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LABELLING AND PRODUCT INFORMATION RELATED TO GENETICALLY MODIFIED ORGANISMS∗

Introduction: General observations on labelling

1. In general, labelling is part of consumer law and competition law. In consumer law, labelling implies a duty on a person (producer, dealer) to put certain data on the product package to provide the consumer with a minimum knowledge about the product. 1/ Consumer law associates the right to information with the protection of human health. In another situation, labelling may be a right of a producer (dealer) to put his or her sign on the product to distinguish it on the market. 2/ This right may belong to an individual (e.g. trade mark) or to several individuals (e.g. eco-label). Both consumer law and competition law recognize the right of choice of the consumer. But this choice is usually not environmentally defined – even the preference for products with an eco-label may be born out of other motives, such as health protection.

∗This analysis was prepared by a consultant to the secretariat, pursuant to paragraphs 34 and 35 of the report of the second meeting of the task force on GMOs (CEP/WG.5/AC.3/2001/3).

I. ANALYSIS OF THE LEGAL MEANING OF THE PROVISIONS OF THE AARHUS CONVENTION RELEVANT TO LABELLING AND ACCOMPANYING INFORMATION ON GMOs.

2. At first glance the Aarhus Convention (hereinafter, the Convention) does not address the issue of labelling of products at all. This fact is not striking insofar as the objective of the Convention is to guarantee the rights of access to information, public participation in decision-making and access to justice in environmental matters (cf. art. 1).

3. Most of the relations that are subject to the Convention are relations between the public (citizens and their organizations), on the one hand, and the authorities (the executive power), on the other. Businesses' (producers', dealers') rights and obligations are more often implicit than explicit.

4. GMOs are explicitly mentioned in the definition of "environmental information" in article 2, paragraph 3. Therefore, all provisions that refer to environmental information refer to GMOs as well. The most important rules limiting access to information related to GMOs seem to be article 4, paragraphs 4(d), (e), (g) and (h), of the Convention. These provisions provide the public authorities with grounds for refusal to provide access to environmental information and one may expect that some of the information related to GMOs could be protected under intellectual property law or may be confidential. It should be stressed that the Convention does not provide a definition of "genetically modified organism", so the analysis is based on the assumption that a definition close to the one adopted in Directive 2001/18/EC or a definition of "living modified organism", as adopted in the Cartagena Protocol on Biosafety, will apply in the context of the Convention.

5. Article 5, paragraph 8, of the Convention stipulates that "Each Party shall develop mechanisms with a view to ensuring that sufficient product information is made available to the public in a manner which enables consumers to make informed environmental choices". This is a "potentially far-reaching provision that could be developed greatly by governments in implementation". 3/ The key words in this text are: "product information", "informed", "environmental choice" and "sufficient".

6. What does available information mean? There are several levels of information. As regards the information that the competent authority holds, this information may include all the data from the application for a permit, a risk assessment, a risk communication, all the data from post-market monitoring, etc. The information that should be present on the label and in the accompanying leaflet is also available information.

7. The notion of "product information" can be used in a narrow and in a broader sense. In the narrow sense, product information would include all the data about the content of the product. The broader sense would include data about the conditions under which the product was created – country of origin, exact place of production, techniques for production, name of the producer. This information may be qualified as "secondary

product information". Practice shows that sometimes such secondary information may be part of the basis for the consumer's choice. For instance, the reference to "organic production" as secondary product information is enough for the average consumer to trust the quality of the product, even if he or she does not know exactly the names of some or all of the components of the product. The choice is influenced by the trust in someone's activity. Another example of the meaning of such "secondary product information" may be the case where the consumer chooses not to buy clothes produced in a country that does not respect international labour law. The respect for ethical principles within different communities is directly connected with this "secondary" product information. The consumer may be influenced if he or she knows about animal experiments in the course of the development of a genetically modified product.

8. Because of its peculiar role and place – the link between the producer (dealer) and the consumer and intermediary of environmental concern – "product information" in article 5, paragraph 8, does not fully overlap with "environmental information" nor with "product information" in consumer law. A comparison between "product information" under consumer law and under article 5, paragraph 8, shows that "product information" under consumer law does not include the environmental motive (and the need for environmental information). Under article 5, paragraph 8, data about the environment at the location where the product is produced – neighbouring property, measures for reducing possible adverse effects on the environment, etc. – will therefore have to be added. On the other hand, some of the "product information" will not fall under article 2, paragraph 3, of the Convention, and may therefore be qualified as "non-environmental information". That is the case with a product that is derived from a GMO – some of the product information in this case may be non-environmental information, but the information about the release into the environment of the GMO in question is environmental information. Both types of information may influence the consumer's environmental choice. In conclusion, article 5, paragraph 8, is the necessary basis for the authorities to collect and to provide information which is related to the product and which may help the consumer to make his or her environmental choice.

9. The notion "environmental choice" depends on the interpretation and on the internal legislation of the Parties. The Convention does not provide a definition of "environment", even if it mentions "the elements of the environment" (cf. art. 2, para. 3). That is why it may be reasonable to refer to the general understanding of "environmental", i.e. connected with the environment.

10. Another implication may appear from the word "choice" in article 5, paragraph 8. In modern society, there are many different legal and ethical rules for the protection of free choice – even the notion of "human rights" is used together with that of "fundamental freedoms". A recent judgment of the European Court of Human Rights 4/ declared illegal the behaviour of a government that had failed to provide information about hazardous activities. The Court's decision was based on article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms. This clearly shows that the respect of the right of choice and the protection of acquired economic interest and privacy are trends in

modern environmental legislation and the modern notion of justice. GMOs are a case in point: GMO releases are known to have occurred frequently in the vicinity of traditional or organic farms. This information may be of importance for the consumer who would like to make an "environmental choice". In short, for the consumer it may be very important to know that the producer of GMOs has not impeded someone else's choice.

11. The word "choice" brings to mind the second pillar of the Convention – public participation. If the access-to-information pillar is related to the intellectual understanding of environmental matters, the public-participation pillar is related to the will to act (to participate) in the decision-making process. Informed environmental choice means acting with a clear understanding of the facts – i.e. both the intellect and the will of the human being are involved. Informed environmental choice seems to be very similar to a "consumer's green vote". This can be another strong argument for the Parties to develop the mechanisms prescribed in article 5, paragraph 8.

12. "Sufficient" product information means that the information available should represent the necessary basis for the "informed environmental choice" of the consumers. Of course, different consumers may need different information. The assessment should be done separately for the information available to the authorities and the information that should be present in the accompanying leaflet or on the label. One possible starting point for discussion may be the information for the labelling provisions under annex IV to Directive 2001/18/EC. Annexes II and III to the same Directive may be a good starting point for discussion on the information available to the authorities which is available to the public upon request.

13. Concerning the possible mechanisms for providing the sufficient product information to the consumer, the Aarhus Convention sets only the general framework. Article 4 of the Convention provides rules for access by the public to information held by public authorities. There are rules which set time limits for response (para. 2), rules for exceptions to the public access to information (paras. 3 and 4), and rules for ensuring that, if some of the information falls under the exceptions, the rest of the information should be made available (para. 6). It seems that the provisions of article 4, paragraphs 4 and 6, will be important for the access to information related to GMOs. The Parties may develop additional mechanisms for providing product information under article 5, paragraph 8. Such additional mechanisms may be the creation of a register with data about the sites where the deliberate release of GMOs has occurred. Another idea may be to oblige dealers to create separate locations (shelves) for GMO-containing products. One could say that article 4 of the Convention sets the minimum standards and that article 5, paragraph 8, opens the door for further procedural guarantees ensuring the flow of sufficient product information.

14. The requirement for "sufficient" product information may also be interpreted as a kind of special standard for the amount of information that the authorities are expected to collect. Article 5, paragraph 1 (a), stipulates that "Each Party shall ensure that public authorities possess and update environmental information which is relevant to their

functions". Read together, the provisions of article 5, paragraphs 1 (a) and 8, mean that the competent authorities shall maintain a sufficient amount of product information so that the environmental choice can be "informed". The words "informed" and "sufficient" are complementary – the first characterizes the knowledge of the consumer, the second refers to the knowledge that may be acquired by the information held by the authorities.

II. ANALYSIS OF THE RELEVANT INSTRUMENTS, AGREEMENTS AND EXISTING PRACTICES IN THE AREA OF LABELLING AND ACCOMPANYING INFORMATION

A. The Cartagena Protocol on Biosafety

15. In accordance with the precautionary approach contained in principle 15 of the Rio Declaration on Environment and Development, the objective of the Cartagena Protocol on Biosafety (hereinafter the Protocol) is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements (cf. art. 1 of the Protocol). The Protocol's definition of LMO (art. 3, subparas. (g), (h) and (i)) overlaps with the definition of GMO under Directive 2001/18/EC, even if the wordings of the two definitions are not exactly the same. It is not possible to say when the Protocol will enter into force as the process of ratification is at an early stage.

16. The idea of the Protocol is to create a system for the exchange of information and for the control over several activities related to LMOs. Such activities are: (a) the intentional introduction into the environment of LMOs and their transboundary movement (arts. 8-10 and 12); (b) the placing of LMOs on the market for direct use as food or feed or for processing (art. 11); (c) the unintentional transboundary movements of LMOs (art. 17); and (d) the transport, handling, packaging and identification of LMOs (art. 18). The notion of "intentional introduction into the environment" seems to overlap with the definition of "deliberate release" of article 2, paragraph 3, of Directive 2001/18/EC.

17. The Protocol stipulates that, prior to the first transboundary movement of LMOs for intentional introduction into the environment of a Party of import, a risk assessment has to be carried out (art. 7). The Protocol describes the content of the risk assessment (annex III). The risk assessment investigates the risks of the LMOs introduced into the environment both for biodiversity and for human health. Under the Protocol, Parties are obliged to establish and maintain appropriate mechanisms for managing risks created by the use, the handling and the transboundary movement of the LMOs.

18. The Protocol does not use the words "label" or "labeling". It uses the term "accompanying information". Such accompanying information is required for the transboundary movement of three categories of LMOs (art. 18, para. 2):

(a) LMOs that are intended for direct use as food or feed, or for processing (these could also be regarded as products in other contexts);

(b) LMOs that are destined for contained use; and

(c) LMOs that are intended for intentional introduction into the environment.

The accompanying information is not the same for all three; it varies in accordance with the characteristics of the LMOs. For LMOs that are intended for direct use, the detailed requirements will be specified no later than two years after the Protocol enters into force.

19. From a legal point of view, the Protocol is one of the rare examples of international agreements that require the submission of a declaration, signed by the LMO exporter, affirming that the movement of the LMO is in conformity with the requirements of the Protocol itself. This may be appropriate for developing the legal framework for implementation of article 5, paragraph 8, of the Aarhus Convention.

20. The accompanying information required for LMOs is:

(a) For LMOs that are intended for direct use as food or feed, or for processing (the products), the accompanying documentation should spell out that they may contain LMOs and are not intended for intentional introduction into the environment, and should provide a contact point for further information (art. 18, para. 2 (a));

(b) For LMOs that are destined for contained use, the accompanying documentation should clearly identify them as LMOs. It should specify the requirements for their safe handling, storage, transport and use. The name of the contact point for further information, including the name and address of the individual and institution to whom the LMOs are consigned, should also be specified (art.18, para. 2 (b));

(c) For LMOs that are intended for intentional introduction into the environment, the accompanying documentation should clearly identify them as LMOs. It should specify the identity and relevant traits and/or characteristics. It should spell out the requirements for their safe handling, storage, transport and use. The contact point for further information and, as appropriate, the name and address of the importer and exporter should be given. Finally, the accompanying documentation should include a declaration that the movement is in conformity with the requirements of the Protocol (art. 18, para. 2 (c)).

21. Another innovation of the Protocol is the creation of a Biosafety Clearing-House with the aim of facilitating the exchange of information and ensuring that the Parties implement the Protocol correctly. This Biosafety Clearing-House will keep summaries of the risk assessments and the environmental reviews of LMOs and information about the products derived from these LMOs. The Biosafety Clearing-House will also be used for posting final decisions regarding domestic use, including placing on the market of an LMO that may be the subject of a transboundary movement for direct use as food or feed, or for processing. This information shall include as a minimum information specified in annex II to the Protocol. The modalities of the operation of the Biosafety Clearing-House shall be considered and decided upon at the first meeting of the Parties to the Protocol and kept under review thereafter.

B. The Codex Alimentarius Commission (and its ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology)

22. The ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology created by the Codex Alimentarius Commission has a mandate to draw up standards, guidelines and principles for foods derived from biotechnology. It has already held two meetings and produced two draft documents: - Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, and the Draft Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant-DNA Plants. 5/ Its final papers should be ready by 2003.

23. The Task Force accepts the definition of "modern biotechnology" used in the Cartagena Protocol.

24. The final documents of the Task Force will not be legally binding. Later some States may transpose its conclusions into their internal legislation, for instance in sub-legislative acts (regulations, by-laws) on the assessment of foods derived from biotechnology. For the purposes of article 5, paragraph 8, of the Aarhus Convention, the Task Force's report may give some additional information and reasons for outlining the framework within which the "environmental choice" may be applied.

25. The Task Force's discussions and draft papers stress that the principles of risk analysis, particularly those for risk assessment, are intended to apply to whole foods and not to specific microbial contaminants or to additives or chemical residues. This approach of the food specialists brings them closer to the environmentalists, who tend to observe the interaction between many factors in the environment.

26. The scope of work of the Task Force is restricted because the following subjects are explicitly excluded:

(a) Risk to the environment;

(b) Animal feed and animals fed such feed, except insofar that these animals had been genetically modified.

27. The Principles for the Risk Analysis of Foods Derived from Modern Biotechnology will form the bulk of the Task Force's output. The list of factors not covered by the Principles will be extended to cover ethical factors, and the moral and socio-economic aspects of research, development, production and marketing of these foods.

28. Within the scope of its work, the Task Force will develop a Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant-DNA Plants. Rules for the scientific approach to assessing possible long-term health effects – unintended/unexpected adverse effects – will be defined as part of this Guideline.

29. According to the Task Force, the safety assessment of genetically modified food would be done by comparison with the so-called conventional counterparts", i.e. "a related plant variety, its components and/or products for which there is experience of establishing safety based on common use as food". 6/ The safety assessment should also identify the so-called unintended effects – change of some phenotypic characteristics of the plant, changes in the regulation of metabolic pathways and others. The unintended effects may be "predictable" or "unexpected". The information about the unintended and the unexpected effects of the food may be important for the environmental choice of the consumer.

30. The Task Force has decided that the risk assessment should be done on the basis of a broad range of scientific data, obtained from a variety of sources, such as the developer of the product, scientific literature, general technical information, independent scientists, regulatory agencies, international bodies and other interested parties. Thus the implementation of the Aarhus Convention may be an incentive for more objective risk assessments and the objective conclusions of these may become part of the basis for the environmental choice.

31. The Draft Principles, prepared by the Task Force, provide for the transparency of safety assessments. Another notion underlining the need of transparency is introduced, namely "risk communication", which is an essential part of both risk analysis and risk management.

32. The Task Force's discussions and draft papers define the need for a transparent and well-defined regulatory framework for the management of risks associated with foods derived from biotechnology. This conclusion may further environmental choice under article 5, paragraph 8, of the Aarhus Convention.

33. The Task Force has taken steps to collect data on existing analytical methods for the detection or identification of foods derived from biotechnology. At present different countries use different methods; there are no internationally validated methods available. The Task Force will study the possibility of using these methods not only for post-market monitoring but for pre-market approval as well. This could be useful for the future development of a framework to implement article 5, paragraph 8. If the labelling provisions are applied in most countries, mechanisms for detecting violations will be needed so that effective sanctions may be imposed.

34. The Task Force has discussed the issues of practicability and the financial implications of post-market monitoring. In this respect, there were proposals for including in the agenda the question of traceability and the means for documentary retrieval of the history and the origin of the product. This issue is directly connected with the obligation of the authorities to provide sufficient information about the product.

35. The question of the frequency of routine review of the safety assessment may be of great importance for the implementation of article 5, paragraph 8, of the Aarhus Convention, given that article 5, paragraph 1 (a), provides that the authorities should

update environmental information. This issue was discussed within the Task Force but no final decision has yet been taken.

36. The Task Force agreed that antibiotic resistance genes used in food production which encode resistance to clinically used antibiotics should not be present in widely disseminated foods. This question is directly linked with the labelling of products under article 5, paragraph 8, of the Aarhus Convention, because it could become part of a code of good procedural practices in GMO matters, should such a code be prepared under the Convention.

C. The United Nations Recommendations on the Transport of Dangerous Goods

37. The United Nations Recommendations on the Transport of Dangerous Goods (ST/SG/AC.10/1/Rev.12) provide very detailed rules for the packaging, labelling and transport of dangerous goods. Dangerous goods are defined by a list. GMOs can fall within the category of "infectious substances" (division 6.2) if they are known to or reasonably expected to cause infectious diseases in humans or in animals. If the GMOs are non-infectious, they would fall within the category of "miscellaneous dangerous substances and articles" (division 9).

38. As far as the "products" referred to in article 5, paragraph 8, of the Aarhus Convention are expected to have a permit to be placed on the market, they are not expected to be qualified as "dangerous goods".

39. It can be assumed that GMOs that may be placed on the market are non-infectious. In this case the problem is not what information should be on the package (the label) for the needs of transboundary movement, but which part of the information contained in the risk assessment or in the permit for placing on the market is important to facilitate the consumer's "environmental choice".

D. Directive 2001/18/EC

40. The objective of Directive 2001/18/EC on the deliberate release of genetically modified organisms, as set out in its article 1, is to harmonize the legal framework for the protection of human health and the environment when:

- Carrying out the deliberate release into the environment of GMOs for any other purposes than placing on the market within the European Community;
- Placing on the market GMOs as or in products within the European Community.

Thus the Directive appears to be the most exhaustive non-national legislative act on GMOs. The motives (their number is impressive – 63) show the complexity of the problems connected with GMOs.

41. Compared to Directive 90/220/EEC, the new Directive (2001/18/EC) is more detailed and specific and therefore has been regarded by some as more stringent. In fact,

the Directive regulates several issues that have a direct link with the "informed environmental choice" of article 5, paragraph 8, of the Aarhus Convention. The Directive sets the basis for:

(a) A permitting regime with a mandatory environmental risk assessment for the deliberate release of GMOs into the environment (arts. 5 and 6);

(b) A permitting regime for the placing on the market of products consisting of or containing a GMO or a combination of GMOs (arts. 13 and 15);

(c) Detailed procedures for the exchange of information between the authorities, the notifier and the public and rules on confidential information (arts. 8, para. 2, 9, para. 2, 11, 13, para. 6, 14, 20, paras. 2, 3 and 4, 21, 24, 25, 26 and 31, para. 2);

(d) A detailed framework for the environmental risk assessment (annex II);

(e) Detailed requirements for additional information held by the authorities for products that are placed on the market (annex IV);

(f) Detailed requirements for the labelling of products placed on the market (annex IV.B.7);

(g) The mandatory assessment report which should be the tool for the authority to respond to the notifier's notification for placing on the market (art. 14);

(h) Mandatory monitoring and reporting about the effect of the placing on the market of a product (art. 20);

(i) The mandatory labelling of products placed on the market (art. 19, para. 3 (e), arts. 21 and 26);

(j) The introduction of penalties for breaches of the national provisions adopted pursuant to the Directive (art. 33).

Each of these issues is related to the requirement of article 5, paragraph 8, of the Convention, for sufficient product information which should enable the consumer to be informed and make an environmental choice.

42. The permitting procedure for the deliberate release into the environment starts with a notification, which should include concrete data (art. 6). The data needed in the notification are described in detail in annex III to the Directive. Additionally, article 6 of the Directive requires that the notification include "a plan for monitoring in accordance with the relevant parts of annex III in order to identify effects of the GMO(s) on human health or the environment". This information or at least the fact that the notifier has submitted such a detailed notification may be quite convincing consumer-related information for those who would hesitate to buy a product which is the result of the deliberate release.

43. The notification for deliberate release should be accompanied by an environmental risk assessment (art. 6, para. 2 (b)). The Directive prescribes the format for the risk assessment in article 4, paragraph 2, and in annex III. The risk assessment should contain bibliographic references and indications of the methods used.

44. In the procedures for the exchange of information between the notifier, the authorities and the public, the Commission has an important role. It acts as an intermediary in disputes (art. 17, para. 7) or as a monitoring authority (art. 20). The Commission also has a role in making some of the information available to the public (art. 24). In future the Aarhus Convention may give similar functions to its secretariat. That is why the Commission's practice and the exchange of information under the Directive are important. At present, the Convention's secretariat does not have any such functions and, therefore, only a very small part of the Directive's exchange of information mechanism may be transposed to the Convention. If, in future, the relations between the Convention's Parties are regulated in more detail, there will be a need for more sophisticated mechanisms for the exchange of information between the Parties and the secretariat.

45. As far as public access to information is concerned, there are public registers where information on the location of the releases of GMOs can be found (art. 31, paras. 2 and 3 (a)). The public also has the right to access the information held by the Commission (arts. 9, para. 2, 20, para. 4, and 24).

46. According to the Directive, some information may not be exempted from public access on the grounds of commercial confidentiality. The methods and plans for monitoring and the environmental risk assessment are explicitly mentioned in this category of information (art. 25, para. 4). Article 25, paragraph 2, is phrased in the spirit of the Aarhus Convention. It states that the notifier must give justification for treating information as confidential, because disclosure might harm his or her competitive position. At present most of the industrialized countries explicitly protect certain data as commercial or trade secret so there is no room for discussion. The new element introduced by the Aarhus Convention (art. 4, para. 4 (d)) is that to exempt data from disclosure there should be a "legitimate economic interest". Public authorities in Parties to the Convention which are also Members of the European Union will therefore also need to apply article 4, paragraph 4 (d), of the Convention when they make decisions under article 25 of the Directive. The exact implications of these texts will be known in the near future. It seems that the "harm of the competitive position" (art. 25, para. 2, of the Directive) and the "legitimate economic interest" (art. 4, para. 4 (d), of the Convention) overlap.

47. The exchange of information between the notifier and the authorities is regulated by several provisions that oblige the notifier to submit different types of reports and information to the public authorities at the different stages of his activity.

48. The Commission plays a major role in the relations between the public and the authorities. The national authorities should send part of the available information to the Commission.

49. The exchange of information under the Directive is worth an in-depth study. If later the Parties to the Aarhus Convention decide to develop their own mechanisms for the exchange of information in GMO matters, the format and the framework established under the Directive may be used as a starting point.

50. The Directive sets out a very detailed format for the accompanying information for products that are placed on the market – the whole of annex IV is dedicated to this subject. Annex IV also contains much information for the control of the notifier's activity. Thus the consumer of a product that consists of or contains GMOs can learn much more about the product than the average consumer of other types of products. Theoretically, this is ideal for making an "informed environmental choice". There is an explicit requirement in article 13, paragraph 2 (f) and annex IV, sect. A, paragraph 8, that the words "This product contains genetically modified organisms" should be placed either on the label or in the accompanying document. The exact content of the accompanying documentation and of the labels will be specified later. The Directive does not lay down special rules for the labelling of products derived from GMOs or obtained by using GMOs. The Directive does provide a definition of "product" in article 2, paragraph 7. This definition implies a "quantitative approach" – it says that "product" means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market. The same approach is followed in article 21, paragraph 2, which says that for products where adventitious or technically unavoidable traces of authorized GMOs cannot be excluded, "a minimum threshold may be established below which these products shall not have to be labelled". These thresholds are to be established later. That is why, for products derived from GMOs or obtained by using GMOs, the labelling will depend on the content of the product and, if this product contains a GMO, it will fall under the labelling provisions of the Directive.

51. The provisions for the mandatory monitoring of products placed on the market contain some very interesting ideas. On the one hand, the notifier has the duty to ensure that monitoring and reporting are carried out under the conditions that are specified in the consent. On the other, the monitoring reports should be submitted to the Commission as well to the national authorities. According to article 20, paragraph 2, the public is invited to put forth any information with regard to human health or to the environment. Thus the purely "information" provisions are phrased in such a way that the public is given a participatory role, which is in a full compliance with the spirit of the Aarhus Convention and particularly with its article 5, paragraph 8.

52. Virtually the whole matter of traceability and the applicability of the analytical methods for the identification of GMOs may become useless if the Member States do not introduce effective penalties for violations of the legislation. Moreover, without technical tools for investigating violations, the legal norm will not be effective.

III. CONCLUSIONS

53. The central question which the present analysis aims to address is whether there are significant gaps in the international or regional frameworks regulating product information (including labelling) in the field of GMOs that could usefully be addressed through further work under the Aarhus Convention. The extent and nature of any such gaps, and the interpretation of the far-reaching concept of "sufficient product information to enable

consumers to make informed environmental choices" referred to in article 5, paragraph 8, of the Convention, are of key importance in determining whether there is a particular niche which the Aarhus Convention can fill.

54. In deciding what constitutes "sufficient product information", one can distinguish between different levels of information, which may be relevant in different contexts. GMO-related product information might range from rather detailed information, such as risk assessments carried out under the Cartagena Protocol (para. 17 above) or risk analyses and safety assessments carried out under the General Principles and the Guideline prepared by the Codex Commission's Task Force (paras. 27-31 above), to simple statements such as "This product contains GMOs". Some of this information might be in the public domain, some not; some might be actively disseminated, e.g. through labelling, whereas some might be available only upon request.

55. The broadest definition of product information extends beyond information on the content of the product to include "secondary product information", e.g. information on the process by which it is produced, perhaps the fate of the product after use, and so on. The task force at its second meeting noted the strong demand for information not only on products containing GMOs but also on "products derived from GMOs and products obtained by using GMOs" (CEP/WG.5/AC.3/2001/3, para. 30).

56. Turning to the question of public accessibility of information, for product information as for other information one can distinguish between the passive and active aspects of providing access to information (broadly corresponding in turn to articles 4 and 5 of the Convention). The issue of labelling clearly falls under the latter heading but it should be remembered that, under the Convention, a regime of passive access to information should underpin whatever labelling requirements are in place. The extent of that regime is therefore relevant to the question of labelling.

57. The broad definition of "environmental information" taken in conjunction with the provisions of article 4 probably means that much of the GMO-related product information held by public authorities is either accessible to the public upon request under the Convention, or falls within an exempt category which has been negotiated and is not likely to be changed in the case of GMOs. However, the notion of "sufficient product information" might also encompass some information falling outside the Convention's definition of "environmental information" and therefore outside the scope of article 4. Furthermore, GMO-related information held by private companies but not by public authorities would also not be covered by the provisions of article 4. It is an open question whether the amount and significance of such information would justify further measures to strengthen the passive right of public access to these two categories of information, but in any case, to the extent that they are not required to be made available under other instruments, they should be recognized as "gaps".

58. As regards the active provision of information, the information involved here will be a small subset of the information which is available to the public or consumer upon request. Furthermore, active dissemination policies and requirements (e.g. through labelling) will need to take account of the fact that different subgroups of the public will have different information needs (e.g. farmers buying GM seed as compared with end-consumers buying GM products in a supermarket).

59. Although labelling (using this term to include both the label itself and the accompanying information circulated with the product) is not the only means of active provision of GMO-related product information to the consumer, it is probably the most important, and the central topic of this analysis. Both the Cartagena Protocol and Directive 2001/18/EC (notably in annex IV) contain certain mandatory requirements for the label and accompanying information (paras. 20 and 50 above). Neither instrument differentiates between which information should appear on the label itself and which may just accompany the product but without being on the label (as mentioned, the Cartagena Protocol does not even refer to the label as such). A more specific approach which differentiates between what is on the label and what is simply accompanying information may be worth considering.

60. More important, neither of the instruments referred to in the previous paragraph requires the inclusion of secondary product information as referred to in paragraph 55 above; nor do their labelling provisions apply to products which are derived from or obtained by using GMOs but do not contain or consist of GMOs. This might also therefore be considered to be a "gap" which the other instruments do not cover.

61. Furthermore, some important elements are included in the labelling only on an optional basis under Directive 2001/18/EC, notably the following data from its annex IV:

- A description of how the product and the GMO as or in the product are intended to be used. Differences in use or management of the GMO compared to similar non-genetically modified products should be highlighted;
- A description of the geographical area(s) and types of environment where the product is intended to be used, including, where possible, estimated scale of use in each area;
- Measures to take in case of unintended release or misuse;
- Specific instructions or recommendations for storage and handling;
- Specific instructions for carrying out monitoring and reporting to the notifier and, if required, the competent authority, so that the competent authorities can be effectively informed of any adverse effect;
- Proposed restrictions in the approved use of the GMO, for example where the product may be used and for what purposes.

To the extent that these are necessary to ensure "informed environmental choice", their inclusion only on an optional basis could be considered to be a further "gap", and consideration could be given to including them on a mandatory basis, to fulfil the objectives of article 5, paragraph 8. In addition, consumer concern over GMOs may result

in pressure for labelling to include the preventive inscription that GM foods may have unexpected effects on health (para. 29 above).

62. Another question is whether there is a need to establish in a more explicit way a framework for the collection and processing of information, having in mind the requirements of article 5, paragraph 1 (a), of the Convention. Of relevance here are the minimum periods for updating the information (see para. 35 above and the detailed provisions for the submission of information under Directive 2001/18/EC). However, as detailed as Directive 2001/18/EC is, it may be argued that it does not fully respond to the protection of the consumer aimed at in article 5, paragraph 8. The mechanisms established under Directive 2001/18/EC and the Cartagena Protocol have greatly improved (or will do) the flow of GMO-related product information from the private sector to the public authorities. The Working Group may wish to consider whether they meet the requirement of article 5, paragraph 1 (b), of the Convention on Parties to establish mandatory systems ensuring "an adequate flow of information to public authorities about proposed and existing activities which may significantly affect the environment".

63. If there is seen to be a need to introduce more specific requirements in this area, one option would be to consider developing some reporting requirements analogous to those envisaged for pollutant release and transfer data. In this context, it is worth mentioning that in the negotiations over the draft instrument on pollutant release and transfer registers (PRTRs), the possibility that GMOs might eventually be covered has been discussed, as well as the possibility that the registers would cover releases/transfers through products. On the basis of the discussions so far, it is unlikely that either of these issues would be included in the first stage of implementing the PRTR instrument. Nonetheless, it could be useful to ensure coordination on this matter between the two working groups.

64. The procedures outlined in Directive 2001/18/EC for the exchange of information between the national authorities, the public and the international authority are far-reaching and could be worthy of deeper investigation and possible adaptation to the Aarhus Convention secretariat. The exchange of information procedure could be adapted according to the intentions for further development under the Aarhus Convention. This could include the exchange of information with the bodies responsible for the implementation of other legal tools. In this regard, the future involvement of the Parties in the activities of the Cartagena Protocol should be kept under review because, although it is at an early stage, the Biosafety Clearing-House (para. 21 above) is the first international mechanism that promotes the international exchange of information in GMO matters. If the Aarhus Convention secretariat were to become a repository or clearing-house for information on GMOs, this would clearly represent an extension of its current remit, which functions at the "meta" level, i.e. focusing on the procedures governing access to environmental information (as well as public participation and access to justice) but not actually being a repository for environmental information in a particular subject area.

65. In order to further the objectives of article 5, paragraph 8, one option would be to draw up some kind of code of good procedural practices in GMO matters. Such a code need not (at least initially) form part of the mandatory provisions of the Convention but could provide useful guidance on the application on article 5, paragraph 8, in the field of GMOs. It could have provisions on:

(a) Which types of GMO-related product information should be held by the competent public authorities;

(b) Mechanisms ensuring the timely collection of this information;

(c) Which types of GMO-related product information should be in the public domain, including guidance on the interpretation of those exemptions in article 4 of the Convention with particular relevance to such information (e.g. what is "legitimate economic interest" in GMO matters when applying article 4, paragraph 4 (d));

(d) Measures for ensuring the effective transfer of the product information to the consumer, e.g. the separation of the products derived from modern biotechnology to another location (shelves) in shops;

(e) Which part of the available information is to be placed in the accompanying leaflet or on the label;

(f) Which part of the available information should be submitted to the secretariat of the Convention.

66. All the technical matters in regard to the analytical methods for the identification of GMOs and to their traceability may be regulated in the light of the technical /scientific results expected to come from the work of the Codex Commission's Task Force (see paras. 33 and 34 above). It is worthwhile exploring the possibilities for documentary traceability of the food (para. 34 above).

67. According to the intentions for further development under the Aarhus Convention, some provisions from the other international agreements may be transposed or developed in the Aarhus Convention as well. In the case of the relevant EU instruments, even if some of their provisions were to be simply replicated under the Convention, the difference in geographical scope can mean that they bring added value to those Parties to the Convention which are not EU member countries or EU accession countries. However, the analysis indicates that some discussion of formulating measures under the Convention which go further than the provisions existing under other instruments could be justified.

68. If it were decided to undertake further action under the Convention with respect to the application of article 5, paragraph 8, in the field of GMOs, it could be worth considering whether this should be done in the context of a more general exercise concerning the application of article 5, paragraph 8. It is clear that some of the issues raised in this paper (e.g. the distinction between content-related product information and process-related product information) would be relevant to products in general, not just to those having a connection with GMOs.

Notes

1/ Lamy droit économique, Concurrence, Distribution, Consommation, LAMY S.A. 1992, paragraphes 8620, 8621, 8625.
2/ Lamy droit économique, Concurrence, Distribution, Consommation, LAMY S.A. 1992, paragraphes 2218, 2219, 2223; and Droit des affaires, G.Guery, 4-ème édition, CLET, p.300.
3/ The Aarhus Convention : An Implementation Guide, p. 80.
4/ McGinley and Egen v. the United Kingdom, judgment of 9 June 1998, which can be found at www.echr.coe.int
5/ The report of the second meeting of the Task Force can be found at http://www.codexalimentarius.net/
6/ Paragraph 7 of the proposed Draft Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant-DNA Plants.