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HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION (ARTICLE 18)

Note by the Executive Secretary

INTRODUCTION

1. In adopting the work plan of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) (decision V/1, annex), the Conference of the Parties to the Convention on Biological Diversity indicated that the Committee should consider Article 18 at its first meeting and, if necessary, at its second meeting as well. In particular, the Conference of the Parties requested the ICCP to consider:

(a) Overview of relevant international rules and standards pertaining to handling, transport, packaging and identification; and

(b) Consideration of modalities for developing standards with regard to handling, transport, packaging and identification.

2. The present note has been prepared by the Executive Secretary to assist the ICCP in these tasks. The following section provides an overview of relevant international rules and standards pertaining to handling, transport, packaging and identification. As one of the purposes of this section is to consider the need for developing standards, it provides a "gap analysis". Consequently, the section concentrates on describing the existing regime for the handling, transport, packaging and identification of living modified organisms (LMOs).

3. In accordance with the ICCP work plan, section II of the note draws some preliminary conclusions and considers the modalities for developing standards with regard to handling, transport, packaging and identification. Based on the information provided in sections I and II, section III sets out suggested recommendations for the consideration of the ICCP. In particular, it suggests that the ICCP may wish to invite Governments and relevant organizations to submit to the Secretariat their current practices pertaining to the requirements of paragraph 2 (a) of Article 18 of the Protocol, with a view to presenting the ICCP at its second meeting with a synthesis/overview of current practices, which would

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allow it to propose recommendations for the first meeting of the Parties to the Protocol on the need for and modalities of developing standards with respect to identification.

I. OVERVIEW OF RELEVANT INTERNATIONAL RULES AND STANDARDS PERTAINING TO HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

4. Article 18 of the Protocol makes a distinction between the "handling, transport and packaging" of LMOs and the "identification" of LMOs. With respect to the handling, transport and packaging of LMOs, paragraph 1 of the Article provides that "each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards".

5. Paragraph 2 sets out the obligations of Parties with respect to the identification of LMOs and provides different obligations for LMOs intended for direct use as food or feed or for processing (LMO-FFPs) (subparagraph (a)), LMOs destined for contained use (subparagraph (b)), and LMOs intended for intentional introduction into the environment (subparagraph c)).

6. Similar distinctions are manifest in regulatory regimes addressing the transport of dangerous goods, where it is common to have requirements dealing with handling, transport, packaging, storing and the like in one set of regulations and labelling in another.

7. Moreover, this distinction is carried through in terms of the anticipated outputs resulting from the ICCP consideration of this issue, which were described as follows in the note by the Executive Secretary on the proposed work plan for the Committee prepared for the fifth meeting of the Conference of the Parties to the Convention (UNEP/CBD/COP/5/6/Add.1):

(a) Detailed requirements regarding documentation accompanying LMO intended for direct use as food or feed or for processing; and

(b) Need for and modalities of developing standards established.

8. Accordingly, the present section will provide an overview of the relevant rules and standards pertaining to the "handling, transport and packaging" of LMOs and then consider the relevant rules and standards with respect to the "identification" of LMOs.

9. The legal and institutional complexity of the relevant rules and standards regarding Article 18 mean that it is not possible to comprehensively describe them in the present. The note therefore limits itself to a selective overview of rules and standards as of 1 September 2000. The information provided has been collected only to inform the ICCP with respect to its consideration of Article 18. Therefore, the rules and standards described have been selected as being representative of general pertinent trends and issues. Some of the rules and standards were not yet in force as of 1 September 2000, and some may have significantly changed since the preparation of this note. The contents of the note in no way purport to provide legal advice as to the requirements for handling, transport, packaging or identification of LMOs.

A. Handling, transport and packaging

10. There are no specific global rules or standards that cover the handling, transport or packaging of LMOs for the purposes of the Protocol. A few of the specific global initiatives considering LMOs or GMOs address the handling, transport and packaging of LMOs in a broad and general manner. For example, the UNEP International Technical Guidelines for Safety in Biotechnology simply provide that:

> "In order to maintain safety levels during transport and transit, organisms with novel traits should be packed and labelled adequately. Packaging and labelling requirements should be commensurate with the level of risk involved. In order to maintain safety during transit and transport, existing international recommendations, agreements and conventions on transport should be taken into account."

11. There are, however, a number of regional initiatives that have established, or are in the process of establishing, specific standards for the handling, transport and packaging of LMOs. The most developed regional regime is the one promulgated by the European Union centred on directives 90/219 and 90/220 and regulations 258/97 and 2309/93. Other regions with some standards or developing standards include that of the Organisation for Economic Co-operation and Development (OECD), the Australian and New Zealand region and the Antarctic region.

12. In addition to the above and perhaps of more relevance in terms of specific and detailed standards, are the general rules governing the international movement of substances and goods. In many cases, LMOs are either specifically covered or will fall within the general definitions of goods. These rules tend to be focused on the mode of transport (generally known as modal requirements). For example, the International Maritime Organization (IMO) has developed rules and standards that deal with the transboundary carriage of goods by sea, which are to a certain extent relevant to the transboundary shipment of LMOs. A well-known set of such standards is the International Maritime Dangerous Goods Code (IMDG Code), but this is by no means the only relevant set of standards developed by IMO. The International Civil Aviation Organization (ICAO) and the International Air Transport Association (IATA) have developed rules and standards that govern airfreight, which are applicable to LMOs (e.g., the ICAO Technical Instructions and IATA Dangerous Goods Regulations). The Universal International Postal Union has developed rules and standards for the shipment of goods by post (see, for example, the 1995 *Manual of the Universal Postal Convention*) that are also applicable to LMOs (i.e., the sending of modified microbial organisms by post).

13. For some classes of goods, especially those that pose a special danger to human or animal health and the environment, more specific or more detailed requirements have been developed by various bodies, which to some extent will also cover LMOs. For example, international rules governing the transport of dangerous goods, microbial organisms, biological control agents, pests, alien and invasive species, bacteria, pathogens, biological waste products, and even animals will to varying extents cover the transboundary movement of LMOs. Examples of these include the International Plant Protection Convention (IPPC) and its various codes of conduct (e.g., the Code of Conduct for the Import and Release of Exotic Biological Control Agents), the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Destruction (i.e., waste categories Y2, Y4 and Y18, as well as hazardous characteristics H6.2 and H12), the Code of Conduct on Responsible Fisheries of the Food and Agriculture Organization of the United Nations (FAO) and the FAO International Code of Conduct on the Distribution and Use of Pesticides. Further details regarding most of these international rules can be found in documents UNEP/Bio.Div/Panels/Inf.4, UNEP/CBD/BSWG/2/3 and UNEP/CBD/BSWG/3/Inf.2.

14. A further layer of rules and standards of relevance are the international rules and standards for quarantine and customs procedures. One important set of rules in this regard is the system of harmonised customs codes developed pursuant to the International Convention on the Harmonized Commodity Description and Coding System administered by the World Customs Organization (WCO).

15. Moreover, regional and national rules and standards need to be taken into account. For example, if the transport of certain LMOs takes place with a member State of the European Union, account may need to be taken of the relevant directives on the transport of dangerous goods by rail (96/49/EC,

96/87/EC and 96/35/EC), road (96/86/EC, 96/35/EC, 95/50/EC and 94/55/EC) or sea (97/34/EC, 96/39/EC, 93/75/EC and 95/50/EC). Reference may also need to be made to:

(a) European Culture Collections' Organization (ECCO). *Shipping of Non-infectious, Infectious and Genetically Modified Microorganisms*: *International Regulations*, 1995;

(b) European Standard EN 829:1996 E: Transport packages for medical and biological specimens, requirements, and tests. Brussels: CEN, European Committee for Standardization;

(c) The World Health Organization (WHO). *Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens*, 1997;

(d) The World Health Organization (WHO). *Laboratory Biosafety Manual*, 1993.

16. Other regulations that need to be considered in Europe at least include: rules governing the protection of workers (e.g., directive 90/679) and control of distribution of agents that could be used in biological warfare and European Union regulation 3381/94/EEC on the control of export of dual-use goods.

17. Finally national regulations will also be relevant. For example, many countries have implemented the modal requirements mentioned above, particularly those related to the transport of dangerous goods. Moreover, in Europe, many of the European Union requirements have been expanded in many of the individual member States. Similarly, other countries have detailed requirements for various aspects of Article 18. For example, a survey of regulations in 1997 concluded that within the United States, Denmark, India, Thailand, the Philippines and Australia there were requirements at the time for specific and detailed packaging requirement to ensure safety during transport and transit not only for LMOs considered as infectious substances but also the following groups of LMO: transgenic plants and plant parts, seeds, microorganisms and/or cells or sub cellular elements, insects, mites and related organisms or other macroscopic organisms; for research, large scale experiments, production, experimental releases, teaching, exhibition, etc.

United Nations Recommendations on the Transport of Dangerous Goods

18. Despite this array of rules, standards and processes of relevance to the transboundary movement of LMOs, an appropriate starting point and relevant set of rules for the consideration of the ICCP are the United Nations Recommendations on the Transport of Dangerous Goods developed by the United Nations, which are popularly known as the “Orange Book” (document ST/SG/AC.10/11/Rev.3) and which are revised annually.

19. The Recommendations are addressed to Governments and international organizations concerned with the regulation of the transport of dangerous goods. The Recommendations are designed to present a core set of provisions that should "allow for the uniform development of national and international regulations governing the various modes of transport". Areas covered include:

(a) List of dangerous goods most commonly carried and their identification and classification;

(b) Consignment procedures; labelling, marking and transport documents;

(c) Standards for packing, test procedures and certification; and

(d) Standards for multimodal tank-containers, test procedures and certification.

20. The Recommendations adopt a system that categorizes goods by the types of risk associated with their transportation. There are nine different classes. The two most relevant for the purposes of the

present note are division 6.2 ("Infectious Substances"); and division 9 ("Miscellaneous Dangerous Substances and Articles").

21. Infectious substances are defined as substances known or reasonably expected to contain pathogens, which are defined as microorganisms or recombinant microorganisms that are known or reasonably expected to cause infectious diseases in humans or animals. This definition is operationalized in the WHO *Laboratory Biosafety Manual* (1993, World Health Organization). This uses four categories related to the pathogenicity of the organisms, the mode and relative ease of transmission, the degree of risk to an individual and the community, and the reversibility of the disease. Group 4 is the most dangerous and relates to:

> "pathogens that cause serious disease in human or animal recipients. These pathogens are highly contagious and effective treatment and prevention methods are not readily available. They present high risks to both individuals and communities."

22. Group 1 includes microbes that are unlikely to cause human or animal diseases and these substances are not covered by the Recommendations. For substances in groups 4, 3 and 2, the Recommendations outline the responsibility of the consignor, general packaging requirements and communication on information, packaging requirements, test requirements of repackaging, responsibility of the carrier, responsibility of the consignee, action to be taken in the event of damage or leakage, international notification. Genetically modified microorganisms and organisms are specifically included in this scheme (see paragraph 6.9.3).

23. "Miscellaneous dangerous substances and articles" cover substances and articles not covered under the other divisions. Genetically modified microorganisms that are not dangerous for animals or humans, but which could modify animals, plants, microbiological substances and ecosystems in a way that does not occur naturally are included in this division. It also comprises genetically modified organisms that are known or suspected to be dangerous to the environment, and which shall be carried in accordance with conditions specified by the competent authority of the country of origin.

24. The Recommendations, even though intended to cover all basic provisions for the safe carriage of dangerous goods, have to be completed by additional requirements which may have to be applied at the national level or for international transport depending on the mode of transport envisaged. Model legislation has been developed for this purpose. A Manual of Tests and Criteria, which assists with the classification of substances, has also been developed.

25. The following modal requirements are the most important examples of the further elaboration of the United Nations Recommendations:

(a) The IMO International Maritime Dangerous Goods Code (IMDG Code);

(b) The ICAO Technical Instructions and IATA Dangerous Goods Regulations;

(c) The European Agreement concerning the Carriage of Goods on the Rhine (ADNR);

(d) The International Agreement on the Transport of Dangerous Goods by Rail (RID);

(e) The European Agreement on the Transport of Dangerous Goods by Road (ADR);

(f) The UPU *Manual of the Universal Postal Convention*, 1995, which contains detailed regulations for the transport of biological substances by post/mail.

26. For example, the IATA Dangerous Goods Regulations require that shippers of microorganisms of various classes of microorganism must be trained by IATA certified and approved instructors. They also

require shippers' declaration forms, which should accompany the package in duplicate, and specified labels are used for organisms in transit by air.

27. The Recommendations have been developed by the United Nations Committee of Experts on the Transport of Dangerous Goods. The Committee is a subsidiary body of the Economic and Social Council (ECOSOC). The United Nations Economic Commission for Europe provides the secretariat for this Committee. Its next session is scheduled for 4-14 December 2000. It will consider publication of the twelfth edition of the Recommendations, its role with respect to implementation of the Agenda 21 and proposal for developing the Recommendations with respect to chemicals. It will also consider activities of international organizations concerned with regulations or recommendation on the transport at the international level of dangerous goods.

28. A chart illustrating the organization of the Committee and its relationship to the rules of other international bodies is provided in annex I below.

B. Identification

29. As with handling, transport and packaging the relevant rules and standards are vast in number and complex in scope and nature. Many of the regimes described in the previous section with respect to handling, transport and packaging also contain rules and standards with respect to documentation that is required to accompany the relevant shipment. For example, the United Nations Recommendations require, *inter alia*, that itemized lists of contents be included within the packaging and that if the packaging is to have a United Nations packaging symbol it must include: a code designating the type of packaging according to the provisions of 9.4, the text "CLASS 6.2", the last two digits of the year of manufacture, the State authorizing the allocation of the mark, indicated by the distinguishing sign for motor vehicles in international traffic, the name of the manufacturer or other identification of the packaging specified by the competent authority and the packaging meeting the requirements of 6.14.8. These requirements are further elaborated in the modal requirements (e.g., the IATA regulations). For example, the IATA DGR lists several thousand substances and classifies them according to the United Nations Recommendations. It also provides a standard formats for a shipper's declaration and waybill, which must accompany any consignment covered by the DGR. A copy of the shipper's declaration form can be found in annex II below.

30. Moreover, identification requirements that have been developed for safety reasons (e.g., veterinary products), quality considerations (e.g., geographical origin of production), control authority considerations (e.g., bills of lading) or product-management considerations (e.g., bar codes) or to convey information factually (e.g., a list of ingredients) will also be relevant to paragraph 2 of Article 18.

31. In addition to these general documentation requirements, a number of other bodies have developed or are developing rules and standards with respect to identification and documentation that is relevant for the purposes of this Note. With few exceptions, these initiatives have to date focused on food safety for consumers. The following provides a brief overview of some of the more relevant, or potentially relevant, activities. It must be stressed at the outset that not all of these activities will necessarily develop international standards or rules of relevance to paragraph 2 of Article 18. Nevertheless, identification is within their mandate, albeit sometimes not the focus of their work, and consequently their activities may become relevant in the future.

Codex Alimentarius

32. The Committee on Food Labelling of the Codex Alimentarius Commission is developing recommendations for the labelling of foods obtained through biotechnology through an amendment to the general standard for the labelling of pre-packaged foods. Section 2 ("Definition of Terms") and Section 5

("Additional Mandatory Requirements") were discussed by the Committee in May 2000. At this meeting, it was decided to advance the section on the labelling of allergens in the draft Recommendations for the Labelling of Foods obtained through Biotechnology for adoption by the Commission at its twenty-fourth session. The Committee also agreed to return the section on definitions for further comments; and agreed to redraft the section on mandatory labelling for redrafting and further comments.

33. In June 1999, The Codex Alimentarius Commission established an Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology to develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnologies or traits introduced into foods by biotechnological methods.

34. The Task Force held its first session from 14 to 17 March 2000. At this meeting, the Task Force established a Working Group (chaired by Japan) to develop:

(a) A set of broad general principles for risk analysis of foods derived from biotechnology, including science-based decision making; pre-marked assessment, post-market monitoring, transparency; and

(b) Specific guidance on the risk assessment of foods derived from biotechnology, including matters such as food safety and nutrition, substantial equivalence, non-intentional effects and potential long-term health effects;

The Task Force agreed to give preference to guidance that was applicable to all foods derived from biotechnology.

35. It also agreed that consideration should be given to the development of guidelines for transparency in decision-making and the participation of all stakeholders in the decision-making process, and that careful attention should be given to the development of adequate and appropriate definitions drawing on other agreed texts.

36. The Task Force further agreed that a list of available analytical methods including those for the detection or identification of foods or food ingredients derived from biotechnology should be prepared, and that this list should indicate the performance criteria and status of the validation of each method. A Working Group chaired by Germany is in charge of compiling the list.

37. A preliminary report to the CAC is due in 2001 with a final report due in 2003.

OECD

(a) Working Group and Task Force

38. In recent years the most directly relevant work of the OECD has been undertaken by the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, established in 1995 to manage the implementation of the OECD programme for harmonization of regulatory oversight in Biotechnology. The activities of Task Force for the Safety of Novel Foods and Feeds, established in 1998 to consider safety of foods and feeds derived from biotechnology, are also relevant. The major task of both the Working Group and the Task Force is to develop so called consensus documents, which comprise technical information for use during the technical assessment of products of biotechnology (i.e. describing the morphology, physiology and ecological characteristics of the taxon concerned, as well as specific traits introduced by biotechnology, such as herbicide tolerance) and are intended to be mutually recognized among OECD Member Countries. Ten such consensus documents have been published to date. There is no consensus document dealing specifically with labelling. An important activity of the Working Group has been the establishment, in cooperation with the United Nations Industrial

Development Organization (UNIDO), of Biotrack, an international database of LMO products and LMO field releases in member countries.

39. In June 1999, G8 Heads of State and Government meeting in Cologne, Germany, requested the Working Group and the Task Force to undertake a study of the implications of the biotechnology and other aspects of food safety. The reports of both the Working Group and the Task Force were submitted to the G8 meeting in July 2000. Neither report came to any relevant conclusions regarding labelling, although they both acknowledged that labelling played a role in some countries attempts to control the products of biotechnology. The G8 Heads of States welcomed these reports and also welcomed the further work agreed to by the OECD Ministers.

40. Under the auspices of the Working Group, the OECD is convening the Workshop on Unique Identification Systems for Transgenic Crops in October 2000. The main objectives of the Workshop is to identify ways to improve the product database (http://www.olis.oecd.org/bioprod.nsf), which currently includes summary information on those products of modern biotechnology which have been approved for commercial use in OECD member countries. A major aim of the Workshop will be to identify the most efficient means of establishing a method of unique identifier for transgenic organisms, and to draft a recommendation to the OECD Working Group on how to move forward with this issue. The recommendation will be based on using existing data basis to assist with identification, with particular attention being given to Biotrack Online and BINAS.

41. A new Ad Hoc Group on Food Safety was established to cover issues that are beyond the scopes of the Task Force and the Working Group. It will cover food safety in general, as well as food safety management issues. The work of the Ad Hoc Working Group encompasses the establishment of a compendium of international food safety systems and a national compendium on current and planned food safety requirements.

(b) OECD Schemes for the Varietal Certification of Seeds Moving in International Trade

42. The OECD Seed Schemes were developed primarily to facilitate international trade in seeds, by harmonizing varietal certification procedures and identification labels. The Schemes are implemented by a total of 48 member and non-member countries across all continents. Their essential purpose is to harmonize the assessment and certification of identity and purity of cultivated crop plant varieties – including genetically modified ones.

43. National and international regulation of products of modern biotechnology, in particular the segmentation of some markets into GMO and non-GMO products, will have a direct impact on international seed trade. In August 1999, the International Seed Federation (FIS) proposed an initiative to examine the feasibility of establishing a system approach, based on the existing OECD seed certification schemes, for measuring and certifying the transgenic purity of seed in response to market-demanded or publicly required thresholds. This approach could include a defined methodology for product identification and traceability, as well as harmonized protocols for operation and monitoring, based on shared and accessible technologies. The initiative reflects the seed industry's resolve to find science-based solutions supported by formal management system controls for responding to public and regulatory concerns.

The International Plant Protection Convention

44. The International Plant Protection Convention (IPPC) was established to promote appropriate measures to prevent and control the spread and introduction of pests of plants and plant products. Its objectives include the development and application of international standards in international trade to

prevent introduction and dissemination of plant pests. The Convention's governing body is currently the Interim Commission on Phytosanitary Measures (ICPM).

45. At its second meeting, in October 1999, the ICPM considered standard-setting in relation to GMOs, in particular risk assessment and testing and release of GMOs. As a result the ICPM established an open-ended working group to further examine the role of the IPPC in relation to GMOs, biosafety, and invasive species. The terms of reference for the working group are to develop a statement on the role of the IPPC in assessing the plant pest risk of GMOs, and the relationship between invasive species and plant quarantine pests. A further task of the working group is to identify the roles and responsibilities of other relevant bodies and any overlaps or potential overlaps with the role of the IPPC and consider the necessity of developing and adopting international standards under the IPPC. The working group met in June 2000. It recommended to the ICPM that standards that specifically address plant pest risks of LMOs be developed under the IPPC as a matter of urgency. It also recommended close cooperation with the CBD. The third meeting of the ICPM in April 2001 will consider these recommendations.

United Nations Economic Commission for Europe (ECE)

46. The first Meeting of Signatories to the ECE Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters established a Task Force on GMOs. The Task Force meet in April 2000 and, *inter alia*, considered the role of labels in informing the public. It concluded that they have an important role in enabling consumers to make informed choices. The Task Force also examined national experiences and examples of good practice and has drawn up recommendations to further implement public access to information on GMO-related issues. The second Meeting of Signatories considered the report of the Task Force, requested that it continue its work and noting the wish of the Ministers that this issue should be addressed at the first meeting of the Parties (ECE/CEP/43/Add.1/Rev, para. 15), it was agreed that the outcome of the next meeting of the Task Force should be presented to an open-ended intergovernmental working group, which would prepare a draft decision for the Meeting of the Parties.

The European Community

47. European Community directive 90/220, on the deliberate release into the environment of GMOs, originally contained only a broad reference to labelling. Following a 1997 amendment, the European Commission established mandatory labelling when a product covered by the Directive consists of or contains GMOs. Directive 90/220 is curently under revision with its adoption due to take place at the end of 2000. The common position adopted by the Council (12/2000/EC of 9 December 1999) specifies that GMOs to be placed on the market shall be subject to adequate labelling requirements in order to provide for clear information on the presence of GMOs. To this end, the words "This product contains genetically modified organisms" shall appear either on a label or in accompanying documentation.

48. Food and food ingredients produced from GMOs have to be labelled according to regulation 258/97 (Novel Foods Regulation) and regulation 1139/98 (labelling of two particular GM soya and maize products). The Novel Foods Regulation requires specific labelling rules for products developed through biotechnology. It lays down mandatory labelling and requires that consumers be informed of differences between a new product and existing equivalent products. The label has to provide the final consumers with information on:

(a) Any characteristic of food property which renders a novel food of food ingredient no longer equivalent to an existing food or food ingredient;

(b) The presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;

(c) The presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns;

(d) The presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in directive 90/1220/EEC (Article 8).

49. Under regulation 50/2000, the above labelling requirements have been extended to include foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms. Regulation No. 49/2000 allows a *de minimis* labelling threshold of 1 per cent (of each ingredient individually considered) for the accidental content of genetically modified material in non-GM products. The labelling provisions are expected to be further developed by the end of this year, in particular, with respects to additives produced through genetic engineering.

The Australia-New Zealand Food Authority Standards

50. The Australia-New Zealand Food Authority (ANZFA) has developed standards for genetically modified foods, which came into effect on 13 May 1999. The regulations (Standard A18) require labelling of foods that are substantially different from their conventional counterparts. In July 2000, the Australian and New Zealand Health Council agreed that the labelling requirements should be extended to all genetically modified (GM) foods, for the purpose of consumer information. The decision provided for a number of exceptions, such as food prepared at point of sale or highly refined food when the effect of the refinement process is to remove the novel DNA or protein. The decision also allows an ingredient to contain up to 1 per cent of unintended presence of GM products.

National measures

51. The most important source of relevant rules and standards are domestic or national ones. Many countries have in recent years taken measures to promote or require labelling of LMOs. Many more are actively considering adopting such measures or developing existing measures. For example, member States of the European Union have implemented the requirements of directive 90/220 and the Novel Food Regulations mentioned above and are considering further developments as well. India has announced that it is in the process of developing legislation requiring the labelling of LMOs. This section provides some other examples of domestic measures with a view to highlighting the range and type of measures being taken by countries, as well as the range of countries invovled. It is not, nor is it intended to be, comprehensive.

52. During 1999, the United States Food and Drug Administration (FDA) reviewed the effectiveness of safety evaluation and labelling requirements of food derived from bio-engineered plant varieties. With respect to labelling, FDA conducted public consultation on the following questions:

(a) Should the FDA policy requiring labelling for significant changes, including changes in nutrients or the introduction of allergens, be maintained or modified? Should FDA maintain or revise its policy that the name of the new food be changed when the common or usual name for the traditional counterpart no longer applies? Have these policies regarding the labelling of these foods served the public?

(b) Should additional information be made available to the public about foods derived from bioengineered plants? If so, what information? Who should be responsible for communicating such information?

(c) How should additional information be made available to the public: e.g., on the Internet, through food information phone lines, on food labels, or by other means?

53. FDA accepted written comments on these issues until 13 January 2000 (also available at http://www.fda.gov/oc/biotech/default.htm). On 3 May 2000, it was announced that FDA is planning to draft labelling guidance to assist manufacturers who wish to voluntarily label their foods being made with or without the use of bioengineered ingredients. The guidelines will help ensure that labelling is truthful and informative. To receive maximum consumer input, FDA announced that it would develop the guidelines with the use of focus groups and would seek comments from the public on the draft guidance.

54. A bill requiring labelling of all foods that contain genetically modified entity was introduced in the United States Congress in November 1999 (Kucinich bill – H.R.3377). It is unlikely that Congress will consider the bill at its current session. Like all bills, H.R. 3377 has to be referred to one or more committees of jurisdiction. In this case, those two committees are House Agriculture Committee, and House Commerce Committee. Currently, neither committee has plans to take up the issue of genetically modified organisms in general, let alone the Kucinich measure in particular. In the view of the committees, the issue is so new and undeveloped that Congress would not be eager to rush in to legislate. On March 2000, Mr. Kucinich introduced additional legislation (H.R.3883) directing FDA to overhaul its procedures for reviewing the safety of genetically modified foods.

55. The Japanese Government recently introduced mandatory labelling requirements for final products containing genetically modified organisms, in response to consumer concerns. A committee in charge of developing rules for labelling was established in 1997 under the auspices of the Ministry of Agriculture, Forestry and Fisheries. The public was encouraged to comment on the draft legislation and the committee received more than 10,000 submissions. The labelling system will apply to a variety of food products, most of them included in the Japanese traditional diet, that contain genetically modified ingredients, such as modified corn, soybeans, potatoes, and rapeseeds. Labelling standards were released in April 2000 and compliance with them will likely become mandatory by April 2001. The labelling system is supposed to give information to consumers to allow them to make an informed choice.

56. In case the presence of genetically modified inputs is not proved, but the producers cannot exclude that some GM materials have been used, this has to be indicated in the label. A voluntary "GM-free" labelling system has already been implemented.

57. On 8 July, China passed a law that will take effect on 1 December 2000 that will require the labelling of genetically modified seeds. The law requires seeds for genetically modified crops to be clearly labelled and have instructions for safe use of the product. The law only pertains to genetically modified seeds, not to food products made from genetically modified crops.

58. In Switzerland, the law on environmental protection adopted in 1995 requires that products, such as seeds, that contain living modified organisms are clearly identified as such. Regulations adopted in 1999 further require that food and products containing or derived from GMOs are clearly labelled if they contain more than 1 per cent of transgenic material.

59. In Canada, the Canadian Council of Grocery Distributors, representing about 80 per cent of Canadian food industry retailers, agreed in September 1999 to develop a voluntary labelling regime for genetically modified foodstuffs in partnership with the Canadian General Standards Board and a variety of stakeholders from industry, environmental groups, consumer groups and academia. The label will indicate whether or not a specific food is obtained through genetic modification. The committee

established for this purpose is developing general principles and models for voluntary declarations, procedures required to verify the truthfulness of these declarations, principles of a certification mechanism, and definitions that are clear and concise. A draft standard is expected to be completed before the end of 2000. This initiative is largely a response to consumer demand for more information on genetically modified foods. The Canadian Government is supporting this approach and considers it to be consistent with its international trade obligations.

60. In October 1999, Thailand announced a partial ban on imports of genetically modified seeds pending clear scientific evidence on their safety. A committee to consider the safety of GM products has recently been set up by the Public Health Ministry. In response to consumer concern, the Thai Food and Drug Administration is considering imposing a mandatory labelling system for all products using genetically modified organisms, starting in 2001. Discussions will be held about how much GMO content in a product should warrant labelling.

61. In March 2000, the Republic of Korea passed legislation regarding mandatory labelling of genetically modified soybean, corn and soybean sprouts. It will enter into force in 2001. Violators are punishable by fines up to $27,000 or three years in prison.

62. Also in March 2000, the Mexican Senate unanimously passed a reform of the General Health Law so that transgenic foods, whether produced domestically or outside Mexico, carry a label that identifies them as such and specifies the type of genetic modification that has taken place. The Mexican Chamber of Deputies still has to approve the bill.

C. Other relevant international rules and standards

63. Efforts to develop rules and standards for handling, transport, packaging and identification of LMOs will also need to take into account other relevant international rules that impose conditions or restrictions on the establishment of such rules and standards. In this respect, particular attention needs to be paid to the relevant principles regarding international trade and liability.

World Trade Organization (WTO)

64. Even though the Cartagena Protocol and the WTO are mutually supportive, clarification of the requirements of Article 18 will nevertheless need to take into account the requirements of the WTO, so as to remain compatible with these rules. In particular, rules or standards developed regarding, packaging, labelling and handling will specifically need to consider obligations under the General Agreement on Tariffs and Trade (GATT), the Agreement on Technical Barriers to Trade (the TBT Agreement) and the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

65. The SPS Agreement deals with food safety, animal and plant health and invasive species. Paragraph 2 or article 2, states that WTO members should ensure that any such measure is based on "scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of article 5". Paragraph 7 of article 5 allows members to adopt measures provisionally “where scientific evidence is insufficient”.

66. Article 5, paragraph 5, provides also that each “Member shall avoid arbitrary or unjustifiable distinctions” in its standards. The SPS Committee has adopted “guidelines” to provide assistance to members in the practical implementation of this provision (see document G/SPS/15).

67. Article 3, paragraph 2, of the Agreement states that:

> "Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant

life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994."

68. Those standards developed by the Office International des Epizooties (OIE), the Codex Alimentarius Commission and IPPC are mentioned specifically in the Agreement and are therefore deemed to be WTO-consistent. For matters not covered by these agreements, “appropriate standards, guidelines and recommendations promulgated by other relevant international organisations open for membership to all Members, as identified by the Committee”, are the relevant criteria. To date, the Committee has not identified any other organizations in this regard.

69. Article 3, paragraph 3, of the Agreement allows members to "introduce or maintain sanitary or phytosanitary measures which result in a higher level of ... protection than ... measures based on relevant international standards, guidelines or recommendations, if there is a scientific justification".

70. The TBT Agreement applies to measures that are outside the scope of the SPS Agreement. Its basic requirements are that measures do not discriminate between “like products” (Article 2, paragraph 1) and are no more trade restrictive than required (Article 2, paragraph 2). The TBT Agreement also encourages WTO members to base their standards or technical regulations on internationally developed standards, but does not explicitly identify the relevant standard-setting bodies. Furthermore, a Government may choose not to base national requirements on an international standard if it considers this inappropriate to achieve its particular objectives. These objectives may include the prevention of deceptive practices, protection of human, animal or plant health or safety (if not covered by the SPS Agreement) or the environment. The TBT Agreement requires notifications similar to those for sanitary or phytosanitary measures, and further requires notification of bilateral technical agreements and compliance by national standard-setting bodies with a Code of Good Practice for the Preparation, Adoption and Application of Standards.

71. Discussions regarding GMO labelling requirements within the WTO have largely been in the context of the TBT Agreement and the "consumer’s right to know", rather than in the context of food safety concerns under the SPS Agreement. A total of 48 notifications were made from 1 January 1995 to 10 June 2000 concerning agricultural and food products derived from biotechnology through the notification provisions of the SPS and TBT Agreements. The notifications were made by: the United States, Japan, Canada, New Zealand, Australia, Switzerland, the European Union, Norway, Germany, the Netherlands, Mexico, Colombia, the Republic of Korea, Malaysia, and the Czech Republic. Interestingly, the European Union notified its regulations pursuant to the TBT Agreement and the United States pursuant to the SPS Agreement.

72. The 1994 General Agreement on Tariffs and Trade (the GATT) contains a further set of rules of relevance. In particular, article III of GATT provides that Members must not discriminate between imports from different sources or between like domestic and imported products. This provision is qualified by article XX, paragraphs (b) and (g), of GATT. Article XX, paragraph (b), allows a contracting party to take measures that are necessary to protect "human, animal or plant life or health". Under paragraph (g) of article XX, a party may take trade measures that are related to "the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption".

73. How these provisions would effect any specific development of Article 18 of the Cartagena Protocol is complex and dependent upon the exact nature of the development. Nevertheless, chapters 2 and 30 of Agenda 21 identified the following principles, which should apply if trade measures are found necessary for the enforcement of environmental policies and which give a general indication of the type of considerations which need to be borne in mind:

(a) The principle of non-discrimination;

(b) The principle that the trade measures chosen should be the least trade-restrictive necessary to achieve the objectives;

(c) An obligation to ensure transparency in the use of trade measures related to the environment and to provide adequate notification of national regulations.

III. CONSIDERATION OF MODALITIES FOR DEVELOPING STANDARDS WITH REGARD TO HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

74. A preliminary conclusion of the review is that despite the variety and array of existing rules and standards none comprehensively cover the scope of Article 18. For example:

(a) Many of the relevant rules governing transport of LMOs only apply within a certain geographical or political region (e.g., the OECD or European Union regimes) – with the consequence that many regions are not adequately covered;

(b) Few of the rules deal with the range of LMOs covered by Article 18. For example, many of the rules and standards focus on requirements for pathogens or dangerous organisms. As a result many types of genetically modified plants, for example, would not be covered by any existing rules and regulations;

(c) Many of the labelling requirements deal with food products (largely outside the scope of the Protocol), not living organisms;

(d) The stated purpose of most of the existing rules and standards is to protect human, animal or plant health, not the environment;

(e) Few regimes provide detailed or specific guidance on methods of safe transportation of such products or organisms that present a danger to the environment.

75. Moreover, those standards and rules that do exist differ in the use of terms, scope and requirements and provide for information to be channelled to different government agencies.

76. The legal and institutional complexity of the relevant international rules for Article 18 means that any specific procedures developed for the Protocol need to be drafted carefully and precisely. For example, careful consideration needs to be given as to which rules and bodies are relevant and whether the relevant existing regulations are inadequate or could simply be amended to meet the purposes of the Protocol. Given the wide range of situations possible within the scope of Article 18, the question is difficult to answer in the abstract, especially because of the rapidly expanding nature of biotechnology and the emergence of new products and applications. Moreover, the further development of existing rules will be warranted only on the basis that the inherent risks associated with the LMOs are different from those of the original organism. Again, it is difficult to generalize about the different risks associated with new products or applications.

77. In such situations, it is difficult to envisage that a single generic approach to the issue will be effective. It will probably be necessary to approach the development of rules and standards for Article 18 in a more focused manner, making more effective use of the resources of the ICCP.

78. Article 18 itself contains an implied priority for action or focus for the work of the ICCP, in that its requirements with respect to handling, transport, packaging and identification of LMOs for contained use or introduction into the environment are to be simply considered by the meeting of the Parties (pursuant to paragraph 3), whereas detailed requirements for the identification of LMO-FFPs are to be decided upon no later than two years after the entry into force of the Protocol (paragraph 2 (a)).

79. It is clear from section II above that not only are the existing rules and standards with respect to identification of LMO-FFPs complex in legal, institutional and substantive terms but that the area is rapidly evolving with several bodies actively considering the promulgation of additional rules and standards. These developments, however, will not comprehensively meet requirements of paragraph 2 (a) of Article 18.

80. Even so, detailed requirements should be developed only in the light of clearly established needs and goals. The latter must be developed by Parties, the ICCP and eventually the meeting of the Parties.

81. Paragraph 2 (a) of Article 18 provides some guidance in this respect. It provides that:

(a) The documentation accompanying the LMO-FFP must:

(i) Clearly identify that the relevant shipment "may contain" living modified organisms not intended for intentional introduction into the environment;

(ii) A contact point for further information, and

(b) That the meeting of the Parties needs to develop further the "specification of their [i.e., the LMO-FFPs'] identity and any unique identification".

82. Identification that a shipment of any goods for food, feed or processing "may contain" LMOs can be achieved by the development of a logo or through the development or amendment of standard shipping forms (e.g., bills of lading). As is evident from section II above, the complex legal and institutional context means that the modalities of implementing any decision to develop such a system will also be complex. Moreover, the experience to date in this regard has highlighted the difficulty of determining the threshold requirements of "may".

83. Information regarding the contact point for further information is a relatively straightforward matter. The exact modalities of how this should be done can only be determined when the other two issues raised by paragraph 2 (a) are decided. An outstanding issue from the negotiations in this regard, and one the ICCP may wish to consider, is whether the contact details should include the developer, notifier, exporter, importer, national competent authority of the Party of import, or the national competent authority of the Party of export or any combination of the above.

84. The Protocol provides for certain information regarding these contact points be provided to the Biosafety Clearing-House. Consequently, reference to the Biosafety Clearing-House may provide a simple and effective means of directing potential users and those that come into contact with the LMO-FFP with additional information regarding identification of relevant persons for action.

85. With respect to the specification of the identity and any unique identification of LMOs, it is worth recalling that Article 11, paragraph 1, of the Protocol provides that when a Party decides to allow the domestic use of an LMO-FFP, it must provide the Parties through the Biosafety Clearing-House with, at a minimum, the following details, as set out in annex II to the Protocol:

(a) Name and identity of the living modified organism;

(b) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism;

(c) Any unique identification of the living modified organism;

(d) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety;

(e) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate;

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

86. How much of the information provided in the notification is feasible, useful and desirable for subsequent shipments of LMO-FFPs is a matter that requires the consideration of the ICCP, Parties to the Protocol and ultimately the meeting of the Parties. Nevertheless, the requirements outlined in the present note, especially the United Nations Recommendations on the Transport of Dangerous Goods provide, relevant precedents. Others will also be relevant. For example, the system of voluntary standards developed by the International Organization for Standardization (ISO) (in particular, ISO 14020:1998, ISO 14021:1999, ISO 14024:1999 and ISO/TR 14025:2000) provides a useful and relevant precedent in terms of process as opposed to substance.

87. In considering this issue, it should be remembered that the measures anticipated by Article 18 are not limited to first-time movements, as is the case for the procedures outlined in Articles 11 for LMO-FFPs and 7-10 for LMOs. The documentation requirements that are the focus of Article 18 are those that are meant to accompany subsequent transboundary movements of LMOs covered by the Protocol. As a result, these requirements presumably should be no more onerous than the existing requirements outlined in Annex II for LMO-FFPs and Annex I for other LMOs covered by Article 18.

88. Moreover, in developing any proposed rules standards, consideration needs to be given to the principles listed in paragraph 73 above.

IV. RECOMMENDATIONS

89. It will be recalled that the anticipated outputs resulting from the ICCP consideration of this issue, as agreed by the Bureau and described in the note by the Executive Secretary on the proposed work plan of the Intergovernmental Committee prepared for the fifth meeting of the Conference of the Parties (UNEP/CBD/COP/5/6/Add.1), were:

(a) Detailed requirements regarding documentation accompanying LMO intended for direct use as food, or feed or for processing; and

(b) Need for and modalities of developing standards established.

90. With respect the first output, it is clear, as noted in paragraph 78 above, that there are persuasive reasons for recognizing that it is a "built-in" priority of the Protocol. Indeed, the Conference of the Parties in adopting the work plan of ICCP acknowledged this priority in agreeing that the anticipated issue for the second meeting of ICCP with respect to its consideration of Article 18 is "modalities for a process for discussion on Article 18, paragraph 2 (a)" by the first meeting of the Parties.

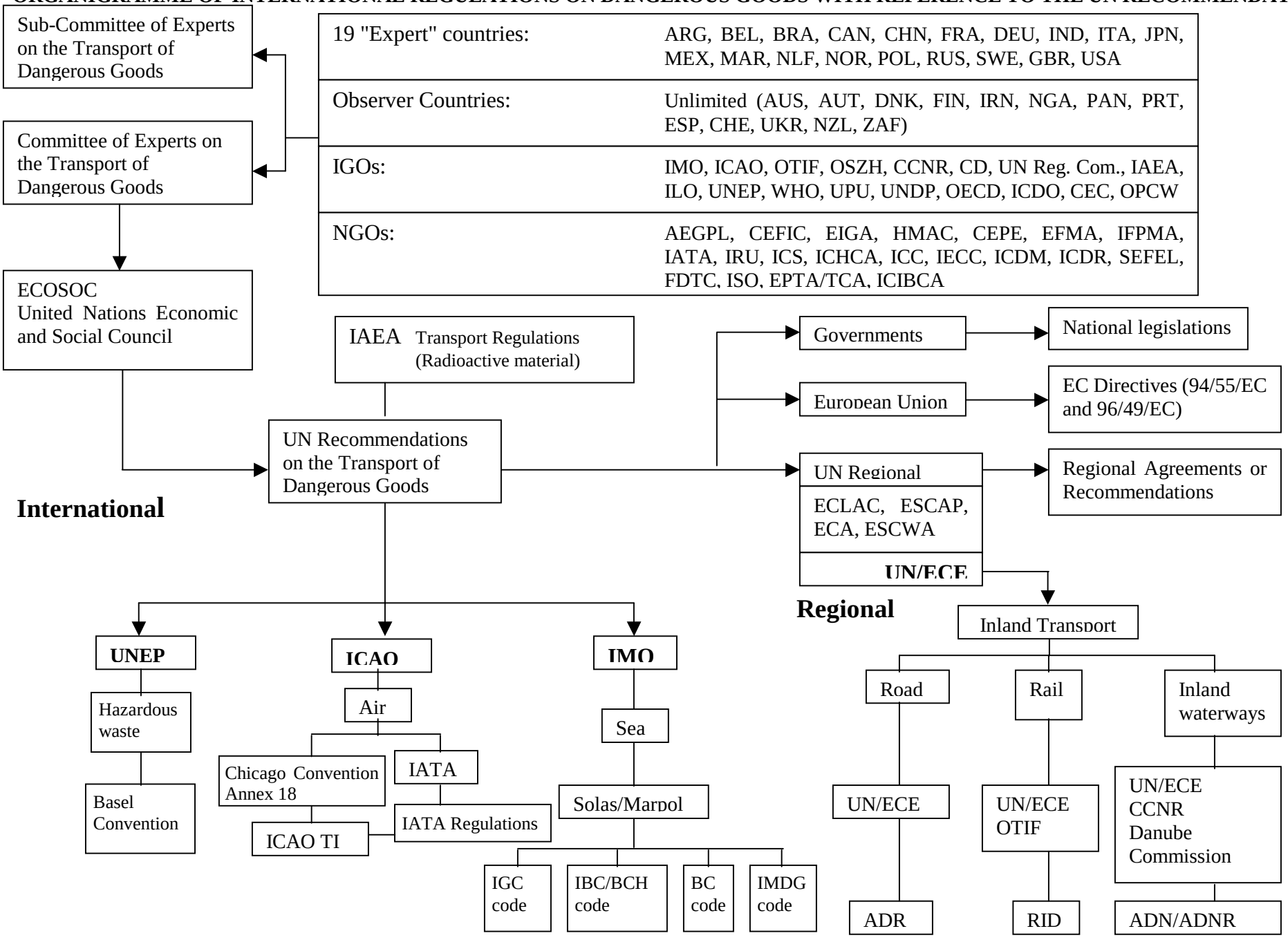
91. As mentioned previously, development of detailed requirements for paragraph 2 (a) must proceed on the basis of submissions from Governments. As is evident from the above, the potential scope of any proposal is vast and will need to take numerous initiatives into account. Accordingly, the ICCP may wish to provide some suggestions as to the focus or criteria for government submissions. For example, it may wish to consider requesting Governments to provide a detailed advice on their rules and regulations. It may also wish to consider requesting views on the modalities for a process for discussion on Article 18, paragraph 2 (a). It may also wish to request the views of Governments on the issues raised in paragraphs 81-88 above. Finally, in order to assist the ICCP at its second meeting, the Intergovernmental

Committee may wish to consider requesting the Executive Secretary to prepare a synthesis of these submissions and a proposal for its consideration at that meeting.

92. With respect to the need for and modalities of developing standards established, it is clear from the above that the extent these standards cover the particular needs of the Protocol varies. In some cases, the relevant governing bodies have carefully considered the particular risks of LMOs and developed appropriate standards. In many cases the relevant standard has only been developed to address a part of the risk covered by the Protocol (typically the risk to human health). In some cases, no standards exist at all. In many cases, existing standards are being developed or reviewed in light of emerging technologies. However, it also clear from the above that due to the variety of relevant initiatives, processes and regimes it will only be possible to proceed in a focused step by step process. Accordingly, the ICCP may wish to identify a limited number of relevant standards and bodies and request the relevant bodies to provide information on how these standards meet the requirements of Article 18. Alternatively, the ICCP may wish to focus on one or more aspects of Article 18, and request all interested bodies to provide information as to their relationship to that part of Article 18. It may also wish to request the Executive Secretary to liaise with or provide additional information with respect to these matters to assist the ICCP in its consideration of the matter. Additionally, because of provisional agenda for ICCP as indicated in its work plan (whereby the Conference of the Parties agreed that, at its second meeting, the ICCP should consider modalities for a process for discussion on Article 18, paragraph 2(a)), the ICCP may wish to provide guidance as to when it expects to consider the information so provided.

Annex I

ORGANIGRAMME OF INTERNATIONAL REGULATIONS ON DANGEROUS GOODS WITH REFERENCE TO THE UN RECOMMENDATIONS



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Abreviations:

IGO:	**International Governmental Organizations**
CCNR:	Central Commission for the Navigation on the Rhine
CD:	Danube Commission
CEC:	Commission of the European Communities
IAEA:	International Atomic Energy Agency
ICAO:	International Civil Aviation Organization
ICDO:	International Civil Defence Organization
ILO:	International Labour Organization
IMO:	International Maritime Organization
OECD:	Organisation for Economic Co-operation and Development
OPCW:	Organization for the Prohibition of Chemical Weapons
OSLZh:	Organization for Cooperation between Railways
OTIF:	Intergovernmental Organization for International Carriage by Rail
UNEP:	United Nations Environment Programme
UPU:	Universal Postal Union
WHO:	World Health Organization

NGO:	**Non-Governmental Organizations**
AEGPL:	European Liquiefied Petroleum Gas Association
CEPE:	European Printing Ink and Artists' Colours Manufacturer's Associations
CEFIC:	European Chemical Industry Council
EFMA:	European Fertilizer Manufacturers Association
EIGA:	European Industrial Gases Association
EPTA/TCA:	European Portable Tank Association/Tank Container Association
FDTC:	Fibre Drum Technical Council
HMAC:	Hazardous Materials Advisory Council
IATA:	International Air Transport Association
ICC:	International Chamber of Commerce
ICDM:	International Confederation of Drum Manufacturers
ICDR:	International Confederation of Drum Reconditioners
ICHCA:	International Cargo Handling Coordination Association
ICIBCA:	International Council of Intermediate Bulk Container Association
ICS:	International Chamber of Shipping
ICME:	International Council on Metals and the Environment
IECC:	International Express Carriers Conference
IFIBCA:	International Council of Intermediate Bulk Container Associations
IFPMA:	International Federation of Pharmaceutical Manufacturers Associations
IRU:	International Road Transport Union
ISO:	International Organization for Standardization
SEFEL:	International Secretariat of Manufacturers of Light Metal packagings

Annex II

SHIPPER'S DECLARATION SPECIMEN DESIGNED FOR MANUAL COMPLETION

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper	Air Waybill No. Page of Pages Shipper's Reference Number (optional)
Consignee	For optional use for Company logo name and address
Two completed and signed copies of this Declaration must be handed to the operator.	**WARNING**
TRANSPORT DETAILS This shipment is within the limitations prescribed for: (delete non-applicable) PASSENGER AND CARGO AIRCRAFT / CARGO AIRCRAFT ONLY Aiport of Departure:	Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.
Airport of Destination:	Shipment type: (delete non-applicable) NON-RADIOACTIVE / RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification							
Proper Shipping Name	Class of Division	UN Or ID No.	Pack-ing Group	Subsi-diary Risk	Quantity and type of packing	Packing Inst.	Authorization

Additional Handling Information

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable International and national government regulations	Name/Title of Signatory Place and Date Signature (see warning above)

Please note that the side borders of the form are RED.
