WORLD TRADE ORGANIZATION

G/SPS/GEN/1252

14 June 2013

(13-3099)

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Committee on Sanitary and Phytosanitary Measures

Original: English

HEALTHIER ANIMALS AND PLANTS AND A SAFER AGRI-FOOD CHAIN A MODERNISED LEGAL FRAMEWORK FOR A MORE COMPETITIVE EUROPEAN UNION

COMMUNICATION FROM THE EUROPEAN UNION

The following communication, received on 13 June 2013, is being circulated at the request of the Delegation of the European Union.

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Following the information found in notifications G/SPS/N/EU/43, G/SPS/N/EU/44, G/SPS/N/EU/45 and G/SPS/N/EU/46 of 17 and 21 May 2013, the European Union would like to provide all WTO Members with further information on the four important legislative proposals contained therein: the so-called "smarter rules for safer food" package. These deal respectively with animal health, plant health, plant reproductive material and official controls.

1 INTRODUCTION

1.1. Ensuring a high level of health for humans, animals and plants is one of the objectives enshrined in the EU founding treaties. Over time, the European Union has built up a comprehensive body of law designed to prevent and manage risks to animal and plant health and the safety of the food chain. This legislative framework has proven, overall, to be effective in both preventing and countering risks.

1.2. However, the global market increasingly exposes the European Union to new challenges. New diseases and pests appear, production methods and techniques radically change, globalisation and increased exchanges have an impact on the spread of hazards and risks and last, but by no means least, consumers' expectations related to their food and the environment are steadily growing.

1.3. **Simplification, modernisation, consistency and convergence with international standards** – these are the major driving principles of the proposed pieces of legislation. By revising the legislative framework currently in place, the European Union aims at increasing effectiveness, consistency and legal clarity; providing greater certainty and predictability, and ultimately, ensuring that measures are risk-based in order to better meet the needs of citizens and businesses in an ever-changing environment. The idea is to better foster productivity in the EU agri-food sector, to ensure the smooth functioning and accessibility of the EU market and to reinforce its competitiveness on a global scale.

1.4. The proposed package aims to consolidate, and in so doing, to also cut back the current EU legislative framework in this area – consisting of almost 70 pieces of legislation – to only four basic, science and risk-based rules concerning:

- animal health requirements: the Animal Health Law – notified under G/SPS/N/EU/45;
- protective measures against pests of plants: the Plant Health Law – notified under G/SPS/N/EU/44;
- rules governing the production and placing on the market of plant reproductive material: the Plant Reproductive Material Law – notified under G/SPS/N/EU/46;

- rules governing official controls and other official activities performed to ensure compliance with the entire set of agri-food chain rules: the Regulation on Official Controls – notified under G/SPS/N/EU/43.

1.5. The last two proposals have also been notified under the WTO Agreement on Technical Barriers to Trade.

1.6. Trading partners are invited to carefully study these important legislative proposals which complement the existing EU framework for ensuring a safe agri-food chain. Partners are invited to submit comments during the extended comment period of 120 days. These comments will be carefully considered by the European Union and integrated, where relevant, into the legislative framework.

2 THE CONTENT OF THE PROPOSALS

2.1 The Animal Health Law (G/SPS/N/EU/45)

2.1. The proposed legislation seeks to help authorities and operators direct their resources where they are most needed in order to prevent and control animal disease.

2.1.1 Simplification

2.2. The legislation seeks to **reduce the administrative burden** by introducing a more coherent framework for the prevention and control of animal diseases, including for vaccination – simplifying requirements where possible. The new legislation will also **clarify the animal health responsibilities** of operators, veterinarians, competent authorities and others. Detailed provisions – such as specific disease control measures, identification and registration rules for certain species and specific measures on intra-EU movement for particular species – are to be dealt with by means of implementing legislation (still to be developed) allowing more flexibility and speed in the legislative process to react to rapidly changing scenarios and/or emergencies. The proposed regulation also encourages the use of **new technologies** for animal health activities such as monitoring pathogens, electronic identification and registration of animals and electronic certification.

2.1.2 Increased flexibility through the use of a risk-based approach

2.3. Criteria for **listing animal diseases** will be introduced on a scientific and evidential basis and will be systematically categorised. This will allow the European Union to better focus on the main and most dangerous diseases, according lower priority to those diseases which pose less risk. Wider use of "**compartmentalisation**" will be permitted (i.e. where some farms are considered safe even during disease outbreaks), allowing a more risk-based approach to animal disease control and potentially fewer trade restrictions.

2.1.3 Imports and exports

2.4. Broad **convergence with OIE standards** will be sought whilst ensuring a firm commitment to high standards of animal health in the European Union. This is expected to significantly reduce the risk of trade disruption. No practical changes in the current framework – which functions well – are envisaged for imports into the European Union. This is particularly the case regarding the requirements for third countries sending animals, germinal products, products of animal origin and other materials that could transmit animal diseases into the EU territory.

2.2 The Plant Health Law (G/SPS/N/EU/44)

2.5. The proposed legislation covers all organisms directly harmful to plants, i.e. insects, mites, nematodes, pathogenic micro-organisms and parasitic plants (now called pests). It covers both **quarantine pests** and **quality pests**. Criteria for deciding on the appropriate assignment of pests are provided in the Annexes that set out principles and measures for the management of phytosanitary risks.

2.6. The geographical scope of the Plant Health Law is **limited to the territories of the EU member States**, excluding overseas countries and territories and also outermost regions, where certain pests against which the European Union needs to be protected are indigenous.

2.2.1 Reinforced early action against outbreaks

2.7. The proposed legislation obliges EU member States to carry out **surveillance** in their territory for the presence of pests in areas where they were not previously known to occur. If pests are detected, EU member States will be expected to carry out eradication measures, including the demarcation of a restricted area(s) consisting of an infested zone surrounded by a buffer zone. In addition, enhanced levels of preparedness and surveillance are required for quarantine pests identified as **priority pests**. Surveillance and eradication obligations will not apply to quality pests. Implementing acts – which provide clear guidance on how the legislation is to be put into practice – may be adopted at a later date to cover (control) quarantine pests that cannot be eradicated from the EU territory.

2.2.2 Reinforcement and modernisation of the internal market provisions

2.8. Where plant material is to be moved within the European Union, the proposed regulation provides for the mandatory use of a **plant passport**, attesting compliance with the legislation on quarantine and quality pests. The simplified and standardised passport is to be issued by operators, under the supervision of the competent authorities. Operators will have to store the information necessary to trace infested consignments, but the passport can also contain data carriers (barcodes, etc.) instead of the current lot number. Where planting materials require a plant passport and also a certification label under EU law on plant reproductive material, the two labels can now be combined in a single document, reducing the administrative burden on operators. Plant passports will be required for all nursery stock, but not for sale to non-professional, final users.

2.2.3 Imports and exports

2.9. Precautionary measures are foreseen for new, **high-risk planting material imported into the European Unio**n, based on a preliminary risk assessment, for up to a maximum period of four years. During this time a full risk assessment shall be performed and the appropriateness of permanent measures assessed. Insofar as **passengers bring regulated plants into the EU territory in their luggage**, they must now fully comply with the relevant requirements and prohibitions.

2.10. Exports of plants, plant products and other objects to third countries are also covered by the proposed regulation. Exports are governed either in accordance with the relevant EU requirements, or, if the third country's rules so allow, in accordance with the requirements of that country. The proposal also provides for the introduction of a **pre-export certificate** for cases where plant material is exported from an EU member State which is not the country of origin. The pre-export certificate is meant to replace the informal guidance document currently in use.

2.3 The Plant Reproductive Material Law (G/SPS/N/EU/46)

2.11. The proposed regulation deals with specific types of plant reproductive material, such as agricultural crops, fruit plants, ornamental plants, vegetables and forest reproductive material. It replaces 12 existing Directives and seeks to fulfil the over-riding aim to **conserve genetic resources and biodiversity** and to take into account the challenges of climate change and of particular forms of farming such as organic production. The objective of the legislation is to continue to supply farmers and breeders with high quality and healthy material. In order to take into account the needs of producers, the regulation will not apply to plant reproductive material intended for testing and scientific purposes and intending for breeding (selection) purposes. In addition, it will not apply to material intended to or maintained in gene banks, organisations and networks of *ex-situ* and *in-situ* or on farm conservation of genetic resources. Furthermore, plant reproductive material exchanged in kind between two persons other than professional operators is excluded from the scope of the regulation.

2.3.1 Simplification and modernisation

2.12. The proposed legislation introduces **harmonised and simplified basic rules** applicable to all types of plant reproductive material (such as freedom from harmful organisms and defects) while maintaining stricter rules for key plants marketed throughout the European Union (i.e. listed plant species which have to undergo tests for distinctness, uniformity and stability).

2.13. Operators and competent authorities are given considerable freedom in completing registration and certification tasks. The **principle of cost recovery** for variety registration (and for certification via the Regulation on Official Controls) is introduced. The current obligation to notify a variety and include it in the Common Catalogues before marketing it throughout the European Union will be abolished to speed up innovation. Registering a plant variety in one EU member State will, as a result of the new rules, become sufficient. The Community Plant Variety Office (CPVO) will have a greater role in variety registration, managing the EU Plant Variety Database and the option of registering a variety directly with the CPVO. The CPVO will also continue to harmonise testing protocols for new varieties and carry out audits to ensure high levels of quality in the registration process. In addition, a **"one-key, several doors" approach** will enable a new variety to be registered for marketing purposes and granted plant variety rights under a single procedure.

2.14. The process of **certifying plant reproductive material** lots before marketing will also be made more flexible. Certification by the operator under the official supervision of the competent authority will be extended to all listed species and marketing categories of plant reproductive material.

2.3.2 Horizontal coordination with other EU policy objectives

2.15. The requirements for **traditional and conservation varieties** and other material have been considerably reduced. No variety testing and certification is required which will considerably improve market access. In addition, the rules have been amended to cater for the possibility to authorise for marketing less homogenous material (e.g. populations). Testing protocols for the agricultural sustainability criteria (e.g. disease and drought resistance) for variety registration will be harmonised for the first time while EU member States may continue to manage testing of new varieties for value for cultivation and use, based on their agro-ecological conditions.

2.3.3 Imports and exports

2.16. The EU equivalence system will be maintained as a basic condition for **imports** from third countries while **exports** shall take place in line with the legal or administrative procedures in place in importing countries. Where a bilateral or multilateral agreement between the European Union and the third country exists, export from the European Union shall comply with the agreement. In its absence, an agreement conducted between the professional operators shall apply.

2.4 The Regulation on Official Controls (G/SPS/N/EU/43)

2.17. By virtue of the new regulation, official controls, currently governed by Regulation (EC) No 882/2004, will be extended to controls on plant health, plant reproductive material and animal by-products which have until now been governed by sector-specific provisions. The current set of rules applicable to controls on residues of veterinary medicines will be repealed to allow this area to be regulated in a more risk-based manner, with a view to protect health, under the same legislative framework.

2.4.1 More effective enforcement mechanisms

2.18. The **toolkit** offered to national enforcers **is simplified and will be more effective**. For each of the sectors covered by the "revision package", EU member States will be asked to designate a single authority responsible for:

- coordinating and ensuring the coherence of a multi-annual control plan and to act as a contact point in relation to official controls;

- the electronic handling and processing of Common Health Entry Documents for all animals and goods subject to controls at the EU border which will be introduced;
- ensuring that transitional measures and temporary or permanent derogations are provided for, as appropriate, while upholding the requirement for all official laboratories to be accredited against ISO standard 17025.

2.19. The proposal also aims at **improving the use of the rules on "administrative assistance"**, i.e. the mechanism which allows cooperation between national control authorities on cross-border enforcement issues, where violations of EU rules need to be pursued not only in the EU member State in which the violation was detected but also in the EU member State where it originates. A new EU-wide mechanism for the rapid exchange of information related to serious and widespread violations will also enable authorities to address fraudulent practices more effectively.

2.4.2 Financing of official controls

2.20. The proposal builds on the current system of mandatory fees (at present only charged to certain operators and/or for certain controls). It strengthens the principle according to which competent authorities should be able to charge businesses in order to recover the costs they incur in carrying out their official control duties along the agri-food chain and in certain related areas. A number of improvements to the current set of rules are proposed with a view to ensuring a consistent and steady stream of resources to the competent authorities and to eliminating the known shortcomings of the existing system. Micro-enterprises will be exempted from the payment of the fees.

2.4.3 Imports

2.21. This revision will have a significant impact on the legal framework governing **official controls on products from third countries**. It provides a set of common rules for all control activities to be performed at EU borders on animals and goods from third countries which require increased attention for health reasons. In this context, it introduces single **Border Control Posts (BCPs)** designed to replace the current Border Inspection Posts (for animals and derived products), **Designated Points of Entry** (for feed and food products of plant origin) and **Points of Entry** (for plants and plant products). A uniform set of rules will apply to the controls carried out at the BCPs and a **Common Health Entry Document** will be used for prior notification of the arrival of consignments and to record official controls and decisions – replacing the standard documents currently in use.[1] While documentary controls will remain systematic for all regulated goods and for animals, common criteria will ensure that identity and physical controls do not exceed what is required in terms of the risk posed by different categories of products. Provision is made for adopting further rules for specific sectors by means of implementing legislation.

3 CONCLUSION

3.1. The agri-food industry is the second largest economic sector in the European Union worth €750 billion a year. It is also one of the largest employers, employing over 48 million people. EU consumers enjoy great diversity, reliability of supply and amongst the highest food safety standards in the world. This comprehensive review of the legislative framework will deliver "smarter rules for safer food" for the benefit of citizens and businesses alike. It will allow EU operators to source new markets for their products, well known for their quality and safety. Equally, it will allow operators in third countries the opportunity to seek new export markets within the European Union – all within a coherent, predictable, simple and yet well-regulated framework.

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[1] The Common Veterinary Entry Document (CVED) in the area of veterinary controls, the Common Entry Document (CED) for non-veterinary controls, and the phytosanitary certificate currently in use in the plant health sector.