

# WORLD TRADE ORGANIZATION

RESTRICTED

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**Working Party on the  
Accession of Montenegro**

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## ACCESSION OF MONTENEGRO

### Additional Questions and Replies

#### Addendum

#### *Comments on Certain Laws from the Republic of Montenegro*

The following submission, dated 21 January 2008, is being circulated at the request of the Delegation of the Republic of Montenegro.

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- **Law on Genetically Modified Organisms**

**Question 1**

**We thank the Government of the Republic of Montenegro for the opportunity to comment on its legislation on genetically modified organisms. Regarding genetically modified organisms, we are concerned that the systems for registering and the requirements for commercializing may be overly-costly and burdensome. Such costs could function as barriers to trade. Once declared safe for placing on the market, use of the product should be free of restrictions. We encourage Montenegro to adopt measures consistent with international standards. Tests for risk assessment should utilize clearly testable scientific hypotheses and testing should include those tests minimally necessary to identify and assess clearly identifiable risks from the use of a product.**

**Chapter II, Article 7: We recognise that a competent organization will provide a risk assessment for the application process for individual biotech products. Will Montenegro accept test results from other competent organizations?**

Answer:

The Ministry of Agriculture, Forestry and Water Management has prepared the draft of the new Law on Genetically Modified Organisms, which has been approved by the Government of Montenegro on its session on 20 December 2007. The draft is now in the phase of public discussion. In accordance with this draft, test results of other competent organizations will not be accepted.

**Question 2**

**Chapter II, Article 10: Does Montenegro intend to apply the regulation and risk assessment to a single biotech event (transformed plant line) or to every food, feed or seed product that might be derived from the genetically-engineered plant?**

Answer:

In accordance with the draft of the new Law on Genetically Modified Organisms, risk assessment and the regulations will apply to every food, feed, or seed product that might be derived from the genetically-engineered plant.

**Question 3**

**Chapter VI, Article 26: What is the basis for imposing a fine rather than simply not processing the application when an applicant fails to meet application requirements?**

Answer:

In accordance with the draft of the new Law on Genetically Modified Organisms there is no fine for the applicant who did not meet the requirements. Under the law that regulates general administrative procedure, the application is refused if the applicant does not meet the requirements.

- **General Comments on Animal and Plant Health Legislation**

**Question 4**

We appreciate the opportunity to provide comments on Montenegro's animal and plant health legislation. We are pleased with the legislation related to food safety, and look forward to reviewing the implementing legislation. Our concern rests primarily with the Ordinance on Bovine Spongiform Encephalopathy (BSE).

**BSE Guidance:** Montenegro, under its Ordinance on BSE, does not allow live animals and a variety of beef and beef products from countries that have had occurrences of BSE. However, the OIE Terrestrial Animal Health Code (OIE Code) clearly states that trade in such products can occur.

The OIE Code aims to assure the sanitary safety of international trade in animals and their products. This assurance is achieved through the detailing of health measures to be used by the veterinary services or other competent authorities of importing and exporting countries in establishing health regulations for the safe importation of animals and animal products.

On 22 May 2007, the OIE adopted the recommendation that the United States be recognised as a "controlled" risk country with regard to BSE. This OIE controlled risk classification provides an objective international definition of the science-based mitigation measures that the United States should follow to effectively manage any BSE risk. The United States regulatory controls in place since January 2004 are consistent with those identified by the OIE and sufficient to permit the United States beef and beef products from cattle of all ages to be traded safely in accordance with international guidelines. Article 2.3.13.11 of the OIE Code provides the following guidelines for the certification of fresh meat and meat products from cattle from controlled risk countries, zones, or compartments:

- The cattle from which fresh meat and meat products were derived passed ante-mortem and post-mortem inspections;
- The cattle from which fresh meat and meat products are derived were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process; and
- The fresh meat and meat products were produced and handled in a manner which ensures that such products do not contain and are not contaminated with specified risk materials as defined in items 1 and 2 of Article 2.3.13.14 of the OIE Code, or mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

**Ordinance on Undertaking the Measures to Prevent Introduction of the Animal Infectious Disease Bovine Spongiform Encephalopathy (BSE) in the Republic of Montenegro (OG RM 23/2005):**

1. **Article 1 and 2:** We are concerned that the law on BSE is inconsistent with OIE standards. While imports of beef and beef products may be banned from any countries that have had occurrences of BSE, Montenegro's BSE law overstates the OIE position by banning all beef and beef products. Is there an exception for controlled risk countries?
2. **Article 2, paragraph 3:** Does Montenegro allow for risk assessments conducted by the OIE for countries that have submitted dossiers?

3. **Article 4, paragraph 10:** Montenegro indicates that meat is acceptable only from animals under 24 months of age that have been tested for BSE. Is this 100 per cent testing? Requiring testing at 100 per cent is inconsistent with OIE guidelines and may serve as a barrier to trade.
4. **Article 7, paragraph 2:** What is the basis for requiring trace-back of animals to the mothers? Is traceability to the herds sufficient?
5. **Exhibit 1:** Please explain why both OIE negligible and controlled risk countries are listed in category 1.

Answer:

The Ordinance on Undertaking the Measures to Prevent Introduction of Animal Infectious Disease Bovine Spongiform Encephalopathy (BSE) in the Republic of Montenegro (RM Official Gazette No.23/05) will be amended in accordance with OIE standards and recommendations by the end of February 2008 and subsequently submitted to the Working Party for review.

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