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PRODUCTS THEREOF

Information Note
Prepared by the Executive Secretary

Introduction
The Open-ended Ad Hoc Working Group on Biosafety at its 4th meeting, while discussing its future work, requested the Executive Secretary to prepare a note on the term "products thereof" to assist it in its deliberations at the next meeting. The term products thereof applies to products from living modified organisms (LMO's) resulting from biotechnology identified in Article 19(3) of the Convention.

A product is a material or object that is manufactured or processed in some way and is intended for commerce, e.g. medical products, food products, engineering products. The term product is also appied to material produced inside living organisms or cells. For example, cell products such as enzymes, hormones, and metabolites. The LMO can also be a product intended for commerce.

For the purposes of this paper three classes of products will be considered, 1) products that are or contain living modified organisms, 2) Inanimate products that are parts of, or may be produced through the biological activity of LMO's, e.g. soya protein, flour, pharmaceuticals; and 3) cell products that are generated in, or have been introduced into the LMO in situ and would normally be contained within the LMO or occur as residue following the death of the LMO.

In order to assist the Working group in its deliberations the note reviews the provisions in the Convention on Biological Diversity and the decisions of the Conference of the Parties on this topic. The note utilizes, as examples of LMOs, genetically modified organisms (GMOs) and provides specific examples of products derived from GMOs. The note further provides a brief overview of existing international instruments and practices put in place by international agencies which have dealt with the issues surrounding products deriving from such organisms, and the experiences of certain member states of the OECD (Organization for Economic Cooperation and Development) and the European Union (EU) in regulating such products.

Background from the Convention text and COP decisions

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Article 8(g) of the Convention requires Parties to, as far as possible and as appropriate, establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biodiversity, taking also into account the risks to human health.

Article 19 (3) provides that, "[T]he parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

The Convention does not define "living modified organisms resulting from biotechnology". The concept is very broad, covering all organisms--whether plants, animals or microbes--resulting from biotechnology that are alive.

By Decision II/5 the Conference of the Parties decided to "seek solution to the above mentioned concerns through a negotiation process to develop, in the field of the safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement, of any living modified organisms resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement."

For the purpose of this note we proceed on the basis that all living organisms are made up of cells containing molecules of DNA (deoxyribonucleic acid) arranged in structural units called genes. Genes contain information that is used by cells as a "recipe" for the organism. That is, the characteristics of any living thing are determined by the information in its genes. DNA is interchangeable within species of animals, plants, bacteria and other organisms by the traditional biological processes of exchanging genes through breeding. In addition through modern biotechnology methods scientists, in some cases, can now transfer the genes that determine many desirable traits from one species of plant or animal to another. This process is commonly referred to as genetic engineering and in such a case the result is a genetically modified organism.

It is of note that the wording in Article 8(g) specifies "adverse environmental impacts that could affect the conservation and sustainable use of biodiversity" and the correlated Article 19(3) uses the terminology "adverse effect on the conservation and sustainable use of biological diversity". Article 8(g) sets the parameter that the effects on biodiversity are mediated through environmental impacts. For an adverse environmental impact to occur material would have to enter the environment in a form or quantity sufficient to result in adverse effect. Central to the discussions of the Working Group is the issue of living organisms since by definition they are capable of reproduction, movement and interaction with components of biodiversity.

Products that are, or containing, LMO's

Commercial products in use that are or may contain LMO's fall into many categories, including agricultural, food, environmental and industrial. Examples include crop plants, grain seeds for milling into flour, seeds for ornamental plants, microorganisms for pollutant degradation, or microorganisms for the production of specialty chemicals through fermentation.

Many food plants are being genetically modified to possess novel traits for that plant, e.g. pest resistance, pesticide resistance, increased amino acid content or extended ripening period. Examples of such modified plants include corn

plants that produce an insecticidal protein to make them resistant to European corn borers, potatoes that resist the Colorado potato beetle, or soybean resistant to glyphosate, a wide-spectrum and widely used herbicide. Frequently the genetically modified organism will receive several genes including the one that confers the trait. For example, the soybean resistant to glyphosate contains genes from a bacterium (Agrobacterium species) to code for the resistance as well as genes from cauliflower mosiac virus (CMV), and petunia that control the expression of the glyphosate resistance gene.

There exists a large body of literature on regulations and policy guidance on genetic engineering and modification of living organisms and their products including but not limited to, material developed through the Food and Agriculture Organization (FAO), World Health Organization (WHO), World Trade Organization (WTO), the Organization for Economic Cooperation and Development (OECD) and the European Community (EC).

The FAO Draft Code of Conduct on biotechnology is the prime source of international guidance on applications relevant to food crops and food sources. Article 1.1 of the draft Code that the aims are to promote the use of biotechnologies for the "conservation and sustainable utilization of plant genetic resources", while simultaneously providing recommendations for their "safe, responsible and equitable use". The draft Code limits its operation to:

(a) Biotechnologies affecting the conservation and utilization of plant genetic resources;
(b) Those biotechnologies used to exploit and modify living organisms so as to produce new tools, goods and products.

Article 4 is significant in that it lists those existing international agreements with which the code is to be implemented in harmony. The Convention on Biological Diversity and the International Plant Protection Convention are named specifically, and a third category including: "other international agreements and understandings setting biosafety standard for the release, import and export of genetically modified plants and micro-organisms; and for protecting biological diversity and plant genetic resources".

Also germane, the FAO International Code of Conduct on the Distribution and Use of Pesticides was developed to assist countries (particularly those which do not yet possess adequate pesticide registration and control schemes) to control the use of pesticides. The Code was developed to regulate pesticides which it defines as "any substance or mixture of substances intended for preventing, destroying or controlling any pest". If an LMO is developed for the purpose of pest control, it could arguably come under the Code.

WHO through the work of its Biologicals Unit, including work conducted by its Expert Committee on Biological Standardization and the Laboratories for Biological Standards has a programme of work designed to assure the quality, safety and efficacy of biological substances used in medicine. The work has two main components: of relevance to this document-

1. The establishment of WHO International Reference Materials which are primary global standards used for calibrating national, regional (eg. European Pharmacopoeial) or manufacturers working standards (physical standards).

2. The development of recommendations, guidelines and requirements on the production and quality control of certain biologicals.

These are essentially sets of recommendations but can be adopted as they stand as definitive national regulations if a Member State so wishes.

Another source of guidance is the World Trade Organization's Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement). Its purpose is to limit the trade-distorting aspects of sanitary and phytosanitary measures taken by States to protect human and environmental health. Such measures are deemed to be applied for the protection of human, animal and plant life or health in the WTO member States from the following threats:

a) From the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease causing organisms;
b) From risks arising from food additives, contaminants, toxins or disease-causing organisms in foods, beverages or foodstuffs;
c) From risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests.

On a regional basis the regulatory framework of the European Community provides another example. Within the European Community (EC), the regulatory framework is based on the European Commission Directives for deliberate release (90/220/EEC) and for contained use (90/219/EEC), each of which was published in 1990.

Part C of Directive 90/220/EEC addresses and defines the procedure to be followed in the case of the placing on the market of products containing or consisting of GMOs. In order for such products to be placed on the market in the Community prior consent must be obtained in accordance with the provisions of the Directive. This procedure involves the submission of a notification to the competent authority in the country of choice of the notifier. Plant varieties approved and registered in any EC member state are combined in a common EC list of varieties for agricultural crops. Once registered, seeds of that variety may be sold in any of the member states.

Many countries have introduced legislation regulating the release and approval of GMOs and GMO products (OECD, 1995; Screen Newsletter, 1995). A cursory examination of the legislation and regulations of OECD countries, show that most OECD countries, with the exception of the United States, indicate that "industrial products" consisting of, or containing, GMOs are included in a wider scope of oversight which covers all GMOs. The system in the United States is that most such products come under the Toxic Substances Control Act (TSCA) and that at present a specific set of guidelines, under TSCA, are used for GMOs which have involved an inter-generic genetic modification.

In the United States, The U.S. Department of Agriculture (USDA) regulates genetically engineered food plants through the Federal Plant Pest Act (FPPA). This legislation authorizes the Animal Plant Health Inspection Agency (APHIS) to regulate movement between states, importation into the U.S., and field testing of "organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests." (Federal Register, Vol. 58).

In Switzerland a new regulation stipulates that all food products and foodstuffs, food additives and processing aids that are derived from or which contain GMOs require premarket approval and must be labelled as 'GVO-Erzeugnis' (GMO-product).

In general, it appears that oversight procedures for GMOs are primarily concerned with living organisms intended for release into the environment. The oversight procedure adopted in the United States includes living organisms as a special category in regulations originally implemented for the control of novel substances. The draft regulations provided by Canada are intended to cover both living organisms and their products under a common set of regulations. In the instance of living organisms intended for consumption or injection there is frequently exemption from oversight, though industrial uses where they could be unintended entry into the environment are covered. No global or international oversight mechanism exists for organisms intended for industrial or environmental applications. National schemes are targetted to specific use categories with few exceptions, for instance, Canada and the EU.

Inaminate Products that are parts of LMOs, or, produced through the biological activity of LMO's

Transgenic microorganisms, animals and plants have been developed that generate important commercial products either as the whole dead organism, components to be harvested and purified from the organism, or as a byproduct of metabolism.

Products such as insulin, growth hormone and tissue plasminogen activator that are currently produced by traditional means or by fermentation of transgenic bacteria may soon be obtained from the milk of transgenic cows, sheep or goats. Products used in the prevention, diagnosis, and control of animal diseases (vaccines for hoof-and-mouth diseases, scours, trypnosomiasis, rabies, tapeworm and liver flukes); animal nutrition and growth promotion (recombinant bovine growth hormone and recombinant hormones to induce superovulation) may also now be generated through the use of genetically modified organisms. Food additives and food processing materials or industrial feed stock such as industrial enzymes, alcohol and specialty chemicals are also amenable to the use of biotechnology in production.

Soy protein is an example of extracted component of the organism, as is flour from genetically modified wheat, tomato paste or ketchup. Examples of food additivies generated through genetically modified organisms such as single amino acids (tryptophan), or processing agents such as chymoprypsin (enzyme) are currently on the market in some countries..

International agreements that address food or pharmaceutical products include the Codex Alimentarius (Codex) and the WHO. Codex is an internationally developed code of food standards. The prime objective of the Codex is the protection of human health. As such, the Codex does not address either the impact of LMOs on the environment or issues of biotechnology generally. In 1989, the Codex discussed the potential impact of biotechnology on food standards again with the sole purpose of addressing human health concerns..

As identified above, the WHO addresses the quality, safety and efficacy of biologicals used in medecine.

The sanitary and phytosanitary provisions of the WTO also apply to inanimate products and allow for assessment and decision on import based on environmental concerns.

A new regulation on novel foods and food ingredients was adopted by the Council in December 1996 and by the European Parliament in January 1997. It has been decided that the novel food regulation will become effective ninety days after its publication; i.e. by end of April, 1997.

Applications of gene technology for the production of processing aids are mainly focused on the use of recombinantly expressed enzymes (Braunschweiger and Conzelmann, 1997). The regulations on enzymes, including those produced by genetic engineering, are not standardised in Europe. The EC directive 90/220/EEC applies only to the release of GMOs, or to products containing GMOs, and therefore does not concern enzymes deriving from recombinant technology. Nor is it likely that the planned novel food legislation of the EC will include enzymes.

In the United States the Food and Drug Administration has the primary responsibility for regulating food additives and new foods. The animal growth hormones bST and pST are under FDA regulation because the agency is required to determine the safety and effectiveness of animal drugs. Before allowing drugs for food-producing animals to be marketed, the FDA requires that these drugs be shown to be safe by rigorous scientific studies.

Inanimate products derived from or through the use of genetically modified

organisms are not in the true sense of the word genetically modified products. The human insulin, bovine growth hormone or single amino acids produced from a genetically modified microorganism is almost indistinguishable from the insulin, growth hormone or amino acid from the traditional source. The differences, if any, are chemical rather than genetic. Products of this type are usually assessed under use specific legislation targetted to the primary concern. Since most of these products are intended for human or animal consumption the legislation addresses human or animal health. Rarely under this legislation are environmental matters addressed.

In the case of industrial products, e.g. alcohol, specialty chemicals, where the product or a by-product from its use might enter the environment the product is commonly assessed under environmental legislation. In the case of the OECD, the Council in Decision C (82) 196 (Final) of December 1982 requires member states to establish procedures to ensure a meaningful assessment of hazard to man and the environment. These assessments could include impacts on biodiversity.

It appears that in several countries non-GMOs and GMO products could also be subject to regulatory oversight under the ambit of other, broader legislation, e.g. legislation concerned with new chemicals/substances, environmental protection, or pollution control.

Where a chemical entity has been assessed and is considered to pose an unacceptable risk either through intended or accidental release into the environment action could be sought under the Legally Binding Instrument for the Application of the Prior Informed Consent Procedure for certain Hazardous Chemicals and Pesticides in International Trade (PIC). This action must be based on prior evidence of adverse effect on the environment or human health.

In situ Products of LMOs

Any living organism generates metabolic products, enzymes, material in membranes in the cells, hormones, toxins. These, when in the live organism, may be considered in situ products. In the case of genetically modified organisms, such as corn modified by the introduction of a Bt gene, both the gene and the protein expressed by the gene, i.e. the gene product, may be considered in situ products.

Notification and assessment of an LMO includes any metabolites or components generated in the LMO in situ. The legislation does not usually contain explict reference to metabolites produced in situ. However, analysis of the information requirements, where available, for performing a risk assessment of the LMO indicate that the assessment includes an assessment of the in situ products of the LMO. For example in the OECD harmonization of regulatory oversight report (OECD Environment monograph 100, Brussels 1995) there is agreement on explicit information requirements including assessment of the in situ products.

Summary

The Conference of the Parties in Decision II/5 call for the identification of relevant categories of LMOs for consideration under the protocol, and stipulate that the protocol may not exceed the scope of the Convention nor override or duplicate any other international legal instrument in this area.

The relevant Articles of the Convention and the relevant decisions of the Conference of the Parties restrict the protocol to living modified organisms resulting from biotechnology.

The inclusion of non-living products of biotechnology would exceed the scope of the Convention as identified in Articles 8(g) and 19(3), and in so far as they are foods or medical products would duplicate provisions in the WHO, FAO and WTO legal instruments.

All products that are, or contain, living modified organisms could be subject to the protocol, but the Working Group may wish to identify categories that are not relevant. No other international legal instrument adequately addresses the issue of adverse impacts on the conservation and sustainable use of biodiversity.

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