

**GROUNDINGS AND PRINCIPLES OF THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES IN THE PRACTICE OF THE WORLD TRADE ORGANISATION<sup>1</sup>****M. Popov, A. Popova**Russian Medical Academy of Postgraduate Education,  
Moscow, Russia

**Abstract.** The performed analysis of the rules of the Agreement on the Application of Sanitary and Phytosanitary Measures and their application by the Dispute Settlement Body of the World Trade Organization (WTO) and the Appellate Body shows that a WTO member country may ban the import of goods if this product has been proven to be hazardous or there are reasonable grounds to assume that the product is hazardous. The requirement to perform risk assessment and the necessity to obtain "significant scientific evidence" are crucial to maintain the balance between the interests of developing international trade and that of human life and health protection. Provided that the import is banned or substantially restricted on a non-discriminatory basis, the importing country has no reasons to fear any significant effects from the ban. Furthermore, even if the ban is later found to be groundless, the importing country has sufficient time to cancel the ban in the absence of any sanctions.

**Keywords:** sanitary and phytosanitary measures, risk assessment, levels of protection.

After joining the WTO, Russia became party to a number of agreements, in particular to the Agreement on the Application of Sanitary and Phytosanitary Measures as of April 15, 1994 (further referred to as the Agreement). Therefore, while introducing sanitary and phytosanitary measures, it is necessary to conform to the rules and requirements established by this Agreement as well as to the accepted practices of the application of the Agreement, with respect to the rulings of the WTO's Dispute Settlement Body on appeal petitions of exporting countries against bans and restrictions imposed by importing countries.

The analysis of the WTO legal provisions and the practice of the application of such norms enables us to formulate the following basic rules of the application of measures banning or restricting the access of dangerous or potentially dangerous goods to domestic markets.

**Measures introduced by the importing country should be based on international standards, recommendations and regulations (Article 3.1 of the Agreement).**

At that, the country can opt for one of the following measures:

a) the measure is fully compliant with the international standard and includes all the elements of this standard (in fact, the international standard is implemented and becomes part of national legislation); and

b) the measure is based on the standard, i.e. it includes some, but not all elements of the standard<sup>2</sup>.

According to Article 3.3 of the Agreement, the importing country may establish a level of protection which is different from that of the international standard provided there is sufficient scientific evidence or if the country claims that this level of sanitary or phytosanitary protection is appropriate according to Clauses 1 – 8 of Article 5 of the Agreement. An acceptable level of protection established by an importing country may be higher than that envisaged by the international standard. The right of the importing country to determine its own level of protection is an important right which is independent and not an exception from the shared

<sup>1</sup> Translated by Ksenya Zemnyanova

<sup>2</sup> DS26 US vs EC - Hormones (measures concerning meat and meat products)

commitment under Article 3.1<sup>3</sup>. Measures adopted by the importing country should comply with the provisions of Article 3.3 and Article 5 of the Agreement.

An importing country may establish the level of sanitary or phytosanitary protection that it believes to be appropriate, and that will be achieved through protection measures. The level of protection may be higher than that envisaged by international standards<sup>4</sup>. Article 3.3 of the Agreement requires that the measures imposing a higher level of protection do not contradict the other provisions of the Agreement including those of Article 5.

The condition that such measures should comply with the provisions in Article 5.1. is intended to counterbalance the right of the importing country to impose its own level of protection. The requirement to carry out risk assessment according to Article 5.1 as well as the necessity to obtain ‘sufficient scientific evidence’ according to Article 2.2 are essential to maintaining the balance between the interests of the development of international trade and the protection of human life and health<sup>5</sup>.

**The right to adopt provisional measures (Clause 5.7 of the Agreement).**

To adopt provisional measures, it is necessary to simultaneously observe four conditions set by Article 5.7 and clarified later by the Appellate Committee in Japan - Agricultural Products II Case:

- (i) the measures are adopted in situations where there is no sufficient scientific evidence;
- (ii) the measures are adopted on the basis of ‘available pertinent information’;
- (iii) the importing country adopting such measures ‘seeks to obtain additional information necessary for a more objective risk assessment’; and
- (iv) the importing country that has adopted provisional measures shall ‘review such measures within a reasonable period of time with respect to the newly obtained information’, according to (iii) above.

If one of the above mentioned conditions is not observed, the contestable measure shall be deemed as breaking the provisions of Clause 5.7.<sup>6</sup>

The sufficiency or insufficiency of scientific evidence is not defined in an abstract way but “in the light of the issue in question”, as the mentioning of relevance and insufficiency in the introductory sentence presumes a link between scientific evidence and something else<sup>7</sup>. In its report, the Appellate Body states that the ‘relevant scientific evidence’ will be deemed insufficient under Article 5.7 if the major portion of available scientific evidence does not allow for appropriate qualitative and quantitative risk assessment as required by Article 5.1 and is defined in Appendix A to the Agreement<sup>8</sup>. It is important that the relevant evidence, be it general or associated with a specific issue, be sufficient to assess the possibility of penetration, establishment and spread of a certain threat in the importing country<sup>9</sup>.

---

<sup>3</sup> DS26 EC - Hormones

<sup>4</sup> DS26 EC - Hormones

<sup>5</sup> DS26 EC - Hormones

<sup>6</sup> DS245 US vs Japan – the Import of Apples

<sup>7</sup> DS245 US vs Japan – the Import of Apples

<sup>8</sup> DS245 US vs Japan – the Import of Apples

<sup>9</sup> DS245 US vs Japan – the Import of Apples

**Obligation to assess risks.**

According to the provisions of Article 5, to introduce protective measures, the importing country must assess the risk of the penetration, establishment or spread of the threat in question.

The terminology used in the Agreement aroused a lot of issues which upon consideration were settled in the following way:

1.1. It is necessary to perform full risk assessment to introduce a minimal quantitatively measurable value of the quantity of risk<sup>10</sup>;

1.2. The determination of the minimal quantity of risk (quantitative risk assessment) is not mandatory but may be done should the importing country assessing the risk wish to do so<sup>11</sup>;

1.3. The range of risk assessment may include factors which may not be analyzable quantitatively by means of laboratory tests and experiments.

Some factors enumerated in Article 5.2 as 'relevant processes and production methods' and 'relevant inspection, sampling and testing methods' may not be necessarily or fully analyzable by laboratory methods, for instance, by the biochemical or pharmacological methods. The risk to be assessed in the course of the risk assessment procedure according to Article 5.1 is not only the risk that can be tested in a scientific laboratory under well-controlled conditions but also the risk in human communities. In other words, it is an 'actual possibility of adverse health consequences in the real world'<sup>12</sup>.

1.4. The list of data that can be used for risk assessment in Article 5.2 of the Agreement is not a closed one<sup>13</sup>;

1.5. A general discussion of a threat that the importing country is trying to protect itself from by introducing sanitary or phytosanitary measures is not the assessment of risk by implication of the Agreement<sup>14</sup>.

In the EC-Hormones Case, the Appellate Body ruled that to assess the risk in accordance with the Agreement it is necessary to research the carcinogenic potential not only of the relevant hormones in general but also of the residue of those hormones found in the meat of the cattle that was injected with growth acceleration hormones<sup>15</sup>. While assessing the risk it is necessary to define potential harm (for instance, oncological diseases or genetic disorders) and identify the exact substance that may potentially cause such harm (for instance, specific hormones that were used in a certain way with a specific aim)<sup>16</sup>.

In the Japan-Apples Case, it was stated that the assessment of red rot infestation was based on the general assessment of possible infestation ways while apples were just one of the potential disease transmitters. It was stated further in the report that the risk of penetration and spread of the disease depended largely on the transmitter (plant). As the contested measure concerns the risk of red rot spread by apples, the main factor to be taken into account when determining whether risk assessment was concrete enough is the nature of the risk the contested measure is intended to protect the country from. Considering this, the Appellate Body ruled that

---

<sup>10</sup> DS26 EC - Hormones

<sup>11</sup> DS26 EC - Hormones

<sup>12</sup> DS26 EC - Hormones

<sup>13</sup> DS245 US vs Japan – the Import of Apples

<sup>14</sup> DS245 US vs Japan – the Import of Apples

<sup>15</sup> DS26 EC - Hormones

<sup>16</sup> DS26 EC - Hormones

the risk assessment concerning all potential disease transmitters in general was not concrete enough<sup>17</sup>.

1.6. Risk assessment must be performed with respect to the sanitary or phytosanitary measure that may be adopted<sup>18</sup>.

At that, risk assessment should not be reduced to the study of solely the measure adopted or to a preferred measure (i.e. it would be wrong to select facts post factum to justify the measure already adopted or to justify one separate measure)<sup>19</sup>.

1.7. Risk assessment performed by the importing country by implication of Article 5.1 should<sup>20</sup>:

(1) include an estimation of the probability of penetration, establishment or spread of the disease;

(2) be performed with respect to sanitary or phytosanitary measures that may be introduced in this case;

(3) specify the disease which the importing country intends to prevent from penetrating, establishing or spreading in its territory, as well as the potential biological and economic consequences associated with the penetration, establishment or spread of such disease;

(4) include the estimation of the probability of the penetration, establishment or spread of the disease, and the envisaged biological and economic consequences; and

(5) include the estimation of the probability of the penetration, establishment or spread of the disease with respect to the sanitary and phytosanitary measures that may be adopted.

Risk assessment that does not comply with these requirements is not the assessment of risk by implication of the Agreement and, consequently, the measure introduced is not based on the assessment of risk<sup>21</sup>.

1.8. The results of risk assessment should provide sufficient justification for the measures introduced<sup>22</sup>;

1.9. The risk assessed should be concrete. Theoretical uncertainty may not be assessed<sup>23</sup>.

1.10. The importing country may set 'zero risk' as the appropriate risk level<sup>24</sup>.

#### **Determination of the appropriate level of protection (Article 5.5 of the Agreement).**

According to Article 5.5 of the Agreement, the importing country may determine its appropriate level of protection without breaking its commitments under the Agreement.

In the EU-Hormones Case, the DSB ruled that if a country performs the three actions below, it would be deemed as violating Article 5.5:

(i) the importing country establishes different acceptable levels of protection in several comparable situations.

<sup>17</sup> DS245 US vs Japan – the Import of Apples

<sup>18</sup> DS18 Canada vs Australia – the Import of Salmon

<sup>19</sup> DS18 Canada vs Australia – the Import of Salmon

<sup>20</sup> DS245 US vs Japan – the Import of Apples, DS18 Canada vs Australia – the Import of Salmon

<sup>21</sup> DS245 US vs Japan – the Import of Apples

<sup>22</sup> DS18 Canada vs Australia – the Import of Salmon

<sup>23</sup> DS18 Canada vs Australia – the Import of Salmon, DS26 EC - Hormones

<sup>24</sup> DS18 Canada vs Australia – the Import of Salmon

For the purposes of Article 5.5, different situations are considered comparable if they include either the risk of penetration, establishment or spread of the same or similar diseases, or the risk of the same or similar biological or economic consequences;

- (ii) such levels of protection contain arbitrary or unjustifiable distinctions, and
- (iii) measures featuring such distinctions 'result in discriminations or disguised restrictions on international trade'<sup>25</sup>.

Besides, several additional warning signals were identified that are indicative of a possible violation of Article 5.5<sup>26</sup>:

- arbitrary or unjustifiable character of the distinctions in protection levels;
- the degree of the distinctions or discrepancies in protection levels;
- the non-conformity of sanitary and phytosanitary measures to Article 5.1 and 2.2 of the Agreement. The conclusion that the introduction of the measures is not based on the assessment of risks to human, animal or plant life and health (because of the absence of risk assessment or insufficient risk assessment) is indicative of the fact that the introduction of the measures is not connected with the protection of human, animal or plant life and health but is a means of restricting international trade disguised as a sanitary or phytosanitary measure, i.e. is a disguised restriction on international trade<sup>27</sup>.

For instance, in DS18 Australia-Salmon Import Case, an additional signal was the fact that while the import of salmon was prohibited, the import of cod and a number of other goods was not restricted although this could entail similar risks. In the opinion of the DSB, the concept of disguised restriction on international trade includes, among others, the restrictions establishing unjustified distinctions between certain products<sup>28</sup>. Such signals alone do not indicate a violation but taken together they may influence the ruling of whether the adopted measures are actually a disguised restriction of international trade<sup>29</sup>.

This analysis of the provisions of the Agreement and its application practice of the WTO Dispute Settlement Body and the Appellate Body leads to the conclusion that a WTO member country may impose a ban on the import of certain goods provided that there is proven evidence of its danger or reasonable ground to believe that it is dangerous. On condition that the import is banned or significantly restricted on non-discriminatory grounds, the importing country may not fear any significant consequences of such ban. Moreover, even if the ban is later recognized as unjustified by the WTO DSB and the ruling is confirmed by the Appellate Body, the importing country has a period of time long enough to lift the ban without any sanctions.

### **A b o u t   t h e   a u t h o r s :**

**Popov Michael Sergeyevich** – Ph.D. (e-mail: mail@nnk.ru, tel.: 8 (495) 641-58 -72).

**Popova Anna Yuryevna** – DSc (Med), professor, Head of Department of organization of sanitary and epidemiological service (e-mail: rmapo@rmapo.ru, tel.: 8 (499) 458-95-63).

---

<sup>25</sup> DS26 EC - Hormones

<sup>26</sup> DS26 EC – Hormones, DS18 Canada vs Australia – the Import of Salmon

<sup>27</sup> DS18 Canada vs Australia – the Import of Salmon,

<sup>28</sup> DS18 Canada vs Australia – the Import of Salmon

<sup>29</sup> DS26 EC – Hormones, DS18 Canada vs Australia – the Import of Salmon