



October 23, 2023

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PUBLIC DOCUMENT

Ambassador Katherine Tai
U.S. Trade Representative
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20006

Re: Docket No. USTR-2023-0010 – Request for Comments on Significant Foreign Trade Barriers for the 2024 National Trade Estimate Report, 88 Fed. Reg. 62421 (Office of the United States Trade Representative September 11, 2023)

Dear Ambassador Tai:

CropLife America (CLA) is providing its submission for the 2024 U.S. Trade Representative's National Trade Estimate (NTE) report. CLA, established in 1933, represents the developers, manufacturers, formulators, and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell, and distribute virtually all the pesticide products used by U.S. farmers, ranchers, and landowners to ensure healthy crops and strong yields.

U.S. farmers depend on pesticides to grow healthy and safe crops, fruits, and vegetables that are used as food, as well as other farm products, including fibers, lumber, and fuel for consumers domestically and around the world. Without modern pesticides, insect pests, weeds, and crop diseases would destroy or reduce crop yields and quality, which would contribute to the substantially reduced availability of U.S.-grown farm and food products. Many U.S.-grown crops are exported, and pesticide-related trade barriers are becoming increasingly important to U.S. growers and CLA.

In addition, pesticides play a vital role in achieving U.S. goals for sustainable productivity by allowing for reduced/zero-till agriculture, and the use of cover crops. These agronomic practices allow U.S. farmers to reduce greenhouse gas emissions, improve soil quality, and sequester atmospheric carbon dioxide. Increasing production while minimizing environmental impacts and preserving natural resources is the greatest challenge for today's farmers, especially in the face of a changing climate and the pressures on agriculture that come with it. Farmers carefully monitor the prevalence and location of pests and diseases affecting their crops. If they must use pesticides, they carefully select the right pesticide and the smallest quantities possible for each pest and crop at issue. In response to changing farm production practices, pesticide manufacturers are developing more targeted, more selective, and safer solutions to control weeds, diseases, and insects that threaten the food supply. These new pesticide innovations allow farmers to use fewer, more targeted pesticides within an Integrated Pest Management system.

Divergent regulatory approaches can restrict the tools available to producers if they want to sell to certain export markets. Such inconsistencies often lead to trade barriers and reduce global food production. The creation of and adherence to science-based global standards and decisions for pesticide residues on food products would contribute to a safe and reliable food supply. We support global science-based approaches that uphold consumer and crop safety and promote fair trade practices for imports and exports.

• Representing the Plant Science Industry •

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An increasing global problem is a hazard-based approach to setting MRLs. This approach identifies a hazard – normally one of the first steps in a risk assessment – and then effectively ends the risk assessment without considering other exposure factors by banning substances altogether as well as commodities that include residues of those substances, even if those trace amounts are well below levels that regulators have determined are safe. This and similar strategies threaten major disruptions to agricultural trade, which in turn can lead to producers rejecting safe and effective tools to protect their crops.

CLA encourages governments to base their pesticide residue regulatory approaches on international standards developed by the Codex Alimentarius, including deferral to Codex MRLs (CXLs). It is also important that the Codex decision-making process remains science-based. Any introduction of other non-science factors into decision-making processes will undermine the scientific integrity of the risk assessment and likely create unnecessary barriers to trade.

Lastly, it is critical that countries comply with the World Trade Organization's (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), which must be enforceable through a binding dispute settlement system. SPS-related trade barriers are already difficult to resolve, and they will proliferate as the dispute settlement system remains broken.

This report will provide brief overviews of several issues CLA members face in a few important agricultural export destinations. This is not an exhaustive list, but it highlights some of the major challenges facing the industry globally due to uncertainty created by regulatory and trade policies. Note that in most cases, CLA is not providing estimates of trade impacts because measuring the economic effects of pesticide regulatory policies is highly dependent on specific actions taken by regulators within the context of uncertain and non-science-based policies.

China

China is the top destination for U.S. agricultural commodities, with nearly \$36 billion exported in 2021. The United States exports a diverse range of food and agriculture products to China, but to date, China has not established a regulatory framework for setting tolerances (MRLs) for these imports. As a member of the Asia-Pacific Economic Cooperation (APEC) forum, China has participated in developing guidance on approaches to achieving pesticide MRL alignment within APEC, particularly for cases where no domestic MRL or CXL exists. The APEC Secretariat published a guidance document that is based on the OECD's guidelines for mutual acceptance of data and confirmation of no risk to consumers in importing countries. Seven years after it was published, China still has not implemented this guidance, though other countries in the region have, including the United States.

While pesticide MRL issues are infrequent with China, the absence of alignment creates uncertainty and unnecessary risks for trade in agricultural commodities. Currently, China is not accepting foreign data unless the lab has been accredited by China. This inadvertently led to domestic and foreign firms having to duplicate data development to comply with both China and OECD standards if they want to register products in both China and other countries. If China were to accept foreign OECD data generated under Good Laboratory Practice (GLP) standards, this would facilitate the registration of new pesticide products, both within and outside China. Currently, domestic Chinese and foreign firms need to duplicate data if they want to register products in both China and other countries. This creates unnecessary costs and delays in the introduction of newer and more effective products to producers.



European Union

Many U.S.-grown crops are exported to the European Union (EU), so EU policies that adversely impact trade are critically important to U.S. growers and CLA. The EU also has a disproportionate global influence on trade issues, so harmful policies adopted there are often copied elsewhere.

Hazard-Based Criteria

In 2009, the EU enacted legislation that introduced “cut-off” criteria for certain aspects, effectively banning the use of pesticides matching those aspects due to intrinsic properties (“hazards”) without any further evaluation of how these pesticides are used and the risks from exposure. Certain MRLs for non-approved pesticides are deleted and set to the default MRL while other MRLs are maintained after all EU product authorizations are revoked and grace periods respected. In cases where MRLs need to be deleted, the EU continues to allow residues for a short transition period.

The Commission has communicated that decisions for MRLs remain risk-based rather than hazard-based and that it will therefore continue to propose import tolerances and implementation of CXLs into EU legislation if a risk assessment carried out by EFSA found them to be safe for consumers. Member States, however, have voiced blocked adoption of such proposals on the basis of, for example,¹ “non-acceptability of import tolerances for substances no longer approved in the EU” (i.e., applying hazard-based criteria) and due to the “negative impact on the competitiveness of European farmers that are deprived of using the same tools as third countries,” which is clearly discriminatory and not based on a risk assessment.

Farm to Fork

The European Commission’s signature effort on agricultural sustainability is its Farm to Fork (F2F) Strategy which was announced in 2019 as part of the European Green Deal. The F2F strategy includes some laudable goals to reduce the environmental impact of agriculture, including lowering greenhouse gas emissions, along with some goals lacking substantial scientific backing like expanding organic production to 25 percent of EU farmland and reducing inputs according to arbitrary targets that are unrelated to the agronomic conditions facing European producers. The EU has since begun to implement this policy and expand its reach beyond the EU border, translating these targets into legislative proposals.

The increasingly stringent standards being imposed on domestic producers in the EU have led to calls for “mirror clauses” that would require exporters to the EU to meet the same standards as EU producers, regardless of whether the agronomic conditions or other relevant criteria are consistent across geographies. Given the diversity in global agriculture, as determined in the United Nations’ Food and Agriculture Organizations’ Global Agro-Ecological Zones methodology, it is imperative that goals to improve environmental outcomes are not a one-size fits all approach. The European Green Deal and F2F initiatives are ambitious, but this first-of-its-kind experiment reflects only the interests of a set of EU stakeholders in their preferred approaches to sustainability and ignores the many challenges that farmers face globally. The proposed solutions in F2F for meeting the EU’s sustainability goals may not be appropriate for producers in other countries depending on their specific agricultural, social, economic, and environmental needs.

¹ See Summary Report of 10-11 May 2023 SCoPAFF meeting, page 17



Registering agricultural products through the U.S. EPA already requires a thorough, science-based risk assessment evaluating potential adverse effects on the environment. The EPA conducts these risk assessments based on conditions relevant to the region where the products are applied. It has listed tolerances (MRLs) for more than 1,300 active pesticide ingredients while the EU has just over 400 (more than a 60% reduction in comparison to 1991). Mirror clauses requiring the production of agricultural goods in the U.S. or any other country to follow prescribed practices in a manner determined by the EU is an unacceptable imposition on peer regulatory agencies. As such, the EU should work to ensure consistency with World Trade Organization (WTO) rules and avoid proposing mirror clauses that would impose EU production and environmental standards on exporting nations.

Neonicotinoid MRLs

Meanwhile, the EU is implementing an MRL approach that is not fit for purpose via a regulation that was approved in 2022 by the Commission's Standing Committee on Plants, Animals, Food and Feed (SCoPAFF). The regulation requires applications for import tolerances for clothianidin or thiamethoxam to demonstrate that the specific uses of the active substances are safe for pollinators or else MRLs are set to the limit of quantification (LOQ). However, the regulation effectively precludes any outdoor use because the "intrinsic properties" of the substances are purportedly harmful to pollinators. This implies that these effects cannot be mitigated and any commodities found with residues above the LOQ would be rejected.

The WTO notification for the draft regulation gave countries 60 days to respond to the proposal (until September 4, 2022). Several major agricultural exporters did respond with their concerns, but instead of considering these concerns, the SCoPAFF forced a vote on September 27, 2022, (just three weeks later) and approved these new restrictions. This will eventually reduce the MRLs to the EU default.

While the Commission heeded the recommendation to allow sufficient time for clearing channels of trade of residues (36 months instead of the more commonly seen 6 months), this action is more trade restrictive than necessary. Its impact is disproportionate to non-EU countries, ignoring the production and regulatory conditions outside the EU, as well as the risk assessments and decisions of regulatory bodies in non-EU countries.

CLA would like to emphasize that MRLs are trading standards, and not appropriate for enforcing compliance with environmental objectives. Rather, MRLs ensure there are no unacceptable health risks from pesticide residues for consumers and provide assurance that good agricultural practices have been followed. The U.S. EPA conducts consumer risk assessments and establishes tolerances (MRLs) for active substances in the United States, either for domestic use or to facilitate trade through an import tolerance application. The European Food Safety Authority (EFSA) conducts similar assessments, both for domestic use or for import tolerance, or when adopting CXLs. The primary objective of MRL setting is to ensure a high level of consumer protection, and the utilization of MRLs as a tool to tackle supposed environmental challenges in other countries is a distortion of the EU's own policy objectives.

Different regions have different needs. Some pesticides not registered in the EU may be necessary in non-EU countries. Some may even be necessary in EU countries (see the database on emergency authorizations for pesticide use). Regardless, MRLs are not an appropriate proxy for what's necessary, and if the EU wants to discuss how national authorities address issues like pollinator protection, it should engage with them directly rather than circumventing their regulatory processes.



India

India was the 14th largest export destination for U.S. agriculture in 2022, but the market is beset with tariff and non-tariff barriers (NTBs) to trade. This situation poses considerable risk to existing trade and hinders its expansion. India does not have a regulatory system to establish food standards for imported commodities. Furthermore, it does not adopt CXLs when domestic MRLs do not exist.

The Food Safety and Standards Authority of India does set domestic MRLs in India. However, the process is not transparent, and MRLs are frequently set at the default level (in 2014, India stopped adopting CXLs). India's Guidance Document & Standard Operating Procedures for fixation of MRLs of pesticides in food commodities claims to have "almost harmonized" with Codex's Joint FAO/WHO Meeting on Pesticide Residues (JMPR), but there are many discrepancies between JMPR's recommendations and India's procedures for MRL setting. Under these circumstances, India should recognize trade standards (e.g., MRLs/tolerances set by EPA) of originating countries for imported products in order to enable safe local consumption.

In August 2017, the government announced quantitative restrictions on pesticide imports. While these were eventually rescinded, uncertainty remains regarding the future implementation of these restrictions. India could be a major manufacturer of pesticides and pesticide ingredients, which would improve the diversity of global supply chains and promote resiliency. However, restrictions on imports, higher duties, and other unpredictable policies have the unintended consequence of making it much more difficult for India to encourage investment in domestic production. India is also pursuing a "Made in India" policy that attempts to use a highly protectionist approach to incentivize domestic manufacturing. This could have the opposite effect of discouraging investment in manufacturing, especially for industries like agrochemical manufacturing that depend on global supply chains.

Korea

The Republic of Korea's Ministry of Food and Drug Safety (MFDS) is responsible for moving the domestic MRL and import tolerances to a positive list system (PLS), in which chemical residues may only occur if MFDS has established a specific tolerance for a detected substance on the food or commodity where it's found. Tolerances established by Codex or the country of origin are not recognized.

Korea's PLS is not inherently disruptive to trade, but MFDS faced a challenging task in ensuring that it could establish tolerances for the many potential combinations of food and residues that can occur in both imported and domestic products. To cope with this, MFDS phased the implementation in several stages, beginning in 2016. In 2022, all existing temporary MRLs were eliminated.

MFDS should be commended for the flexibility it has shown in striving to make the transition to a PLS as smooth as possible. However, it is still concerning that MRL values are set consistently lower than those of the United States or Codex, even though the scientific evidence does not support this. For example, for one active ingredient, the residue definition is the sum of two isomers, and the MRLs in the U.S., Canada, Codex, EU, and Japan are set at the sum of the Limits of Quantitation of the two isomers. The import tolerance MRL set in Korea based on the same data is half of the MRL of the other countries, creating a trade barrier. There is a critical need for further harmonization of MRL values to enable market access to imported foods and prevent trade disruptions. CLA encourages USTR and other relevant U.S. agencies to seek opportunities to identify and improve harmonization criteria for MRL setting.

Mexico



Mexican President Lopez Obrador's administration is advancing a populist agricultural policy agenda against pesticides and other agricultural production technologies. As a member of the WTO and USMCA, Mexico has international obligations to base its policies on scientific evidence and risk assessments, while maintaining a predictable and transparent regulatory framework. Mexico's failure to comply with its international commitments, along with corresponding domestic law, threatens the integrated North American agricultural markets. In particular, the supply chain for grains is threatened by its ban on genetically modified corn, as well as the rejection of other traits that provide herbicide resistance.

Mexico's Federal Commission for the Protection Against Sanitary Risk (COFEPRIS) is responsible for processing regulatory actions, administrative/legal changes, and product authorizations. The functioning of COFEPRIS as an independent regulatory agency was also compromised through a 2020 reorganization, placing it under the Undersecretary for Prevention and Promotion of Health in the Ministry of Health. Previously, COFEPRIS was a decentralized agency with administrative, technical, and operational autonomy and funding. On December 31, 2020, a Presidential decree was published calling for a phase-out of glyphosate and GMO corn by January 2024. In 2021, Mexico began quantitative limits on imports of the herbicide glyphosate. A revised decree was published in February 2023, with instructions to Mexican agencies to substitute glyphosate by March 31, 2024.

In addition, COFEPRIS faces a backlog of over 2000 pesticide registration applications. Companies seeking registration are unable to estimate regulatory timelines for products intended for sale in Mexico. This backlog has a detrimental effect on U.S. companies that sell these products in Mexico but also harms Mexican producers who may lose access to vital production technologies. This in turn is harmful to U.S. consumers, particularly low-income consumers who will have to pay more for the fresh fruits and vegetables that Mexico currently provides in abundance and exports to the U.S. market.

COFEPRIS is also developing regulatory initiatives that could drastically impact the pesticide industry. One is intended to discourage the registration and use of chemical pesticides by using guidance from non-scientific and politicized sources, such as the National Commission of Human Rights (CNDH), and the inappropriate application of the precautionary principle. Another initiative is an amendment to pesticide regulations ("Reglamento PLAFEST") to alter Highly Hazardous Pesticide (HHP) classifications.

Under the Lopez Obrador administration, Mexico has embraced an approach to the "precautionary principle" that is not consistent with the precautionary approach laid out in Article 9.6.5 of the U.S.-Mexico-Canada Agreement and Article 5.7 of the WTO SPS Agreement. These international commitments allow Mexico to maintain restrictions, but only in the face of insufficient scientific evidence, and oblige Mexico to seek out the additional information needed for more objective risk assessments. The 2020/23 Presidential decrees were not proposed in response to insufficient scientific evidence, which is extensive for both GMO crops and pesticides. While these SPS commitments do not directly apply to domestic pesticide registrations, Mexico is likely in violation of the Technical Barriers to Trade (TBT) provisions of both agreements. As a result, Mexico's pesticide regulatory system has become increasingly unpredictable, non-science-based, and politicized.

Taiwan

Taiwan is the 6th largest market for U.S. agricultural exports, valued at \$4.3 billion in 2022. It is a major market for a range of U.S. commodities, including soybeans, corn, wheat, apples, cherries, grapes, and vegetables. Taiwan has been working to approve MRLs and import tolerances (ITs) since 2006. However,



implementation of its positive list system of country-approved MRLs has been slow and continues to lack predictability and transparency. These missing elements create trade barriers and, in some cases, have affected the introduction and use of new technologies in markets like the United States that export to Taiwan. The lack of transparency in the IT setting process and infrequent publication of new MRLs adversely impacts trade and is a major concern for U.S. producers, exporters, and CLA.

In 2014, the United States Department of Agriculture (USDA) Foreign Agricultural Service (FAS) worked with stakeholders to provide Taiwan with a priority list of ITs needed; many ITs were established although subsequent approvals have been erratic. Although MRLs are trade enforcement standards that indicate proper use of a crop protection tool on a crop, ITs seem to be perceived by Taiwan consumers as a health standard. Establishing MRLs and MRL violations are politically sensitive and publicly watched in Taiwan, resulting in a 2017 halt in approvals and reevaluation of the pesticide approval system for example. Since May 2017, Taiwan has canceled 160 MRLs and set new restrictions for MRLs and ITs. While new ITs have been established, they are frequently set below levels justified by scientific evidence. Industry and governments continue to work to address the situation.

Trade policy priorities in Taiwan primarily involve moving towards a more risk-based regulatory framework that is built on a predictable and scientifically sound policy environment. This would increase the availability of tools for U.S. producers who need to combat pests and diminish the risk of product rejection in the Taiwan market due to misaligned regulatory measures. However, while registrants are able to track the review status of their applications, they do not have realistic timeframes to communicate to growers regarding when the ITs will be established. This has become a significant issue for U.S. growers who require MRLs to be in place in Taiwan before using pesticide products to combat diseases and pests. These issues and the resulting delays leave growers with few options for pesticide tools and reduce U.S. agricultural exports to Taiwan.

Conclusion

CLA appreciates the opportunity to comment for the NTE report. We look forward to our continued engagement with USTR to address pesticide regulatory issues as we seek to reduce friction in international trade, eliminate trade barriers, and encourage regulatory approaches for pesticides that are based on science and sound risk assessments in conformity with international trade rules and standards.

Sincerely,

A handwritten signature in cursive script that reads "Susanne Wasson".

Susanne Wasson
Interim President and CEO
CropLife America