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Unidas
para la
Agricultura
y la
Alimentación

COUNCIL

Hundred and Twenty-third Session

Rome, 28 October-2 November 2002

REVISION OF THE TEXT OF THE INTERNATIONAL CODE OF CONDUCT ON THE DISTRIBUTION AND USE OF PESTICIDES

1. The FAO International Code of Conduct on the Distribution and Use of Pesticides (hereafter referred to as the Code) is the globally accepted standard for pesticide management which, together with supporting technical guidelines, has served as the foundation for the implementation and improvement of pesticide legislation and management in many countries, in particular developing countries. The Code was adopted in 1985 and amended once, in 1989, to include provisions for the Prior Informed Consent (PIC) Procedure in Articles 2 and 9. A draft Revised Version of the Code was presented to the Thirty-first Session of the FAO Conference on November 2001.
2. The revision of the Code was required to accommodate the adoption of the "Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade" in September 1998 and to reflect changing approaches to pest and pesticide management. The revised Code now provides the framework for the management of pesticides throughout their lifecycle. The continued relevance and importance of the updated Code as a globally accepted standard were stressed by all Members during the Thirty-first Session of the Conference.
3. At this Conference, Members supported the revised text of the Code and praised its potential contribution to the safe use of pesticides for human health and environmental safety. The Conference noted that the revised text was acceptable, with the exception of one paragraph in Article 6, "Regulatory and Technical Requirements" (paragraph 6.1.7 and its subparagraphs 6.1.7.1 and 6.1.7.2). The Conference agreed to seek the earliest possible solution regarding these paragraphs and thereafter the adoption of the revised text of the Code. To this effect, the Conference decided that a technical consultation consisting of government-designated experts should be held as soon as possible, focusing only on the above-mentioned paragraphs. The

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Conference authorized the FAO Council, at its Hundred and Twenty-third Session in October/November 2002, to consider the text resulting from this Consultation and, if appropriate, approve the Revised Version of the Code Reference is made to the report of last year's Conference C 2001/REP and the relevant paragraphs 64-69.

4. Following the request of the Conference, the Secretariat consulted with the Chairs of the regional groups to elaborate the details of the expert consultation, in particular with regard to size, participation and timing. The process to address the paragraphs in question, agreed upon by the Regional Chairs during last year's Conference, was as follows:

1. Circulation of the Revised Draft of the Code to all governments, requesting specific comments on the paragraphs in question before the end of November 2001.
2. Compilation of all inputs and comments received from governments and their consideration by the participants in a Technical Consultation held 27-29 May 2002 in Rome.
3. Circulation of the outcome of the Consultation to governments for their final comments.
4. If there were to be substantial final comments, a working group would be established at Council; otherwise the text would be submitted directly to Council.

5. The report of the Consultation is attached. It also contains a draft of the Code, amended to incorporate the text for Article 6 proposed by the Technical Consultation. This report was sent to the Ministries of Agriculture of FAO Member countries with a Note Verbale in early July 2002. Governments were requested to review the proposed amendment to the text of Article 6 and provide comments by 20 August 2002. At the time of preparing this note, FAO had received comments from a few countries and announcements from others that comments would be forthcoming. Whilst some of the comments have been supportive others have raised concerns. The comments received are also attached.

Suggested Action by the FAO Council

6. Based on the authorization given by the Thirty-first Session of the FAO Conference to the FAO Council in November 2001, the Council is invited to consider the text of Article 6 (paragraphs 6.1.7 and 6.1.8) proposed by the Technical Consultation as well as the comments received and, if appropriate, to approve the Revised Version of the Code or, if deemed necessary, to establish a working group.

**REVISED VERSION OF THE INTERNATIONAL CODE OF CONDUCT ON THE
DISTRIBUTION AND USE OF PESTICIDES**

TECHNICAL CONSULTATION RELATING TO PARAGRAPH 6.1.7

**Report of Technical Consultation
Held in Rome, 27 – 29 May 2002**



**FOOD AND AGRICULTURE ORGANIZATION
OF THE UNITED NATIONS**

ROME 2002

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Annex 1: List of participants

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Annex 3: Final Revised Version of the International Code of Conduct on the
Distribution
and Use of Pesticides (with the incorporation of
the new paragraphs 6.1.7 and
6.1.8)

1. INTRODUCTION

- 1) The Technical Consultation relating to paragraph 6.1.7 of the Revised Version of the International Code of Conduct on the Distribution and Use of Pesticides (Code) was held in Rome from 27 to 29 May 2002 following the decision made at 31st Session of the FAO Conference.
- 2) The objective of the meeting was to discuss paragraph 6.1.7 and sub-paragraphs 6.1.7.1 and 6.1.7.2 of the Code and to reach consensus on a draft text in order to allow the submission of a final revised text of the Code to the 123rd Session of the FAO Council in October/November 2002 for adoption.
- 3) The meeting was attended by Government-designated experts and advisors from 16 countries, together with observers from WTO, pesticide industry and public interest groups. The list of participants is attached as Annex 1.

2. OPENING OF THE MEETING

- 4) The meeting was opened by Mr. M. Solh, Director of the Plant Production and Protection Division of FAO, who welcomed the Government-designated experts, participants and observers on behalf of the Director General of FAO, Mr. J. Diouf.
- 5) Mr. Solh expressed his gratitude to the participants for their attendance of this meeting, and for their co-operation. He expressed his confidence that the Technical Consultation would result in an agreed draft text for paragraph 6.1.7 and its subparagraphs.
- 6) Mr. N. Van der Graaff, Chief of the Plant Protection Service of FAO, outlined the scope of the Consultation and summarized the revision process adopted by the Regional Chairs during last year's Conference. The four steps involved were:
 1. The circulation of the Revised Draft of the Code to all governments requesting specific comments on the paragraphs in question before the end of November 2001.
 2. The compilation of all inputs and comments received from governments for distribution to the Technical Consultation participants.
 3. The intent to circulate the outcome of the Consultation to governments for their final comments.
 4. If there are substantial final comments, a working group will be established at Council; otherwise the text will be submitted directly to Council.

3. ELECTION OF THE CHAIRPERSON AND APPOINTMENT OF THE RAPPORTEUR

7) The Consultation requested the Secretariat to chair the Consultation. Mr. Van der Graaff, acted as Chairman and Mr. G. Vaagt, Senior Officer Pesticides Management Group, acted as Rapporteur. It was noted that this approach was unusual, but was valuable in allowing for active participation of all participants.

4. ADOPTION OF THE AGENDA

8) The Agenda as adopted is shown in Annex 2.

5. SUMMARY OF THE COMMENTS RECEIVED

9) The FAO Secretariat introduced and summarized the document containing the compilation of comments received from governments.

10) A total of 36 countries had provided written comments to the Consultation and a further 6 delegates at the meeting presented their government views verbally on the draft text of paragraph 6.1.7. The majority of comments supported the version of the Code that had been presented to the 31st Session of the FAO Conference. Eight countries expressed reservation over the draft paragraph in its present form, of which 5 countries proposed alternative text and 3 countries proposed deletion.

6. GENERAL CONSIDERATIONS

11) The Consultation had no intention to interpret provisions of the TRIPS Agreement, in particular Article 39.3, as this is clearly the role of WTO and outside the competence of FAO;

12) The representative of WTO indicated that there were differences in the ways countries have implemented TRIPS.

13) A number of members expressed the special needs of some developing countries with respect to guidance on how to address data protection at the national level in the registration process of pesticides;

14) Some members were of the view that the issue of the protection of intellectual property was not relevant to the objectives of the Code, while some others were certain that this issue was part of the objective of the Code.

7. DISCUSSIONS ON PARAGRAHS 6.1.7, 6.1.7.1 and 6.1.7.2

15) The Consultation considered the following text, this being the wording of the draft version of the Code, that had been circulated to governments for comments;

Governments should:

6.1.7 *without prejudice to the provisions of TRIPS¹(Article 39) relating to protection of undisclosed information (34):*

6.1.7.1 *when registering pesticides, prevent the use of data generated by one company to support the registration of another, unless by agreement with the owner of the data or unless an appropriate period of protection, as defined by national legislation, has expired;*

6.1.7.2 *provide public access to information, particularly relating to human health and environmental safety, provided adequate steps are taken to prevent the use of unauthorized data to support the registration of the product of another company.*

16) The Consultation noted that sub-paragraphs 6.1.7.1 and 6.1.7.2 of the draft version of the Code addressed different aspects of the protection of data and the access of the public to information relevant to human health and environmental safety.

17) The Consultation could not agree on whether the above text was an interpretation of the TRIPS Agreement or not and if it went beyond the provisions of Article 39.3 or not.

18) The Consultation reaffirmed that the interpretation of TRIPS was outside the scope of this voluntary Code and would not be acceptable to all FAO Members, in particular to those countries which are also members of the WTO.

19) After a lengthy debate, the Consultation agreed to include a reference to Article 39.3 of the TRIPS Agreement in the paragraph of the Code under consultation.

20) The Consultation recognized the importance of public access to information relating to human health and environmental safety in order to improve public confidence in the regulatory process for pesticides. The decisions as to which information is to be made public and how such information should be made available would be national responsibilities.

8. CONCLUSIONS AND RECOMMENDATIONS

21) The text of paragraph 22 below was agreed upon by the Consultation to replace paragraph 6.1.7 and its two subparagraphs 6.1.7.1. and 6.1.7.2.

22) *Governments should:*

6.1.7 protect undisclosed test and other data against unfair commercial use in a manner consistent with Article 39.3 of the TRIPS Agreement;

¹ TRIPS : World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights

6.1.8 *provide public access to appropriate information related to human health and environmental safety.*

23) The meeting recommended that this new wording be circulated to governments for their final comments and subsequently be presented at the 123rd Session of the FAO Council for consideration and, if appropriate, for approval of the revised Code.

24) The Consultation recommended renumbering the paragraphs of Article 6.1 accordingly.



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**TECHNICAL CONSULTATION RELATING TO PARA 6.1.7 - REVISED VERSION OF
THE INTERNATIONAL CODE OF CONDUCT ON THE DISTRIBUTION AND USE OF
PESTICIDES**

Rome, 27 – 29 May 2002

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**TECHNICAL CONSULTATION RELATING TO PARA 6.1.7 - REVISED VERSION OF
THE INTERNATIONAL CODE OF CONDUCT ON THE DISTRIBUTION AND USE OF
PESTICIDES**

Rome, 27 – 29 May 2002

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**TECHNICAL CONSULTATION RELATING TO PARA 6.1.7 - REVISED VERSION OF
THE INTERNATIONAL CODE OF CONDUCT ON THE DISTRIBUTION AND USE OF
PESTICIDES**

Rome, 27 – 29 May 2002

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27 – 29 May 2002

Rome, German Room

TECHNICAL CONSULTATION

RELATING TO PARA 6.1.7

REVISED VERSION OF THE INTERNATIONAL CODE OF CONDUCT ON THE DISTRIBUTION AND USE OF PESTICIDES

1. Opening of Session.
2. Introduction.
3. Election of the Chairperson and Rapporteur.
4. Adoption of Agenda.
5. Discussion on paragraph 6.1.7. and its subparagraphs 6.1.7.1 and 6.1.7.2. of the Code of Conduct with a view in obtaining an agreed text.
6. Adoption of the Report
7. Closure.



**Food and
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Annex 3

**International Code of Conduct
on the Distribution and Use
of Pesticides**

Revised Version

(Draft)

Rome, 2002

Contents

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Article 10.	Labelling, packaging, storage and disposal
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Annex 1.	International policy instruments in the field of chemicals management, environmental and health protection, sustainable development and international trade relevant to the Code
Annex 2.	FAO Council Resolution xx/XX

References

A. ARTICLE 1. OBJECTIVES OF THE CODE

1.1 The objectives of this Code are to establish voluntary standards of conduct for all public and private entities engaged in or associated with the distribution and use of pesticides, particularly where there is inadequate or no national legislation to regulate pesticides.

1.2 The Code is designed for use within the context of national legislation as a basis whereby government authorities, pesticide manufacturers, those engaged in trade and any citizens concerned may judge whether their proposed actions and the actions of others constitute acceptable practices.

1.3 The Code describes the shared responsibility of many sectors of society to work together so that the benefits to be derived from the necessary and acceptable use of pesticides are achieved without significant adverse effects on human health or the environment. To this end, all references in this Code to a government or governments shall be deemed to apply equally to regional groupings of governments for matters falling within their areas of competence.

1.4 The Code addresses the need for a cooperative effort between governments of pesticide exporting and importing countries to promote practices that minimize potential health and environmental risks associated with pesticides, while ensuring their effective use.

1.5 The entities which are addressed by this Code include international organizations, governments of exporting and importing countries, pesticide industry, application equipment industry, traders, food industry, users, and public-sector organizations such as environmental groups, consumer groups and trade unions.

1.6 The Code recognizes that training at all appropriate levels is an essential requirement in implementing and observing its provisions. Therefore, governments, pesticide industry, users of pesticides, international organizations, non-governmental organizations (NGOs) and other parties concerned should give high priority to training activities related to each Article of the Code.

1.7 The standards of conduct set forth in this Code:

1.7.1 encourage responsible and generally accepted trade practices;

1.7.2 assist countries which have not yet established regulatory controls on the quality and suitability of pesticide products needed in that country to promote the judicious and efficient use of such products and address the potential risks associated with their use;

1.7.3 promote practices which reduce risks in the handling of pesticides, including minimizing adverse effects on humans and the environment and preventing accidental poisoning resulting from improper handling;

1.7.4 ensure that pesticides are used effectively and efficiently for the improvement of agricultural production and of human, animal and plant health;

1.7.5 adopt the "life-cycle" concept to address all major aspects related to the development, regulation, production, management, packaging, labelling, distribution, handling, application, use and control, including post registration activities and disposal of all types of pesticides, including used pesticide containers;

1.7.6 are designed to promote integrated pest management (IPM) (including integrated vector management for public health pests);

1.7.7 include reference to participation in information exchange and international agreements identified in Annex 1, in particular the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* (1)².

² Numbers in brackets throughout the text refer to the references listed at the end of this document.

Article 2. Terms and definitions

For the purpose of this Code:

Active ingredient means the biologically active part of the pesticide.

Advertising means the promotion of the sale and use of pesticides by printed and electronic media, signs, displays, gift, demonstration or word of mouth.

Application equipment means any technical aid, equipment, implement or machinery which is used for the application of pesticides.

Application technology means the actual physical delivery and distribution process of a pesticide to the target organism or to the place where the target organism comes into contact with the pesticide.

Banned pesticide means a pesticide for which all uses have been prohibited by final regulatory action, in order to protect human health or the environment. The term includes a pesticide that has been refused approval for first-time use, or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment.

Disposal means any operation to recycle, neutralize, destruct or isolate pesticide waste, used containers and contaminated materials.

Distribution means the process by which pesticides are supplied through trade channels to local or international markets.

Environment means surroundings, including water, air, soil and their interrelationship as well as all relationships between them and any living organisms.

Equivalence means the determination of the similarity of the impurity and toxicological profile, as well as of the physical and chemical properties, presented by supposedly similar technical material originating from different manufacturers, in order to assess whether they present similar levels of risk.

Extension service means those entities in the country responsible for the transfer of information, technology and advice regarding the improvement of agricultural practices, including production, handling, storage and marketing of agricultural commodities.

Formulation means the combination of various ingredients designed to render the product useful and effective for the purpose claimed; the form of the pesticide as purchased by users.

Good Agricultural Practice in the use of pesticides includes the officially recommended or nationally authorized uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable.

Hazard means the inherent property of a substance, agent or situation having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property).

Integrated Pest Management (IPM) means the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human health and the environment. IPM emphasizes the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms.

Label means the written, printed or graphic matter on, or attached to, the pesticide or the immediate container thereof and also to the outside container or wrapper of the retail package of the pesticide.

Manufacturer means a corporation or other entity in the public or private sector or any individual engaged in the business or function (whether directly or through an agent or entity controlled by or under contract with it) of manufacturing a pesticide active ingredient or preparing its formulation or product.

Marketing means the overall process of product promotion, including advertising, product public relations and information services as well as the distribution and sale on local or international markets.

Maximum residue limit (MRL) means the maximum concentration of a residue that is legally permitted or recognized as acceptable in or on a food or agricultural commodity or animal feedstuff.

Packaging means the container together with the protective wrapping used to carry pesticide products via wholesale or retail distribution to users.

Personal protective equipment means any clothes, materials or devices that provide protection from pesticide exposure during handling and application. In the context of this Code, it includes both specifically designed protective equipment and clothing reserved for pesticide application and handling.

Pesticide means any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or substances which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.

Pesticide industry means all those organizations and individuals engaged in manufacturing, formulating or marketing pesticides and pesticide products.

Pesticide legislation means any laws or regulations introduced to regulate the manufacture, marketing, distribution, labelling, packaging, use and disposal of pesticides in their qualitative, quantitative, health and environmental aspects.

Poison means a substance that can cause disturbance of structure or function, leading to injury or death when absorbed in relatively small amounts by human beings, plants or animals.

Poisoning means occurrence of damage or disturbance caused by a poison, and includes intoxication.

Product (or pesticide product) means the pesticide active ingredient(s) and other components, in the form in which it is packaged and sold

Product stewardship means the responsible and ethical management of a pesticide product from its discovery through to its ultimate use and beyond.

Public sector groups means (but is not limited to) scientific associations, farmer groups, citizens' organizations, labour unions and environmental, consumer and health organizations.

Registration means the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose an unacceptable risk to human or animal health or the environment.

Repackaging means the authorized transfer of a pesticide from any commercial package into any other, usually smaller, container for subsequent sale.

Residue means any specified substances in or on food, agricultural commodities or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products and impurities considered to be of toxicological significance. The term "pesticide residue" includes residues from unknown or unavoidable sources (e.g. environmental) as well as known uses of the chemical.

Responsible authority means the government agency or agencies responsible for regulating the manufacture, distribution or use of pesticides and more generally for implementing pesticide legislation.

Risk is a function of the probability of an adverse health or environmental effect, and the severity of that effect, following exposure to a pesticide.

Severely restricted pesticide means a pesticide for which virtually all use has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a pesticide that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment.

Tender means request for bids in purchasing of pesticides.

Toxicity means a physiological or biological property which determines the capacity of a chemical to do harm or produce injury to a living organism by other than mechanical means.

Trader means anyone engaged in trade, including export, import and domestic distribution.

Use pattern means the combination of all factors involved in the use of a pesticide, including the concentration of active ingredient in the preparation being applied, rate of application, time of treatment, number of treatments, use of adjuvants and methods and sites of application which determine the quantity applied, timing of treatment and interval before harvest.

Article 3. Pesticide management

- 3.1** Governments have the overall responsibility to regulate the availability, distribution and use of pesticides in their countries and should ensure the allocation of adequate resources for this mandate (2).
- 3.2** The pesticide industry should adhere to the provisions of this Code as a standard for the manufacture, distribution and advertising of pesticides, particularly in countries lacking appropriate legislation and advisory services.
- 3.3** Governments of pesticide exporting countries should, to the extent possible:
- 3.3.1** provide technical assistance to other countries, especially those lacking technical expertise in the assessment of the relevant data on pesticides;
 - 3.3.2** ensure that good trading practices are followed in the export of pesticides, especially to those countries with limited or no regulatory schemes.
- 3.4** Pesticide industry and traders should observe the following practices in pesticide management, especially in countries without legislation or means of implementing regulations:
- 3.4.1** supply only pesticides of adequate quality, packaged and labelled as appropriate for each specific market (3);
 - 3.4.2** in close cooperation with procurers of pesticides, adhere closely to provisions of FAO guidelines on tender procedures (4);
 - 3.4.3** pay special attention to the choice of pesticide formulations and to presentation, packaging and labelling in order to reduce risks to users and minimize adverse effects on the environment;
 - 3.4.4** provide, with each package of pesticide, information and instructions in a form and language adequate to ensure effective use and reduce risks during handling;
 - 3.4.5** be capable of providing effective technical support, backed up by full product stewardship to field level, including advice on disposal of pesticides and used pesticide containers, if necessary;
 - 3.4.6** retain an active interest in following their products to the end- user, keeping track of major uses and the occurrence of any problems arising from the use of their products, as a basis for determining the need for changes in labelling, directions for use, packaging, formulation or product availability.

3.5 Pesticides whose handling and application require the use of personal protective equipment that is uncomfortable, expensive or not readily available should be avoided, especially in the case of small-scale users in tropical climates (5). Preference should be given to pesticides that require inexpensive personal protective and application equipment and to procedures appropriate to the conditions under which the pesticides are to be handled and used.

3.6 National and international organizations, governments and pesticide industry should take coordinated action to disseminate educational materials of all types to pesticide users, farmers, farmers' organizations, agricultural workers, unions and other interested parties. Similarly, users should seek and understand educational materials before applying pesticides and should follow proper procedures.

3.7 Concerted efforts should be made by governments to develop and promote the use of integrated pest management (IPM). Furthermore, lending institutions, donor agencies and governments should support the development of national IPM policies and improved IPM concepts and practices. These should be based on scientific and other strategies that promote increased participation of farmers (including women's groups), extension agents and on-farm researchers.

3.8 All stakeholders, including farmers and farmer associations, IPM researchers, extension agents, crop consultants, food industry, manufacturers of biological and chemical pesticides and application equipment, environmentalists and representatives of consumer groups should play a proactive role in the development and promotion of IPM.

3.9 Governments, with the support of relevant international and regional organizations, should encourage and promote research on, and the development of, alternatives posing fewer risks: biological control agents and techniques, non-chemical pesticides and pesticides that are, as far as possible or desirable, target-specific, that degrade into innocuous constituent parts or metabolites after use and are of low risk to humans and the environment.

3.10 Governments and the application equipment industry should develop and promote the use of pesticide application methods (6, 7) and equipment (8, 9, 10, 11) that pose low risks to human health and the environment and that are more efficient and cost-effective, and should conduct ongoing practical training in such activities (12).

3.11 Governments, pesticide industry and national and international organizations should collaborate in developing and promoting resistance management strategies to prolong the useful life of valuable pesticides and reduce the adverse effects resulting from the development of resistance of pests to pesticides.

Article 4. Testing of pesticides

4.1 Pesticide industry should:

4.1.1 ensure that each pesticide and pesticide product is adequately and effectively tested by recognized procedures and test methods so as to fully evaluate its efficacy (13), behaviour, fate, hazard and risk (14) with regard to the various anticipated conditions in regions or countries of use;

4.1.2 ensure that such tests are conducted in accordance with sound scientific procedures and the principles of good laboratory practice (15);

4.1.3 make available copies or summaries of the original reports of such tests for assessment by responsible government authorities in all countries where the pesticide is to be offered for sale. Evaluation of the data should be carried out by qualified experts. If translated documents are provided, their accuracy should be validated;

4.1.4 ensure that the proposed use pattern, label claims and directions, packages, technical literature and advertising truly reflect the outcome of these scientific tests and assessments;

4.1.5 provide, at the request of a country, methods for the analysis of any active ingredient or formulation that they manufacture, and provide the necessary analytical standards;

4.1.6 provide advice and assistance in the training of technical staff involved in the relevant analytical work. Formulators should actively support this effort;

4.1.7 conduct residue trials prior to marketing, at least in accordance with Codex Alimentarius and FAO guidelines on good analytical practice (16) and on crop residue data (17, 18, 19) in order to provide a basis for establishing appropriate maximum residue limits (20).

4.2 Each country should possess or have access to facilities to verify and exercise control over the quality of pesticides offered for sale or export, to establish the quantity of the active ingredient or ingredients and the suitability of their formulation, according to FAO or WHO specifications³, when available (21, 22, 23).

4.3 International organizations and other interested bodies should, within available resources, consider assisting in the establishment of analytical laboratories, or strengthening existing laboratories, in pesticide importing countries, either on a national or a regional basis. These laboratories should adhere to sound scientific procedures and guidelines for good laboratory practice, should possess the

³ WHO : World Health Organization

necessary expertise and should have adequate analytical equipment and supplies of certified analytical standards, solvents, reagents and appropriate, up-to-date analytical methods.

4.4 Exporting governments and international organizations should play an active role in assisting developing countries in training personnel on trial design and conduct, the interpretation and evaluation of test data, and risk/benefit analysis. They should also promote maximum availability to, and use by developing countries of, appropriate international assessments and evaluations of pesticide hazards and risks.

4.5 Pesticide industry and governments should collaborate in post-registration surveillance or conducting monitoring studies to determine the fate of pesticides and their health and environmental effects under field conditions (14, 24).

Article 5. Reducing health and environmental risks

5.1 Governments should:

5.1.1 implement a pesticide registration and control system along the lines set out in Article 6;

5.1.2 periodically review the pesticides marketed in their country, their acceptable uses and their availability to each sector of the public, and conduct special reviews when indicated by scientific evidence;

5.1.3 carry out health surveillance programmes of those who are occupationally exposed to pesticides and investigate, as well as document, poisoning cases;

5.1.4 provide guidance and instructions to health workers, physicians and hospital staff on the treatment of suspected pesticide poisoning (25);

5.1.5 establish national or regional poisoning information and control centres at strategic locations to provide immediate guidance on first aid and medical treatment, accessible at all times (25);

5.1.6 utilize all possible means for collecting reliable data and maintaining statistics on health aspects of pesticides and pesticide poisoning incidents, with the objective of establishing the WHO harmonized system for identifying and recording such data (25). Suitably trained personnel and adequate resources should be made available to ensure the accuracy of information collected;

5.1.7 provide extension and advisory services and farmers' organizations with adequate information about practical IPM strategies and methods, as well as the range of pesticide products available for use;

5.1.8 ensure, with the cooperation of pesticide industry, that where pesticides are available through outlets which also deal in food, clothing, medicines or other products for consumption or topical application, they are physically segregated from other merchandise to prevent contamination and/or mistaken identity. Where appropriate, they should be clearly marked as hazardous materials. Every effort should be made to publicize the dangers of storing foodstuffs and pesticides together (26);

5.1.9 utilize all possible means for collecting reliable data, maintaining statistics on environmental contamination and reporting specific incidents related to pesticides;

5.1.10 implement a programme to monitor pesticide residues in food and the environment.

5.2 Even where a control scheme is in operation, pesticide industry should:

5.2.1 cooperate in the periodic reassessment of the pesticides which are marketed;

5.2.2 provide poison-control centres and medical practitioners with information about pesticide hazards and on suitable treatment of pesticide poisoning;

5.2.3 make every reasonable effort to reduce risks posed by pesticides by:

5.2.3.1 making less toxic formulations available;

5.2.3.2 introducing products in ready-to-use packages;

5.2.3.3 developing application methods and equipment that minimize exposure to pesticides;

5.2.3.4 using returnable and refillable containers where effective container collection systems are in place;

5.2.3.5 using containers that are not attractive for subsequent reuse and promoting programmes to discourage their reuse, where effective container collection systems are not in place;

5.2.3.6 using containers that are not attractive to or easily opened by children, particularly for domestic use products;

5.2.3.7 using clear and concise labelling.

5.2.4 halt sale and recall products when handling or use pose an unacceptable risk under any use directions or restrictions.

5.3 Government and industry should cooperate in further reducing risks by:

5.3.1 promoting the use of proper and affordable personal protective equipment (5);

5.3.2 making provisions for safe storage of pesticides at both warehouse and farm level (26, 27);

5.3.3 establishing services to collect and safely dispose of used containers and small quantities of left-over pesticides (28);

5.3.4 protecting biodiversity and minimizing adverse effects of pesticides on the environment (water, soil and air) and on non-target organisms.

5.4 To avoid unjustified confusion and alarm among the public, concerned parties should consider all available facts and should promote responsible information dissemination on pesticides and their uses.

5.5 In establishing production facilities of a suitable standard in developing countries, manufacturers and governments should cooperate to:

5.5.1 adopt engineering standards and operating practices appropriate to the nature of the manufacturing operations and the hazards involved, and ensure the availability of appropriate protective equipment;

5.5.2 take all necessary precautions to protect workers, bystanders, surrounding communities and the environment;

5.5.3 ensure the proper siting of manufacturing and formulating plants and adequately control wastes and effluents;

5.5.4 maintain quality-assurance procedures to ensure compliance with the relevant standards of purity, performance, stability and safety.

Article 6. Regulatory and technical requirements

6.1 Governments should:

6.1.1 introduce the necessary legislation for the regulation of pesticides and make provisions for its effective enforcement, including the establishment of appropriate educational, advisory, extension and health-care services, using FAO guidelines as far as possible (2, 29, 30). In so doing, they should take full account of local needs, social and economic conditions, levels of literacy, climatic conditions and availability of appropriate pesticide application and personal protective equipment;

6.1.2 strive to establish pesticide registration schemes and infrastructures under which products can be registered prior to domestic use and ensure that each pesticide product is registered before it can be made available for use (29, 30, 31);

6.1.3 conduct risk evaluations and make risk management decisions based on all available data or information, as part of the registration process;

6.1.4 use the principles described in the FAO Manual on the Development of Pesticide Specifications for determining equivalence of pesticides (21);

6.1.5 promote the advantages of, and cooperate with other governments in, the establishment of harmonized (regionally or by groups of countries) pesticide registration requirements, procedures and evaluation criteria, taking into account appropriate, internationally agreed technical guidelines and standards, and where possible incorporate these standards into national or regional legislation (32, 33);

6.1.6 establish a re-registration procedure to ensure the periodic review of pesticides, thus ensuring that prompt and effective measures can be taken if new information or data on the performance or risks indicate that regulatory action is needed;

6.1.7 *protect undisclosed test and other data against unfair commercial use in a manner consistent with Article 39.3 of the TRIPS Agreement⁴ (34);*

6.1.8 *provide public access to appropriate information related to human health and environmental safety;*

6.1.9 collect and record data on the import, export, manufacture, formulation, quality, quantity and use of pesticides in order to assess the extent of any possible effects on human health or the environment, and to follow trends in pesticide use for economic and other purposes;

⁴ TRIPS : World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights.

6.1.10 permit pesticide application and personal protective equipment to be marketed only if they comply with established standards (5,8,9);

6.1.11 detect and control illegal trade in pesticides;

6.1.12 when importing food and agricultural commodities, recognize good agricultural practices in countries with which they trade and, in accordance with recommendations of the Codex Alimentarius Commission, establish a legal basis for the acceptance of pesticide residues resulting from such good agricultural practices (19, 20) in a manner that is consistent with the WTO⁵ requirements so as not to lead to technical barriers to trade.

6.2 The pesticide industry should:

6.2.1 provide an objective pesticide data assessment together with the necessary supporting data on each product, including sufficient data to support risk assessment and to allow a risk management decision to be made;

6.2.2 provide national regulatory authorities with any new or updated information that could change the regulatory status of the pesticide, as soon as it becomes available;

6.2.3 ensure that the active ingredient and other ingredients of pesticide products being marketed correspond in identity, quality, purity and composition to the substances tested, evaluated and cleared for toxicological and environmental acceptability;

6.2.4 ensure that active ingredients, and formulated products for pesticides for which international specifications have been developed, conform with the relevant FAO specifications for agricultural pesticides (22), and with WHO pesticide specifications for public health pesticides (23);

6.2.5 verify the quality and purity of pesticides offered for sale;

6.2.6 when problems occur, voluntarily take corrective action and, when requested by governments, help find solutions to difficulties;

6.2.7 provide their national governments with clear and concise data on export, import, manufacture, formulation, sales, quality and quantity of pesticides.

6.3 Technical assistance funding agencies, development banks and bilateral agencies should be encouraged to give high priority to requests for assistance from developing countries which do not yet have the facilities and expertise for pesticide management and control systems.

⁵ WTO : World Trade Organization

Article 7. Availability and use

7.1 Responsible authorities should give special attention to drafting rules and regulations on the availability of pesticides. These should be compatible with existing levels of user training and expertise. The parameters on which such decisions on availability are based vary widely and must be left to the discretion of each government;

7.2 In addition, governments should take note of and, where appropriate, use the WHO classification of pesticides by hazard (35) as the basis for their regulatory measures and associate the hazard class with well-recognized hazard symbols. When determining the risk and degree of restriction appropriate to the product, the type of formulation and method of application should be taken into account.

7.3 Two methods of restricting availability can be exercised by the responsible authority: not registering a product or, as a condition of registration, restricting the availability to certain groups of users in accordance with a national assessment of the hazards involved in the use of the product.

7.4 Governments and industry should ensure that all pesticides made available to the general public are packaged and labelled in a manner which is consistent with the FAO guidelines on packaging and labelling (3) and with appropriate national regulations.

7.5 Prohibition of the importation, sale and purchase of highly toxic and hazardous products, such as those included in WHO classes Ia and Ib (35), may be desirable if other control measures or good marketing practices are insufficient to ensure that the product can be handled with acceptable risk to the user.

Article 8. Distribution and trade

8.1 Governments should:

8.1.1 develop regulations and implement licensing procedures relating to the sale of pesticides, so as to ensure that those involved are capable of providing buyers with sound advice on risk reduction and efficient use (26);

8.1.2 take the necessary regulatory measures to prohibit the repackaging or decanting of any pesticide into food or beverage containers and rigidly enforce punitive measures that effectively deter such practices;

8.1.3 encourage, to the extent possible, a market-driven supply process, as opposed to centralized purchasing, to reduce the potential for accumulation of excessive stocks. However, when governments or other agencies purchase pesticides, the procurement should be based on established FAO tender procedures for pesticides (4);

8.1.4 ensure that any pesticide subsidies or donations do not lead to excessive or unjustified use which may divert interest from more sustainable alternative measures.

8.2 Pesticide industry should:

8.2.1 take all necessary steps to ensure that pesticides entering international trade conform at least to:

8.2.1.1 relevant FAO (22), WHO (23) or equivalent specifications (where such specifications have been developed);

8.2.1.2 principles embodied in relevant FAO guidelines on classification, packaging, marketing, labelling, procurement and documentation (3, 4, 26);

8.2.1.3 rules and regulations laid down by the UN Recommendations on the Transport of Dangerous Goods (36), and by international organizations concerned with specific modes of transport (e.g. ICAO⁶, IMO⁷, RID⁸, ADR⁹ and IATA¹⁰).

⁶ ICAO : International Civil Aviation Organization

⁷ IMO : International Maritime Organization

⁸ RID : International Regulations concerning the Carriage of Dangerous Goods by Rail

⁹ ADR : European Agreement concerning the International Transport of Dangerous Goods by Road

¹⁰ IATA : International Air Transport Organization

- 8.2.2** endeavour to ensure that pesticides manufactured for export are subject to the same quality requirements and standards as those applied to comparable domestic products;
- 8.2.3** ensure that pesticides manufactured or formulated by a subsidiary company meet appropriate quality requirements and standards. These should be consistent with the requirements of the host country and of the parent company;
- 8.2.4** encourage importing agencies, national or regional formulators and their respective trade organizations to cooperate in order to achieve fair practices as well as marketing and distribution practices that reduce the risks posed by pesticides, and to collaborate with authorities in stamping out any malpractice within the industry;
- 8.2.5** recognize that a pesticide may need to be recalled by a manufacturer and distributor when its use, as recommended, represents an unacceptable risk to human and animal health or the environment, and act accordingly;
- 8.2.6** endeavour to ensure that pesticides are traded by and purchased from reputable traders, who should preferably be members of a recognized trade organization;
- 8.2.7** ensure that persons involved in the sale of pesticides are trained adequately, hold appropriate government licences (where such licences exist) and have access to sufficient information, such as material safety data sheets, so that they are capable of providing buyers with advice on risk reduction and efficient use;
- 8.2.8** provide, consistent with national requirements, a range of pack sizes and types that are appropriate for the needs of small-scale farmers and other local users, in order to reduce risks and to discourage sellers from repackaging products in unlabelled or inappropriate containers.
- 8.3** The procurer (government authority, growers' association, or individual farmer) should establish purchasing procedures to prevent the oversupply of pesticides and consider including requirements relating to extended pesticide storage, distribution and disposal services in a purchasing contract (4, 37).

Article 9. Information exchange

9.1 Governments should:

9.1.1 promote the establishment or strengthening of networks for information exchange on pesticides through national institutions, international, regional and sub-regional organizations and public sector groups;

9.1.2 facilitate the exchange of information between regulatory authorities to strengthen cooperative efforts. The information to be exchanged should include:

9.1.2.1 actions to ban or severely restrict a pesticide in order to protect human health or the environment, and additional information upon request;

9.1.2.2 scientific, technical, economic, regulatory and legal information concerning pesticides including toxicological, environmental and safety data;

9.1.2.3 the availability of resources and expertise associated with pesticide regulatory activities.

9.2 In addition, governments are encouraged to develop:

9.2.1 legislation and regulations that permit the provision of information to the public about pesticide risks and the regulatory process;

9.2.2 administrative procedures to provide transparency and facilitate the participation of the public in the regulatory process.

9.3 International organizations should provide information on specific pesticides (including guidance on methods of analysis) through the provision of criteria documents, fact sheets, training and other appropriate means (38).

9.4 All parties should:

9.4.1 support the process of information exchange and facilitate access to information regarding pesticide residues in food and related regulatory actions;

9.4.2 encourage collaboration between public sector groups, international organizations, governments and other interested stakeholders to ensure that countries are provided with the information they need to meet the objectives of the Code.

a) Article 10. Labelling, packaging, storage and disposal

10.1 All pesticide containers should be clearly labelled in accordance with applicable guidelines, at least in line with the FAO guidelines on good labelling practice (3).

10.2 Industry should use labels that:

10.2.1 comply with registration requirements and include recommendations consistent with those of the recognized research and advisory agencies in the country of sale;

10.2.2 include appropriate symbols and pictograms whenever possible, in addition to written instructions, warnings and precautions in the appropriate language or languages (3);

10.2.3 comply with national or international labelling requirements for dangerous goods in international trade and, if appropriate, clearly show the appropriate WHO hazard classification of the contents (3, 35, 36);

10.2.4 include, in the appropriate language or languages, a warning against the reuse of containers and instructions for the safe disposal or decontamination of used containers;

10.2.5 identify each lot or batch of the product in numbers or letters that can be understood without the need for additional code references;

10.2.6 clearly show the release date (month and year) of the lot or batch and contain relevant information on the storage stability of the product (21).

10.3 Pesticide industry, in cooperation with government, should ensure that:

10.3.1 packaging, storage and disposal of pesticides conform in principle to the relevant FAO, UNEP¹¹, WHO guidelines or regulations (27, 28, 37, 39, 40) or to other international guidelines where applicable;

10.3.2 packaging or repackaging is carried out only on licensed premises where the responsible authority is satisfied that staff are adequately protected against toxic hazards, that the resulting product will be properly packaged and labelled, and that the content will conform to the relevant quality standards.

10.4 Governments should take the necessary regulatory measures to prohibit the repackaging or decanting of any pesticide into food or beverage containers and rigidly enforce punitive measures that effectively deter such practices.

¹¹ UNEP : United Nations Environment Programme

10.5 Governments, with the help of pesticide industry and with multilateral cooperation, should inventory obsolete or unusable stocks of pesticides and used containers, establish and implement an action plan for their disposal, or remediation in the case of contaminated sites (41), and record these activities

10.6 Pesticide industry should be encouraged, with multilateral cooperation, to assist in disposing of any banned or obsolete pesticides and of used containers, in an environmentally sound manner, including reuse with minimal risk where approved and appropriate.

10.7 Governments, pesticide industry, international organizations and the agricultural community should implement policies and practices to prevent the accumulation of obsolete pesticides and used containers (37).

(a) *Article 11. Advertising*

11.1 Governments should control, by means of legislation, the advertising of pesticides in all media to ensure that it is not in conflict with label directions and precautions, particularly those relating to proper maintenance and use of application equipment, appropriate personal protective equipment, special precautions for children and pregnant women or the dangers of reusing containers.

11.2 Pesticide industry should ensure that:

11.2.1 all statements used in advertising are technically justified;

11.2.2 advertisements do not contain any statement or visual presentation which, directly or by implication, omission, ambiguity or exaggerated claim, is likely to mislead the buyer, in particular with regard to the "safety" of the product, its nature, composition or suitability for use, official recognition or approval;

11.2.3 pesticides which are legally restricted to use by trained or registered operators are not publicly advertised through journals other than those catering for such operators, unless the restricted availability is clearly and prominently shown;

11.2.4 no company or individual in any one country simultaneously markets different pesticide active ingredients or combinations of ingredients under a single brand name;

11.2.5 advertising does not encourage uses other than those specified on the approved label;

11.2.6 promotional material does not include recommendations at variance with those of the recognized research and advisory agencies;

11.2.7 advertisements do not misuse research results, quotations from technical and scientific literature or scientific jargon to make claims appear to have a scientific basis they do not possess;

11.2.8 claims as to safety, including statements such as "safe", "non-poisonous", "harmless", "non-toxic" or "compatible with IPM," are not made without a qualifying phrase such as "when used as directed". *[However, reference to use within specified IPM programmes may be included if validated by the regulating authority and the claim qualified accordingly];*

11.2.9 statements comparing the risk, hazard or "safety" of different pesticides or other substances are not made;

- 11.2.10** misleading statements are not made concerning the effectiveness of the product;
- 11.2.11** no guarantees or implied guarantees, such as "more profits with..." or "guarantees high yields," are given unless definite evidence to substantiate such claims is available;
- 11.2.12** advertisements do not contain any visual representation of potentially dangerous practices, such as mixing or application without sufficient protective clothing, use near food or use by or in the vicinity of children;
- 11.2.13** advertising or promotional material draws attention to the appropriate warning phrases and symbols as laid down in the FAO labelling guidelines (3);
- 11.2.14** technical literature provides adequate information on correct practices, including the observance of recommended application rates, frequency of applications and pre-harvest intervals;
- 11.2.15** false or misleading comparisons with other pesticides are not made;
- 11.2.16** all staff involved in sales promotion are adequately trained and possess sufficient technical knowledge to present complete, accurate and valid information on the products sold;
- 11.2.17** advertisements encourage purchasers and users to read the label carefully, or have the label read to them if they cannot read;
- 11.2.18** advertisements and promotional activities should not include inappropriate incentives or gifts to encourage the purchase of pesticides.

11.3 International organizations and public sector groups should call attention to departures from this Article.

Article 12. Monitoring and observance of the Code

12.1 The Code should be published and should be observed through collaborative action on the part of governments, individually or in regional groupings, appropriate organizations and bodies of the United Nations system, international, governmental and non-governmental organizations and the pesticide industry.

12.2 The Code should be brought to the attention of all concerned in the regulation, manufacture, distribution and use of pesticides, so that governments, individually or in regional groupings, pesticide industry, international institutions, pesticide user organizations, agricultural commodity industries and food industry groups (such as supermarkets) that are in a position to influence good agricultural practices, understand their shared responsibilities in working together to ensure that the objectives of the Code are achieved.

12.3 All parties should observe this Code and should promote the principles and ethics expressed by the Code, irrespective of other parties' ability to observe the Code. The pesticide industry should cooperate fully in the observance of the Code and promote the principles and ethics expressed by the Code, irrespective of a government's ability to observe the Code.

12.4 Independently of any measures taken with respect to the observance of this Code, all relevant legal rules, whether legislative, administrative, judicial or customary, dealing with liability, consumer protection, conservation, pollution control and other related subjects, should be strictly applied.

12.5 Governments and other parties concerned:

12.5.1 are encouraged to observe the provisions laid down in any international instruments to which they are party, concerning chemicals management, environmental and health protection, sustainable development and international trade, relevant to the Code (Annex 1);

12.5.2 are encouraged, if they have not yet joined, ratified or acceded to such instruments, to evaluate the appropriateness of so doing as soon as possible.

12.6 FAO and other competent international organizations should give full support to the observance of the Code.

12.7 Governments, in collaboration with FAO, should monitor the observance of the Code and report on progress made to the Director-General of FAO.

12.8 Pesticide industry is invited to provide reports to the Director-General of FAO on its product stewardship activities related to observance of the Code.

12.9 NGOs and other interested parties are invited to monitor activities related to the implementation of the Code and report these to the Director-General of FAO.

12.10 Governing Bodies of FAO should periodically review the relevance and effectiveness of the Code. The Code should be considered a dynamic text which must be brought up to date as required, taking into account technical, economic and social progress.

Annex 1

International policy instruments in the field of chemicals management, environmental and health protection, sustainable development and international trade, relevant to the Code

International policy instruments which address one or more aspects of the life-cycle of a pesticide include, but are not limited to, the ones listed below. Some have direct operational implications for pesticide distribution and use, while others provide a more general policy context. Dates of entry into force are given for those instruments that were legally binding at the time of adoption of the revision of this Code.

A. International policy instruments with direct operational implications for pesticide management.

- The *Codex Alimentarius*, and more specifically the Codex Committee on Pesticide Residues, operational since 1966 (42);
- The *Montreal Protocol on Substances that Deplete the Ozone Layer*, adopted in 1987 and entered into force in 1989, and its subsequent amendments (43);
- The *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal*, adopted in 1989 and entered into force in 1992 (40);
- *The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, adopted in 1998 (1);
- *The Stockholm Convention on Persistent Organic Pollutants*, adopted in 2001 (44).

B. International policy instruments that provide a general policy context for pesticide management.

- The *Convention Concerning Safety in the Use of Chemicals at Work*, adopted in 1990 and entered into force in 1993 (45);
- The *Rio Declaration on Environment and Development*, proclaimed by the United Nations Conference on Environment and Development in 1992 (46);
- *Agenda 21 – Global Programme of Action on Sustainable Development*, and more specifically chapters 14 (*Promoting Sustainable Agriculture and Rural Development*) and 19 (*Environmentally Sound Management of Toxic Chemicals, Including Prevention of Illegal International Traffic in Toxic and Dangerous Products*), adopted in 1992 (47);
- The *Convention on Biological Diversity*, adopted in 1992 and entered into force in 1993 (48);
- The *Convention Concerning the Prevention of Major Industrial Accidents*, adopted in 1993 and entered into force in 1997 (49);
- The *Rome Declaration on World Food Security* and *The World Food Summit Plan of Action*, adopted in 1996 (50);

The *World Health Declaration and Health-for-all in the 21st Century*, adopted in 1998 (51).

Annex 2

FAO Council Resolution xx/XX

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**REVISION OF THE TEXT OF THE INTERNATIONAL CODE OF CONDUCT
ON THE DISTRIBUTION AND USE OF PESTICIDES**

**COMPILATION OF COMMENTS FROM GOVERNMENTS
RELATING TO PARAGRAPHS 6.1.7 AND 6.1.8**

Rome, August 2002

Comments Received in Reply to Note Verbale G/AGP-22Rev. 2
of 17 July 2002

Argentina

Costa Rica

Germany

Indonesia

Japan

Morocco

Niger

Norway

South Africa

Switzerland

ARGENTINA:

I have the pleasure to refer to your note G/AGP-22/Rev. 2 regarding approval of the FAO International Code of Conduct on the Distribution and Use of Pesticides.

On the express instructions of my Government, I have the pleasure to inform you that my country has no objections to the amendments suggested for paragraphs 6.1.7 and 6.1.8 at the Technical Consultation in relation to paragraph 6.1.7 of the Revised Version of the International Code of Conduct on the Distribution and Use of Pesticides (Rome, 27 to 29 May 2002).

COSTA RICA:

With regard to the outcome of the Technical Consultation held from 27 to 29 May of this year in Rome, and during which amendments were explicitly requested to paragraph 6.1.7 and subparagraphs 6.1.7.1 and 6.1.7.2 of the Revised Version of the FAO International Code of Conduct on the Distribution and Use of Pesticides, to read as follows:

6.1.7 Protect undisclosed test and other data against unfair commercial use in a manner consistent with Article 39.3 of the TRIPS Agreement;

6.1.8 Provide public access to appropriate information related to human health and environmental safety;

we wish to inform you that, once the document has been revised to include this outcome of the Technical Consultation, we have no substantial comments to make and agree with protecting registration information against unfair use, and with providing public, but regulated, access solely in the context of risk to human health and environmental safety.

GERMANY:

Germany can still agree to the language found by the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards, and Prior Informed Consent in 2001 which reads as follows:

"Article 6.1.7. Governments should without prejudice to the provisions of TRIPS (Article 39) relating to protection of undisclosed information (34):

6.1.7.1 when registering pesticides, prevent the use of data generated by one company to support the registration of another, unless by agreement with the owner of the data or unless an appropriate period of protection, as defined by national legislation, has expired;

6.1.7.2 provide public access to information, particularly relating to human health and environmental safety, provided adequate steps are taken to prevent the unauthorized use of data to support the registration of the product of another company."

As far as we can see this wording is in line with the current EU-legislation.

Germany cannot agree to the revised version, which was recommended by the government consultation in May 2002.

This version may cause difficulties, because it is strongly related to the TRIPS Agreement which is silent on important issues relating to the registration of new and existing chemical entities. Further, the relevant TRIPS provision, Article 39.3, does not differentiate between complete data reports and summary information, does not define the period when information can or cannot be disclosed, refers only to new chemical entities, and does not cover the generation of data for new uses or for the re-registration of older compounds.

If the proprietary rights to use of data of the companies are not ensured, needed innovations may become critical in the future. Companies will no longer be interested in intensive research programs, if the financial return of investment cannot be calculated.

Nevertheless, if there is no consent possible for the first recommendation, it should be tried to find a way to combine the old version

"Governments should protect the proprietary rights to use of data."

with the recommendation for Article 6.1.8

"Governments should provide appropriate information related to human health and environmental safety."

Such a version would be short and includes, that sufficient information of the public is ensured while the proprietary rights of the companies are guaranteed as laid down in national legislations.

INDONESIA:

In responding to your letter Ref. PL 32/1Prog 431 dated 6 August 2002 regarding the comments on the revised version of the International Code of Conduct on the Distribution and Use of Pesticides, I am pleased to inform you that Indonesia does agree to the revised version. In line with this, Indonesia would also like to propose a revision to the Article 6, Para 6.1; Sub Para 6.1.7.1 of the International Code of Conduct on the Distribution and Use of Pesticides as follows:

In principle, supporting data requested for registration are provided by applicants, however, data of long term toxicity, inhalation, decomposition time and environmental toxicity generated by FAO

publication or any other related institutions might be applied as its property rights are due. Unless data of formulation's toxicity, formulation's composition, efficacy, marine toxicity, resistency and resurgency are available, they are supposed to be done individually.

JAPAN

Article 6.1.7

Japan does not have any objection on the proposed text, while it has some concern on the protection of data on Agricultural Chemical Products from unfair commercial use. Although this text is based on article 39.3 of the TRIPS agreement, it seems that each country may have a different understanding on the text, especially on intellectual property rights. This may cause some troubles, especially in countries which have no or poor regulation for protection intellectual property rights.

Article 6.1.8

The provided text can be read as if there is no limitation to access information related to human health and environmental safety by public, while Japan believes that adequate steps should be taken to protect data from unfair commercial use by a third party. This concept is consistent with article 6.1.7 and Japan thinks it better to clearly mention this concept also in the Article 6.1.8. Therefore, Japan proposes to add the phrase of the prior draft Article 6.1.7.2, namely, "provided adequate steps are taken to prevent use of unauthorized data to support the registration of the product of another company" at the end of the proposed text of Article 6.1.8.

MOROCCO:

I have the pleasure to inform you that the Ministry of Agriculture has no specific objection to the revised version of the FAO International Code of Conduct on the Distribution and Use of Pesticides and approves the recommendations of the Technical Consultation and the new wording of paragraph 6.1.7.

NIGER:

With reference to circular letter G/AGP-22/Rev. 2 of 17 July 2002 regarding comments of the Government of Niger on paragraph 6.1.7 of the report of the Technical Consultation, held in Rome from 27 to 29 May 2002, please find attached the comments of the relevant services of the Niger.

"Subparagraphs 6.1.7.1 and 6.1.7.2 should be included as follows:

- Subparagraph 6.1.7.1: when registering pesticides, prevent the use of data generated by one company to support the registration of another, unless by agreement with the owner of the data or unless an appropriate period of protection, as defined by national legislation, has expired.

Subparagraph 6.1.7.2: provide public access to information, particularly relating to human health and environmental safety, provided adequate steps are taken to prevent the unauthorized use of data to support the registration of the product of another company.”

NORWAY

Referring to your letter dated 17 July 2002 we have reviewed the Revised Text (paragraphs 6.1.7 and 6.1.8) of the Draft Revised Version of the FAO Code of Conduct on the Distribution and Use of Pesticides.

We support the proposal made by the Technical Consultation held in Rome 27-29 May 2002 (among others attended by Norway). We do hope that this revised text finally will be accepted by all members at the FAO Council Session in November 2002.

SOUTH AFRICA

Your letter dated 17 July 2002 requesting comments on paragraph 6.1.7 and 6.1.8 refers. South Africa is in agreement with the revised text of the above-mentioned paragraphs. The revised text is consistent with Article 39.3 of the TRIPS Agreement.

SWITZERLAND

Please find below Switzerland's remarks on the revised version of the International Code of Conduct on the Distribution and Use of Pesticides.

These comments refer to paragraphs 6.1.7 and 6.1.8:

Para. 6.1.7

Switzerland agrees with the substance of this paragraph, which prevents test and other confidential data from being used illicitly, leading to unfair commercial use for the registration of plant protection products.

Para. 6.1.8

Switzerland agrees with the substance of this paragraph, provided that the term "appropriate information" does not refer to the data obtained from the testing mentioned in para. 6.1.7, but refers to information of broad interest to pesticide use (for example, toxicological assessments based on exposure evaluations of the registration authorities, MRLs, ecotoxicological classifications, technical

conditions of use, withdrawal times). Ensuring public access to appropriate information on the proper use of pesticides and the risks to human health and environmental safety is a responsible way of safeguarding public health and of providing the transparency needed in the authorization of plant protection products.

Para. 6.1.8 of the previous version ("improve relations in relation to collecting and recording data on import, export, manufacture, formulation, quality and quantity of pesticides") is no longer included in the revised text of the present version. Switzerland considers that this text should be reinserted into the revised version.