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Report Name: Plant Protection Products and Maximum Residue Limits of Pesticides Regulations

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Report Highlights:

This report outlines Turkey's regulatory system for licensing Plant Protection Products (PPP) and Maximim Residue Limits (MRL) for pesticides. PPP's require a license to be used and sold in Turkey. For a PPP to be licensed in Turkey, it must have been licensed first in the European Union (EU) or a Group of Eight (G8) country (the U.S, Germany, UK, France, Italy, Japan, Canada, or Russia). Turkey's regulation of pesticide MRLs is similar to that of the European Union, but not fully harmonized.

Executive Summary:
Turkey regulates PPPs by licensing them via the Regulation on Licensing and Placing on the Market of Plant Protection Products. Once licensed, a PPP can be used and sold in Turkey for 10 years if licensing conditions remain same during this period. Maximum Residue Limits of pesticides are regulated by the Turkish Food Codex Regulation on Maximum Residue Limits of Pesticides. The General Directorate of Food and Control (DGFC) of the Ministry of Agriculture and Forestry (MinAF) is the authority for regulating and implementing of PPPs in Turkey.

Plant Protection Products and Maximum Residue Limits of Pesticides Regulations-Turkey

The Regulation on Licensing and Placing on the Market of Plant Protection Products was published in the Official Gazette dated 11/9/2017 as no. 30235. The Regulation covers rules and procedures of licensing and placing on the market of plant protection products such as pesticides, plant growth regulators, attractants, repellents, insect growth regulators, nutrition blockers, bio-preparations, bio-activators, and substances treating physiological diseases. Companies seeking a plant protection product license must first get a Plant Protection Product Dealing Certificate. The validity period of this certificate is three years and can be renewed three more years under certain conditions.

The General Directorate of Food and Control (DGFC) of the Ministry of Agriculture and Forestry (MinAF) is the authority responsible for developing and implementing policy for all plant protection products, including pesticides. According to the Regulation, PPPs can be placed on the market only if they are licensed, in other words approved, by a committee established under DGFC. Members of the Committee are experts from research institutes, DGFC, other relevant government agencies, and academia.

The first requirement for a PPP to be licensed in Turkey is that it has already been licensed or approved in an EU or G8 country. A PPP which is intended for research and development purposes is not required to be licensed. A PPP which is produced in Turkey only for the purpose of being exported to another country does not require licensing either. Once licensed, a PPP might be placed on the market for 10 years if licensing conditions are maintained. DGFC may license a PPP temporarily (for 120 days) for a specific pest which causes considerable economic loss unexpectedly (in emergency cases) to be used under controlled conditions in the season of production.

The Regulation on Licensing and Placing on the Market of Plant Protection Products sets the rules and requirements of PPP to be licensed. It is accessible at the link :
https://www.mevzuat.gov.tr/Metin.Aspx?MevzuatKod=7.5.24072&MevzuatIliski=0&sourceXmlSearch=bitki%20koruma%20urunleri%20ruhsat in the Turkish language

Documents and information required for PPPs to be licensed in Turkey are given below:

If a PPP contains an active substance which has not been licensed before; the required information and documents are given in Annex-3 of the Regulation. This is quite detailed information related to the technical substances in question, including: information related to the formula, confidential prescription, analytical methods, quality control data, the production method of formula, analysis methods related to

excipient and filler substances, package information, toxicological information, ecotoxicological studies, biological information and trials reports, sample labels of the product from the countries in which it has been authorized, studies related to resistance, studies related to residues, sample label, safety data sheet, mixability studies, analysis report, distribution authorization certificate given by the manufacturer, brand trademark registration by Turkish Patent and Trademark Office, and any other information that DGFC requests. Please see Annex-3 of the Regulation for detailed requirements.

If a PPP contains an active substance licensed before with a different ratio and/or formula; the required information and documents are given in Annex-4 of the Regulation. These are technical substance specifications, formula specifications and confidential prescription information prepared according to Annex-3 of the Regulation; analytical methods; quality control data; formula manufacturing method; analysis methods related to excipient and filler substances; package information; acute toxicological studies related to formula; a biological effectivity trial report; other countries' advice and labels samples, if any; studies related to residue prepared according to the information given in Annex-3 of the Regulation; label; safety data sheet; mixability studies; a product analysis report; a distribution authorization certificate given by the manufacturer; the brand trademark registration of Turkish Patent and Trademark Office; and any other information that DGFC requests. Please see Annex-4 of the Regulation for detailed requirements.

If a PPP contains more than one active substance as a mixture; the required information and documents are given in Annex-5 of the Regulation. If active substances of the mixture are licensed: the information and documents required in Annex-3 of the Regulation for each active substance and formula, information about the purpose and benefit of the mixture, if the mixture exists in the Pesticide Manual, acute toxicological studies of the mixture, the Safety Data Sheet, dose information, countries which approved the mixture, and residue information are required. If active substances are not licensed for that plant in question, then Pre-harvest Interval (PHI), maximum residue limit (MRL) are also required. If active substances are not licensed: information and documents required in Annex-3 of the Regulation for each active substance and formula, information about the purpose and benefit of the mixture, if the mixture exists in Pesticide Manual, acute toxicological studies of the mixture, and a Safety Data Sheet are required. If one of the active substances is licensed but the other one is not then information and documents required for licensed and not licensed active substances explained above are required. Moreover, biological efficacy trials and study reports, other countries' advice and sample labels if any, residue studies as per Annex-3, a Safety Data Sheet, mixability studies, analysis report, the distribution authorization certificate given by the manufacturer, the brand trademark registration of Turkish Patent and Trademark Office, and any other information that DGFC requests is mandatory. Please see Annex-5 of the Regulation for detailed requirements.

Licensed PPPs are accessible at the link https://bku.tarim.gov.tr/BKURuhsat/Index in the Turkish language.

Maximum Residue Limits (MRLs) MRLs of PPP are available at the link https://bku.tarim.gov.tr/MRLOrani/Index in the Turkish language.

Maximum residue limits of pesticides are regulated by the **Turkish Food Codex Regulation on Maximum Residue Limits of Pesticides** which was published in the Official Gazette dated 11/25/2016 as no: 29899, taking into consideration the European Union Regulation (EC) no. 396/2005 of the

European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin.

Regulation 29899 sets the maximum residue limits of pesticides in fresh, processed, or composite food of animal and plant origin defined in the Annex-1 of the Regulation. This is also applicable for infant formulas, follow-on formulas and cereal-based baby formulas in addition to their vertical Communiques's requirements. The Regulation does not apply to products not intended for food use, sowing or planting, or for testing of active substances during the approval process.

The Turkish Food Codex Regulation on Maximum Residue Limits of Pesticides has five Annexes**.**

These Annexes are;

Annex-1-A : Animal and plant origin products for which MRLs are applicable. Code number, category, group, sub-group, scientific name and part of product for which MRLs are applicable are defined in this Annex.

Annex-1-B : Other products which are linked to the main products defined in Annex-1-A and for which the same MRLs apply. Category, Code number, group or sub-group, widely used name/synonym, and scientific name of product for which the MRLs are applicable are defined in this Annex.

Annex-2 : MRLs of pesticides which are allowed to be used in Turkey. Name of active substance, product and product groups for which the MRL is applicable, MRL (mg/kg) and explanation about that MRL where needed are defined in this Annex.

Annex-3-1 : MRLs of pesticides (for product groups) that are authorised in the EU.

Annex-3-2A : Temporary List of pending MRLs of pesticides (for product and/or product groups) in the EU.

Annex-3-2B : Temporary List of pending MRLs of pesticides (for product and/or product groups which do not exist in Annex-3-1) in the EU.

Annex-3-3 : Pesticides which are not required to have a set level of MRL.

Annex-4 : Pesticides which are not allowed to be used anymore –forbidden- in Turkey.

Annex-5 : Detection limits of pesticides for which evaluations were completed for product groups.

The Regulation and its annexes are accesible at the link :
https://www.mevzuat.gov.tr/Metin.Aspx?MevzuatKod=7.5.23064&MevzuatIliski=0&sourceXmlSearch=pestisit
in the Turkish language.

Attachments:

No Attachments.