Based on Article 12, paragraph 1 of the Regulation on the Government of the Republic of Montenegro (RM Official Gazette No. 15/94 and 4/97), and related to Article 12, paragraph 6 of the Law on Plant Health Protection (RM Official Gazette No. 28/06), Articles 34c, 34d and 34e of the Veterinary Law (RM Official Gazette No. 11/04 and 27/07) and Articles 56, 57 and 58 of the Law on Food Safety (Official Gazette of Montenegro No. 14/07), the Government of Montenegro on its session held on _______________2007, has adopted the following

REGULATION

ON THE PROCEDURE FOR NOTIFICATION OF SANITARY AND PHYTOSANITARY MEASURES

I. BASIC PROVISIONS

Article 1

This Regulation shall regulate the manner of providing information and notification procedures with respect to sanitary and phytosanitary measures, in accordance with relevant international agreements binding on Montenegro.

Article 2

For the purpose of this Regulation sanitary or phytosanitary measure shall be any measure applied to:

- protect animal or plant life or health within the territory of Montenegro from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- protect human or animal life or health within the territory of Montenegro from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- protect human life or health within the territory of Montenegro from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- prevent or limit other damage within the territory of Montenegro from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures referred to in paragraph 1 of this Article shall comprise laws, regulations or ordinances that are applicable generally and regulate inter alia the following: end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety, as well as regulations that establish such measures.
II. RESPONSIBLE AUTHORITY

Article 3

The enquiry point responsible for providing information and notification with respect to sanitary and phytosanitary measures referred to in Article 2 of this Regulation shall be the Ministry of Agriculture, Forestry and Water Management (hereinafter referred to as: the Ministry).

III. ENQUIRY POINT

Article 4

The enquiry point of the Ministry shall provide information and copies of relevant documents and shall provide answers to all reasonable enquiries from the members of relevant international organizations and other interested parties regarding the following:

- any sanitary or phytosanitary regulations adopted or proposed in Montenegro;
- any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated in Montenegro;
- risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;
- the membership and participation of Montenegro or of its relevant bodies, in international sanitary and phytosanitary organizations and systems, as well as in relevant bilateral and multilateral agreements and arrangements, and the texts of such agreements and arrangements.

Where available, the Ministry may provide any other relevant information.

Article 5

Where copies of documents are requested by interested parties, such copies shall be supplied upon payment of a fee reflecting actual costs of the service rendered, and shall, apart from the real cost of delivery, be the same for domestic and foreign persons.

Any copies of documents referred to in paragraph 1 of this Article shall be supplied in their original language.

IV. NOTIFICATION

Article 6

The Ministry shall notify sanitary or phytosanitary regulations to relevant international organizations, including the World Trade Organization, unless otherwise provided for by the applicable rules of the relevant international organization or by the legislation of Montenegro.
The notification referred to in paragraph 1 of this Article shall take place ex officio whenever:

- an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation; and
- and the proposed regulation may have a significant effect on trade.

Significant effect on trade between two or more countries referred to in paragraph 2, subparagraph 2 of this Article, may those caused by one or more sanitary or phytosanitary regulations, by a specific product, group of products or products in general.

**Article 7**

In the notification procedure referred to in Article 6 of this Regulation, the Ministry shall:

- publish a notice at an early stage of preparation of the sanitary or phytosanitary regulation in such a manner as to enable interested parties to become acquainted with the proposal to introduce a particular regulation;
- notify members of relevant international organizations, in accordance with the applicable rules, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation;
- performs notifications at an early stage to enable interested parties to review the regulations in order to submit amendments and comments and eventually have them included in the proposed regulation;
- provide upon request to interested parties copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;
- without discrimination, allow reasonable time for interested parties to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

The sanitary or phytosanitary regulation referred to in Article 6 of this Regulation shall be adopted after the expiration of 75 days after the day of notification.

**Article 8**

Where urgent problems of human, animal and plant health protection arise or threaten to arise in Montenegro, if necessary, the Ministry may adopt sanitary or phytosanitary regulation without previous notification referred to in Article 7 of this Regulation if:

- immediately notifies members of the relevant international organizations, in accordance with the applicable rules, of the particular sanitary or phytosanitary regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);
- provides, upon request, copies of the regulation to the members of the relevant international organizations;
allows members of the relevant international organization to make comments in writing, discuss these comments upon request, and takes the comments and the results of the discussions into account.

**Article 9**

Where the sanitary or phytosanitary regulation that may be subject to notification requirements under this Regulation is prepared and adopted by the other administrative authority, such authority shall, at an early stage of preparation of the regulation, notify the Ministry the following:

- information on the authority responsible for adoption of sanitary or phytosanitary regulation (telephone number, fax, e-mail and information about the person appointed to liaise with the Ministry);
- the legal grounds for adopting the regulation;
- indication of provisions of the relevant international agreement that require the notification to be made;
- countries to which the regulation applies, if applicable;
- field and scope of application of the regulation;
- list of products covered by the regulation;
- brief description of the content of the regulation;
- if the regulation is being adopted in the urgent procedure, purpose and reasons for adoption and justification for the urgency;
- information on international standards, guidelines and recommendations on which the regulation is based upon;
- departure from international standards, guidelines and recommendations, if any, and reasons for such departure;
- date of intended adoption or date of adoption and date of entry into force of the regulation;

The notice referred to in paragraph 1 of this Article shall be submitted to the Ministry on the form N that is printed with this Regulation and is its integral part.

The notice referred in paragraph 1 of this Article shall be accompanied by a draft of the prospective sanitary or phytosanitary regulation.

**Article 10**

The Ministry shall decide on the necessity for submitting notification to the relevant international organization based on the received notice referred to in Article 9, paragraph 1 of this Regulation.

In the case of initiation of notification procedure referred to in paragraph 1 of this Article, the responsible administrative authority shall, after being informed by the Ministry, delay the adoption of the sanitary or phytosanitary regulation for a period of not less than 75 days from the date of the notification.

Upon the Ministry’s request, the responsible authority referred to in Article 9, paragraph 1 of this Regulation may decide to extend the time period referred to paragraph 2 of this Article.
All submitted notifications referred to in Article 6 of this Regulation shall be published on the web site of the Ministry.

Article 11

Upon the request of the members of an international organization, the Ministry shall provide a copy of the draft sanitary or phytosanitary regulation and the translation on English language. In case of voluminous documents, translation of the summary shall be provided.

The Ministry shall forward the comments received from members of international organization to the administrative authority responsible for preparation of the regulation and their request the answer to those comments.

The answer to the comments shall contain a statement that the comments will be considered, partly or fully, in the preparation of the sanitary and phytosanitary regulation.

If the comments are not to be accepted, reasons for such a decision shall be given.

The answer to the comments shall be forwarded to the member of the international organization who has submitted them.

Where the rules of the international organization so provide, any negotiations with the member of the international organization whose comments have not been accepted shall be conducted by the Ministry in cooperation with administrative authority responsible for preparation of the sanitary or phytosanitary regulation.

Article 12

The Ministry shall be responsible to receive any notification of a draft sanitary or phytosanitary regulation from any member of relevant international organizations, under the applicable rules.

A copy of any notification received, the Ministry shall forward to other administrative authorities responsible for sanitary or phytosanitary matters.

Received notification shall be published on the internet web site of the Ministry.

Article 13

If the administrative authority responsible for the subject matter of the sanitary or phytosanitary regulation or any other interested party finds that the adoption of a sanitary or phytosanitary regulation notified by another country may have a significant effect on trade, it may submit to the Ministry a substantiated written proposal for the amendments to the notified draft.

The proposal referred in paragraph 1 of this Article may include a request to the Ministry to require the adoption of the draft sanitary or phytosanitary regulation be delayed and to initiate negotiations on the issue, if available under the rules of the relevant international organization.
Article 14

Provisions of Articles 6-11 of this Regulation shall apply to any significant change or amendment of the sanitary or phytosanitary regulations, including any change of scope of products covered.

V FINAL PROVISION

Article 15

This Regulation shall enter into force on the eighth day after its publication in „Official Gazette of Montenegro“.
The Government of Montenegro
THE MINISTRY OF AGRICULTURE, FORESTRY AND WATER MANAGEMENT

<table>
<thead>
<tr>
<th>SANITARY AND PHITOSANITARY MEASURES</th>
<th>Language: Montenegrin / English</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOTIFICATION</strong></td>
<td></td>
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</tbody>
</table>

1. **Country:** MONTENEGRO

2. **Other competent administrative authority:**

3. **Name of products which are contained (whenever possible tariff number):**

4. **Regions or countries whereon the regulation may have effect:**

5. **Name, language and number of pages of notified document:**

6. **Description of content:**

7. **Subject of notification:**
   - [ ] food safety; [ ] animal health; [ ] plant protection; [ ] protect human life from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; [ ] territory protection from other damages

8. **International standard, guideline or recommendation:**
   - [ ] Codex Alimentarius Commission, [ ] World Organization for Animal Health (OIE), [ ] International Plant Protection Convention, [ ] Without standards
   
   If measure deviate from international standards, guidelines or recommendations write in relevant references and identified deviation:

9. **Relevant documents and language on which are documents available:**

10. **Proposed adopting date:**

11. **Proposed entering into force date:**

12. **Latest date for submitting of comments:**
   
   **Enquiry point for notification:**
   
   The Ministry of Agriculture, Forestry and Water Management
   Rimski trg no.46, PC »Vektra« 81000 Podgorica
   TEL: (+381) 81 482-109; FAX: (+381) 81 234-306
   Web: www.minpolj.vlada.cg.yu

13. **Measure text may be downloaded:**
   - [ ] Enquiry point
   - [ ] Other authority (address, fax number and e-mail address):