

Understanding the Revision Process of the Regulation on Novel Foods

By Eduardo Escobedo, Economic Affairs Officer, Biodiversity and Climate Change Section, UNCTAD

Background



As indicated by the European Commission, research shows that market interest and demand for biodiversity products and services is growing, giving countries rich in biodiversity a comparative advantage. Furthermore, it has been demonstrated that trade can serve as an incentive and contribute to the sustainable use and conservation of biodiversity, as well as the supporting local communities and small and medium size enterprises (SMEs) to increase their supply side capacity through sustainable management practices that in turn generate local income and jobs and, ultimately, contribute to poverty alleviation.

Given that the world's greatest concentration of biodiversity is found in tropical developing countries, this represents a huge potential in terms of sustainable use and commercialisation of an array of products and services derived from its biodiversity.

Despite this potential, in many cases, developing countries are not able to take full advantage of their comparative advantages due to supply-side constraints and the existence of multiple trade barriers that have led to lengthy and costly processes that require extensive scientific and historical data to prove their safety.

The Regulation on novel foods, an EU regulation that was adopted in 1997 and which has the main objective of establishing harmonised rules for the placing of novel foods in the Community with a view to ensuring a high level of human health and consumers' protection, has posed important barriers to producers of traditional foods from developing countries wishing to place their products in the EU market.

With the intention of improving and bringing greater coherence to EU legislation in this area, the EC began a consultation process with stakeholders that was carried out during the period of 2002-2007. As a result of this process, the Commission of the European Communities published the proposal for amendment of the Regulation (EC) No 258/97 on novel foods on January 14 2008.

The proposed revision to the Regulation aims to:

Streamline the authorisation procedure, develop a safety assessment system that is better adjusted for traditional food from third countries, which is considered a novel food under the current Regulation;

Clarify the definition of novel food, including new technologies with an impact on food, and the scope of the novel food Regulation;

- Improve the efficiency, transparency and application of the authorisation system, which also contributes to better implementation of the Regulation, and empower consumers by informing them about food;
- Ensure legal clarity by making necessary changes and updating the legislation.

The legislative procedure

With the Commission's proposal published, the EU legislative process to adopt the new Regulation was launched under Article 251 of the EC Treaty establishing a co-decision procedure.

The co-decision procedure is based on the principle of parity between the legislative institutions of the EU which means that neither the European Council nor the Parliament can adopt legislation without the other institution's assent.

In accordance with the procedure, the EC's proposal was forwarded simultaneously to the Council and the Parliament. It was also sent to the Economic and Social Committee for their opinion. The Committee adopted its opinion on 29 May during its 445th Plenary Session.

The Committee supports the improvement of the Regulation through the proposed centralised evaluation and authorisation procedures. Furthermore, it highlights the importance of the clarity and comprehension in the final Regulation to enable operators to apply it. In regards to the treatment of traditional foods from third countries the Committee states that there is a need to simplify the existing authorisation procedure and that the notification procedure proposed could result in simplification to a large extent. Finally, it underlines the importance of the protection of intellectual property in order to promote innovation and competition.

On 27 May 2008, the Council produced its progress report based on the examination of the EC's proposal by the Working Party on Foodstuffs. The report identifies a series of issues where it states that it is possible to consider that there is broad agreement and other that need further consideration. Some of the key elements of the report include the need for clarification of definitions included in the proposal, the abolition of applicant linked authorisation with protection of proprietary data or new scientific evidence in some cases, the need for further information related to the notification procedure proposed for traditional foods from third countries, the treatment of borderline products that could be classified as medicinal, and criteria to that should be introduced regarding data protection.

The European Parliament has named the Committee on Environment, Public Health and Food Safety responsible for preparing and adopting its position. It has appointed Mrs. Kartika Liotard as rapporteur and expects a first reading of the proposal in December 2008 with a vote in the EP Plenary in January 2009. Furthermore, the Parliament has asked the Committee on Agriculture and the Committee on Internal Market and Consumer Protection for opinions on the proposal.

The rapporteur's draft report was circulated on 26 June 2008. The report emphasises the objective of attaining a high level of food safety, consumer protection, environmental protection and the protection on animal health and calls on the observance of the precautionary principle as laid down under EU Laws, in all cases. The report clearly states that all other objectives are of secondary importance.

The Parliament is proposing the inclusion of environmental and animal protection within the scope of the Regulation. This goes beyond the scope of the current Regulation which focuses on human health. This proposal has received mixed reaction from stakeholders

regarding the reasons behind the inclusion of these issues and the possible impacts this might have on the application process especially in reference to the additional scientific data and requirements that this would entail for producers and exporters and thus the additional costs involved. Certain actors also fear that revisiting the scope of the Regulation will result in further delays in the revision process and thus a losses in trade.

The report also calls on further clarification of the definition of novel foods and other associated definitions. It makes reference to the lack of clarity in the Commission's proposal and provides specific amendments that seek to clarify or replace the definitions included in the proposal.

Regarding traditional foods from third countries, the report highlights the importance of clarifying what an assessment of history of safe use would entail and establishing a clear period of time that would need to be proven to guarantee safety. In this respect, it recommends a period of 50 years rather than the wording of "one generation" included in the proposal.

On the issue of intellectual property protection, the report underlines several inconsistencies referring to the 5-year data protection clause proposed by the Commission, and rather, proposes to retain the existing regulation on confidentiality of manufacturing data.

Where do we stand?

At the moment, the European Commission is waiting to receive the position and recommendations of the Parliament so it can amend its original proposal taking into consideration the proposals of the Parliament which it may incorporate either unaltered or reworded. To this effect, although there is no established deadline for the Parliament to provide its recommendation to the Commission, the Rapporteur has established a deadline for early October where parliamentarians can propose amendments to the proposal before



it is taken for a first reading in early December. With this in mind it is expected that the Parliament will vote on its recommendation in January 2009 and will forward these recommendation to the Commission for its consideration.

As mentioned above, the Commission will then revise its proposal and send it to the European Council for its first reading. As a result of its first reading the European Council can either accept all the amendments proposed by the Parliament and incorporated by the Commission into the proposal or it can adopt a common position which is then sent to the Parliament together with a statement of reasons of why the Council does not share the views expressed by the Parliament. In case it accepts all amendments, the act can be adopted.

In the case of the common position, the EP then has a second reading with the difference that the reading will not be on the Commission's amended proposal but on the Council's common position. The EP has three months from the date of receipt of the common position to take action. There are three possibilities of action the EP can take, 1) accept the common position without amendments, 2) reject the Council's position by an absolute

majority vote, or 3) propose amendments to the common position. In the first case, the act can be adopted. In the second case, the act is deemed not to have been adopted and the procedure is ended (the EP has never used this prerogative). In the third case, the EP's recommendations are passed to the Commission and the Council.

The Commission will then decide if it agrees with all of the EP's amendments. In the case of disagreement with even one amendment by the Commission, the Council will then need a unanimous vote to accept the EP's overall position.

Once the Commission provides its opinion to the Council, the Council will accept or reject the EP's position. If it accepts the position, the act can be adopted. If it rejects the position a conciliatory committee will be set up with the objective of facilitating a final joint text of acceptance to both institutions.

At the moment it is still unclear how the legislative procedure will evolve in the case of the revision process for the Regulation on novel foods. In case the Council accepts the proposal in its first reading it is expected that the act will be adopted during the first semester of 2009.

The revision process in the international context

Since the Regulation on novel foods deals with market access issues which have development implications in many biodiversity-rich developing countries, it is not a surprise that the revision process is being followed closely by a broad number of international stakeholders from all continents.

Regarding the international legal framework, the European Commission notified the proposal to the Agreement on Technical Barriers to Trade (TBT) of the WTO. This has caused ample debate on whether the Regulation actually deals with TBT issues or with sanitary and phytosanitary (SPS) issues in which case the WTO SPS Agreement would take precedence. The Commission has stated that the mandatory labelling provision of novel foods belong to the scope of the TBT Agreement. Furthermore, it has been informally stated that due to the fact that most of the novel foods are not covered by the tariff structures of the WTO Agreement on Agriculture, then the SPS Agreement would not apply.

Nevertheless, different stakeholders believe that the objective set out by the Regulation to ensure that novel foods and food ingredients: a) do not present a danger to the consumer; b) mislead the consumer; or c) differ from the foods or food ingredients they are meant to replace such that their consumption would be nutritionally disadvantageous, refers to a measure within the scope of the SPS Agreement.

The evolution of this debate regarding whether the measure falls within the scope of the TBT or SPS agreement will be crucial to the analysis of WTO compatibility of the final text of the Regulation.

Other international fora have also put into question the compatibility of the Regulation with other international obligations of the EU. Such is the case of the Convention of Biological Diversity which promotes the conservation and sustainable use of biodiversity. As many of the novel foods that would fall under the Regulation are harvested, transformed and traded in biodiversity-rich developing countries, there is a debate on how the impacts of this Regulation would affect the objective of this Convention. These sorts of questions have also been raised in relation to the EU's broader development agenda and how the Regulation could enter in conflict with it.

Notwithstanding ongoing debates in several parts of the world, potential interested countries have been slow in reacting to the process. According to Commission sources, only a few general comments have been received from countries regarding the proposal

and ongoing debate in Europe. Without more involvement of international actors in the process it is difficult to foresee that many of the outside concerns will be taken into consideration by the EU's institutions.

Opportunities to contribute to revision process

EU and international actors all agree on one key thing: the high degree of political and technical complexity of the issues addressed within the proposed regulation. This can be seen as a big opportunity or a great risk but at the end is more a mix of both.

The major risk of this complexity comes from not filling the technical and scientific knowledge and information gaps before major decisions are taken. As was noted in the paragraphs above, there have been calls from all sides of the negotiation for more clarity and more information regarding definitions and processes defined in the proposal. This



have to do from issues of how to determine the novelty of a product to how do you assess the history of safe use of a food.

Deadlines within the process have already set for taking decisions. The process is continuing its course and a final Regulation could be adopted as early as May or June next year. The question here is what the possible impact of taking these decisions without producing adequate knowledge and information will be in the final outcome of the process.

This risk also provides the greatest opportunity to contribute to this process. The documents that have been circulated by the European institutions all point to further clarification and considerations regarding a number of well defined issues.

There is a wide range of experiences that producers of novel foods have had with the current Regulation and with

other regulations in other countries that could serve as learning platform to contribute to filling information gaps. Furthermore, international and regional institutions have been working on these issues for several years and could provide important inputs to the process. Finally, governments of exporting countries should become more active in the process and share their concerns with the relevant actors in Europe to ensure that their interests are taken into account during the discussions.

In this process the main challenge is time. As the process advances and decisions are taken it will become more difficult to find spaces to contribute, so the time to act is now.

Relevant link

<http://www.biotrade.org>

Contact

Eduardo Escobedo

UNCTAD, Palais des Nations, CH-1211 Geneva, Switzerland

Telephone: +41 22 917 5607

Fax: +41 22 917 0247

<http://www.unctad.org>

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Paul Bordoni / GFU

<http://www.underutilized-species.org/>

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