

From:
Comunidad Andina (Andean Community)
General Secretariat
Lima 27
Peru

Subject: Implementation of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients

Dear Mr Byrne,

In response to the European Commission's invitation to third parties to submit their comments on the discussion document prepared by the Directorate-General for Health and Consumer Protection and on any other aspect of the Regulation on novel foods and novel food ingredients, the General Secretariat of the Andean Community would like to comment on certain aspects of the Regulation, for consideration by the Commission.

I. Preliminary remarks: interest of the Andean Community in having access to the European market for novel foods and novel food ingredients

The five Member States of the Andean Community — Bolivia, Colombia, Ecuador, Peru and Venezuela — are home to a wide range of natural resources, representing around one quarter of the Earth's total biodiversity. The tropical Andean regions alone are the original source for Andean-Amazon plant genetic resources from which it is estimated around 35% of the world's agri-food and industrial production comes.

Over the past few years, the countries in the Andean Community have paid greater attention to international trade in biodiversity products in response to the increasing international demand for these products and the growth in "green markets" for organic products meeting international environmental standards. Countries in the Andean region are making intense efforts to identify new markets and disseminate information to expand the range of products. In particular, a major effort has been made to promote and facilitate "biotrade"*.

Nonetheless, many of the foods resulting from Andean biodiversity have not found their way onto international markets, particularly the European market, despite the fact that a wide range of the phylogenetic and zoogenetic resources available in the Andean countries — both from the Andean altiplano and from the coastal and Amazonian plains — form part of the traditional diet in Andean countries and their safety has been properly assessed by the national authorities, third countries and approved bodies. For the General Secretariat, increased exports of these products will be an important source of income for

* In this connection, at the World Summit on Sustainable Development held in Johannesburg last August, the Andean Community signed an agreement with UNCTAD and the Andean Development Cooperation known as the Andean Biotrade Programme, the purpose of which is to boost investment and trade in biological resources with a view to meeting the objectives of the Convention on Biological Diversity and promoting sustainable development. The agreement was signed in the presence of European countries such as Germany, the Netherlands and Switzerland.

people in the subregion and, in particular, for those living in the Andes and Amazon basin.

II. Initial comments: the scope of the Regulation

The General Secretariat considers that food products originating in Andean-Amazon biodiversity, which are known to be safe for human health, cannot be treated as transgenic or innovative products or products obtained by processes that are not currently used or the like, for the purposes of applying food safety controls.

Article 1 of the Regulation states that its purpose is to regulate the placing on the market within the Community of novel foods or novel food ingredients, regarding as “novel” foods those which “have not hitherto been used for human consumption to a significant degree” in the Community before 15 May 1997 and which fall into the categories specified in the Regulation. These categories include: foods that contain or are produced from genetically modified organisms; foods with a new molecular structure; foods to which has been applied a production process not currently used; foods and food ingredients consisting of or isolated from plants; and food ingredients isolated from animals. Despite the differences between the categories, the Regulation makes all these products subject to the same type of procedure, conditions, analysis, production of evidence, deadlines and formalities.

Although the Regulation does not apply to foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use, this exception is limited to just a part of the wide range of products of Andean-Amazon biodiversity and, in practice, is difficult to demonstrate.

The lack of any real differentiation by class or category of product which, if it existed, would result in different requirements, conditions etc. produces an evidential and administrative burden for foods derived from our biodiversity. As this “burden” was specifically designed for genetically modified and “innovative” products, it is disproportionate and excessive in view of the objectives pursued by the Regulation and, more generally, in terms of the legitimate aim of protecting the health and lives of human beings that is recognised by the rules of the World Trade Organisation. As such, it may constitute an unjustified obstacle in gaining access to the European market.

It should be pointed out that the European Commission’s discussion document, which refers to “exotic traditional foods” (to which group the products of Andean-Amazon biodiversity might be considered to belong), to some extent acknowledges that such foods constitute a group that can be clearly distinguished from the other categories to which the Andean-Amazon products have been incorrectly assigned.

Since the potential risks to human health and the environment arising from the use of transgenic products constitute one of the main reasons (recitals 5, 8 and 9) for adopting the Regulation, the European Commission’s recent initiative to set up a separate system and specific criteria for the authorisation and traceability of foodstuffs containing genetically modified organisms also signals a recognition that, because of their nature, origin and associated risks, these products should not be regulated by the same provisions that may be applicable to products of biodiversity. By the same token, it is essential that products of biodiversity be distinguished from innovative products or those obtained by processes not currently used. Recognition of this fact should necessarily lead to exclusion of biodiversity products from the scope of the Regulation or, at least, a revision of its conditions relating to such products.

III. Comments concerning the analytical, evidential and procedural burden

The General Secretariat of the Andean Community considers that the requirements, documentary evidence and procedures laid down for foods regarded as “novel” by the European Community should be proportional to the nature of the foods in question, which should be classified according to the risks that they may entail for consumers.

The Regulation was designed to deal with questions of food safety assessment, mainly for innovations in the field of biotechnology. However, it included as “novel foods” the products of Andean-Amazon biodiversity simply because such products do not originate in the European Community or form part of a different diet found in other cultures, ignoring the fact that their characteristics differ radically from those of transgenic or innovative products or products obtained by processes not currently used.

As a result, these types of foods are subject to formalities and procedures that would not normally be necessary when trading in foodstuffs. One of the principles of the World Trade Organisation is that, although countries are entitled to take measures to protect the health and lives of individuals, such measures should be limited to what is needed to achieve this objective and should not be introduced without sufficient scientific evidence. When setting levels of health protection, countries must also avoid making arbitrary or unjustified distinctions. Thus, provided it is shown that the reasonable level of protection required by the importing country has been met, health certificates issued by the exporting country are an acceptable way of demonstrating that the foods are fit for human consumption.

Despite this, the Regulation in various ways makes access to the European market for products of Andean-Amazon biodiversity more difficult. These include:

- a) the complexity of the evidence required, which causes serious problems when applying for authorisation to market the product;
- b) wide powers of discretion for the European authorities to determine the adequacy of the evidence produced, the safety and history of use of a food, the appropriate level of consumption in the Community before May 1997, and equivalence;
- c) too few alternative means of obtaining authorisation, because certificates issued by the exporting country, third countries or recognised bodies are not accepted;
- d) lengthy assessment periods, with the result that it may take, on average, four years before a decision allowing the food to be imported is made;
- e) unnecessary duplication of formalities, an assessment being required on a case-by-case basis and for each individual application, and not according to the product;
- f) high costs for each transaction as a result of the above.

The same problems arise when demonstrating the applicability of the exclusions mentioned in the Regulation, such as for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use.

The European Commission should also attempt to clarify the scope of the “novel food” concept used in the Regulation, given that the latter applies to the placing on the market within the Community of foods which, before 15 May 1997, “had not hitherto been used for human consumption to a significant degree within the Community”. In fact, there are various foods which were marketed before the Regulation came into force, although their consumption may not have been to the “significant degree” required by the Regulation because they were only available in one or two European countries, or were intended for a select group of consumers, e.g. specific ethnic groups or consumers of exotic foods. To

these must be added those foods that European countries traditionally reserve for animals even though they form part of the human diet in our own countries (e.g. maize). It seems unnecessary for the checks and, in general, the scope of the Regulation to cover these categories of foodstuffs, particularly when they form part of the traditional diet in third countries, are well-known and, in addition, have a history of safe food use.

If a product could not be shown to be fit for human consumption by means of health certificates or there were sound reasons for doubting its fitness, and in order to avoid unjustified discrimination, the current procedure could perhaps be replaced by simplified notification and recognition procedures according to the extent to which the product is consumed or known in third countries, and provided the WTO rules and principles are complied with.

The principle of proportionality would be flouted if all the “novel” foods were subject to the same main procedure and the simplified procedure were done away with. This would also constitute a clear case of discrimination because situations that are totally different would be treated in exactly the same way.

IV. Comments on the type of legal instrument used and the person initiating the procedure

The General Secretariat of the Andean Community takes the view that, in the absence of a health certificate, the procedure used for approving products of Andean-Amazon biodiversity should be objective and general in its effect. Consequently, it should be possible for applications to be submitted by any person (natural or legal) who has an interest in doing so.

The European Commission has identified two options for authorising the marketing of novel foods: retaining the current system of decisions addressed to individuals, or adopting general regulations instead of decisions so that it is not necessary to request authorisation if the product concerned has already been assessed and authorisation given, regardless of who made the initial application.

The second option, i.e. issuing regulations with a general effect instead of decisions, would clearly avoid the unnecessary duplication of procedures and also enable applicants to save time and resources. The rationale for this approach is based on the fact that the assessment of foods from Andean-Amazon biodiversity should relate to the product itself, which is always fundamentally the same, regardless of the person making the application or the form in which the product is presented for sale (e.g. natural, packaged, dry or dried).

Accordingly, it would also be sensible to amend the Regulation so that applications for authorisation can be submitted not only by the person responsible for placing the novel food on the European market but also by the operators of processing plants and any moral or legal person with an interest in marketing the product.

V. Conclusions

- It is not appropriate that food products derived from Andean-Amazon biodiversity which demonstrably have no adverse effects on human health should be regarded as equivalent to transgenic or innovative products, products obtained by processes not currently used, or similar products.

- It is not appropriate to draw up a general classification that groups together, and replaces, all categories of novel foods.
- The requirements, documentary evidence and procedures specified for foods regarded as “novel” by the European Community should be proportionate to the nature of the foods concerned, which should be classified according to the risks that they may entail for consumers.
- A distinction based solely on the origin of the food or the dietary habits of a particular society does not justify subjecting the food to formalities and procedures which would not normally be necessary in commercial transactions. In accordance with the rules and principles of the World Trade Organisation, although countries are entitled to adopt health measures to protect the health and lives of individuals, these measures should be limited to what is required to achieve the objective and not be introduced without sufficient scientific evidence. When setting levels of health protection, countries must also avoid any arbitrary or unjustified distinctions.
- The health certificate issued by the exporting country is a sufficient basis for approving foods as being fit for human consumption.
- If fitness for human consumption could not be demonstrated by means of a health certificate or there were sound reasons for doubting such fitness, and in order to avoid unjustified discrimination, it might be practical to look at less restrictive or arbitrary means allowing products of Andean-Amazon biodiversity access to the Community market. These could include simplified notification and examination procedures, which could be applied depending on the extent to which the product was consumed or known, provided the WTO rules and procedures were followed.
- Similarly, in the absence of a health certificate, the formalities involved in obtaining approval for products of Andean-Amazon biodiversity should be objective and have a general effect. This would mean that the application could be presented by any person (natural or legal) with an interest in doing so.
- In line with the World Trade Organisation’s rules and principles, the Regulation should not apply (in addition to foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use in the European Community) to the following:
 - (i) foods and food ingredients which form part of the traditional diet in third countries, are well known and have a history of safe food use in these countries;
 - (ii) traditional, exotic or “ethnic” foods and food ingredients which were in any way marketed within the European Community before 15 May 1997.

Yours sincerely

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General Secretary of the Andean
Community

cc: Ambassador Mendel Goldstein
Head of Delegation to the European Commission