

# **MEETING ON THE CONTROL OF PESTICIDES**

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## Preface

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There is no area of the chemicals field where the multiplicity of work is so obvious as in the pesticides sector. A crucial question is whether co-operation between countries and between international organizations and programmes could be closer and still more efficient.

In a great number of countries there are legal requirements (registration/approval) for accepting the use of a certain pesticide in the country. Particularly in industrial countries the procedure includes evaluation of a great amount of data regarding the active ingredient and/or the formulated product. A further harmonization of national procedures would increase the possibility of mutual acceptance of data which would be in the interest of both governments and industry.

Existing international guidelines for testing and evaluation of chemicals including pesticides have been issued at different times and by various organizations. In the interest of the overall chemical safety and for economic reasons it would be useful if a broad discussion could take place regarding the status of current guidelines with a view to co-ordinate as far as possible the requirements for testing and evaluation of industrial chemicals and pesticides.

After informal discussions with representatives of competent authorities in a few other countries we came to the conclusion that it would be timely to gather high level representatives of a number of governments of countries having pesticide control programmes and relevant international organizations. The objective of this meeting will be to discuss in an open and free atmosphere the needs for the future, the possibility of a closer co-operation in the pesticides field and how to promote a still more efficient partitioning of work among interested international organizations.

A similar informal meeting was held at Hässelby Castle, Stockholm in 1978. That meeting was devoted to the control of toxic substances with special regard to environmental chemicals. The invitation to participate in the Hässelby Castle meeting was accepted by fifteen governments and six international organizations. The meeting identified specific new work and activities that were needed and invited several international organizations to take on certain elements. It resulted in the immediate establishment of the OECD Special Programme on the Control of Chemicals and eventually to the establishment by WHO of the International Programme on Chemical Safety. The Hässelby meeting still has a bearing on the current distribution of work among international programmes in the field of chemicals safety.

It is our hope that this meeting could in some aspects act as a catalyst for increased international efforts on co-operation and harmonization.

# OVERVIEW OF THE INTERNATIONAL CO-OPERATION ON PESTICIDES

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## Background

An extensive international co-operation on chemical safety is ongoing nowadays. The development of the current activities has taken place mainly after World War II. The beginning of this development coincided with the establishment of several new international organizations. The increased awareness of chemical risks was very much due to the appearance of new, more powerful pesticides. Concern on potential risk was expressed regarding at least three different sectors: the public health field, the occupational area and the environment. Some notices demonstrating this concern follow.

The First World Health Assembly (1948) adopted a resolution calling for activities with the aim of preventing risk by the use of insecticides. This action initiated a far-reaching work comprising at the outset chemistry and specifications of pesticides, toxic hazards of pesticides to man, safe use of pesticides, aircraft disinsection and application and dispersal of pesticides. More than 30 reports dealing with various aspects of vector control have been issued in the WHO Technical Report Series.

Because of their responsibilities in the field of food safety FAO and WHO established the JMPR (Joint FAO/WHO Meeting on Pesticide Residues) in 1963. This body has remained a key instrument regarding problems on pesticide residues in food. The initiative to create JMPR goes back to a recommendation in 1959 by the FAO Panel of Experts on the Use of Pesticides in Agriculture. JMPR is an important advisory body to the Codex Alimentarius Commission (founded in 1962) in its development of standards for food products.

In 1956 the Council of Europe set up a Committee of Experts on Pesticides. Within the framework of this Committee the booklet Agricultural Pesticides was published in 1962. Under the name Pesticides a sixth edition of the booklet was issued in 1984. The Committee of Ministers of the Council of Europe adopted a Resolution in 1970 in which member states were urged to take more active steps to ensure the correct use of pesticides to protect both public health and the environment.

The establishment of the OECD Chemicals Group in 1971 is a response to a recommendation given by an ad hoc Study Group on Unintended Occurrence of Pesticides convened in 1969. This Group in turn was a follow-up of an OECD Symposium held in 1966 under the title Unintended Occurrence of Pesticides in the Environment.

## Main Current Activities

### WHO Expert Committee on Vector Biology and Control

As a response to Resolution WHA 1,12 passed by the World Health Assembly in 1948 an Expert Committee on Insecticides was set up. The Report of the First Session of the Committee was published in the WHO Technical Report Series as No 4. In 1976 the Committee was renamed and has since been called Expert Committee on Vector Biology and Control. The last meeting of the Expert Committee was held in 1990.

Three of the Reports of the Committee have had the title: Safe Use of Pesticides. The last of them was published in 1985 (Tech. Report Ser.No 720, 60 pp). To indicate the character of the Report the titles of the six chapters may be quoted. They read:

Development in vector control: human safety aspects  
Review of new data on insecticides for control of vectors  
Review of selected compounds for control of rodents and molluscs of public health importance  
Protection of people who use pesticides  
Prevention and treatment of poisoning  
Summary of recommendation

Three Annexes to the report have the following titles:

Annex I. Assessment of exposure by direct and indirect means  
Annex 2. Training of community health workers in the prevention of pesticide poisoning  
Annex 3. Treatment of poisoning due to organophosphorus, carbamate, and organochlorine insecticides, anticoagulant rodenticides, and paraquat

The two most recent reports of the Committee published in the Technical Report Series are the following:

- \* Urban Vector and Pest Control, Techn. Report Series No 767, 77 pp. Geneva, 1988
- \* Chemistry and specifications of pesticides, Techn. Report Series 798, 77 pp. Geneva 1990

The secretarial functions for the Committee are handled by the Division of Vector Biology and Control, WHO. This Division is the origin of the WHO recommended classification of pesticides by hazard. Guidelines to classification (Unpublished WHO Document VBC/84.2), presently WHO/PCS/90.1. Since 1990, the responsibility for these activities has been transferred to the International Programme on Chemical Safety (IPCS).

## JMPR

The Joint FAO/WHO Meeting on Pesticides Residues (JMPR) serves in an advisory capacity to FAO, WHO and the Codex Alimentarius Commission in matters regarding pesticide residues. JMPR is composed of two entities: The FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues, which is administered by the IPCS. After meeting in 1963, JMPR has met annually since 1965.

JMPR comprises two separate groups of scientists. The FAO Panel has responsibility for reviewing pesticide use patterns, data on the chemistry and composition of pesticides, and methods of analysis of pesticide residues, and for recommending Maximum Residue Levels (MRLs) that might occur in food commodities following the use of pesticides according to good agricultural practices. The WHO group has responsibility for reviewing toxicological and related data and for estimating (where possible) an Acceptable Daily Intake (ADI) for humans. During the joint meetings, the two groups co-ordinate their activities and issue a joint report.

The reports from JMPR are published in the FAO Plant Production and Protection paper Series. Normally three volumes are published after each meeting comprising: (i) the report; (ii) evaluations:

residues; (iii) evaluations: toxicology. As of 1990, the cumulative list of reports and documents comprises 61 titles.

More than 200 pesticides have been evaluated by JMPR so far. Many pesticides have been reconsidered several times.

When a pesticide is evaluated the first time, a toxicological monograph is published that summarizes the toxicological and related data that were reviewed. The biological data cover biochemical aspects (absorption, distribution, excretion and biotransformation), toxicological studies as studies including acute toxicity, short-term studies, long-term/carcinogenicity studies, reproduction studies, and special studies as appropriate, such as mutagenicity, teratogenicity, and delayed neurotoxicity studies. The monograph concludes with a list of studies which will provide information valuable for the continued evaluation of the compound. When pesticides are re-evaluated, monograph addenda - which summarize the new data on the compound, are published.

The WHO Secretariat of JMPR is the responsibility of the International Programme on Chemical Safety (IPCS). Recently a volume has been published in the IPCS Environmental Health Criteria series with the title Principles for the Toxicological Assessment of pesticide residues in Food. According to a statement by Dr. J.L. Herrman, WHO Joint Secretary of JMPR the publication reflects the views of a large number of international experts who are involved with the toxicological assessment of pesticides. In addition, by concentrating on the procedures used by the WHO Expert Group on Pesticide Residues, it faithfully reflects the principles used in the evaluation of pesticide residues by JMPR.

#### Environmental Health Criteria documents

In 1973 WHO launched the Environmental Health Criteria Programme with the objectives to

- \* assess existing information on the relationship between exposure to environmental pollutants (or other physical and chemical factors) and man's health, and to provide guidelines for setting exposure limits consistent with health protection, i.e., to compile environmental health criteria documents;
- \* identify new or potential pollutants by preparing preliminary reviews on the health effects of agents likely to be increasingly used in industry, agriculture, in the homes or elsewhere.
- \* identify gaps in knowledge concerning the health effects of recognized or potential pollutants or other environmental factors, to stimulate and promote research in areas where information is inadequate, and
- \* promote the harmonization of toxicological and epidemiological methods in order to obtain research results that are internationally comparable.

The responsibility for this programme was taken over by IPCS (International Programme on Chemical Safety) when it was established in 1980.

Some 120 volumes have been published so far. About 90 volumes are devoted to chemicals or groups of chemicals. Some 30 of them deal with pesticides.

The current structure of an Environmental Health Criteria (EHC) document has the following pattern.

## Summary

Identity, Physical and Chemical properties, Analytical Methods

Sources of Human and Environmental Exposure

Environmental Transport, Distribution, and Transformation

Environmental Levels and Human Exposure

Kinetics and Metabolism

Effects on Organisms in the Environment

Effects on Experimental Animal and In Vitro Test Systems

Effects on Man

Evaluation of Human health Risks and Effects on the Environment

Recommendations

Previous Evaluations by International Bodies

An EHC document contains a comprehensive evaluation of the risks of the chemical dealt with. It comprises both risks to human health and to the environment. The length of an EHC document varies considerably (from some 25 to more than 400 pages).

## FAO Code of Conduct on the Distribution and Use of Pesticides

In addition to its participation in JMPR, considerable work regarding pesticides has been carried out by FAO.

Already in 1970 FAO issued guidelines and a Model Scheme for the establishment of national organizations for the registration and control of pesticides. An ad hoc government consultation on International Standardization of Pesticide Registration Requirements was arranged by FAO in Rome in 1977. This event was followed by a Second Government Consultation on International Harmonization of Pesticide Registration Requirements held in Rome in 1982. These two consultations form the basis for the FAO Code of Conduct on the Distribution and Use of Pesticides approved by the FAO Conference in November 1985. The Code was amended in 1989 when the so called Prior Informed Consent procedures were incorporated.

The objectives of the Code are to set forth responsibilities and establish voluntary standards of conduct for all public and private entities engaged in or effecting the distribution and use of pesticides, particularly where there is no or an inadequate national law to regulate pesticides.

The Code comprises twelve Articles related to: (i) Objectives of the Code; (ii) Definitions; (iii) Pesticide management; (iv) Testing of pesticides; (v) Reducing health hazards; (vi) Regulatory and technical requirements; (vii) Availability and use; (viii) Distribution and Trade; (ix) Information exchange and prior informed consent; (x) Labelling, packaging, storage and disposal; (xi) Advertising; (xii) Monitoring the observance of the Code. Article by article the code suggests how to distribute the responsibilities among government, industry and others concerned. It gives advice on ways and means for the promotion of safety and efficacy. Reference is made to issued FAO Guidelines, WHO recommended classification and other guides.

A great number of guidelines for the implementation of the Code have been issued by FAO. The following should be mentioned in particular.

Guidelines for legislation on the control of pesticides, 15 pp, Rome, 1989

Guidelines for the registration and control of pesticides, 42 pp, Rome, 1985

Addenda to guidelines for the registration and control of pesticides, 11 pp, Rome, 1988

Revised guidelines on environmental criteria for the registration of pesticides, 51 pp, Rome, 1989

In the guidelines for registration and control of pesticides chapter 8 contains detailed information required for registration. Five sub-sections comprise details concerning data on (i) Chemical and Physical Properties; (ii) Efficacy ; (iii) Toxicity for Assessment of Human Health Hazards; (iv) Residues in Agricultural Procedure; (v) Prediction of Environmental Effects. This part of the guidelines (10 pp) is complimented or replaced by Addendum I of the two Addenda to these guidelines. Addendum II deals with proprietary rights to data.

The Revised Guidelines on environmental criteria for the registration of pesticides (51 pp) comprise two parts. Part I deals with principles and includes, in addition to an introduction, sections on exposure, effects, hazard, ecological significance and risk. Part II, Guidelines for Appropriate Test Procedures, deals with (i) Physical-chemical properties; (ii) Fate and mobility in the environment; and (iii) Effects on the environment.

#### Council of Europe

As of 1962 the Council of Europe has published booklets on pesticides. The sixth edition appeared in 1984 and a seventh edition is foreseen to be published in 1991.

The volume Pesticides, 6th edition comprises 126 pages and includes the following chapters:

- Layout of model data sheet
- Identity, properties, specifications and uses
- Guidance on toxicity data
- Guidance on residue data
- Guidance on environmental phenomena and wildlife data
- Guidance for registration of biological agents used as pesticides
- Guidance on efficacy data agriculture, horticulture and forestry practice
- Guidance on the disposal of surplus pesticides and pesticide containers
- Guidance on the classification and safety labelling of formulated pesticide products
- Clearance

#### UNEP/IRPTC

A direct result of the 1972 UN Conference on the Human Environment was the establishment of a permanent United Nations Environment Programme (UNEP). In 1976 the International Register of Potentially Toxic Chemicals (IRPTC) was created by UNEP. By fostering the establishment of international conventions and soft law concerning chemically oriented environmental problems UNEP has contributed considerably to the promotion of chemical safety. One of the main objectives of its specialized entity IRPTC is to identify, or help identify, potential hazards from chemicals, and to improve the awareness of such hazards.

As far as pesticides are concerned a few things are of special interest to note. A considerable portion of the about 600 chemicals for which IRPTC has elaborated Data Profiles are pesticides. The London Guidelines for the Exchange of information on Chemicals in International Trade comprise the so

called PIC (Prior Informed Consent) procedure. Based on this a similar procedure has been incorporated in the FAO Code of Conduct on the Distribution and Use of Pesticides. FAO and UNEP co-operate closely on the implementation of the PIC procedure. IRPTC has co-operated actively in the elaboration of the UN Consolidated List of Products Whose Consumption and/or Sale Have been Banned, Withdrawn, Severely Restricted or Not approved by Government. A considerable part of the list (102 pages out of 246) deals with agricultural chemicals of which most are pesticides.

### OECD Chemicals Programme

The OECD Chemicals Programme is the most comprehensive administratively oriented informational programme on chemical safety. Although its origin goes back to concern on unintended occurrence of pesticides in the environment the programme has comprised few activities specifically focusing on pesticides. The reason is that after a few initial efforts to tackle specific chemicals, OECD has more and more developed general approaches to chemical safety problems.

One of the important features of OECD is that it provides for an opportunity for consensus building among governments and in some cases further collective commitments for action by means of formal Decisions and Recommendations of its Council.

Some of the most far-reaching results of the general approach are the adoption of a great number of guidelines for testing of chemicals, principles of good laboratory practice, Decision on the mutual acceptance of data in the assessment of chemicals, Recommendation concerning the minimum pre-marketing set of data (MPD) in the assessment of data and Recommendations concerning protection of proprietary rights and exchange of confidential data.

OECD products have found a place in a number of settings outside the OECD. The OECD Principles of Good Laboratory Practice have been used in the IPCS work on chemical safety and are referred to in the FAO Code of Conduct on the distribution and use of pesticides. The FAO Guidelines for implementation of the Code refers to the use of the OECD Test Guidelines.

While a major part of the current OECD work is devoted to existing chemicals, including studies on high production volume chemicals and ways and means for risk reduction, work continues on other areas such as test guidelines, GLP compliance, hazard assessment guiding principles.

# A National Perspective on International Pesticide Activities

Statement of  
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## INTRODUCTION

1. The United States is honored to have this opportunity to address such an auspicious Conference. We applaud the initiative of the Swedish Government to convene this conference and establish a framework for our discussion. Sweden has brought us together to examine the possibilities that lie before us to realize greater harmony in the world of pesticide regulation. The time is right. Many forces have converged to make this conference seminal to the future of our work to control pesticides and treated agricultural commodities in international trade. Our public is demanding stricter health and environmental controls in a time of shrinking budgets. Our international trading partners are demanding ready access to our markets with little disruption to the flow of trade. Yet disruptions occur precisely because of our need to ensure and demonstrate the safety of commodities for the consumer. How can we meet these apparently conflicting demands without compromising our health and environmental standards?
2. The U.S. has identified several goals for its participation in international activities related to pesticide regulation. We believe that these goals are shared by many of the other countries represented here today. First and foremost, we are committed to the protection of the public health and environment from the adverse effects of pesticides to assure that benefits exceed risks of pesticide use. Second, we hope to facilitate agricultural production and international trade by working toward more compatible regulatory systems. Third, we are eager to find better ways to use scarce regulatory resources more efficiently, to "share the burden" of the testing and assessment of pesticides, as the Swedish Government has proposed. We find this concept intriguing, and hope that we can agree upon some of the first steps that will be necessary to reach that goal. The U.S. believes that whatever steps we choose to take should build upon the accomplishments of the international organizations which have faced these issues before us.
3. We have a unique opportunity to make conscious choices about our mutual goals, and our distribution of resources. Prudent yet bold decisions about future cooperative efforts could result in significant advances in our national control programs. I believe that international efforts can support the work of national governments, as well as the reverse. Thus, the U.S. would like to foster a mutually beneficial relationship with other countries involved in similar regulatory functions, and to build upon the good faith we have built in other relationships.
4. Here, I believe it appropriate to emphasize a key issue. The impetus for this meeting clearly indicates that we are at a critical juncture in our deliberations. We have gained much experience in pesticide regulation; in large part, this complements the extensive work of several international organizations. We must build upon this work. The U.S. would like to take this opportunity to acknowledge the significant accomplishments of the United Nations Food and Agriculture Organization and the International Program on Chemical Safety, and the Joint Meeting on Pesticide Residues. It is our belief that our future work must build upon the accomplishments of these organizations; their continued role is integral to successful implementation of international pesticide programs.

5. These organizations and other international cooperative efforts have laid the foundation for future work. Yet because national governments have not, for a variety of reasons, accepted, integrated and implemented the agreements reached in the international organizations, the problems they were meant to address remain. A productive use of our time here would be to focus on the strategies needed for national governments and international organizations to continue the work begun. We need to engage in a frank discussion of the current state of international cooperation in pesticide management, and make conscious choices about the division of responsibilities. In thinking about how we might improve the effectiveness and acceptance of these programs we need to evaluate carefully the progress of each in meeting our goals. To what extent do the existing programs address the problems before us? Will these programs, if fully implemented, truly resolve our problems? What benefits can we directly attribute to their resolution? This meeting is a good opportunity to discuss some of these long-range concerns, as well as those of a more immediate nature -- whether there are duplications of effort by international organizations which should be addressed, or gaps in need of being filled.

6. We think it desirable to pursue an orderly expansion of the international trade in food and other commodities. Different national pesticide residue limits on food can create enormous obstacles to trade in treated agricultural commodities. While international limits are often used as a reference point in establishing national limits, the U.S. for one is not able to adopt them automatically. It has been suggested to the U.S., in the midst of specific trade disputes, that if the U.S. were to automatically adopt tolerances established by an international organization, for instance, some trade disruptions might be resolved or prevented. We do agree that automatic adoption might solve the immediate trade dispute, but such action would also likely exacerbate other problems, such as public anxiety about the safety of imported foods, or scientific uncertainty about the basis of the tolerance in question. We all know that other countries have also adopted national limits that differ from the international one, so unilateral action by the U.S. would not resolve the problem. International limits can reach their full potential only when they are available for all pesticide-commodity combinations of interest at the international level and are widely accepted by governments. This can occur only when governments agree on principles of their development. It is here that I believe our efforts can be most productive.

7. We also have an enormous opportunity here to recognize the need for and promote alternative pest control methods. The concept of pollution prevention is a philosophy which is guiding the Environmental Protection Agency's approach to many health and environmental issues. Increasingly, our programs are designed to meet our goals in this area. In this context, the U.S. looks forward to the presentation on the Indonesian Integrated Pest Management (IPM) Program, because we believe that continued and even greater reliance on such methods as IPM will minimize potential ecological and health threats. Both the cost and effectiveness of pest control measures can be enhanced through IPM approaches.

8. In our deliberations, we should also keep in mind that a variety of factors -- including, financial resources, regulatory infrastructures and conditions of use in some developing countries -- may preclude safe use of many chemical control measures. The FAO deserves considerable credit for its efforts to assist developing countries. The FAO International Code of Conduct on the Distribution and Use of Pesticides lays the foundation for the promotion of health, safety and environmental goals in developing countries, by promoting better informed decision making in importing countries. For those countries which lack sophisticated regulatory infrastructures, the FAO has provided an invaluable educational service with its regulatory management training programs and workshops.

9. I must also take note of the recent achievements of the OECD workshop on Importing Chemicals (Formal Title: Workshop to Facilitate Implementation of International Information Exchange Schemes Related to Banned or Severely Restricted Chemicals). Representatives from Asia, Latin America and Africa requested that OECD donor agencies provide greater support for the development of alternatives to hazardous pesticides. In the world of pest management, there is an increased awareness of the need for

alternatives. The decisions we make this week may help promote such control measures as integrated pest management, and the reduction of chemical dependency. I hope we can put our work in this greater context of sound environmental protection measures. While much of our future efforts will inevitably, and appropriately, focus on alternative pest control measures for the future, our immediate task is to deal with the system and concerns at hand.

10. There is much to be done. We hope this Conference will reach agreement on priorities for future cooperative efforts in pesticide regulatory matters and will identify strategies to develop solutions to the problems that countries have experienced both in pesticide regulation and in international trade in pesticide products and treated agricultural products.

## STATEMENT OF ISSUES

11. There are a number of compelling reasons for seeking international harmonization of pesticide regulations. They stem from the reality that we are all operating in a world of limited financial resources, that our regulatory requirements may create unnecessary economic dislocations, that science is continually evolving, and that we are motivated to address the public perception, and perhaps mis-perception, that pesticide products and pesticide residues in food jeopardize the public health and threaten the quality of our environment.

12. **Scarce Resources** The growing demands made on national and international pesticide review organizations and on the pesticide industry have severely strained available resources. The resource problem is exacerbated by the lack of harmonized data requirements and testing guidelines regarding pesticide safety evaluation. Individual national registration systems which offer varying degrees of acceptance for studies generated for other national systems have often led to conflicting data requirements and study protocols. This means that industry may have to conduct multiple tests on the same endpoint and governments are duplicating each other's reviews of the test data. The duplication of data development • and its evaluation by national authorities and/or international organizations may be a wasteful effort. This duplicity of effort does not move any of us closer to meeting the broader goals of environmental and public health protection. The OECD Test Guidelines and Mutual Acceptance of Data developed in the early 1980's did much to advance the international community in this area. It may be time to revisit that effort, update it as necessary, and move forward. Scarce resources, both public and private, require us to maximize their use, to enable us to carry out our mandate of environmental protection.

13. **Trade Disruptions.** It is clear that agriculture is an international business. Additionally, there has been a steady globalization trend among the support industries for agricultural production, such as the pesticide industry, with an increasing amount of pesticide manufacturing occurring in developing countries. It is essential to encourage continued growth in the agricultural sector. Yet growth is not without its costs. Any move toward harmonization should be a move forward, promoting the highest achievable standards of health and environmental safety, reached through a careful balance of risks and benefits, rather than reliance upon the lowest common denominator.

14. International organizations with responsibilities for promoting industrial and pesticide chemical safety have recognized that improved international harmonization of chemical regulation and management would facilitate international trade and would reduce costly redundant testing. Recent examples of differences in national approaches to regulating certain pesticides, plainly show how different pesticide requirements create barriers to trade, leading to confusion and economic hardship. The hardship is shared by all: the regulatory agencies which must quickly react to a trade crises, the pesticide producers which must provide data on short notice, and the exporters whose commodities may have been detained or refused entry because of illegal residues.

15. **Scientific Advances.** At the same time national approaches to risk assessment are becoming more divergent and less convergent, and we continue to identify areas of profound scientific disagreement, in good measure, because of lingering uncertainties. Many of these differences and other obstacles to harmonization were identified by Codex Committees, strongly re-enforced and emphasized at the March 1991 Food Safety Conference in Rome, and later acknowledged by the Codex Alimentarius Commission. At those meetings, it was agreed that there is a need for greater international harmonization of risk assessment principles. Differences in approaches to risk assessment quite naturally can lead to regulatory decisions that may vary from country to country.

16. **Public Concerns.** While many in the international scientific and regulatory community are calling for greater harmonization, others at the national level, in particular those representing consumer and environmental organizations, are voicing distrust of internationally established standards. This distrust can be attributed to a number of points.

17. In the U.S., we in the regulatory agencies have been grappling with how to address constructively growing consumer concern about the health and environmental effects of pesticides. There appears to be a perception among consumer groups and among the general public that the pesticide products themselves are largely under-regulated and that the time has come for more stringent safety standards. Concerns are expressed over worker exposure and ecological effects but more often involve issues of food safety and the levels of pesticide residues permitted on foods. We have also been faced with extensive criticism of the pesticide residue monitoring system we have in place. Lack of confidence in the tolerance setting system's ability to establish protective levels and of the monitoring system's ability to detect illegal residues results in a crisis of confidence in the safety of domestically produced foods, as well as imported ones. Uncertainty about the reliability of the international standard setting process has negatively influenced the public's perception of the protectiveness of international standards. To some extent, this has inhibited our government's ability to operate as effectively as possible in the international arena.

18. As many of you are no doubt aware, much of this public concern has been expressed in Congressional activity. These concerns led, in part, to the 1988 enactment of legislation requiring EPA to accelerate the reassessment of the safety of older pesticides. Additionally, legislation has been introduced in the U.S. Congress which would significantly change the way the U.S. regulates exported pesticides and would place new requirements on imported commodities. The Administration has not supported the particular bill in question, but we have requested greater authority to control pesticide exports, consistent with the internationally agreed upon system of Prior Informed Consent. While it is unclear whether this Congressional activity will result in any legislative changes, it is illustrative of the breadth and depth of the public concern and our task to allay those concerns via frank dialogue and effective communication.

19. No doubt the crisis of public confidence we are experiencing at home is due in part to our failure to communicate effectively the nature and scope of our programs, and the related international efforts. It is clear that scientific fact does not entirely support the public concern; a significant education gap exists which needs to be addressed. We at EPA have recognized that in order for us to succeed in our work, we must build the public's confidence in the viability of our domestic regulatory system. There is an opportunity for all of us at this meeting to affect the public's perception of the international system. One way of doing so is to expand the opportunities for constructive public participation in our deliberations. In order to achieve greater participation, it is important to make the public aware of our goals, to communicate that national and international goals are entirely consistent with protection of health and the environment, and to educate them about the scientific and technical issues at hand.

20. The U.S. Government's position in international activities often reflects concerns expressed to us by the public, and we have taken steps to increase opportunities for public participation in recent years. It

is imperative to consider these voices, both at the national and international level, and accommodate them where possible. To the extent we can reach consensus and compromise, solutions are often both more practicable for the regulated community and more acceptable to the public at large.

## TOPICS TO DISCUSS

21. No doubt there are innumerable ways of looking at the subject of how to improve harmonization of national pesticide programs. In general, the issues are related to economics, to science, and regulatory requirements. Obviously, economics is a motivating factor. Governments are expending considerable resources, and it is highly likely that we would be able to achieve our goals in a more efficient way. The question is how to do so. Much as been said of the substantial costs to the pesticide industry related to test data generation. It would be extremely helpful for industry to identify specific duplicative efforts. Any suggestions for economies that can be worked into the process could be useful; the governments here need to consider the mechanism necessary to receive such suggestions and the way to incorporate them into regulatory programs.

22. In terms of science issues, I believe that the Rome Standards Conference, and the work of the Codex Committees, made significant advances in the identification of some of the fundamental science issues which result in barriers to scientific agreement and barriers to trade. Additional work is planned -- changes in some of the work of Codex committees, a meeting here in Sweden in May of 1992 and possibly an international conference on risk assessment. I urge this group to give it the high priority it deserves.

23. Given that these issues are being considered elsewhere, I would suggest that this forum focus discussion on those topics of a regulatory nature. We may also wish to consider an appropriate mechanism for following the progress of the implementation of the recommendations and the agreements reached in those fora.

24. **Transparency.** The issue of the relative transparency of both national data evaluation systems and regulatory decisions as well as the transparency of international organizations' processes has often been raised, particularly in the context of trade negotiations, but the role of transparency in the enhancement of scientific understanding can not be underestimated. We must be able to understand the rationales and assumptions that support one another's actions. The process by which we reach our decisions must be open to scrutiny. One of the most important steps organizations can take toward fostering international agreements is to open national standard setting processes to public view. Ultimately, we will be able to identify differences in risk assessment and management approaches, and the many potential areas for harmonization.

25. This issue is key to the success of our deliberations. If the supporting rationale for our regulatory decisions is not elaborated, those decisions are more vulnerable to challenges. Rather than focusing the debate on the issues involved, debate can be easily misdirected to irrelevant considerations, and confusion and mistrust reign. Pesticide users and manufacturers also benefit from predictable, clear requirements and understandable procedures. As regulatory agencies, we owe the regulated community a clear explanation of the rules we expect them to follow. Additionally, an open, orderly regulatory process fosters greater public participation.

26. **Data Protection.** Industry has legitimate concern about the protection of intellectual property and its considerable investment in data generation to support regulatory approvals. Governments clearly have a responsibility to afford proprietary information the appropriate protection. Agreements have been reached on this topic, yet it is unclear the degree to which they have been implemented, creating a climate of uncertainty for industry. At the same time, industry has a responsibility to ensure that complete data sets

are made available to all countries and international organizations which are reviewing the chemicals. Additionally, industry can be of assistance by supporting the public's access to significant health, safety and environmental data.

27. **Data Requirements.** There are three separate and distinct aspects of the issue of data requirements. First, there is the determination of what specific data are necessary. As is clear, the foundation for a regulatory decision is the supporting scientific data. If each country is reviewing different data, different conclusions will undoubtedly result. All member countries of the FAO have agreed to FAO guidelines on data requirements. We may want to decide if we should take steps to advance national compliance with those requirements, or if they should be reviewed and perhaps revised. Second, there is the aspect of data guidelines. How are the data generated? Can we develop mutually satisfactory test procedures and protocols and if so, how do we do it? Any measures that we can take which would advance the transportability of data from country to country would no doubt result in savings to industry, and ultimately to the availability of public resources. Third, we must consider how the data will be interpreted. The first two aspects I have laid out here, agreeing upon the data requirements and developing the data guidelines, are first and foremost the concern of government. Meeting the requirements and conforming with the guidelines are the concern of industry. The third aspect, how the data are interpreted, are clearly within the sole purview of government. Agreement on what data are required and how the data are developed is the foundation for complementary data interpretation.

28. **Coordination of Review Schedules.** I hope the Conference can determine the extent to which it may be possible to coordinate national and international review schedules. In terms of the reregistration of older pesticides, the pace of the work to be done by EPA has been established by the U.S. Congress, and it is substantially faster than that of the international organizations. It is not a schedule that can be easily amended across the board. This is a reality in which the U.S. must operate. Countries represented here surely must also face similar realities and our respective tasks are not, on the whole, coordinated. It be possible for the U.S. to change the review schedule for a particular chemical, if there is a significant need expressed by another country. We may also want to consider the extent to which national review schedules can be incorporated into those of the international organizations. At the very least, if we become familiar with each other's review schedules, it may be possible to alleviate the immediate impact our respective decisions may have on one another. I hope this Conference can reach agreement on the strategies and mechanisms for doing so.

29. However, in terms of registration of new pesticides and the first-time setting of maximum residue levels and tolerances, there may be substantial room for coordination of schedules and national priorities. Of course, this aspect largely depends upon industry's cooperation in submitting the same applications for registrations and tolerance petitions to countries and international organizations at the same time. If this is not possible, it may be possible to establish a channel for communication, so that governments can keep each informed of such activity.

30. In addition, I think it appropriate to point out that the agricultural industry should share the responsibility in avoiding trade disruptions. If industry is selling a pesticide product to be used on a commodity destined for an export market and residues occur, industry should first ensure that a tolerance is in place in the country of ultimate importation, and that an international limit is established. Further, it is incumbent upon a producer of commodities for export to know the regulatory status of the product he is using, and whether a tolerance or an MRL is in place for residues of the pesticide in the country where he intends to market his crop.

31. It may be useful for this group to establish priorities for the review of new and problem chemicals based upon how widely they are used on products in international trade, or perhaps based upon

other criteria such as potential residue levels, acceptable daily intake levels, or use on major commodities in international trade. Perhaps industry could be of assistance in identifying those chemicals.

32. **Data reviews.** Much of the work of our regulatory programs is devoted to the review of data. The Conference may wish to discuss strategies and mechanisms for harmonizing evaluation procedures. It has been suggested that a possible next step could be sharing our reviews multinationally and with international organizations. While we see considerable merit in the proposal to "share the burden" in some way, we see fundamental differences in the way in which countries approach risk assessment which impede our ability to share the review workload at this stage. Before we can get to the point of sharing reviews, we must ensure that proper focus is given to risk assessment issues. Even with our differences in approach, sharing summaries of our reviews and identifying the data bases may be worthy of discussion.

33. It is perhaps in this area where greater cooperation and harmonization would have a significant effect on our programs and our resource expenditures. Yet it is also this area which is the most difficult to address. Data reviews form our scientific understanding of risk, which is integral to our risk management process. Our risk management process includes a number of factors, such as social values, cultural perceptions, national priorities. We would be remiss if we did not acknowledge their influence. By its very nature, resolving the differences in our national and international risk assessment process and improving the degree of national acceptances is a long term goal. We will only reach that goal if we first reach agreement on ways of reconciling our data review processes, as one of the first steps.

34. Because conditions of use and exposure scenarios may differ considerably from country to country, it is likely that risk decisions will differ as well. We must be prepared to defend our positions based upon sound scientific principles. There is a great need for harmonization in the process for assessing toxicity, yet many of the obstacles here are contentious, and perhaps intractable in the short term. We may want to identify areas where the possibility of harmonization is greater, such as in coordinated data requirements and compatible test guidelines. This forum can make great progress here.

35. **Hazard classification and labelling.** An illustration of the link between testing and data evaluation is in the area of hazard identification and communication. Harmonization of hazard classification and labelling is an issue of growing international importance. Action is underway in the ILO, WHO, IPCS and the FAO which has developed guidelines for pesticides which link labelling with the WHO hazard classification system and the results of acute toxicity testing.

36. Any international system should be as broad based as possible. From the standpoint of sound science and universal recognition of hazard warnings all products whether a pesticide or other should use a consistent system of hazard identification and warning including internationally recognized symbols.

37. **Animal welfare.** It is clear that greater consistency in data requirements will reduce the number of tests conducted and thus reduce the number of additional animals sacrificed. The U.S. is aware of substantial progress that can be achieved in both the welfare of animals used in scientific experiments and the reduction of the number of test animals. It is an issue that we should all keep in mind when discussing data requirements and test protocols.

## FUTURE PROSPECTS

38. I believe that there are opportunities here that we must not squander. The ideas that we develop here can help set the agenda and focus for our work for the 1990's. In so doing, we should acknowledge and seek ways to strengthen and support the respective roles of international organizations in the international pesticide forum.

39. We must build upon the accomplishments of international organizations, and the work that governments have already agreed to, such as the OECD test guidelines, the WHO JMPR principles for toxicological assessment, and the FAO guidelines on a variety of registration issues. I hope we can focus our deliberations on ways of implementing, or revising as appropriate, much of this work.

40. Before I close, I would like to take this opportunity to summarize and recommend several goals for this group to consider. First, let us determine systematically the extent of the problems we face. Second, let us identify areas where we may be able to harmonize approaches and regulatory requirements. Third, let us identify what is already being done to harmonize regulatory approaches and requirements (especially by international organizations) and, where gaps remain, identify those that need to be filled. Fourth, let us develop mechanisms to promote these goals and set priorities for our efforts. Fifth, let us renew our commitment to promote the national resolve at home to pursue those goals. And sixth, founded on the assumption that greater understanding and communications can move us in the direction of harmonization, let us agree to further develop principles of regulatory transparency.

41. To do this, each and every regulatory program must be open to scrutiny. We need to clearly contrast and compare these programs. Disclosure of this information will make it possible to identify our differences and similarities, and indicate the areas most ripe for harmonization. When we take regulatory decisions, the reasons for them must be plainly articulated. We should establish a communication network whereby such decisions affecting international trade can be relayed to each other in a timely and orderly fashion.

42. **Conclusion.** We all have systems which are based on certain fundamental principles: the protection of the public health and environment. We must ensure that the system has a solid foundation in order for us to build upon them. We need harmonized systems which will maximize the benefits of pesticides, while minimizing the inherent risks. We need harmonized systems which will eliminate technical barriers to trade, and at the same time build greater scientific consensus. Elimination of technical trade barriers will be no achievement if done at the expense of protective standards. We need harmonized systems which will reduce unnecessary economic burdens on individual governments, on the international community and on pesticide users and manufacturers. We need harmonized systems capable of dealing with the new challenges which will confront us in the future.

# The Danish Experience with the International Cooperation and Regulation of Pesticides

Claus Hansen  
Danish Environmental Protection Agency

First I would like to thank the organizers - especially Vibeke Bernson - for the opportunity to share with you the Danish experience with international work in the field of pesticide regulation.

Denmark is a small country. As we say in Denmark "Small is beautiful" but sometimes it is also difficult as will become apparent from the following.

But first of all a few facts about Denmark for your information since I do not assume that you are familiar with Danish conditions. This is however crucial to an understanding of the way we deal with pesticides and to a recognition of the limits of international agreement on eg. test guidelines and criteria for the acceptance of pesticides.

As I said before Denmark is a small country - to be specific 43075 sq.km. Sweden is 449790 sq.km and the United States is 9363130 sq. km.

Let me show you some statistics of how the area is used in Denmark:

	1965	1978	1982	1982%
cities	389	514	535	12
hedgerows, ditches etc	137	88	113	3
arable land	2693	2655	2651	62
forests	472	479	501	12
meadows	325	268	246	6
heath, dunes etc	223	223	198	5
lakes, streams	68	64	64	1

As you can see there is not much nature outside the agricultural area which comprises ca. 2/3 of the entire area corresponding to almost 30000 sq. km. We therefore have to pay special attention to the flora and fauna within the agricultural area and the activities of the farmers in the agricultural area is of obvious public and therefore political interest.

Another point that could be made is that Denmark is not divided into water catchment areas as is the case in many other countries. In fact the entire country is one big (or small) water catchment area. Since all drinking water comes from ground water (which can be used with minimal treatment) we are particularly keen on protecting this resource.

For comparison Sweden has approximately an equal area occupied by agriculture as Denmark leaving much more nature outside. I could not find the same data for U.S.A. but perhaps someone present could give us the figures.

The geographical situation also poses a number of problems in relation to mutual acceptance of test results from the field. This is true both in regard to climate and geology.

The pesticide regulation is based on the principle that a pesticide must be approved before it is imported, sold or used. This system has been in operation now for 11 years.

About 1000 products are on the market representing 200-250 active ingredients. This figure is declining as a result of the ongoing reevaluation. The administration is part of the Danish Environmental Protection Agency and it is the sole authority responsible for the approval of pesticides (except for evaluation of efficacy). This applies both to new pesticides and to old pesticides that were on the market before the new law was enacted. The reevaluation which is taking place at the moment is a 5 year project to be completed by the end of 1992.

There is a permanent staff of 18 people in all and this is augmented by 6 temporary consultants working within the agency. A number of consulting firms outside the agency is assisting the agency in the completion of the reevaluation.

A central part of this legislation is the establishment for active ingredients of criteria with fixed cut off values beyond which approvals can not be given. Another important issue is the obligatory alternative evaluation by which a product/active ingredient not exceeding the criteria but nevertheless possessing some undesirable properties has to be substituted by a less harmful product.

This legislation contributes to the establishment of a high level of protection.

In my presentation I will give you examples of the Danish experience from work in

EEC  
Nordic  
Council of Europe/EPPO  
Helcom  
GIFAP

## **EEC**

EEC approval of plant protection products.

This is the aspect of work in the EEC that I will talk about. I have chosen not to mention other areas ( prohibition directive, classification and labelling etc).

Without going into details of chronology it can be said that the negotiations on the directive concerning the EEC approval of pesticides have been longlasting but gaining momentum in the last 2 years culminating with the adoption of the directive this year by a qualified majority against the vote of Denmark.

I have chosen to divide my talk into two sections. One section which deals with the articles ( that is the legal aspects) and one dealing with the requirements for documentation.

### **Legal aspects**

First some background information.

The Agricultural Directorate, DG VI, is responsible for this legislation. This may be one of the reasons why- as we feel it- environmental protection has not had a sufficiently high priority in the work so far. The purpose of the directive is the harmonized approval procedure for plant protection products ( against pests and weeds). According to the directive an EEC positive list should be prepared of active ingredients whose use does not pose a danger to the health of man and animals or to the environment. Member states then have the authority to approve products for use in their territory. Products can only be approved if the active ingredient is on the list.

Member states have 2 years after the adoption of the directive to translate it to national legislation.

According to the directive's principle of mutual recognition of national approvals a member state can only refuse to approve a product already approved in another member state if relevant agricultural, plant health or environmental conditions are not comparable.

The directive lays down an administrative frame and procedure for marketing plant protection a.i.'s and products. The directive does not - except in a very general and overall way - describe the criteria to be used when approving plant protection products or putting a.i.'s on the positive list.

In relation to this it has been a problem that the Commission consistently has refused to discuss this substance and state these principles in the articles. It has been crucial to Denmark that the harmonisation should secure a high level of protection in order to maintain the present Danish level. In the light of the before mentioned mutual acceptance this is of obvious importance. This should have been a central issue in the negotiations and Denmark has found it clearly unsatisfactory that this discussion has been postponed till after the adoption of the directive. I return to this under the heading Uniform Principles.

### **Documentation aspects.**

Throughout the entire process when data requirements were discussed it became apparent that it was more important to be able to present a directive proposal for adoption before the establishment of the internal market than to have an in-depth discussion of all the very important aspects of data requirements. Therefore all discussion of testing has been postponed till later. This includes all aspects except the headlines, which by the way showed a clear tendency to sum up to the largest common denominator. Therefore the annexes in their present form includes a quite large list as almost any national requirement was added indiscriminately. The discussion of what requirements were applicable to what applications was to be taken in the discussion of the Uniform Principles or to be solved during the initial work of the standing committee.

### **Uniform Principles.**

As indicated before a number of vital issues were never discussed in detail and consequently no decisions were made. This was the case for items like

- what criteria should be used when placing active ingredients on the positive list ( was it acceptable to have pesticides on the list if they were clearly teratogenic)
- what kind of documentation would apply to what kinds of products
- given a certain test result could further testing be stopped or would it be necessary go into another type of testing
- and if this further testing gave a certain result should this lead to a denial of approval

For a long period we believed that answers to these types of questions would be given in the so-called Uniform Principles.

The Uniform principles therefore appeared to be of the utmost importance since they would define not only what kinds of requirements will apply to the different kinds of products but even more important they will set forth decision rules for placing active ingredients on the positive list. This was at least the way things were perceived in Denmark.

The reason for this last modification is that Denmark has been kept much in the dark with regard to the work on the Uniform Principles due to the way the work has been arranged. The DG VI has made a contract with a consultant and he is preparing a proposal with the help of people of his choice. It is clear therefore that a few nations are given particular influence on this proposal - these nations probably represent a majority thereby securing the adoption of the proposal.

Clearly this was an extremely unsatisfactory situation for a country that could claim to have one of the most longlasting experiences with the approval of pesticides and the use of criteria in this process.

I will round this topic up by saying that since the Uniform Principles do not include the criteria for putting active ingredients on the positive list and if this most important topic is to be sorted out during the actual dealing with applications I foresee if not chaos then a difficult situation.

And it is in any circumstance one more illustration of the fact that this legislation has been adopted without much idea of what the implications/consequences would be.

The possible future benefits for Denmark of this directive are really not known at this moment.

### **Nordic.**

The cooperation between the nordic countries is an old tradition and within the last years a further even more stringent formalisation has taken place. This has increased the mutual benefit of the work.

The benefits we feel have been achieved at two levels: at a practical level and at a mental level.

At the practical level we have come a long way in harmonizing our data requirements and in the formal presentation of these demands i.e. the application form. We have also come a long way in benefitting from each others work in evaluating company documentation. We have even agreed on the formal way of writing these evaluations.

At the mental level you can not overestimate the reassurance you get when you discover during intense discussions of common problems that other people/authorities think the same way as you do. This way of thinking in the same way is experienced to a lesser degree when we consider the EEC and this is of course part of the explanation that the nordic countries has made so much progress towards agreement compared to what has been achieved in the EEC.

To the benefits mentioned before could be added a long list of additional examples but I will not at this moment go further into this.

We also feel that Denmark as part of both Scandinavia and EEC can bridge the two areas although our membership of the EEC makes it difficult to form binding agreements with the other nordic countries.

### **Council of Europe/EPPO ( European and Mediterranean Plant Protection Organization.**

First of all I must confess that I have only a limited knowledge of these two organisations.

The council of Europe is known to me primarily because of the booklet (which I actually find very good) in which recommendations are given regarding the testing of pesticides.

EPPO I know only for their recommendations on how to conduct field trials for testing efficacy.

When we first became aware that these two organisations were entering the field of ecotoxicology ( testing and assessment) the first reaction was - not another institution developing their set of rules,

recommendations or whatever. We already had OECD, EEC, BBA, EPA, FAO, GIFAP - you name them.

So as an authority with only a limited number of people we chose not to take any interest in this work.

However at a congress on earthworm toxicology we discovered that it was the intention to make the recommendations available to the EEC.

Should this work be taken over by the Commission as their proposal for Uniform Principles for the assessment of the acceptability of pesticides on the positive list I think that you could really say that Denmark made the wrong choice when we decided not to participate in this work. Perhaps we could be blamed for not recognizing how things are connected - I do not know.

It does however perfectly illustrate the necessity for an international coordination of the activities within the field of pesticides with clear division of roles.

### **Helcom.**

Previously Helcom worked for the protection of the Baltic by establishing negative lists of active ingredients that were considered to cause pollution of the Baltic Sea. Negative lists are however difficult for Denmark in relation to the way the EEC system works (Germany should have the same problem).

Denmark therefore suggested that Helcom countries should define key properties, criteria and cut off levels above which pollution of the Baltic would be presumed. Furthermore to make this operational the countries should have approval systems based on the use of these criteria. This recommendation was recently adopted in october 1991 by the technical committee. The recommendation will be presented for final approval in the Helcom commission in february 1992.

The lists are maintained as examples of compounds that should not be given approvals with an approval system based on criteria. Denmark considers this a rather successful example of how two systems can be

bended towards each other although the direct benefits of this sort of work lies more in the effect it has in the political sphere in terms of influencing attitudes.

### **GIFAP.**

To those of you who do not know this organisation ( if there are any) it is the international organisation of producers of agrochemicals. I know GIFAP in two contexts: from lobbyism in the EEC (for instance in relation to the aforementioned directive) and from negotiations when Denmark developed the criteria for not approving pesticides. We discussed our draft with GIFAP during a one day meeting. We had a useful exchange of opinions which resulted in some modifications and although GIFAP far from agreed on the criteria I think that a better mutual understanding has emerged.

### **Summary**

Let me sum up this presentation by stating that from a Danish viewpoint as illustrated by what I have said there is a very strong need for an international coordination within this field making it clear not only who's doing what but also for what purpose.

To make sure that the international cooperation is for the benefit of the environment and people and to aid the development of a sustainable agriculture we would like to draw attention to these points

- since pesticides are intrinsically toxic and are often spread over vast areas sufficient information must be available to evaluate their toxicological and ecotoxicological properties and based on this evaluation either to approve or not approve the pesticide in question
- to this end an international cooperation on the development of tests and demands for documentation is strongly emphasized
- that this international cooperation does not hinder progress. To secure a high level of protection it is vital that countries with experience and resources act as locomotives.
- by requiring a high level of protection the development of environmentally safer pesticides is initiated and integrated management practices are stimulated

It is our hope that the discussions over the next three days will accomplish the above mentioned.

# FAO's Activities in the Field of Pesticide Risk Assessment and Management

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The Food and Agriculture Organization of the United Nations has two types of programmes. Firstly, it has a Regular Programme that is funded through assessment of its member countries. Secondly, it executes a technical assistance programme, which is chiefly provided for through funds in trust. The Regular Programme, for which the activities and budget are decided every second year by the FAO Conference, concerns information analysis and exchange; policy advice and short term technical assistance. The major part of technical assistance is, however, provided for through funds in trust. In these cases, the Organization executes projects on behalf of its member governments.

The activities of FAO in the field of pesticides, result from the importance of these chemicals in the field of agricultural pest control. FAO's involvement in such programmes date back to the late 50's; the Organization's programme address both risk assessment and risk management.

The main activity of FAO concerning risk assessment is its cooperation with WHO in the Joint Meeting on Pesticides Residues (JMPR). FAO's input in this activity is made through the Panel of Experts on Pesticide Residues in Food and the Environment. Experts in the Panel are selected on basis of their ability, knowledge and experience and serve in their personal capacity. The Panel and the Joint Meeting serve in an advisory capacity to the Codex Alimentarius Commission (Codex Commission on Pesticide Residues, CCPR).

Through JMPR, evaluations are made of pesticides in food. The FAO Expert Panel makes recommendations for Maximum Residue Levels while the WHO appointed experts recommend Acceptable Daily Intakes. Maximum Residue Levels and determinations are based on Good Agriculture Practices to allow for a minimum contamination with pesticides. The definition of Good Agricultural Practices has been under discussion for a long time and FAO, at the request of the CCPR, is in an advanced stage of developing a Guideline on the Evaluation of pesticide residue data and the estimation of maximum residue levels in food and feed.

Although MRLS are based on Good Agricultural Practices, they should take into account Acceptable Daily Intake levels so that food complying with Codex MRL's is safe for human consumption. Evaluations are published in JMPR reports and in evaluation reports. Annually, some 6 to 7 pesticides are evaluated. Furthermore, reevaluations are made.

FAO provides technical assistance to help member governments to establish the required infra structure and train staff to monitor pesticide residues in agricultural produce and in food.

FAO's main document in the field of pesticide management is the International Code of Conduct on the Distribution and Use of Pesticides. The Code was adopted by the Conference of FAO in 1985. It represents

a wide consensus between governments, pesticide industry and non-governmental organizations. The Code resulted from a long period of negotiations; its implementations encompasses all earlier work of the Organization on pesticide management.

The Code includes articles on pesticide management; the testing of pesticides; the reduction of health hazards; regulatory and technical requirements; the availability and use; distribution and trade; information exchange; labelling, packaging storage and disposal; and advertising. The Code was amended by the FAO Conference in 1989 to include the principle of Prior Informed Consent.

The basic function of the Code is to serve as a point of reference to all parties concerned with pest management. All parties should promote the principles and ethics expressed by the Code, irrespective of other parties' abilities to observe the Code. Governments should monitor the Observance of the Code and report on progress to the Director-General of FAO who will report periodically to the Committee on Agriculture. The Code is supplemented with a number of technical guidelines that amplify and explain particular articles and sub-articles. Fourteen guidelines have been published while some eleven are in various stages of preparation. These guidelines include aspects of legislation, registration, storage, handling, labelling, disposal application and trade. For the development of these guidelines, often outside expertise is required, including expertise from pesticide industry through GIFAP. An independent expert panel reviews the guidelines in detail and, in cases, they are also reviewed by FAO Government Consultations.

To assist in pesticide procurement, FAO produces specifications for plant protection products. These are prepared in cooperation with the Chemical Collaborative Pesticide Analytical Council. Relatively simple pesticide data sheets are produced in cooperation with WHO.

FAO provides assistance to developing countries to meet the requirements of the Code of Conduct. The Organization is operating a project, funded by the Government of Japan, to assist in the implementation of the Code in the Asia and Pacific Region and in the Caribbean. In addition, it is now starting a project for Africa which is funded by the United Nations Development Programme while a donor has been identified for a programme in Central America. These projects aim at assisting governments to implement the responsibilities assigned to them under the Code. Furthermore, the Organization has been providing short term assistance through its Technical Cooperation Programme to strengthen pesticide legislation and regulations and control and has, in cooperation with other Organizations (including EPA), organized regional and sub-regional workshops.

Since the inclusion of PIC into the Code, FAO and UNEP are executing a joint programme on the implementation of Prior Informed Consent. In this respect, it should be noted that the PIC procedure is also included in UNEP's "London Guidelines for the Exchange of Information for Chemicals in International Trade".

Prior Informed Consent addresses the export and import of pesticides that are banned or severely restricted for reasons of human health or the environment, and certain pesticide formulations with a high level of acute toxicity. Shipment of such pesticides should not proceed without the consent of the appropriate government authority in the importing country.

FAO and UNEP have developed procedures on which pesticide should be included in the Prior Informed Consent process; for decision making in the importing country; and for the communication of such decision to other governments, in particular those of exporting countries.

The necessary documentation has been developed to determine which bans or severe restrictions are to be notified to the joint FAO/UNEP secretariat for inclusion in the PIC procedure. This documentation also

explains further procedures, in particular it describes the role of the Designated National Authority in the importing and exporting country. Countries have appointed National Designated Authorities and the joint secretariat has asked for updated inventories of banned and severely restricted pesticides. Furthermore, a number of pesticides have been placed on an initial PIC list. Five or more countries had already reported to UNEP/IRPTC that these pesticides were banned or severely restricted, while others were reported to cause severe problems due to acute toxicity. Decision Guidance Documents for six of these pesticides have been completed and been sent to DNA's for decisions; others are presently completed. During these activities, the FAO/UNEP secretariat has been guided by a Joint Group of Independent Experts.

The present initial phase of PIC will be followed up by the implementation of the full procedure in early 1992. To facilitate its implementation, the Governments of the Netherlands has made a trust fund available, while FAO is in its budget for the next biennium proposing additional financial provisions for the implementation of PIC. However, substantial extra budgetary funds will be required to allow UNEP and FAO to assist developing countries to establish the infrastructure required to execute the PIC procedure.

An additional immediate requirement for pesticide management is the disposal of large quantities of obsolete and outdated pesticides. Large stocks are available in a number of developing countries and these pesticides are mostly stored in a completely inadequate manner. FAO, in cooperation with UNEP, USAID, GT2 and other agencies, is exploring possibilities for a safe disposal.

Pesticides are used to control agricultural pests. Pest control should make use of all available control methodologies in an integrated manner. In such Integrated Pest Management System, these methodologies should be used in a compatible way taking into consideration economical aspects, human health and the environment. Pesticides have a place in such systems but they should be used on an as needed bases only. On the other hand, there are systems where pests can exclusively be controlled through biological control, and other non-chemical control methodologies.

FAO prepares studies on particular pest problems especially for cases where there is a perceived mis or overuse of pesticides. Based on such studies it prepares action programmes to be implemented by governments. Such implementation is often through donor assistance. The programme is guided by the FAO/UNEP panel on Integrated Pest Management. The programme has succeeded in attracting trust funds for a substantial field programme. Major projects exist or are in advanced stages of development in South East Asia, some African countries and in Central America. Major crops covered are rice, cotton and vegetables. The ultimate aim of the programme is to enable farmers to make their own informed decisions in pest management. Very substantial sums will be required for IPM implementation, and a major effort of a number of aid agencies is necessary.

The final objective of the IPM programme is to promote pest control that is ecologically sound and contributes to the sustainability of Agriculture. FAO is proposing a framework for its activities on sustainable agriculture to its next Conference in November. Integrated Pest Management has been identified as one of the major trusts of this Programme.

# OECD Chemicals Programme in Relation to Pesticide Management

J.E. Brydon, Organisation for Economic Co-operation and Development (OECD), Paris, France

1. The OECD Chemicals Programme originally focussed in the late 60s on unintended occurrence of pesticides in the environment. The work has evolved to cover anticipatory policies for chironomid management or general. While there are now no activities devoted specifically to pesticides, there are a few important activities which have a direct pesticide dimension and there are many which could be seen to support pesticide management.

2. There are two features of the OECD generally that are important in developing and implementing its work. First, OECD provides a forum for consensus building among government technical and policy experts around the various projects and its elements. In practice, this results in a commitment by the agencies which the experts represent to the harmonized policy or action in question. Secondly, collective actions are taken or commitments made by means of formal Council Acts. In general, Council Recommendations indicate a collective commitment to implement certain policies, e.g. GLP compliance, and Council Decisions are binding commitments of governments to take specified actions, e.g. banning the use of PCBs.

3. The Chemicals Programme now has two broad strategic elements:

- • Co-operative Investigation of Priority Chemicals and Co-operative Risk Reduction of Selected Chemicals of Concern. The investigation has a primary focus on chemicals of the highest production volume in OECD countries and involves cooperative activities of the governments and voluntary testing by the chemical industry in order to share the burden of the work. The risk reduction activities include concerted actions to limit or eliminate the risk of designated chemicals, and recently the development of co-operative risk reduction strategies for chemicals of common concern.

- • Development of Principles, Methods and Other Practical Instruments. Under this activity many of the necessary instruments and policies for Member countries to identify, assess and control the risks associated with chemicals are developed cooperatively. One important goal of this work is the harmonization of approaches and procedures by which all OECD countries manage their chemical control.

4. The details of the work involved can be found in the brochure "The OECD Chemicals Programme" (1) and elsewhere (2). This paper will attempt to point out the ongoing OECD activities which are relevant to pesticide management and in which manner they are relevant.

## Areas of Direct Relevance to Pesticide Management

a) OECD Guidelines for Testing of Chemicals

5. Since the late 70s, some 78 test guidelines have been developed, adopted and published in an open-ended continually updated OECD publication (3). They are designed to be used in the development

of data that is needed for the assessment of the hazard or the risk of a chemical to human health and the environment. The grouping of the methods points to the various uses of the data (e.g. environmental exposure, human health effects). There is an ongoing programme to review and update the guidelines to incorporate the latest scientific progress and experience. In addition, OECD has embarked on a review of all test guidelines to be finished by 1994 to introduce any animal welfare considerations that are feasible, including the introduction of in vitro alternative methods.

6. The OECD Test Guidelines are used by the major pesticide companies worldwide in preparing their dossiers for the registration of pesticides. FAO Guidelines for implementing its Code of Conduct for Pesticide Management refers to their use. The publication had a large number of subscribers and OECD also provides copies to some non• Member countries on request. It should be noted that while guidelines in all categories are being used for pesticide registration purposes, there are some specific registration requirements (e.g., leachability in soils) which do not have a relevant OECD test guideline.

b) OECD Good Laboratory Practice (GLP) Principles

7. The GLP Principles (4) were developed in the early 1980s in order to promote the generation of high quality data in support of government requirements for data, including pesticide registration. IPCS promotes the use of OECD GLP Principles globally and has developed a manual of GLP implementation. FAO also refers to OECD GLP in its Code of Conduct. Recently, ECE has examined proposals for extending GLP to laboratories in Eastern and Central Europe. These OECD GLP principles seem to be universal in the sense that they can be and are being applied in any test laboratory whether devoted to industrial and consumer chemicals, pesticides, pharmaceuticals or food additives.

c) Compliance of a Laboratory with GLP Principles and Mutual Recognition of Compliance Monitoring Procedures

8. The OECD has devoted much attention to three aspects of this subject:

(i) Implementation of GLP Principles and Quality Assurance Procedures in test laboratories. (4)

(ii) Inspection of laboratories and conduct of study audits. OECD has developed guidance for governments in setting up GLP inspection and monitoring programmes. (5)

(iii) Mutual Recognition of Compliance Monitoring Procedures. Assurance to second countries that a laboratory in the first country has implemented GLP. This is an important aspect of the acceptance by a second country of data that is generated in laboratories in the first country.

These aspects of compliance with GLP are incorporated into a Decision of OECD Council of 1989 (6). It clearly applies to the generation of data in support of registration of pesticides.

d) Mutual Acceptance of Data

9. This important principle enshrined in an OECD Council Act of 1981 (7), states that if data are generated by using OECD Test Guidelines and by following OECD GLP Principles, the data are acceptable to government authorities in all Member countries. It is already an important practical device to assist pesticide companies to register their product in foreign countries. Even though this mechanism seems to work very well, the OECD Secretariat has a reporting mechanism whereby companies can report contraventions of the Act and the Secretariat undertakes a confidential enquiry. The purpose is to identify the nature of the specific non• acceptance of data, to try to resolve the problem and to find ways to avoid such problems in the future. So far, there has been six such reports and subsequent enquiries.

e) Hazard and Risk Assessment

10. Work in this area has evolved since the early 70s when the principles of pre-market or pre-manufacturing evaluation of a chemical were developed into Council Acts of 1974 and 1977 (8, 9). This led to an agreed package of data • the Minimum Pre-market Set of Data (10) • that could be used to do an initial prediction of the hazard of a new chemical before it goes on the market. Some of these principles and criteria were revisited recently when a simple data package was developed for existing chemicals • the Screening Information Set Data (...). The data required for a comprehensive assessment or prediction of human health or environmental risk is addressed in a major OECD report in 1986 (11). The relevance of this to the data requirements for assessment of pesticide safety is obvious.

11. Some of the specific hazard assessment projects which have some relationship or relevance to pesticide safety are: the Data Interpretation Guides (12); ongoing work on evaluation of effects of chemicals on aquatic organisms and food webs; estimation of environmental exposure and environment-related human exposure; prediction of workplace exposures; data estimation techniques and the use of structure/activity relationships; strategies for using in vitro tests for mutagenesis/carcinogenesis; and finally, the development of principles and a framework for assessing the environmental hazard of a chemical.

f) Confidentiality and Proprietary Rights

12. Protection of the Confidentiality of commercially valuable data and the proprietary right to the use of certain data are of continuing concern to the chemical industry. Therefore, the 1983 OECD Council Acts (13, 14, 15) dealing with these matters and the commitment of OECD Member countries to the implementation of the Acts are of direct interest in the pesticide registration process. No follow-up to this work is currently planned or under way but further work, e.g. a review of the list of non-confidential data, could be useful for all concerned.

### Areas of OECD Work which have some Impact on Pesticide Management

#### Co-operation on Existing Chemicals

13. Under this work, an OECD list of 1 500 High Production Volume Chemicals (HPV) has been developed by merging reports from 17 countries. This list includes 17 chemicals which are believed to be pesticides exclusively and 59 pesticides which have other uses as well. The priority for OECD work involves those chemicals with apparently little safety data available (2). This work involves organising co-operative data collection, testing and assessment of HPV chemicals among Member countries. By this "sharing of the burden" and the application of the MAD principle, duplication is avoided of efforts for governments and Industry participating actively in this programme and denies benefits because testing and assessment of these chemicals which are on the market in many countries is undertaken much more efficiently by this cooperative programme. Pesticides have been set aside on the assumption that they probably have a complete data package, and that probably the data is confidential in government dossiers and therefore "unavailable". If priorities change, the HPV pesticides and adjuvants could be revisited.

14. EXICHEM is a pointer-system database indicating who is doing work on which chemicals with respect to testing, assessment or risk management. There are 14,000 entries on 5 000 chemicals. The database has entries which identify planned or ongoing work in pesticides but it is probably incomplete. By focussing special attention on pesticides, it could be made more complete and thereby serve the information needs of pesticide control authorities.

15. The Clearing House mechanism could also be of use for pesticide investigations. For this, a country interested in work on a chemical calls on like-minded countries to indicate their interest, their objectives, the nature of their work and available data, with a view to sharing the data or the work to be undertaken, e.g. exposure data or an assessment document. Sixty clearing houses have operated so far, some of which have already been concerned with pesticides, e.g. organotins.

16. The co-operative OECD work on the risk reduction originated with Swedish work reviewing older existing pesticides. The initial pilot project has five chemicals under consideration for risk reduction activities. Methylene chloride and Hg compounds are two of the five. One of the uses of methylene chloride is as an aerosol propellant, including domestic pesticides. This suggests not only that the pilot project is relevant to pesticide management but also that other candidate risk reduction chemicals may also have pesticide uses.

#### Final Considerations

17. While OECD does not undertake work uniquely directed to pesticides management, several projects have a direct relevance. The work on test guidelines, GLP and risk assessment could readily be stretched to cover some aspects of pesticide registration. Furthermore, special projects to address specific problems or issues could be undertaken using the lead country approach or an experts workshop. However, the resources of the Secretariat are already stretched to implement an expanded workplan for 1991-1993. Any OECD pesticide work, therefore would carry an implication of either shifting priorities or the need for increased resources.

#### ANNEX

##### PRODUCTS OF THE OECD CHEMICALS PROGRAMME

1. The OECD Chemicals Programme, OECD, Paris, 1988.
2. OECD's Work on Investigation of High Production Volume Chemicals. International Environmental Reporter 13, number 6, p. 263-272 (1990).
3. OECD Guidelines for Testing of Chemicals, continuing series, first published 1981.
4. Good Laboratory Practice in the Testing of Chemicals, 1982.
5. Final Report of the Working Group on Mutual Recognition of Compliance with Good Laboratory Practice. OECD Environment Monograph No. 15, 1988.
6. Decision-Recommendation on Compliance with Principles of Good Laboratory Practice [C(89)87].
7. Decision concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30].
8. Recommendation on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215].

9. Recommendation establishing Guidelines in respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C (77) 97].
10. Decision concerning the Minimum Pre-marketing set of Data in the Assessment of Chemicals [C(82)196].
11. Existing Chemicals: Systematic Investigation • Priority Setting and Chemicals Reviews, 1986.
12. Data Interpretation Guides for Initial Hazard Assessment of Chemicals, 1984.
13. Recommendation concerning the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96].
14. Recommendation concerning the Exchange of Confidential Data on Chemicals (C(83)97).
15. Recommendation concerning the OECD List of Non-Confidential Data on Chemicals (C(83)98).

# Summary of Points Related to Pesticide Risk Reduction in Developing Countries, Using the Example of Rice-Growing Tropical Asia

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FAO IPM Rice Programme in Asia

1. In rice growing tropical Asia, the conditions of pesticide risk reduction are quite different from the OECD countries.

1.1 Nearly all active ingredients are imported from developed countries; there are local formulating industries but except for a few (largely organochlorine) pesticides in India and China, none are produced from precursors.

1.2 The majority of pesticides sold (by dollar value and formulated product volume) are insecticides. Rice consumes more insecticides than any other single crop (except cotton in India and China, where rice is second).

1.3 Nearly all insecticides are used in dosages of hundred of grams a.i. per hectare, rather than lower dosages commonly found when pyrethroids dominate the market. The range of insecticides available is more limited than in OECD countries, for example, organophosphates and organochlorines dominate the insecticide market.

1.4 The extent and effectiveness of pesticide regulations, including bans, severe restrictions and safety guidelines, is substantially less than in OECD countries, due to lack of implementing resources (money, equipment, people, and political will) more than lack of regulations per se.

1.5 Sources of information for farmers are quite limited. There is some radio advertising and extension meetings, but the bulk of information comes from pesticide dealers and other farmers.

1.6 Medical services in these countries are much less available, and practical, maintainable protective clothing unaffordable.

2. In OECD countries pesticides are reduced by changing the kinds of chemicals used especially using lower active ingredients per hectare per treatment. In rice growing tropical Asia pesticides are reduced by lowering the number of applications made by farmers per season. The dosages of pesticides used, already below the manufacturers' "recommended rates" remains the same. This strategy does not require shifting to more expensive and less available pesticides in order to achieve reduction.

3. Tropical rice agroecosystems have well developed biological control of herbivorous insect populations through the population regulating capacities of predators and parasitoids. When commercial (all broad spectrum) insecticides are applied, natural control is disrupted -- generational survival rises from 2% to 14% -- and populations of planthoppers explode. The contribution of pesticides to national rice production in tropical Asia has not been well demonstrated in the last 15 years. As national policy makers and multilateral institutions such as the Asian Development Bank incorporate these findings, they develop new policies. National Integrated Pest Management (IPM) policies do not specify a percentage reduction target,

but do ban and restrict insecticides because of their demonstrated ecological impacts on natural enemies of rice pests and/or on other species in aquatic ecosystems.

4. Indonesia has taken bold steps in its IPM policy. Over 85% of the insecticides registered on rice in 1986 were banned on rice. The national pesticide subsidy of over US\$ 120, million per year in 1985 was eliminated by January 1989. Over one million person-days of direct training in field skills to apply IPM were given in 20 months, making the Indonesian National IPM Programme the largest environmental field training effort in the world. According to final 1990 statistics from FAO, between 1986 to 1990 Indonesia's rice production rose by 10.4%, and rice yields per hectare rose by 10.1%. Indonesia has the third highest national rice production of any country and the highest rice yields of any tropical Asian country. Rice farmers reduced the number of insecticide applications per season from 4.5 in 1986 to 2.2 in 1989. A survey of over 2000 farmers showed that after completing IPM field training farmers further reduced their insecticide application frequency to 0.8 per season. On a national basis, the annual production of formulated pesticides, which is the total supply as no formulated pesticides can be imported, dropped by 61% between 1987 and 1990.

5. As pesticide markets in OECD countries shrink from their own pesticide reduction efforts, the chemical industry is more aggressive in expanding its markets in developing countries. In the case of rice, Japan is particularly important because half the world's market for rice insecticides (\$455 out of \$910 million in 1988) is found in Japan, where rice prices are subsidized at more than six times world trade price. In January 1992, in the context of GATT negotiations, Japan announced it planned to shift from a ban on imported rice to a 600% tariff, reducing that tariff to 15% over seven years to allow farmers to adjust to world trade. If the Japanese market for rice insecticides shrinks by over 80%, there will be a tremendous oversupply relative to consumption.

6. Developing countries such as those in tropical rice-growing Asia depend on GATT to facilitate their access to developed country markets. This leaves their markets potentially open to aggressive pesticide marketing. With respect to international cooperation, it is especially important for developing countries to have complete and deep documentation of the actions of regulatory agencies and of industry in relation to regulatory actions. As well as published bans and severe restrictions on specific pesticides, it is also essential that developing countries are informed about the withdrawal of a compound by producers from the regulatory process in any country, either by negotiated settlement or unilaterally. These documents are important to policy makers who must support their decisions in the face of powerful interest. As many of these actions are in the context of re-registration procedures, it is important for offices concerned with re-registration to publish their actions and the scientific bases for these actions.

7. The instruments provided by UNEP--IRPTC (especially the London Guidelines) and the FAO Code of Conduct (especially the PIC provision) are very important to policy makers in developing countries. In particular, the involvement, as Designated National Authorities, of environmental protection agencies not under agriculture ministries or departments provides healthy balancing expertise as countries strengthen their pesticide policies.

8. IPM programmes at national and regional levels provide a means of reducing pesticide-associated risks that is complementary to the actions of regulatory agencies. IPM implementation should include field training of farmers and extension personnel as well as policy changes. OECD countries are traditionally very active in supplying overseas development assistance. The donor agencies of these countries are increasingly responsive to considerations of environmental quality. Efforts should be made to harmonize the actions of donor agencies with the standards of environmental protection agencies in the same countries. Personal protection from exposure to a given compound is always more difficult in developing countries, so that even stricter standards on what chemicals are allowed should be kept in aid projects in developing countries.

9. Donor agencies in OECD countries should be encouraged to promote pesticide risk reduction through supporting IPM programmes in developing countries and programmes that promote the flow of pesticide regulatory information among developed and developing countries.

# The Swedish Fifty Percent Cut Off

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In spring 1986, when the Inspectorate was just a couple of months old, we were charged with a Governmental commission together with the Board of Agriculture and the Swedish Environmental Protection Agency to develop a scheme of action on how to reduce the risks of health and the environment, resulting from the agricultural use of pesticides.

The overall aim was risk reduction but in order to find a measurable quantitative aim, the government had stated that the use of agricultural pesticides should be reduced by 50% in five years time.

## Starting point

The starting year was set to 1986 and the reduction should be measured as ton active ingredients compared with the mean use in 1981-85 to allow for annual variations.

The mean quantity of active ingredients in agricultural pesticides sold in 1981-1985 was 4,500 tons of which 3,500 tons were herbicides. In comparison with other countries this is already a rather low figure for an arable land of just less than 3 million hectares.

The risk reduction action scheme was divided into three main groups.

- \* Change to pesticides that are less hazardous to health and the environment.
- \* Reduction of the use (50%)
- \* Special measures to protect health and the environment.

## 1. Aim: Less hazardous pesticides approved

### 1. Action taken Enforcement Result

5 years approval time for pesticides	Ordinance on Pesticides (1985)	450 pesticide products expire at the end of 1990
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Old pesticides should by 1990 have the same documentation as is required for new pesticides	Policy of the new inspectorate with support in the governmental action program for 160 products	The manufacturer did not apply for renewed approval
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During 1990 review of 300 pesticides (170 ai)	Transitional regulations from old to new legislation	242 approved 50 rejected
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Phasing out of unacceptable pesticides that could not be substituted by less hazardous	After discussions with all interested parties; phasing out plan is established	Date of expire set
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NEW: Outlining principles for assessing unacceptable properties in pesticides	At present only advisory approved	Less hazardous
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January 1986 - 681 pesticide products approved  
 January 1991 - 337 pesticide products approved

Those approved are better documented and less hazardous. However, there is no aim to keep the number of approved products low as long as they are well documented and meet our health and environmental criteria. Therefore, the number of approved pesticide products probably will increase in the years to come.

2. Aim: 50% reduction of the use of agricultural pesticides

Action taken	Enforcement	Result
Withdrawal of old pesticides TCA, Sodium chlorate documentation or suspected high risks	Review program and race-mate of phenoxyes	Withdrawal of e.g. pesticides with insufficient documentation
		1/3 lower use
Conditioning testing was subsidized	Voluntary good order	Better equipment in of spraying equipment 75% of the cost
		1/3 lower use
Use of lower doses than was originally recommended especially of herbicides in spring	Voluntary - Educational Field trials with full dose, 1/2 dose, 1/4 dose all over the country	1/3 of the decreased cereals use

Use of lower doses than originally recommended for herbicides especially in spring cereals. The original proposal was to test herbicides at several doses in the official trials in order to get better support for the advisory officers to contribute with differentiated advice to farmers. When the University of Agriculture went through their field trials they found a substantial documentation supporting the best yields at half the recommended dose at an 80% herbicidal efficacy. The fact that the best yield for the crop was obtained at half the recommended dose is probably due to the stress the crop is exposed to by the 90-95% herbicidal efficacy. The dose recommendation has of course to be differentiated in consideration of high amounts of weed, type of soil and crop rotation system.

The full dose insurance of - always enough - can be switched by more knowledge and education to what is enough in just that field.

### 3. Aim: Special measures to protect health and the environment

Action taken	Enforcement	Result
Type approval of spraying equipment	Ordinance on type approval obligatory from 1991	Better equipment
3 days education for all fulfilled 1988-90	Obligatory educational risks for health and pesticides	Better awareness of agricultural sprayers of the environment
Stricter rules for spray-pesticides consideration should be given the risks of environmental damage	Ordinance on spraying surface water	Less contamination ing pesticides; special program

#### Special measures

Type of approval of spraying equipment - mandatory from 1991 - has not influenced the present risk and quantitative reduction in the use of pesticides but is part of the program that will have an influence on the future.

For the fulfilment of the program the three-day training and education program for all professional agricultural sprayers has been of great importance. The course is intended to increase the consciousness of the risks and thereby give safer handling and it presents a good opportunity for farmers to discuss practical behaviour in order to minimize health and environmental problems.

Special rules to minimize the environmental risks when spraying pesticides were enforced in 1988.

It is prohibited to fill field crop sprayers directly from lakes or water-courses to reduce possible pollution of surface water. The rules also contains provisions concerning allowed wind speed when spraying, protection zones for lakes and watercourses, etc.

#### In conclusion

How has it been possible to achieve the desired aim to reduce the use by 50%? Working in the program I feel that the key point was, that the commission was given to the agricultural, health, and environmental authorities as a shared task. Therefore, instead of devoting our time to endless discussions on the size of various relative risks, all parties concerned agreed that pesticide usage is associated with potential risks for the farmer, the consumer of food commodities and for the environment and that these risks should be reduced as far as possible.

The Ministry of Agriculture and the Ministry of the Environment joined forces to formulate a practical aim (50% reduction) and the authorities prepared in collaboration in the various actions outlined before to fulfil this aim.

I feel confident that such a co-operative procedure can be applied to both other national and international pesticide programs.

## References

Most of the papers produced within the program activities are written in Swedish, but there are two papers in English which provide some more details than could be given in the present paper.

V. Bernson, Regulation of Pesticides in Sweden in Brighton Crop Protection Conference Pest and Diseases, 1988, pp 1059-1064.

V. Bernson and G. Ekström. Swedish Policy to Reduce Pesticide Use, Pesticide Outlook, Vol 2, (3), 1991.

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# MEETING REPORT

## Background

Upon invitation by the Swedish National Chemicals Inspectorate (KemI) participants from twelve countries (Australia, Austria, Belgium, Denmark, Finland, Germany, the Netherlands, Norway, Sweden, Switzerland, United Kingdom and the United States) and nine international entities (UNEP, FAO, WHO, IPCS, Council of Europe, OECD, CEC, GIFAP and the World Wildlife Fund) met at Saltsjöbaden, Sweden, 29-31 October, 1991, to discuss issues related to the control of pesticides. The meeting was chaired by Dr. Kerstin Niblaeus, Director General of KemI.

The two main themes on the agenda were Possible Improvement of the Co-operation on Pesticides Control and Opportunities for Risk Reduction in the Pesticides Field.

The meeting noted that all organizations present had carried out substantial work to promote safety and efficacy in the use of pesticides. Nevertheless, there are gaps to fill and a need for further development and cooperation.

The evaluation and adoption of the FAO Code of Conduct for the Distribution and Use of Pesticides was mentioned as a landmark for increased safety in the use of pesticides. The ongoing collaboration between FAO and UNEP within the framework of the Code and the London Guidelines was seen as particularly important in the implementation process of the Code. It was noted with satisfaction that the recognized IPCS work to evaluate chemicals included a considerable portion of pesticides. The OECD Guidelines for Testing of Chemicals and the OECD Principles of Good Laboratory Practice were considered to be of increasing importance within the field of pesticides. The FAO/WHO Joint Meeting on Pesticide Residues (JMPR) was commended for its long-standing record in this particular field. The work of the CEC on chemicals control has actively contributed to harmonization of rules and procedures between EC countries but has had ramifications also outside the EC area.

In the field of assessment of pesticides several improvements seemed desirable.

The meeting recommended with respect to

### Data requirements

- that common core data sets which are mutually acceptable for registration of new and old active ingredients be identified, taking into account an inventory of data sets currently required for the registration of new active ingredients and the registration of old. The common core data set should include relevant data on mammalian toxicity, ecotoxicity, environmental fate, residue, efficacy and exposure.

OECD should take the lead with input from Gifap and FAO.

### Test Guidelines

- that guidelines be developed to fill gaps for the purpose of pesticide registration, taking into account current experience in industry;
- the development of additional OECD test guidelines taking into account other possibly existing guidelines;
- the recognition of international test guidelines in as many countries as possible.

This work should be undertaken within OECD

#### Data Evaluation

- that the greatest possible consistency in determining the acceptability of old data, in data evaluation procedures and the interpretation of test results be developed, taking into account inter alia ongoing work with the European Communities and US EPA.

This work should be coordinated by IPCS with lead responsibility for environmental studies to be with OECD and for health studies to be with IPCS.

#### Data protection/confidentiality

- that as a minimum, sufficiently detailed summaries of health and safety (including environmental) data be available to the public taking into account the protection of proprietary rights.

#### Mutual acceptance of data

- that the principles of mutual recognition of data be expanded to non-OECD countries with capability to guarantee the sufficient quality of the data.

Gifap needs to identify countries where mutual acceptance of data is a problem and work with FAO and national governments to encourage greater use of the OECD Principles of the Mutual Acceptance of Proprietary Rights.

#### Harmonization of review schedules

- that countries to the greatest extent possible coordinate review schedules for reregistration of pesticides.

The US will host a workshop to lay the groundwork for coordination of review schedules. Follow-on work is to be identified by workshop participants.

#### Classification and labelling

- that consistent schedules for classification and labelling of chemicals including pesticides be developed, taking into account ongoing work within ILO, OECD, CEC, FAO and elsewhere.

## Risk Assessment/Evaluation

In order to indicate a way to go to increase the consistency in risk assessment the meeting chose evaluation for carcinogenicity as an example. This field is one of several important areas. A meeting should be held to provide for an in-depth discussion how decisions and conclusions are reached. Preparations for such a meeting should include an inventory of procedures used, and terminology applied by national governments and international organizations.

IPCS should develop a long-range strategy for review of risk assessment issues.

Several upcoming meetings were noted including the Swedish meeting on "The Role of Science in Pesticide Management", and the IPCS meeting on Principles for Risk Assessment.

It was the feeling of the meeting that as governments complete their reviews of chemicals, these be made widely available to other governments and international organizations.

A prerequisite for substantial progress in all this work is an increased transparency on how countries and international organizations arrive at their decisions and conclusions.

As far as Risk Reduction Projects are concerned the meeting recognized that without defining the size of risks, the usage of agricultural pesticides is associated with potential risks for the users, the consumers, the public and for the environment.

Further, the meeting recognized that the present use of agricultural pesticides is often not optimal, either from a sustainable agricultural point of view, or from an environmental, occupational or public health point of view.

Therefore, the group recommended that national and international efforts be taken to reduce the risks from agricultural pesticide usage while developing optimal agricultural production.

Several of the participating countries have ongoing programs aimed to reduce the risks for health and the environment posed by the use of agricultural pesticides. Denmark, the Netherlands and Sweden reported the most extensive programs with quantitative goals such as 25-50% reduction of use over a period of 5-10 years, combined with other measures to reduce the risks. Finland, Norway and Switzerland reported instruments for agricultural pesticide risk reduction, and others e.g. the EC has general policy objectives to reduce to a minimum the use of agricultural pesticides.

The most extensive programs started from national political declarations to reduce agricultural pesticide usage. The launched programs included quantitative goals and time frames and were based on voluntary participation and consultation with interested parties.

FAO reported that in Asia, pest outbreaks induced by widespread agricultural insecticide use can threaten rice production. To ensure the continued growth of rice production, Asian governments have implemented Integrated Pest Management (IPM) programs that reduce agricultural insecticide use dramatically. These programs:

- reduce and remove previous subsidies that encouraged higher agricultural insecticide use;
- strengthen extension, training, and applied research capabilities; and

- provide intensive field training to hundreds of thousands of farmers.

FAO reported how Indonesia's National IPM Policy eliminated pesticides subsidies of over \$120 million per year. Its national IPM program gave over one million person-days of training in 20 months. National pesticide use dropped by more than 60% between 1987 and 1990 while national rice production increased by more than 14%. This reduction was due to lower frequency of field applications by farmers.

The following instruments for pesticide risk reduction have been used by a number of countries. These include but are not limited to:

Regulatory Actions such as:

- Re-evaluation of existing agricultural pesticides including pesticides in horticulture, and forestry;
- Restrictions on use of existing compounds where appropriate; and
- Standards for application machinery.

Research Development and Demonstrations covering:

- Resistant crop varieties;
- Reduced dosages of agricultural pesticides;
- Integrated Pest Management (IPM) systems; and
- Environmental Risk Models.

Education and Training for users, sellers, and handlers of agricultural pesticides under programs such as:

- Certification schedules;
- Implementation of the International Code of Conduct for Pesticides.

Public or private sector extension services for farmers and growers.

Public Information Campaigns such as:

- Labelling;
- Alternatives to agricultural pesticides;
- Notification of Use of Agricultural pesticides, especially hazardous compounds; and
- Campaigns to influence consumer preferences.

Financial Measures specifically including:

- Subsidy rationalization such as
  - Support for investment costs for agricultural pesticide reduction;
  - Facilitation of the transition to biological farming; and
  - Alterations of price support programs.

Levies that increase the costs of agricultural pesticides to users such as:

- Levies assessed per kilogram of compound used; and

- Levies assessed per hectare of land treated.

Monitoring systems for quantitative estimates of:

- Contaminants in drinking water;
- Emissions associated with usage of agricultural pesticides; and
- Use of agricultural pesticides.

In conclusion the meeting recommended the following as far as risk reduction projects are concerned:

National governments should be encouraged to establish risk reduction programs noting that reported actions of the type listed above have been implemented whilst maintaining agricultural yield.

Risk areas of prime concern will vary with local/regional conditions such as pest infection pressure, crops cultivated, climate, etc.

Establishment of such programs would be greatly facilitated by additional international and regional activities such as:

- Sharing information on ongoing activities, experiences and results from risk reduction programs.
- Compilation and sharing of monitoring data.
- At the national levels, coordination between domestic and foreign aid programs with due consideration given to local conditions.

The meeting called upon countries and international bodies to support national pesticide risk reduction programs, and to develop appropriate criteria and policies to encourage introduction of such programs both in developed and developing countries.

The above stated characteristics and instruments for agricultural pesticide risk reduction are in many respects also applicable to non-agricultural pesticides eg. wood preservatives, slimeicides, and anti-fouling paints and governments are therefore encouraged to also consider risk reduction programs for non-agricultural pesticides.

#### Strengthened co-operation

A common requirement for improved safety and efficacy in the use of pesticides is a strengthened cooperation between national governments, UN organizations, regional intergovernmental organizations like OECD, the Council of Europe and the European Communities

# THE CONTROL OF PESTICIDES,

Saltsjöbaden, Sweden, 29-31 October 1991

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