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Report Name: Update on Turkiye's Pesticide MRLs and Registration Requirements for Plant Protection Products

Country: Turkiye

Post: Ankara

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Report Highlights:

This report provides the latest information on Turkiye's regulatory system for establishing maximum residue limits (MRLs) for pesticides on food products and how to license plant protection products (PPPs). Turkiye's pesticide MRLs are similar to that of the European Union, but not fully harmonized. Pesticide MRLs for imported products are updated every few years. For a PPP to be licensed in Turkiye, it must be first licensed in the European Union (EU) or a G8 country.

Maximum Residue Limits (MRLs) for Pesticides: [1]
The Ministry of Agriculture and Forestry's (MinAF) General Directorate of Food and Control (DGFC) is the competent authority for establishing pesticide MRLs in accordance with the Turkish Food Codex Regulation on Maximum Residue Limits of Pesticides ("pesticide MRL regulation"). This regulation, which was notified to the WTO (SPS/TUR/114) and later published in the Official Gazette in September 2021 (no. 31611), sets MRLs to protect consumers from pesticide residues on plant and animal origin food products for human consumption, including infant formulas and baby foods. The regulation does not apply to products that are not intended for food use.

In preparing the pesticide MRL regulation, MinAF considered the EU Regulation (EC) no. 2005/396 - Maximum residue levels of pesticides in or on food and feed of plant and animal origin.[2] While the intent is to harmonize with the EU pesticide MRL regulation, Turkiye's pesticide MRL regulation is not fully harmonized. Some of the reasons for this difference is because Turkiye has different pest pressures, different weather conditions, and grows different crops than Europe.

In line with its customs union agreement with the European Union, Turkiye is in the process of harmonizing its agricultural regulations and standards, including MRLs with those in the EU. However, MinAF does not have a predefined schedule for harmonizing its current pesticide MRLs to match with the latest updates to MRLs in the EU. Instead, the Ministry periodically reviews changes to MRLs in the EU and makes the corresponding revisions to its pesticide MRLs, where deemed necessary. Turkiye notified its current pesticide MRL regulation to the WTO in 2020.

The pesticide MRL regulation has five annexes (Excel file with separate tabs for each annex) that provide further detail on scope and application of pesticide MRLs. The content of each annex is briefly summarized below. Updates to the annexes only occur when the pesticide MRL regulation is revised every few years.

> **Annex-1-A:** Generic list of animal and plant origin products for which pesticide MRLs are applicable.
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> **Annex-1-B:** Detailed list of animal and plant origin products defined in Annex-1-A for which pesticide MRLs are applicable.
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> **Annex-2:** List of pesticide MRLs for domestic products. This list only contains MRLs for PPPs that are licensed and approved for use in Turkiye. For the most up-to-date list of pesticide MRLs for domestic products, please refer to the DGFC website in the Turkish language.
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> **Annex-3:** List of pesticide MRLs for imported products; these limits closely align with EU MRLs. Import MRLs are updated every few years when the pesticide MRL regulation is revised. (Note: MinAF does not currently have a formal procedure for parties interested in requesting an import tolerance.)

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[1] Veterinary drug MRLs are covered under a separate regulation - The Turkish Food Codex Regulation on Pharmacologically Active Substances and Their Classification Regarding Maximum Residue Limits in Foodstuffs of Animal Origin.
[2] EU Regulation (EC) no. 2005/396 - Maximum residue levels of pesticides in or on food and feed of plant and animal origin was in effect from April 5, 2005, through December 14, 2022.

Annex-4: List of pesticides prohibited for use in Turkiye.

Annex-5: List of pesticides for which MRLs are not required for imported products.

Licensing Requirements for Plant Protection Products (PPPs)
In addition to pesticide MRLs, DGFC is the competent authority responsible for developing and implementing policy for all PPPs, including pesticides. PPPs are regulated under The Regulation on Licensing and Placing on the Market of Plant Protection Products ("PPP regulation"). The PPP regulation, which was first published in the Official Gazette in November 2017 (no. 30235) and later amended in 2020 and again in 2021, sets the rules and procedures for licensing and placing PPPs on the market. PPPs include compounds such as pesticides, plant growth regulators, attractants, repellents, insect growth regulators, nutrition blockers, bio-preparations, bio-activators, and substances treating physiological diseases.

According to the PPP regulation, PPPs can only be placed on the market 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 considered for licensing is registration in the EU or a G8 country.

Companies seeking to license their PPPs must first get a Plant Protection Product Dealing Permit from the DGFC. The permit authorizes the company to file a licensing request and supporting documentation, as outlined below, with DGFC. The validity period of this permit is three years and upon the request of the applicant it can be renewed three more years under certain conditions.

Once licensed, a PPP might be placed on the market for 10 years if licensing conditions are maintained. DGFC may temporarily license a PPP (120 days) for emergency use in cases where a pest has caused considerable economic losses. In these emergency cases, the PPP will be used under controlled conditions. A PPP which is intended for research and development purposes or is only produced for export is not required to be licensed.

Required Documents and Information for PPP Licensing:
For PPPs containing an active substance which has not been licensed before; The required information and documents are given in Annex-3 of the PPP 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.

For PPPs containing an active substance licensed before with a different ratio and/or formula; The required information and documents are given in Annex 4 of the PPP regulation. These are technical substance specifications, including: formula specifications and confidential prescription information prepared according to Annex 3, 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, 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.

For PPPs containing 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 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 in the mixture are not licensed: information and documents required in Annex 3 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.

Attachments:

No Attachments.