. Biopesticidal fungi have been known since the 1880s, bacteria since the start of this century and viruses and other micro-organisms for more than 50 years. There are no documented incidents of harm being caused by the use of biopesticides. In addition, since most biopesticides occur naturally, there have undoubtedly been many occasions when biopesticides have caused epizootics in insects, infected large plant populations or attacked plant disease micro-organisms in large numbers. This means that many non-target organisms including other species of insects, plants and fungi, as well as birds, wild mammals, and probably in some cases humans, have been exposed to many actual and potential biopesticides. Yet references to any of these organisms is absent or very rare in the records of human or veterinary medicine and science. However, nature remains largely unobserved by man so incidence of harm might pass unnoticed or be attributed to other causes. The possibility of future harm can never be excluded.

### Available data

Documented historical information on biopesticides is available mainly for the insecticidal bacterium, *Bacillus thuringiensis* although information about other bacteria, fungi, viruses and nematodes is now accumulating. (This includes toxicological and human exposure data as well as experience with the use of commercial products, although longer-term environmental and ecological data is more difficult to obtain.)

## DATA REQUIREMENTS

The UK was the first country formally to publish guidelines for biopesticides around

1979. In the US, the EPA used draft documents as an operational guideline from around 1978 until it published its rationale in November 1982 in Subpart M - *In regulating biorational pesticides EPA will recognize that biorational pesticides are inherently different from conventional pesticides, and will take steps to substantiate by scientific data the expectation that many classes of biorational control agents pose lower potential risks than conventional pesticides...the Agency will take into account the fundamentally different modes of action of biorationals and the consequent lower risks of adverse effects from their use.*

The EPA recognized it was in a new field and, requesting as much outside help as was available, specifically forecast improved guidelines. *Hazard investigations of microorganisms used as biological control agents are not on as firm a basis as is the case with conventional chemical control agents simply because the field is relatively new and the interpretation of laboratory data in the light of mammalian hazard is difficult. Nevertheless the Agency must use current methodology to assess the potential hazards associated with the use of microbial control agents. Much information is generated during the course of research and development of a microorganism as a microbial pest control agent, and industry is expected and, in many areas, required, to submit the information as part of the application for registration. The Agency looks to researchers in industry, academia, and Federal and State agricultural organizations for comment and information on the design and development of more relevant testing methodology so that specific issues of concern regarding the registration and use of microbial agents can be addressed.*

The EPA proposed a tier system, at the time a new approach to safety testing. *Four of the major section series....use a tier testing scheme to ensure that only the minimum data necessary to make a scientifically sound regulatory decision are developed. This scheme eliminates the need for submittal of extensive data for those pesticides which are determined to be safe on the basis of Tier I data. The Agency believes many biorational pesticides will require only Tier I testing.*

*As with all biorational pesticides, the concept of maximum hazard testing is used early in the tier testing regime. The concept of maximum hazard testing is that the most challenging exposure, in terms of route of exposure, species and age of test animal, dose administered and similar factors, will be used in Tier I to identify any potentially hazardous agents. The agency recognizes that the use of the maximum hazard testing approach will require flexibility in determining the appropriate and feasible dose(s) and route(s) of administration.*

The reason for citing so much of the EPA's original rationale is that since then, most other legislation and registration requirements have been similarly based on the tier testing principle in which Tier 1 tests are relatively short and severe. Any indications that the biopesticide might cause harm can be used to require additional tests. In addition, most other legislation similarly recognizes the relative paucity of data about and experience with regulating biopesticides as well as the wide inherent variability of the products and their modes of action. For the present, a case-by-case approach is taken by most regulatory authorities. Finally, virtually no evidence has been adduced since the publication of Subpart M in 1982 that calls into question the underlying premise that biopesticides are inherently safer than synthetic chemicals. As result, the logic underpinning the EPA's approach and the use of the tier system remains valid today.

## APPLICATIONS FOR REGISTRATION

The sections of data required in applications for registration in various countries are shown in Table 1. At first glance it appears not very harmonious. A study of the guidelines for data within each section suggests that, in general, similar information is required by all. However, in practice, small variations in interpretation can have a profound effect on just how harmonious the various requirements are, for example, in the European Union.

### The European Union

In the EU, *"Council Directive concerning the placing of plant protection agents on the market"* (91/414/EEC) of July, 1991 required governments of the Member States to enact into law the principles of the Directive by July 26, 1993. However, the Directive was only a framework, an outline of the way in which plant protection agents should be administered and judged. The Directive specified that uniform principles for operation would be established by July 15, 1992. The uniform principles were intended to establish which data will be required for applications for registration in the Member States and to ensure that these data were interpreted in a consistent way. Until this process is complete, mutual recognition of registrations will not occur. At present, uniform principles for testing of chemicals have been agreed and a plan for re-evaluating and re-registering existing chemicals has been initiated. These achievements have meant that with the limited resources at the disposal of the various national regulatory bodies, little progress has yet been made on similar uniform principles for registration of biopesticides.

National bodies have begun issuing guidelines for the registration of biopesticides including Denmark and France. These conform in principle to the Directive but small differences in interpretation appear to be leading back to a nationally diverse rather than a harmonized system. By increasing biopesticide registration costs, incentives may be reduced for developing these alternatives to chemical pesticides.

For example, France is likely to require a 90 day toxicology study as part of Tier 1. If so, it will be the only country (in the world thus far) to specify this as a requirement in Tier 1 testing. Denmark may impose a *de facto* requirement for Tier 2 testing for every biopesticide by using a very strict interpretation of what constitutes an *unusually long residence time* in its assessment of the results of Tier 1 studies. A number of other issues remain in deciding how best to minimize risk.

One reason for the emergence of these different interpretations is the lack of communication among the countries of the EU on the setting of uniform standards for registering biopesticides. Real real harmonization will become much more difficult once each country has passed legislation enacting its own interpretation of the Directive. One short-term solution would be to establish an EU-wide committee of experts on biopesticides to guide implementation policy and to ensure communication and agreement among Member States.

### Canada

Other obstacles to international harmonization arise when a country proposes guidelines that are radically different from others'. A recent example is Canada, which in 1993 proposed

that Tier 1 biopesticide tests should include a 30-day study on each of no less than 20 species of terrestrial arthropods. Such a requirement would minimize the risk from biopesticides by making it unlikely that any company could afford to seek Canadian registration.

It is possible that this proposal arose from the summing together of tests thought desirable by a number of different experts. Following a review meeting in May 1994, it is likely that this proposal will be modified. However, its publication may have unintended consequences. Other, less sophisticated countries, may give more credence to the proposal just because it was published and may expend time and resources on considering whether they, like Canada, should seriously consider this requirement. For this reason, H D Burges, one of the formative thinkers on the registration of biopesticides and an advocate of rational deductive thinking in making regulations, never supported publishing suggestions that were unlikely to be acted upon.

## CONCLUSIONS

Legislation for and registration of biopesticides are required in order to ensure that society obtains the maximum benefit from these products while being exposed to the minimum risk of harm. Everyone wants safe products and all agree such assessments are essential. However, costs are increased with relatively little gain in safety by having different legislation and registration requirements in different countries. For this reason, everyone is, in principle at least, in favour of international harmonization.

Furthermore, registration of biopesticides is, or at least should be, mainly a technical process. It requires properly validated experiments to generate data followed by presentation in the conventional scientific way - Materials, Methods, Results and Conclusions. Evaluation should be carried out by scientific experts and registrations issued or denied on defensible criteria. It can be difficult for the layman to see any justification for the present lack of harmonization. It can appear to be a way of keeping bureaucrats employed.

Harmonization is a goal that forms part of the policy objectives of many countries. For example, the recent General Agreement on Trade and Tariffs (GATT) harmonizes a number of trading conditions which, taken together, are intended to contribute to increased worldwide prosperity. Harmonization remains a key *raison d'être* of the European Union. Although there may be social and economic grounds for maintaining the disparate regulations of different countries with respect to, for example, banking, similar considerations should not apply to legislation on or registration of biopesticides. The application of scientific principles and methods should provide universal, harmonized standards on which legislation and registration can be based.

The main development over the past few years has been a growing confidence in the stability and validity of the principles underlying the regulations under which registrations are considered and granted. In the future, to achieve international harmony in legislation and registration requirements for biopesticides, uniform principles in testing, in validation and in interpretation will be required. If this can be achieved, the development of new biopesticides will accelerate and the world's dependence on chemical pesticides will be reduced.

Table 1 Sections required in applications for registration of biopesticides in various countries

| | USA | UK | EU | Canada | Australia | New Zealand |
|---|---|---|---|---|---|---|
| 1 | Product analysis | Introduction | Identity of organism | Index | Introduction | Identification |
| 2 | Toxicology[1] | Information on formulated product | Biological properties | Label | Chemistry, manufacture, biological properties | Toxicology |
| 3 | Residues | Identity of AI | Further information | Character-istics and specification | Toxicology | Residues |
| 4 | NTO hazards | Biological properties | Analytical methods | Human health and safety testing | Toxicokin-etics and metabolism | Environ-mental and wildlife data |
| 5 | Environ-mental fate | Manufacture, formulation | Toxicology | Metabolism | Residues | Biological properties |
| 6 | Efficacy | Application | Residues | Residues | Occupational health and safety | Label |
| 7 | EUP data | Efficacy | Fate and behaviour in environment | Environ-mental fate | Environ-mental | - |
| 8 | Label | Toxicology | Ecotoxicology | Environ-mental toxicology | Efficacy and NTO safety | - |
| 9 | - | Effects on humans | - | Efficacy and benefits | - | - |
| 10 | - | Residues | - | - | - | - |
| 11 | - | Environ-mental and wildlife hazards | - | - | - | - |

[1] Toxicology includes toxicological, pathogenicity and infectivity studies

# AGROCHEMICAL REGISTRATION IN JAPAN

H. HOSODA

Nihon Nohyaku Co Ltd, No. 2-5, Nihonbashi 1-chome, Chuo-ku, Tokyo, Japan.

T. SASAKI, T. MIYAKAWA

Society of Agricultural Chemical Industry, No. 5-8, 1-chome Muromachi, Nihonbashi, Chuo-ku, Tokyo, Japan.

## ABSTRACT

For the registration of agrochemicals in Japan, a considerable amount and variety of data is required by its regulatory system. Among such documents, in terms of toxicology, residue chemistry, environmental fate or environmental toxicology, the following points are apparent when compared with international standards such as the EU or EPA. As to toxicology studies and guidelines, there is no practical difference internationally. It seems difficult for crop residue studies to be considered as a part of international harmonization when variable factors in climatic or geographical differences among countries are taken into account. A noticeable point here is the international harmonization of MRLs derived from the crop residue data rather than the residue study itself. Endeavours to harmonize Japanese MRLs to international standards are being made through the establishment of "Food Standards". With regard to environmental fate or environmental toxicology studies, while the major scope of data requirements is in line with international harmonization, some particular test animals are required in those studies reflecting Japanese circumstances, e.g. approximately 54% of agricultural land space is paddy field and approximately 63% (w/w) of total agrochemicals used in Japan is applied to paddy fields.

## INTRODUCTION

For many reasons the development costs for new agrochemicals, indispensable materials for crop protection, are increasing year by year and a huge amount of money is invested for the maintenance of existing products. A considerable portion of these investments is expended for the safety evaluation. In this context, the necessity of thorough safety evaluation cannot be argued while to make the most of the safety evaluation data, the product of such investment, is a vital need for the industry. International harmonization of data requirements and data evaluation related to agrochemical registration procedures in various countries is, therefore, highly desirable. It will avoid a scientifically less meaningful duplicity of investment and will enhance the economical efficiency of the investment, where resources could be spent more profitably for the development of new technology or molecules useful for future crop protection.

To achieve international harmonization, it is important for international communities to understand the backgrounds or situations upon which national laws or regulations are based

and the possible means by which harmonization could be attempted. I therefore welcome this opportunity to introduce an overview on the status of product safety evaluation in Japan.

## REGISTRATION SYSTEM IN JAPAN

Production, marketing and use of agrochemicals in Japan are regulated under the agrochemical registration systems of the Agricultural Chemicals Regulation Law through the Ministry of Agriculture, Forestry and Fisheries (hereinafter abbreviated as MAFF). In this law, the agrochemicals are defined as " fungicides, insecticides and other chemicals used for control of fungi, nematodes, mites, insects, rodents or other animals and plants or viruses which are injurious to crops; and growth accelerators and germination depressors and other chemicals used for the promotion or depression of physiological functions of the crops". Based upon the interpretation of the word "control", the utilization of natural enemy insects which show predatory activities on a certain range of harmful pests and the use of sex pheromones must be registered as agrochemicals. Since agricultural products normally reach the market quickly and crops which need to be stored for a certain period are normally kept at low temperature, the need for post harvest use is limited in Japan. Reflecting such circumstances, only a small number of fumigants are registered as post harvest use.

Product safety of agrochemicals is evaluated by the joint work of ministries under the Agricultural Chemicals Regulation Law. The Environment Agency is responsible for evaluating crop, soil and water residue data for the establishment of directions for safe use. The Ministry of Health and Welfare (hereinafter abbreviated as MHW) reviews toxicology data and reports its results to the Environment Agency to support the establishment of the directions for use.

When applying for registration, an applicant must submit to MAFF several sets of a dossier consisting of data on biological efficacy, phytotoxicity, toxicology, residue chemistry, environmental fate and environmental toxicology, along with an application form and product samples.

## DATA REQUIREMENT FOR PRODUCT SAFETY

### Toxicology studies

Toxicology studies should be conducted in compliance with GLP regulations stipulated by MAFF. Bilateral GLP arrangements have been agreed upon by MAFF with many countries as a part of international harmonization.

The kinds of studies required range from acute to chronic toxicity or reproduction studies etc, and guidelines for these studies are generally harmonized with international standards. Among these data requirements, the Japanese authority specifically requires a pharmacological study. The major purpose of this study is to analyse the acute toxic reactions and to collect valuable information to predict and characterise possible acute poisoning and to consider the appropriate treatments. Effects on the central nervous system or on the respiratory and blood circulatory systems etc are included and tested to accomplish the objective of the study. In the United States, neurotoxicity studies which investigate the

functional and morphological effects on rats, are uniquely required.

A point requiring much more discussion for international harmonization on guidelines or evaluation of data is the maximum tolerated dose (MTD) for a carcinogenicity study. OECD, EPA and Japanese guidelines for an oncogenicity study state that "the highest dose level should be sufficiently high to elicit signs of minimal toxicity without substantially altering the normal life span by the toxic effects other than tumours". The definition of MTD is the same for all three guidelines, however guidance for determination of MTD is slightly different under each guideline. Moreover, the OECD or Japanese guidelines state that the highest concentration for a diet mixture should not exceed 5%, while the EPA guideline recommends a dose of 1 mg/kg body weight/day, equivalent to a dietary concentration of approximately 2% in the rat and 0.7% in the mouse. Since the carcinogenicity study is important for various reasons, time consuming and costly, it would be desirable to achieve international harmonization on this issue.

Crop residue studies

When discussing international harmonization of crop residue studies, it is essential to take climatic or geographical factors into account. Furthermore, in the establishment of MRLs based on crop residue studies, allocation of an ADI in conjunction with food factors determined by national dietary habits must be considered. Therefore, crop residue studies may not be a part of international harmonization. The Japanese systems in this area can be simplified as follows.

Crop residue data to support an application for registration must cover at least 2 trials for each crop concerned. Field trials to obtain samples for analysis must be conducted as supervised trials at official institutes such as national, prefectural or publicly funded experimental research stations. Residue analysis must be performed in duplicate with cross-checking in two different laboratories for the purpose of assuring accuracy in analysis.

The administrator of the Environment Agency establishes the Standard for Withholding Registration, based on the crop residue data submitted to MAFF, to ensure the proper use of agrochemicals indicating residue levels in crops which could not cause any adverse effect on consumer health. A standard is established for each of the 9 crop groups (Table 1) while registration is granted on a crop by crop basis, not on a crop group basis. Therefore, for a label extension for a certain crop, of which the Standard for Withholding Registration has been established for the group, an applicant must provide data to show that the residue level of the crop does not exceed the Standard for the group.

MHW is responsible for establishing Food Standards based on the Food Sanitation Law and controls agrochemical residue levels in foods which do not cause any adverse effect on consumer health. Under this law, the standard is applied not only for the control of agrochemical residues in locally produced food but is also applied for foods imported from foreign countries. A total of 103 Food Standards for active ingredients of agrochemicals have been established (by 4th notice in 1994). International standards such as Codex MRLs etc are taken into account in establishing the Food Standards in the light of all possible efforts made for international harmonization.

Table1. Crop Residue Group of "Standard for Withholding Registration"

| Group | | Crops in the Group |
|---|---|---|
| 1. | Rice | rice cultivated in paddy field<br>rice cultivated in upland field |
| 2. | Wheat, Millets | barley, wheat, buck wheat, corn, etc. |
| 3. | Fruits | orange (unshu), summer orange, apple<br>Japanese pear, pear, peach, grape, water melon,<br>melon, musk melon (makuwauri), strawberry, fig,<br>kiwi, pineapple, etc. |
| 4. | Vegetables | radish, lettuce, cabbage, cauliflower, green pepper,<br>cucumber, immature kidney bean, immature soy<br>bean, immature corn, etc. |
| 5. | Potatoes | potato, taro, Amorphophallus conjac (konnyaku),<br>yam, etc. |
| 6. | Beans | soy bean (matured), red bean, kidney bean,<br>peanuts, etc. |
| 7. | Tea | tea |
| 8. | Sugar material | sugar beat, sugar cane |
| 9. | Hop | hop |

Environmental fate studies

Approximately 54% of Japanese agricultural land is used as paddy fields for rice cultivation and about 63% (w/w) of total agrochemicals consumed in Japan is applied on the paddy field. These circumstances are extensively different from the United States or European Countries. Furthermore, greater than 70% of the potable water resource is derived from surface water in Japan. These factors have inevitably produced unique data requirements which are different from those of the United States or the EU with regard to field environmental fate studies. In contrast, laboratory studies are generally harmonized, with the exception of the following points.

Among laboratory studies, guidelines for hydrolysis and photolysis in water differ in a certain degree between those of the OECD, EPA and Japan. International harmonization is expected in future. Even the same laboratory studies using soils, such as degradation or adsorption/desorption studies, generally require the use of local soils which represent the nation or area. As each country has different soil conditions, geographical harmonization in this area needs much more discussion.

Since large amounts of pesticides are directly applied to paddy watering systems in Japan, water contamination is controlled by various standards or regulations. The requirement of a paddy water residue study to be conducted using practical paddy field conditions is a distinct feature reflecting Japanese circumstances. In the registration process, the Japanese MAFF establishes the Standard for Withholding Registration for agrochemicals applied to paddy fields based on the results of the paddy water residue study. After amendment of the Agricultural Chemicals Regulation Law in April 1993, such standards for 22 active ingredients were established.

As the regulations relate to pesticide uses and water quality control after registration and marketing of products, there are two standards. Standards for Drinking Water, controlled by MHW based on the Water Supply Law (amended in December 1992) have been established for 4 active ingredients. Standards for Environmental Water, controlled by the Environment Agency under a Basic Law for Environmental Pollution Control (amended April 1993) have also been established for the same 4 active ingredients. Although not published, it is speculated that the Japanese authorities are setting the standards for water quality at the level of 10% of the ADI with 2 litre consumption per day as a general rule, by referring to the concept of potable water standard of the WHO.

Since the quality of drinking water is monitored at the water catchment site before introducing surface water into a purification system, the Standards for Drinking Water are inevitably set at the levels of the Standards for Environmental water (Table 2). When levels of contamination exceeding the standard are found at the water catchment site, the Water-Works Bureau is required under the Water Supply Law to ensure that the contamination is kept below the standard by employing an appropriate method. The registration of an agrochemical may be withheld or its use pattern amended by the Agricultural Chemicals Regulation Law in conjunction with the Basic Law for Environmental Pollution Control.

Table 2. Standards for Drinking Water and for Environmental Water

| Common Name | Standard (mg/l) |
|---|---|
| Thiram | <0.006 |
| Simazine | <0.003 |
| Benthiocarb | <0.02 |
| 1,3-dichloropropene | <0.002 |

Environmental toxicology study

The kinds of studies required for Japanese registration are almost the same as the United States or European Countries. In some studies, however, it is necessary to use specific test species relevant to Japanese environmental particularities.

As a part of aquatic studies, acute toxicity studies on carp and daphnia are essentially required. In addition, studies on aquatic organisms inhabiting paddy sediments such as loach or crayfish etc, estuarine fishes like mullet or freshwater fish such as rainbow trout are required depending upon the nature or use of products. Among requirements for nontarget insects, an acute toxicity study on silkworm is specifically required, reflecting Japanese agricultural practice. Studies on the effects on natural enemies such as predators or parasites must be conducted on species important for local ecosystems in Japan.

## CONCLUSION

With regard to Japanese registration data requirements from the view-point of international harmonization, it is evident that some specific studies are being required for the evaluation of environmental fate or environmental toxicology, which reflect Japanese agricultural practice or environmental conditions. However, since the Japanese government has started to actively participate in the OECD Pesticide Forum for establishing internationally acceptable agrochemical guidelines, it is expected that Japanese guidelines for agrochemical registration might take this route to international harmonization in the context of the OECD Program. The Society of Agricultural Chemical Industry (SACI) believes that this OECD Forum should be further promoted.

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# INTERNATIONAL HARMONISATION OF PESTICIDE CONTROL PROCEDURES - THE OECD PESTICIDES PROGRAMME

N.J. GRANDY, J. RICHARDS[1]

Organisation for Economic Co-operation and Development, 2 rue André Pascal, 75775 Paris Cedex 16, France

## ABSTRACT

The OECD Pesticide Programme, initiated in 1992, has activities in five areas: (i) Test Guidelines; (ii) Data Requirements for Registration; (iii) Hazard Assessment; (iv) Re-registration; (v) Risk Reduction. It was initiated at the request of OECD Member countries who wish to increase international co-ordination and co-operation in pesticide assessment and control. The work is overseen by a Pesticide Forum comprised primarily of government regulators, but including representatives from other international organisations, industry and environmental groups. Surveys of countries' data requirements for the registration of chemical and biological pesticides are completed and work on Test Guidelines has been defined, prioritised and begun. Countries have worked together to compare pesticide re-registration processes and assessment reports and a workshop to identify ways to harmonise hazard/risk assessment procedures has been held. A survey of pesticide risk reduction activities in OECD Member countries and selected FAO countries is in progress.

## INTRODUCTION

OECD began work on pesticides in 1992 in response to Member countries' increasing interest in improving international co-operation in pesticide assessment and control. Countries believed that OECD could make an important additional contribution to the existing pesticide activities already underway in other international organisations. In particular, countries were interested in working through OECD to reduce national differences in pesticide registration procedures that cause redundancy in product testing by industry and in the review of these data by national regulatory authorities.

In January 1993 Member countries agreed to continue and expand its work on pesticides through establishment of a 3-year Pesticide Programme. The Pesticide Programme is overseen by a Pesticide Forum comprised primarily of government regulators from the Member countries but which also includes representatives from the Commission of the European Union (CEU), from other international organisations (e.g. IPCS, UNEP, FAO, CoE, EPPO), and from industry and environmental groups. The Forum currently meets every nine months to review the Programme's progress and to agree on future work.

The Pesticide Programme has three principal goals: (i) to achieve harmonisation of national pesticide assessment and control procedures; (ii) to achieve more efficient re-registration of pesticides through Member country co-operation; (iii) to promote the reduction

of risks from the use of pesticides. To address these goals, the Programme has activities in five areas: (i) Test Guidelines; (ii) Data Requirements for Registration; (iii) Hazard Assessment; (iv) Re-registration; (v) Risk Reduction.

This paper will describe briefly the objective, achievements and ongoing work for each of these five activities.

## TEST GUIDELINES

### Objective

The objective for the work on Test Guidelines is to revise and develop OECD Test Guidelines appropriate for pesticides in order to increase the mutual acceptance among Member countries of data used in pesticide assessment.

### Survey of Test Guideline requirements

This activity was initiated in 1992 with a survey asking Member countries and industry (via GIFAP) to identify existing OECD Test Guidelines which need to be revised and new guidelines which should be developed to satisfy the requirements of pesticide registration schemes. The results of the survey, in terms of the numbers of revisions and new Guidelines proposed are shown in Table 1 below.

TABLE 1. Results from the Test Guideline Survey indicating the numbers of revisions and new Guidelines proposed.

| Test area | No. of Guideline revisions proposed | No. of new Guidelines (or endpoints) proposed |
|---|---|---|
| Physical-chemical properties and environmental fate | 8 | 45 |
| Ecotoxicology | 9 | 32 |
| Human health effects | 27 | 9 |
| Total | 44 | 86 |

Most of the revisions proposed were for human health effects Guidelines, although they were of a general nature (i.e. updating to keep pace with scientific progress). Proposed revisions in the other areas were of a more fundamental nature, indicating that for use with pesticides, additional factors beyond those normally required for general chemicals should be taken into account (e.g. metabolites). Regarding needs for new Guidelines, most proposals were for physical chemistry/environmental fate and ecotoxicology. This was expected since data requirements in these areas for general chemicals cover many fewer endpoints than do those for pesticides.

Priority setting and current status of work

The outcome of the Test Guideline Survey indicated that a considerable amount of work was needed and that priorities had to be set before work could begin. Three Task Forces (physical-chemical properties and environmental fate, ecotoxicology, and human health and exposure) were established in June 1993 to propose priorities (i.e. in terms of high, medium and low). In doing so, the Task Forces were asked to consider, *inter alia*, the frequency with which any particular data requirement is requested for pesticide registration (i.e. from results of the Data Requirements Survey for conventional plant protection products - see below) and the availability of existing methods from other fora (e.g. EPA, BBA, FAO, ISO, etc.).

The Task Force recommendations for work of highest priority and the current status of the Test Guideline work in these areas are shown in Table 2. Of the thirty Task Force high priority recommendations, work was already ongoing for nine of them (indicated by * in Table 2) when the Task Force met. A further nine activities have since been initiated and revisions of two Guidelines (Guideline 105, Water Solubility and Guideline 407, Repeated Dose Oral Toxicity) are in the final stages. New activities will be initiated as the work indicated above progresses taking into account priorities from other parts of the Test Guideline Programme with which work on pesticide testing is fully integrated.

TABLE 2. Task Force proposals for work of highest priority and current status of work.

| Task Force recommendations for work of highest priority | Current status (Sept 1994) |
|---|---|
| Environmental fate and behaviour | |
| - Revision of Guideline 106, Adsorption/Desorption * | - still under revision |
| - New Guideline for laboratory soil column studies | - being drafted |
| - New Guideline for aerobic/anaerobic metabolism in soil | - being drafted |
| - Technical workshop on soil selection | - being held January 1995 |
| - New Guideline for aerobic/anaerobic degradation in water/sediment systems | - being drafted |
| - New Guideline for photodegradation in water | - no progress |
| - New Guideline for hydrolysis | - no progress |
| Physical/Chemical Properties | |
| - Revision of Guideline 105, Water Solubility * | - revision in final stages |
| - Revision of Guideline 107/117, Octanol/Water Partition Co-efficient * | - revision of 107 in final stages |
| Ecotoxicology | |
| - Revise Guideline 201, Algae growth inhibition | - no progress |
| - Revise Guideline 202, Part I, Daphnia acute toxicity | - no progress |
| - Revise Guideline 202, Part II, Daphnia reproduction * | - revision progressing well |
| - New Guideline for fish growth test * | - under development |
| - Develop guidance for testing of difficult substances * | - under development |
| - Revision of Guideline 305, Bioconcentration in fish * | - revision in near final stage |

TABLE 2 (cont). Task Force proposals for work of highest priority and current status of work.

| Task Force recommendations for work of highest priority | Current status (Sept 1994) |
|---|---|
| Ecotoxicology (cont). | |
| - New Guideline for soil micro-organisms | - work initiated |
| - New Guidelines for honey bees, acute oral, acute contact, residues on foliage | - acute oral & contact being drafted |
| - New Guideline for avian acute oral | ) Joint OECD/SETAC |
| - Technical workshop on issues surrounding avian testing (acute, dietary, reproduction, acceptability) | ) Workshop on avian ) toxicology, Dec '94 |
| Human Health and Occupational Exposure | |
| - New Guidance on applicator (bystander) exposure | - under development |
| - New Guidelines on dermal penetration/percutaneous absorption (*in vivo* rodent, *in vitro*, human volunteers) | - draft methods for *in vivo* & *in vitro* available |
| - Revision of Guideline 417, Toxicokinetics | - no progress |
| - Revision of Guideline 407, Repeat Dose Oral Toxicity * | - revision in final stages |
| - Revision of Guideline 408, Subchronic Oral Toxicity | - no progress |
| - Guidelines on immunotoxicity (revision of Guideline 407, new Guidelines for Tier 2 and (repeat-dose) neurotoxicity including guidance on cholinesterase inhibition) * | - status report available |
| - Revision of Guideline 451, Carcinogenicity Studies | - no progress |
| - Revision of Guidelines 452/453, Chronic Toxicity and Combined Chronic Toxicity/Carcinogenicity | - no progress |
| - Revision of Guideline 416, Two-Generation Reproduction Toxicity, to include postnatal development and male fertility | - no progress |

* activities which were already ongoing when the Task Forces met

## DATA REQUIREMENTS FOR REGISTRATION

### Objective

The objective of this work is to promote international harmonisation in pesticide registration data requirements.

### Surveys of Member countries' data requirements

#### Data requirements for conventional plant protection products

The activity on Data Requirements for Registration was begun in 1992 with a survey of Member countries' requirements for conventional plant protection products (i.e. chemical

pesticides). The results of the survey are available as OECD Environmental Monograph No. 77 (OECD, 1994).

The purpose of this survey was to compare countries' current data requirements as a starting point for work towards harmonization. The survey focused principally on chemical pesticides used for plant protection although it also addressed, in less detail, products intended for uses other than plant protection (e.g. insect control in buildings) and products of biological origin.

The survey produced a detailed listing of countries' data requirements for the following test areas: (i) chemical identity; (ii) physical-chemical properties; (iii) function, mode of action and handling; (iv) analytical methods; (v) efficacy; (vi) fate and behaviour in the environment; (vii) residue chemistry; (viii) toxicology and metabolism; and (ix) ecotoxicology. Included in this list was information on whether compliance with principles of Good Laboratory Practice (GLP) was required and how often the data element was required, i.e. always, frequently (in more than 80 per cent of registration submissions), less frequently (in fewer than 80 per cent of registration submissions, or not required. The survey also collected general information on countries' approaches to implementing their data requirements. This included information on: (i) the registration processes; (ii) classification and labelling; (iii) tier testing; (iv) waivers of certain data requirements; (v) biological and biologically derived pesticides; (vi) inert ingredients and (vii) pesticidal products other than those used from plant protection - types of notification/approval.

Seventeen countries and the CEU participated in the survey. The countries were Australia, Austria, Canada, Denmark, Finland, Germany, Italy, Japan, the Netherlands, Norway, Portugal, Sweden, Switzerland, Turkey, the United Kingdom and the United States. Belgium, France and Ireland indicated that they followed the position of the CEU.

For those countries and the CEU who completed the questionnaire, the responses indicated that there is already a high degree of similarity in the data requirements for conventional plant protection products. In most major test areas, there is significant commonality both in the data elements themselves (for both active ingredients and formulations) and in the frequency with which they are required. Similarities also exist in that data requirements for certain test areas are dependent on whether the pesticide is for indoor or outdoor use.

The responses also indicated that many countries have adopted similar approaches to implementing their data requirements for the registration of plant protection products. Most countries organise their data requirements in tiers and have the flexibility to waive requirements in certain situations.

Despite the substantial overlap in data requirements and general registration approaches, the survey did reveal some important areas of divergence. Data requirements in the areas of efficacy and ecotoxicology showed fairly substantial differences. The two areas where countries diverged most sharply were in data requirements for biological pesticides and regulatory approaches for pesticides other than plant protection products.

Data requirements for biological pesticides

Following the outcome of the survey of data requirements for conventional plant protection products, the Pesticide Forum requested that a similar survey be done for biological pesticides. This survey, using a questionnaire similar to that for conventional plant protection products, was initiated in August 1993 and the report is in preparation. Following approval by the Member countries, the survey results will be made available as an OECD Environment Monograph.

The questionnaire focused principally on micro-organisms (such as bacteria, algae, fungi, viruses and protozoa) but also collected general information on six other types of products that are identified by at least one Member country as biological pesticides: pheromones, insect growth regulators, plant growth regulators, plant extracts, macro-organisms (such as predatory insects), and transgenic plants (i.e. plants that have been modified to have pesticidal properties). The questionnaire covered both naturally occurring and genetically modified products, and it requested information about general regulatory approaches and policies, as well as specific data requirements for registration.

Possibilities for further work

Future OECD work on data requirements will involve using the results of the two surveys as a basis to develop common core data sets for registration that could be agreed by all Member countries. This work would be linked closely with the working on Test Guidelines, since differences in requirements often result from use of different Test Guidelines. OECD may also consider work towards agreed core data sets for registration of pesticides used for non-agricultural purposes, focusing initially on those categories of products that all or most countries define for regulatory purposes as pesticides.

## HAZARD ASSESSMENT

Objective

The objective of OECD's work on hazard assessment is to harmonize assessment procedures for chemicals, including pesticides, so that countries can use part or all of each other's assessments in lieu of conducting new assessments themselves.

Hazard Assessment Programme

Work on hazard assessment of pesticides has been fully integrated into the ongoing Hazard Assessment Project of the Chemicals Programme. The first activity that specifically addressed pesticides was a May 1994 Workshop on Environmental Hazard/Risk Assessment held in London. Other important activities include the development of a Compendium of Hazard/Risk Assessment Methods (environment and human health) and on the development of harmonised assessment reports.

OECD Workshop on Environmental Hazard/Risk Assessment

The objective of the workshop was to recommend ways for OECD to build consensus among countries on procedures for environmental hazard/risk assessment of chemicals. As a starting point, the workshop examined and compared hazard/risk assessment approaches currently used by countries and international organisations. One of the most important features of the workshop was that it covered both pesticides and industrial chemicals. It therefore brought together regulators and industry representatives responsible for these two areas, providing an uncommon opportunity for the two groups to compare approaches and share ideas.

As background to the workshop, a document comparing existing schemes for ecological hazard and risk assessment was prepared; this will be published (after minor revision) as an OECD Environment Monograph. This document reviews thirteen important schemes used by various OECD countries or international organisations to support current regulatory requirements (e.g. OECD, EC, EPPO/CoE, US EPA, Japan, Canada, Netherlands, Sweden, ECETOC).

The outcome of the workshop was a list of recommendations for specific OECD activities in the following areas: (i) development of testing methods and guidance for terrestrial effects assessment; (ii) improvement of extrapolation methods; (iii) development of testing strategies; (iv) harmonization of models for estimating environmental concentrations of chemicals; and (v) development of criteria for assessing the validity of non-standard data. Several broader recommendations were also made; the most important of these being to improve the transparency and increase harmonization of assessment reports so that they could be shared by countries more easily.

The Workshop report will also be made available as an OECD Environment Monograph.

Compendium of Hazard/Risk Assessment Methods

Work was initiated in April 1994 on the development of a compendium of methods for environmental and human health assessment of new and existing chemicals, including pesticides. Government regulators, institutes, international organisations and scientific societies have been asked to send information on methods available to the OECD Secretariat. This information will be complied into a loose-leaf Compendium of assessment methods in a manner similar to that used for the OECD Guidelines for the Testing of Chemicals.

Harmonisation of assessment reports

The incentive for OECD to work on the harmonisation of assessment reports comes from a number of areas, including OECD's Existing Chemicals Programme and the Pilot Project to Compare Pesticide Data Reviews (see below). This work, which is in its early stages, will involve reaching agreement among Member countries on the essential elements that need to be included in assessment reports and the degree of detail needed in order that the reports could be used by other countries. Existing guidance on report formats and contents, such as that of the CEU for general chemicals and pesticides, will be taken into

account. The proposed output is one (or more) consensus documents rather like those for OECD Good Laboratory Practice.

## RE-REGISTRATION

### Objective

The objective of this project is to share the work of evaluating pesticide risks among OECD Member countries.

### Pilot project to compare pesticide data reviews

OECD's work on pesticide re-registration began in October 1992 with a workshop hosted by the US EPA in Washington, D.C. Participants at this workshop agreed that the simultaneous re-registration of pesticides in many different countries provided both a need and an excellent opportunity to increase international co-operation. Specifically, countries agreed to pursue the goal of 'sharing the burden' of pesticide data review by using each other's data review reports rather than proceeding individually to evaluate many of the same pesticides.

The most important outcome of the workshop was the initiation of a Pilot Project to Compare Pesticide Data Reviews. The purpose of the 'Pilot Project' was to compare existing data review reports done by different countries and international organisations. To this end, the project analysed available reports on a select group of pesticides, in order to determine how different countries and organisations had evaluated the same or similar data on health and environmental effects. The project compared all key aspects of the reports: their structure, content and degree of transparency; the original data sets reviewed; the endpoints assessed; the specific hazard levels identified; and the final hazard characterization of the pesticide. Based on this comparison, the project considered the extent to which existing data review reports might already be used to complement or replace a separate national review. The project also recommended ways to increase the exchange and use of reports among OECD countries in the future.

Seven pesticides that were known to have been reviewed by multiple countries and/or international organisations, and which therefore provided the opportunity for comparison of data review reports, were selected for the Pilot Project. These pesticides were: amitraz, diazinon, dicofol, dinocap, endosulfan, iprodione and pyridate.

For each of these pesticides, the project compared countries' reviews in the test areas of toxicology, ecotoxicology and environmental fate, with a less detailed analysis in the area of physical chemistry. The areas of efficacy and exposure were intentionally excluded so as to keep the focus on hazard identification and the assessment of data that would be common to all countries.

Two potential problems were addressed early in the project: First, any confidential business information was removed from the data review reports so as to avoid infringement of industry rights with regard to the original pesticide data. The project was thus designed to ensure that the analysis focused not on the pesticide data but on the data review reports.

Second, certain reports or report summaries were translated into English for purposes of the project, although language differences posed fewer problems than expected.

The principal work of the Pilot Project was done by seven OECD Member countries who volunteered to take a lead role in collecting, analysing and comparing available data review reports on the seven pesticides. Three other countries and two international organisations also participated in the Pilot Project by submitting their data review reports for analysis and by commenting on draft documents written by the lead countries. Table 3 shows the lead country and participants for each Pilot Project pesticide.

TABLE 3. Pilot project pesticides and participants

| Pesticide | Lead Country | Participating Countries, Organisations |
|---|---|---|
| Amitraz | Germany | Canada, Food and Agriculture Organisation (FAO), US |
| Diazinon | Switzerland | Australia, Canada, Finland, UK, Sweden, US |
| Dicofol | Denmark | Germany, the Netherlands, United States, World Health Organisation (WHO), FAO |
| Dinocap | Sweden | Australia, Switzerland, UK, US, FAO/WHO |
| Endosulfan | United States | Australia, Canada, Denmark, FAO, Germany, Sweden |
| Iprodione | Finland | US, Canada, UK, Australia, WHO |
| Pyridate | The Netherlands | Australia, Canada, Germany, Switzerland, US |

The central finding of the Pilot Project was that mutual use of pesticide data review reports among OECD counties, and co-operation in re-registration, could begin straight away. Despite the considerable differences among existing data review reports, the Pilot Project found that many could usefully complement another country's independent review. Moreover, the project found that in certain areas, where study results are straightforward and countries' analyses consistent, existing reports could already be used in lieu of a separate national review.

The Pilot Project was equally optimistic about the future prospects for greater co-operation in pesticide review and mutual use of data review reports. While several barriers to such co-operation were identified, the project concluded that none of these barriers were insurmountable. The project thus recommended that work begin immediately in five main areas: (i) report structure and content; (ii) studies reviewed; (iii) terminology and criteria for hazard identification; (iv) the data review process; and (iv) exchange of reports.

A workshop to review the outcome of the Pilot Project and to propose further work for OECD, particularly in promoting the exchange of reports, will be held in the Netherlands from 17 to 19 October 1994. The report of the Pilot Project will be made available as an OECD Environment Monograph.

## RISK REDUCTION

### Objective

The objective of this activity is to promote the reduction in risks to human health and the environment from the use of pesticides.

### Survey of Activities in OECD and Selected FAO Countries

Work in the area of pesticide risk reduction began in mid-1994 with a survey conducted jointly by OECD and FAO, of their respective Member countries' activities to reduce the risks associated with pesticide use in agriculture, forestry, and other plant protection areas. The survey questionnaire asked countries to provide information in three areas: (i) the framework for risk reduction activities including the structure of programmes and activities, their legal basis, and reasons for initiating them; (ii) a description of activities and results including goals, participation, monitoring or enforcement, progress in implementation, and results; and (iii) conclusions including identification of most and least successful activities, difficulties encountered, and recommendations for best avenues to pursue.

Responses to the survey will be summarised in a report that will serve as background for an OECD workshop on pesticide risk reduction in 1995. The goal of this workshop will be twofold: (i) to share information about risk reduction approaches, and (ii) to consider future work in pesticide risk reduction that might be done by OECD or as a joint OECD/FAO project. The report on current activities will also be distributed widely so as to give countries an opportunity to see how others are approaching the task of pesticide risk reduction.

## REFERENCES

OECD. (1994) Data Requirements for Pesticide Registration in OECD Member Countries: Survey Results. *OECD Environment Monographs No. 77, 139pp.*

## NOTE

1. The opinions presented in this paper do not necessarily represent the opinions of the OECD or its Member countries and should therefore be viewed as soley those of the authors.