REGULATION OF THE EUROPEAN UNION ON THE MAXIMUM RESIDUE LEVELS OF PESTICIDES – COMMENTS AND CRITICISMS

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ABSTRACT

Contrary to commitments to gradually reduce and eventually eliminate tariff barriers, governments, particularly developed countries, are increasing the construction and application of non-tariff barriers. While these barriers may be intended to protect consumers, they are actually protective and have a detrimental effect on international trade. The European Union is one of the world's largest and most demanding agricultural consumer markets. Each year, numerous consignments, particularly agricultural products, are rejected for import due to non-compliance with EU regulations. Under these circumstances, the most difficult cause for agricultural products is non-compliance with pesticide residue regulations. The European Union's 396/2005 regulation on pesticide residue levels in food is analyzed and reviewed in this article.

Keywords*:* Agricultural Products, SPS Measures, MRLs, Regulation.

INTRODUCTION

On February 23, 2005, the European Parliament and Council adopted Regulation No. 396/2005 establishing maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA implications (hereinafter Regulation 396/2005). (EC, 2005). Regulation 396/2005 is intended to protect consumer and animal health by limiting and controlling pesticide residues in food and feed, as well as to facilitate commercial activities by establishing common standards; however, this Regulation is not intended to protect the environment.

Regulation 396/2005 establishes the maximum allowable residue level of pesticides in food and animal feed derived from plants or animals intended for human or animal consumption. Regulations apply to all items, including fruits and vegetables, dried beans, oily seeds, grains, spices, sugar plants, and animal products, and the list of these items is constantly updated. On the other hand, Regulation 396/2005 will not apply to products intended for the manufacture of non-food products, sowing or cultivation, testing of authorized active substances, or export to third EU countries where the importing country requires special treatment to avoid the introduction of harmful organisms.

Regulation 396/2005 introduces a new rule that establishes a default limit for drugs whose maximum residue levels are not specified (MRLs). By default, the limit is set to 0.01 mg/kg. The limits established by previous Directives are incorporated into the Annex II specific maximum residue levels. Annex III establishes temporary maximum residue levels that are permissible in limited circumstances. Additionally, paragraph 25 of the Preamble reaffirms that the Council of

Europe will consider the maximum residue levels established by the International Food Standardization Commission (Codex) in order to regulate level residues while taking into account issues of good agricultural practice. Simultaneously, paragraph 26 emphasizes that the maximum residue requirement that applies to imported goods will apply to domestic goods as well, in order to maintain the principle of national treatment.

Deviations from the limits, even if they exceed the maximum residue level, may be permitted if the product is not intended for immediate consumption and appropriate control measures are in place. applicable to ensure that such products are not made available to consumers or other EU member states, and to notify the European Commission There are no residue limits on a number of the active ingredients listed in Annex IV. The European Commission will develop and coordinate a control program in accordance with Regulation 396/2005, which will define specific samples to be included in national control programs to ensure compliance with maximum residue levels. Annually, this control program is reviewed and approved.

Prior to Regulation 396/2005, the EU's pesticide residue regulation was based on four European Council Framework Directives: I Directive 76/895/EEC regulates fruits and vegetables; (ii) Directives 86/362/EEC and 86/363/EEC regulate grain and animal-derived foods; and (iii) Directive 90/642/EEC regulates animal feed. These four Directives established a range of permissible residue levels for a variety of commodity groups. In May 2001, the European Commission announced that the fifth round of the Simplification of Domestic Market Law (SLIM) initiative would focus on reducing the legal burden and costs for legal users with respect to pesticide residues in fruits and vegetables. The SLIM initiative was launched in 1996 as an early manifestation of the approach to better regulation. According to the SLIM report, which was published in November 2001, EU regulations governing maximum residue levels must be completely revised and simplified. The report's primary recommendation is to replace the four Maximum Residue Level Indicators with a single regulation that applies to all food products and a more straightforward method for determining maximum residue levels. Additionally, the EU recommends reconsidering the rules requiring maximum residue levels to be set at the limit of detection for any unauthorized food-pesticide combination in order to expedite Member States' efforts to establish maximum residue levels. In response to this report, the European Commission proposed a Regulation in March 2003 that would harmonize the maximum residue levels permitted in EU-sourced products, plants, and animals.

Register Applies the Maximum Residue Level

All entities with a legitimate health interest, including civil society organizations and commercial organizations such as product producers, growers, importers, and producers. The parties listed in Annex I may also file a request for the application of maximum remuneration to an EU member state under the provisions of Article 7 of Regulation 396/2005, including a request for wrong import.

The following information must be provided to an EU member state upon application, according to paragraph 1 of Article 7 of Regulation 396/2005:

(i)The applicant's name and address are one example.
(ii) The profile also includes:
   a) An application summary;
   b) The main point of the request for the use of a maximum residue level;
   c) A document list; and
   d) A copy of a GAP (Good Agricultural Practice Standard) related to the active ingredient's specific use.
(iii) A thorough review of scientific evidence on issues concerning the substance in the profile; and

(iv) The data required to establish a maximum level of estimates are listed in Annexes II and III of Regulation (EC) No 91/414.
(v) If necessary, the receiving Member State may request additional information about the application within a specified time frame; however, the entire application process will not exceed two years.

Choose Whether to Apply, Adjust, or Cancel the Maximum Residue Level

The Commission will prepare the application, modification or cancellation of a maximum residue level, or decision to reject the application immediately upon receipt of the competent authority's opinion and consideration of such opinion, and within three months at the latest, in accordance with the procedure set out in paragraph 2 of Article 45 of Regulation 396/2005.

Before the Committee can decide whether to apply, adjust, or cancel a maximum residue level, the following factors must be considered:

i) Scientific and technical knowledge that is available;
ii) The possibility of pesticide residues arising from sources other than current pesticide use, as well as the effects of accumulation and simultaneous reaction of the active substance, when methods to assess that impact are available;
iii) The findings of any potential risks to consumers with high consumption and high vulnerability, as well as to animals, if applicable;
iv) The outcome of any review and decision to change the use of plant protection products;
v) Codex (CXL) maximum residue levels or a set of Good Agricultural Practices (GAP) developed in a third country for the legal use of an active ingredient in that country;
vi) Other legal factors pertaining to the subject matter under consideration.

Temporarily Apply Maximum Residue

Temporary maximum residue levels for active ingredients that have not yet been decided whether to include or exclude from Annex I of Directive 91/414/EEC will first be established and listed in Annex III of Regulation 396/2005, except for those listed in Annex II to Regulation 396/2005, in accordance with the procedure outlined in paragraph 2 of Article 45, taking into account information provided by EU member states.

i) The maximum residue levels that are still listed in the Appendix to Directive 76/895/EEC;
ii) At the national level, there are currently no regulated maximum residue levels.

When issuing interim maximum residue levels regulations, the Commission shall consider the opinion of the competent authority; if such opinion is required, the provisional maximum residue levels for these active ingredients specified in Article 23 can be applied and listed in Appendix III under the provisions of Clause 1 of Article 22; or, if appropriate, active ingredients can be listed in Appendix III. Temporary maximum residue levels will be set at the lowest possible level in all member countries based on best agricultural practices.

Furthermore, if the active ingredients are not listed in Annex I of Directive 91/414/EEC or Annex II of Regulation 396/2005, the establishment or modification of maximum residue levels will be implemented and listed in Annex III of Regulation 396/2005. When the provisional maximum residue level is established as specified in point b Clause 1 Article 15 of Regulation 396/2005, it will be removed from Annex III of Regulation 396/2005 one year later. Date of incorporation or omission of the active substance concerned in Annex I to Directive 91/414/EEC, in accordance with the procedure specified in paragraph 2 of Article 45 of Regulation 396/2005. However, if one or more Member States request it, the provisional maximum residue level may be kept in place for an additional year, pending confirmation that any scientific research is required to support the application. Setting the maximum residue level has been completed. If such confirmation is provided, a temporary maximum residue level will be maintained for the next two years, as long as no unacceptable safety concerns for the consumer are identified utilize.

As such, all foods will be expelled from the European market if these products contain illegal pesticides or the residues of plant protection drugs are higher than the limits imposed by the EU given.

Legal Issues Relating To the Eu's Regulations on Mrl

As a precautionary measure, a default MRL level of 0.01 mg/kg is applied to pesticides that are not listed in the aforementioned Regulation. This is particularly true for imported products grown outside the EU using pesticides not included on the Regulatory list. However, the EU's default MRL is extremely low (*i.e.* extremely stringent), and the number of pesticides approved by the EU is significantly less than that of China and the United States (New Zealand and Canada have also established a default MRL (0.1 mg/kg), which is tenfold higher than the EU regulation and thus ten times lower than the EU standard) (VCCI, 2019).

In theory, an exporting country could request that the EU establish an MRL for pesticides that are not specifically listed in the EU Regulation. However, due to the complexity and cost of the application and approval processes, this requirement is extremely difficult to meet in practice. Additionally, a critical issue is that the list of drugs used in the production and processing of agricultural products issued by the aforementioned countries is extremely limited and is revised annually or multiple times per year. As a result, exporting countries and enterprises that do not update regularly will face numerous difficulties when exporting goods to the aforementioned markets. Additionally, because these drugs are not approved, these regulations will restrict the use of novel drugs and inventions in manufacturing (USTR, 2014).

Another example is the EU's rejection of a number of Kenyan exports of fresh foodstuffs because they did not meet the EU's maximum pesticide levels requirements. As a result, the EU reduced the pesticide Dimenthoate's maximum residue level from 0.2 mg/kg to 0.02 mg/kg in 2011. Kenyan exporters incurred a loss of approximately $ 192 million as a result of this adjustment. The above-mentioned harm is caused by two factors: I Kenya is unaware of the change in EU regulation, and thus continues to export products to the EU under the 0.2 mg/kg MRL standard, which are refused entry due to non-compliance with the New MRL (ITC, 2014).

Apart from the beneficial effects on consumer health, the following three points of nonconformity with Regulation 396/2005 can be deduced from the EU regulations on maximum residue levels:

First, by limiting drug and chemical use to those listed in the Annexes to Regulation 365/2005, countries face undue trade and production barriers. something else Due to the fact that each production area has its own unique climatic, natural, and cultivation methods, as well as manufacturing methods, the medicines and chemicals used will vary. Simultaneously, as science and technology advance, the development of new drugs and chemicals to aid agricultural production accelerates. As a result, the EU's acceptance of maximum residue levels for chemicals and medications on its list is illogical.

Second, the EU will establish a default level of 0.01 mg/kg for drugs and chemicals that are not on the mandatory list. This provision contradicts both the general spirit of Regulation 396/2005 and the SPS Agreement's provisions. To be precise, under Article 2.2 of the SPS Agreement, if WTO member countries wish to implement a measure that is likely to affect international trade, such measures must be based on scientific evidence and cannot be maintained unless sufficient scientific evidence is provided that is consistent with the general world standard. Despite the EU's commitments, many chemicals and drugs specified in Regulation 396/2005 require higher concentrations than those specified in general Codex regulations in the absence of specific scientific evidence. It should be specified that the Codex level of regulation will apply to drugs and chemicals for which the EU's default ratio of 0.01 mg/kg is unsuitable,

but the EU has not done so. The EU has violated SPS Agreement Articles 2.2, 5.1, 5.2, 5.3, and 5.7 as a result of the above-default residue level provision.

Third, when a TBT or SPS measure is amended, applied for, or enacted, member states are responsible for notifying the WTO's specialized committee and other members, as specified in Annex B of the SPS Agreement. That is, if the EU wishes to issue a regulation similar to Regulation 396/2005, it must notify the World Trade Organization and other countries and provide them with a reasonable period of time to comment. However, the EU is not required to notify the WTO or other countries if it simply updates or modifies indicators relating to the maximum residue level of one or more specific substances. If other member states fail to update EU data on a regular basis, they face an unpredictable, opaque, and high-risk situation.

CONCLUSION

Regardless of non-tariff barriers imposed by importing countries, exporters must improve product quality, production capacity, investment, technological innovation, and product competitiveness in order to achieve the goal of sustainable development (Disdier, 2008). (Fugazza, 2013). Technical trade barriers affect international trade in general, and agricultural export and import in particular, in a bidirectional fashion (FAO, 2013). Although it is difficult to export agricultural products to the EU due to the EU's high demand for agricultural products, exporting countries continue to view the EU as a critical trading partner for goods in general and agricultural products in particular. Agricultural products must comply with Regulation 396/2005 in order to access the EU market; this type of regulation is also criticized for imposing more trade restrictions than necessary (Vang-Phu Tran & Mohamad yub Dar, 2020). The following research will examine the labeling and marketing regulations in the European Union.

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