STATEMENT

OF

THE U.S. GRAINS COUNCIL

NATIONAL CORN GROWERS ASSOCIATION

AND

MAIZALL

TO THE U.S. INTERNATIONAL

TRADE COMMISSION

ON

Global Economic Impact of Missing and Low Pesticide Maximum Residue Levels (Investigations No. 332 - 573)

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I. Introduction

On behalf of the U.S. Grains Council, National Corn Growers Association and MAIZALL, we appreciate the opportunity to provide our perspective on the global economic impact of missing and low pesticide maximum residue levels (MRLs). Our three organizations have worked collaboratively on the following comments.

The U.S. Grains Council is a private, non-profit organization representing U.S. producers of corn, sorghum, barley and co-products such as ethanol, distiller's dried grains with solubles (DDGS), and corn gluten feed and meal, as well as associated agribusinesses. Founded in 1960, the Council now has 13 international offices, representatives in an additional 15 locations and a network of consultants and partnerships that support programs in more than 50 countries. Our members, leadership and staff fundamentally believe exports are vital to global economic development and to U.S. agriculture's profitability.

We work in cooperation with our sister organization, National Corn Growers Association (NCGA), and MAIZALL, the international maize alliance.

Founded in 1957, NCGA represents nearly 40,000 dues-paying corn farmers nationwide and the interests of more than 300,000 growers who contribute through corn checkoff programs in their states. NCGA and its 48 affiliated state organizations work together to create and increase opportunities for corn growers.

MAIZALL is an international alliance of maize grower associations representing farmers in Argentina, Brazil and the United States. MAIZALL shares the common goal of communicating the benefits of modern agricultural production technologies and practices, as well as advocating for trade-enabling policies and regulatory processes related to agricultural biotechnology, Plant Breeding Innovation (PBI) and crop protection products. MAIZALL's members are NCGA, the U.S. Grains Council, Abramilho (Brazil) and Maizar (Argentina).

MAIZALL, NCGA and U.S. Grains Council all bring a unique and complementary perspective to the topic at hand. Whether through the lens of the local farmer, the export market development efforts or the macro trends of farming in the Americas, we hope to shed light on the impacts and considerations that high-volume, bulk commodities face when moving around the globe. We believe that crop protection products play a critical role in the global food production system and that missing or low MRLs can have lasting and detrimental impacts on our ability to sustainably supply the world with its food and feed. We are concerned by a growing trend where countries are moving away from international standards or reliance on science-based, risk-based approaches to setting MRLs, resulting in new barriers to trade.

U.S. Corn Production

More than 300,000 farmers across the United States grow corn for food, fuel and fiber use. The versatile product provides a nutritious and sustainable food source for the global livestock sector, supplies the world with a renewable fuel source and replaces petroleum and other non-renewable ingredients in a wide variety of industrial products. The U.S. corn crop is annually worth more than $50 billion and employs hundreds of thousands of people in the U.S. and around the globe.

For centuries, farmers have found innovative ways to produce more efficiently and effectively, and in the last few decades the pace of innovation has increased exponentially. Improvements to corn production systems and technologies have resulted in a dramatic increase in crop yields, without a corresponding match to increases in land use and inputs. Corn farmers today are more than six times more productive on an annual per acre basis than their predecessors were less than a century ago.

Along with hybridized corn, transgenic seeds and equipment advances, the introduction of crop protection products in the middle of the 20th century propelled the industry to what it is today. Not only did these products make farming more efficient, most importantly they made food production more consistent.

Outside of agriculture, no other industry is subject to the same number of variables that are both unpredictable and uncontrollable. Crop protection products are a defense mechanism providing farmers a small measure of control in an otherwise fickle environment. No longer do we regularly see entire crops wiped out because of the infestation of a single insect pest or disease.

Farmers continue to face pest, disease, weed and weather challenges year after year, but crop protection products mitigate their adverse impact on crops. Additionally, due to other complementary technologies, such as biotechnology and the adoption of precision agriculture and conservation practices, farmers have been able to control these variables with more targeted use of crop protection substances. By enabling more resilient crops, crop protection products have contributed to a more reliable food and fuel supply on which the world has come to rely and enjoy. Without them, farmers will once again be more vulnerable to the unknowns awaiting them at the beginning of each growing season.

Product Safety

Crop protection products are some of the most regulated and tested products anywhere in the world. All products in use today have been tested by the U.S. Environmental Protection Agency (EPA), many of which have been used for decades with no findings of harmful effects to human health or the environment when used properly. EPA reviews each product every 15 years to ensure continued safety and account for any new information or data. Outside of the U.S., numerous science-based governmental bodies have also tested these products with similar findings.

Within the U.S., EPA regulates the use of crop protection products by providing application guidelines that farmers must follow in order to maintain access to the products. It is within the farmer's best interest to apply these products properly, as they will be held liable for any applications that do not adhere to product labels. It is also in their best interest to use them in a judicious and conservative manner as each farmer looks to manage his or her input costs and ensure the safety of workers and family members on the farm.

Conservation and Sustainability

Climate science points to wide-ranging challenges for the global community in the decades ahead if the rate of warming does not slow. Increased weather variability and extreme weather events will add additional stress on the global food system's ability to deliver a reliable and consistent

food supply to a population that is expected to grow to 9.7 billion people by 2050[1]. Crop protection products are one necessary tool for achieving this goal amidst a growing list of challenges to global agriculture. Without access to crop protection products, global food security will be challenged as farmers lose options to control devastating insects and diseases.

Plant diseases occur through the right combination of environmental conditions and pathogen presence in susceptible plants. Although farmers can partially control one of those factors through the selection and adoption of hybrids or varieties that are less susceptible to certain diseases, even a plant with resistance to some diseases cannot protect against every possible option. In this way, farmers have almost no control over the development of plant diseases in their crops. Their only option for mitigating the impact of the disease is the use of a fungicide that will control the further spread of the pathogen and decrease the potential for yield and economic loss.

For example, within the last five years U.S. corn farmers have faced a new disease, tar spot, which is believed to have entered the U.S. in a storm system moving north from Mexico. Within the last few growing seasons the disease has presented itself in major swaths of the corn belt, in some cases reducing yields by 30 to 40 bushels per acre. While the academic and seed communities are working diligently to better understand the disease with intentions of diminishing its impact, farmers are facing this pest with few control options. Fortunately, fungicides are one tool that can help farmers mitigate the losses from this new disease. If fungicidal control was not an option, farmers would be forced to risk planting their crop each year without knowing if or when this disease will cause economic harm. This is one only example of the value of crop protection products for modern pest control.

Another benefit of crop protection products is a farmer's ability to control weeds. Prior to the introduction of these substances, farmers were forced to rely on tillage to manage weeds in their fields. With the adoption of these substances, farmers quickly saw labor efficiencies and increases in production, as well as another positive benefit in the form of better environmental outcomes. Because herbicides can control these problematic weeds without tillage, farmers began to use conservation tillage practices in place of the intense tillage previously required for control.

[1] United Nations, Department of Economic and Social Affairs, Population Division (2019). World Population Prospects 2019: Highlights. ST/ESA/SER.A/423. https://population.un.org/wpp/Publications/Files/WPP2019_Highlights.pdf.

Conservation tillage, defined as tillage systems leaving at least 30 percent of the soil surface covered by crop residue at crop planting, has now been widely adopted by farmers around the U.S. A 2018 ERS report noted that conservation tillage was used on 65 percent of U.S. corn acres, as measured during the 2016 growing season.[2] The use of these practices substantially reduces soil erosion. Between 1980 and 2011, soil erosion was reduced by 67 percent per bushel of corn produced and by 43 percent per acre of corn planted. Without these products, farmers will be forced to use tillage to control weeds in their fields, nullifying any sustainability gains made over the previous few decades.

Conservation tillage enables fewer trips over their field over the course of a growing season, thus reducing energy consumption and decreased environmental impact. Additionally, plants are known consumers of carbon dioxide, pulling it out of the atmosphere and storing it in the soil through their roots. Tillage breaks up the soil carbon which is then released back into the atmosphere. If farmers must revert to using heavy tillage to control weeds the agriculture industry will likely decrease its ability to capture and store carbon in the soil and therefore decrease its ability to positively address climate change.

Alternatively, crop protection tools and the sustainable practices they make possible, allow farmers to be part of the solution in addressing global climate challenges.

Continued Technological Progress

Recent technologies introduced to the market have increased the precision with which farmers use and apply inputs. GPS-guided sprayers enable farmers to make consistent passes across the field without overlap, which reduces the amount of product supplied while also saving the farmer valuable time and money. Automatic shutoff systems reduce the likelihood that crop protection products will be applied outside of the field, conserving field borders and adjacent lands like waterways.

Rapid advances in automation and machine learning show great potential for future pest control options. While not yet in widespread use across the corn belt, several new application

[2] https://www.ers.usda.gov/webdocs/publications/90201/eib197_summary.pdf?v=1783.8

technologies show promise. For example, one new application tool uses cameras and sensors to distinguish weeds from the planted crop to enable hyper-targeted applications instead of broadcast applications. The industry is still very early in its understanding of what is possible and scalable for large acreage crops. Yet all signs point to continued advances that will maximize the efficiency and effectiveness of all inputs, including crop protection products.

The Bulk Commodity System

Each farmer tackles the conditions on his or her farm by utilizing different products or even different rates of application for each field. There is an obvious variation even at a single-farm level, which is then transported to a variety of storage options. It is also normal practice for post-harvest crop protection to be applied, which will also vary depending on the type of storage being used. Climate patterns and field conditions vary greatly at the state and regional level in the U.S., which implies different stressors on crops and variable crop protection product usage patterns.

An understanding of global grain flow is critical to addressing MRLs in export markets. It is important to recognize that grain is first harvested at the farm-level (where a variety of crop protection strategies are used over the course of the growing season) and put into country elevators or on-farm storage. Even the farmers that have access to on-farm storage (which can be over 30,000 MT but often stores less than 7,000 MT) may sell some of their grain at harvest to a local elevator as they often have more grain than they do grain storage.

To further complicate this, it is possible that on-farm storage may include grain harvested from previous years, where a different crop protection strategy might have been used. Even when this is not the case, it is likely that each farmer may split his or her crop and send the harvest to a variety of different locations.

As grain moves through the system it may end up in a subterminal elevator, which has the capability of loading river barges or 110-railcars. Each subterminal elevator has a network of feeder elevators in the region (the previously mentioned on-farm and country elevators). Each subterminal elevator can be over 600,000 MT but is often less than 50,000 MT. This demonstrates that it takes several farms, each of which incorporates a variety of crop protection practices) to add to the necessary volume of operating in an economically sustainable manner. Corn that is bound by rail for Canada or Mexico would end the bulking/blending process here.

However, if it is bound for one of the other export markets that is accessed via vessel, it then is further combined to accommodate the 15,000 – 70,000 MT vessels that are constantly loaded out of export elevators. The sheer volume requirements for meeting the world's demand means that exporting countries compete in a high-volume, low-price system. To remain competitive, corn farmers must maximize their yields and have their grain delivered as efficiently as possible. However, even the most productive corn farmer cannot supply the needs of an entire customer. Due to these high-volume requirements, grain products are bulked and blended according to quality standards, which would ultimately require many different farms with many different practices to meet the necessary volumes.

Because of this bulking and blending process that occurs as the grain flows through the supply chain, grain products cannot be traced back to individual farms or the pre- or post- harvest treatments that are used as they are moved through the export commodity system. In summary, grain from different farms, years, and growing conditions may be grown using different crop protection applications and is likely to be commingled in bulk grain channels.

Just as a grain trade company cannot trace a corn product back to the farm-level, an individual farmer does not know who the end-customer of his corn crop will be. Each farmer applies the tools that he or she deems necessary at any given moment, following the U.S. label and the safe practices set forth by EPA in determining when or how to apply a particular substance. Because of this, divergent MRLs can cause significant challenges for bulk commodities. Grain trade companies must mitigate their risk and liability when selling a vessel to a particular country.

The efficiencies of the bulk commodity supply chain, made possible through considerable time and resource investment over many years, have allowed us to compete on a global scale. However, based on how the bulk commodity system works, if an MRL is not aligned with that of the U.S.' MRL and /or international standards established by Codex, there is a potential risk for rejected shipments or increased testing. Or, as is the case in the European Union, there is also a possibility that farmers may lose access to substances that have undergone rigorous testing and received U.S. approval and possibly internationally recognized as safe and legal, in order to continue supplying an overseas market.

A related concern is that third nations will subsequently ban or restrict the use of these substances in a “ripple effect”, ignoring international science-based, risk-based standards. Most recently Thailand proposed a ban on three pesticides (Glyphosate, Paraquat, and Chlorpyrifos). While the ban has been delayed there is continued concern on the impacts on international trade.

All of these factors can create obstacles to trade and are of mounting concern, particularly as the world becomes more interconnected and MRL issues become more prevalent.

II. International Role of Plant Protection Products

Commonalities Across Corn Growing Countries

Through MAIZALL, we have come to understand that many highly-adopted U.S. practices are also common in other growing regions of the world. In fact, MAIZALL and its farmer members from Brazil, Argentina and the United States represent more than 50 percent of global corn production and more than 70 percent of global corn exports. Product safety, conservation and sustainability efforts, climate resiliency and the adoption of precision agriculture technologies are also common themes for crop protection usage in these countries.

Each of these countries demonstrates a commitment to reducing pesticide usage while still meeting the growing global demand for corn. However, these substances play a critical role in increasing yields and efficiencies, two especially critical elements for developing countries that are looking to improve their food security, enhance their economic growth and compete in the global marketplace.

From this perspective, the MRL challenges of U.S. farmers are consistent with those from other major corn growing regions. In Brazil and Argentina, corn is bulked, blended and marketed in the same manner as it is in the United States. Therefore, when a substance that is important for combating pest and disease pressures has divergent MRLs in a major export destination, serious risks for the flow of global grain trade are present.

MRLs As Trade Enabling Instruments

MRLs play an important role in enabling trade. An MRL is a trading standard that reflects both risk and hazard from exposure in a given environment, and then sets a scientific limit that reduces that risk exponentially below any level that could be considered a health hazard. An MRL is not a representation of food safety but rather a mechanism for ensuring that farmers follow safe label practices when using pesticide products. For the most part, one can assume that a farmer correctly following the label will not trigger a residue above that of the MRL.

However, because farmers use products and follow labels based on the registration of their own home country, proper label use does not indicate whether a residue sample will cause challenges in an external market. For example, proper label use of a U.S. substance will only ensure that the crop does not exceed the U.S. MRL. For the global grain trade, this means that an understanding of export market MRLs are crucial for access into a market.

Challenges can also arise, though, when a product is not utilized in an export country. As substances address specific pest and disease challenges, some substances will be ineffective or unnecessary in a climate with different pressures. Therefore, a product that is common in one country's production may not be useful in another. In these situations, it is possible that an MRL may not be established at all, and a missing MRL for a key substance could cause an entire shipment to be rejected disrupting trade.

III. Regulating MRLs

Approaches to Setting U.S. MRLs

In the United States, MRLs are set during the registration of a crop protection product. Before a pesticide may be marketed and used in the United States, EPA evaluates the proposed pesticide to ensure overall safety of the product. Crop protection products that pass this evaluation are granted a registration that permits their sale and use. Registration approval requires a finding that the pesticide will not pose unreasonable adverse effects to human health or the environment when used in accordance with labeling directions. After a pesticide is registered, subsequent

reviews occur to ensure currently registered crop protection products continue to meet safety standards.

Before a pesticide may be used on a food crop, EPA will set a tolerance, or MRLs, which is the amount of pesticide residue allowed to remain in or on each treated food commodity. Tolerance setting requires a variety of scientific studies for the EPA to review and conduct a risk assessment. Registrants must submit scientific data to identify possible harmful effects on humans, the amount of the chemical likely to remain in or on food and potential other sources of exposures to the pesticide.

In setting the MRL, EPA must find that the pesticide can be used with "reasonable certainty of no harm." EPA evaluates the toxicity of the pesticide and its break-down products, how much of the pesticide is applied and how often, and how much of the pesticide remains in or on food by the time it is marketed and prepared. Further, EPA studies all possible routes of exposure to a pesticide. For example, residues on each crop use as well as exposure from drinking water and residential exposure. EPA performs dietary risk assessments to ensure that all tolerances established for each pesticide are safe, considering food consumption by infants and children.

Before a tolerance is officially set, the public has an opportunity to comment on the proposed new pesticide tolerance. After reviewing public comments and all the scientific data, EPA then announces the tolerance in the Federal Register. This announcement includes an assessment of risks posed by the pesticide and the safety finding that allows establishment of the tolerance or exemption. A 60-day period for filing objections and hearing requests is provided after publication of the tolerance.

The Use of Crop Protection Products in Brazil

The United Nations Food and Agriculture Organization (FAO) ranks Brazil as the 44th largest global user of crop protection products, behind European countries such as Belgium, Italy, Ireland, Portugal and Switzerland. Data from the FAO statistical service indicates an average application of 4.31 kilos per hectare in 2016, the year used as a reference.[3]

[3] (FAO 2018) Codex Alimentarius (FAO), Vol. 3, Section 3, 1995, http://faostat.fao.org/beta/en/#data/QC

Regarding pesticide spending per hectare, Brazil averaged, in 2018, a total of $111.2 / ha while in France it was approximately $174 / ha, Germany $ 210 / ha and Japan $455 / ha, according to FAO (2018).

To provide some perspective on this usage of crop protection products, consider that for every US $1 spent on crop protection products, about 142 kg of food is produced. This is more than double that of the European Union's 62 kg, according to a study by German consultancy Kleffmann and EMBRAPA (2018). It can also be noted that while pesticide consumption in Brazil grew by 14 percent between 2013 and 2018, agricultural production grew by 40 percent in the same period. [4]

Each of these crop protection products is accompanied by manuals or packaging information on the characteristics of each substance, the correct mode of application and the urgent measures in case of possible poisoning due to misuse. In addition, public sector entities such as EMATER (the Brazilian technical assistance and rural extension service) and SENAR (the national rural educational service) in the private sector carry out training activities for the workers involved in the application of these substances.

Pesticide Regulations in Brazil

Brazil regulates the use of these products through several laws, including Law No. 7802, of July 11, 1989, which provides for research, trials, production, marketing, residues and packaging, registration, classification, control, inspection and inspection of crop protection products. [5]

Also detailed in Law No. 7802/89 are the penalties for misuse of these substances, as provided in the article below:

> "Art. 16. An employer, responsible professional or service provider who fails to use the necessary health and environmental protection measures shall be subject to the penalty of imprisonment from 2 (two) to 4 (four) years, in addition to a fine of 100 (one hundred) to 1,000 (one thousand) MVR. In case of guilt, the person will be punished with

[4] EMBRAPA (2018), 50 Tons de Verde, Evaristo Miranda
[5] Lei 7802/1989: http://www.planalto.gov.br/ccivil_03/LEIS/L7802.htm

imprisonment from 1 (one) to 3 (three) years, plus a fine of 50 (fifty) to 500 (five hundred) MVR."

Mechanisms for Monitoring Pesticide Usage in Brazil

In addition to their regulations, Brazil has several mechanisms for monitoring and controlling pesticide residues in food. The Food Pesticide Residue Analysis Program (PARA) in Brazil, created by the Brazilian Ministry of Health in 2001, aims to continuously evaluate the levels of pesticide residues in foods of plant origin that reach the consumer's table.[6] The program is part of the National Health Surveillance System (SNVS) and is coordinated by ANVISA (Brazil's regulatory health agency), in conjunction with state and municipal health surveillance agencies and laboratories.

Since the creation of PARA, more than 30,000 samples have been analyzed for 25 types of foods of plant origin. The selected foods represent about 70 percent of vegetable food consumption in Brazil, including corn, onion, beans, grapes, oranges, bananas and apples. The most recent results by the Program, published on their website show that, in the period between 2013 and 2015, 80.3 percent of the samples had results with no residues present or with residues below the MRL. Only 19.7 percent of the samples presented nonconforming indices, with the primary cause of these incidents being the use of products without specific authorization for the crop in question.

The National Plan for the Control of Residues and Contaminants (PNCRC) of the Ministry of Agriculture also aims to evaluate the quality of products of plant origin produced throughout the national territory and to monitor the occurrence of pesticide residues and chemical and biological contaminants in products for both the domestic and export markets.[7] The Program carries out annual controls, and in its last publication, in 2019, showed that 97 percent of the analyzed products presented presence levels below the MRL.

[6] Programa de Análise de Resíduos de Agrotóxicos em Alimentos (PARA): http://portal.anvisa.gov.br/programa-de-analise-de-registro-de-agrotoxicos-para

[7] Plano Nacional de Controle de Resíduos e Contaminantes em Produtos De Origem Vegetal - (PNCRC/Vegetal):http://www.agricultura.gov.br/assuntos/inspecao/produtos-vegetal/copy_of_pncrc-vegetal

It should be added that these samples are collected by Federal Agricultural Tax Auditors on farms, processors and supply centers, and follow the recommendations of the United Nations Food and Agriculture Organization[8]).

The PNCRC program consists of 4 subprograms:

- Monitoring - generates information on the frequency, levels and distribution of residues and contaminants in the country; and the results guide the investigation and control actions in the inspection of products of vegetal origin that have the official classification standard (POC);
- Investigation - starts when a violation is detected in the monitoring subprogram and consists of investigation procedures;
- Imported Products - collects samples in the so-called primary zone, i.e. ports, border posts and airports; and
- Exploratory - verifies the occurrence of residues and contaminants that do not yet have established maximum limits and levels and generates information about their presence in crops of interest to MAPA.

Frequent evaluation at technical meetings on pesticide use in Brazil indicates that, in general, pesticide standardization and occurrence control are in line with international standards. It is believed that the small number of higher residue cases stem from farmers' needs to use some kind of product not yet authorized in Brazil (including due to the delay on the part of the three entities responsible for registering them) or the lack of more effective and widespread training of all the segments of the supply chain, from marketing of crop protection products, to application in crops and horticulture.

The Use of Crop Protection Products in Argentina

The responsible use of crop protection products in Argentina is governed by Good Agricultural Practices (GAP). In 2009 the Ministry of Agriculture created the National Commission of Good Agricultural Practices, which is in charge of promoting and raising awareness of GAP at all levels of the agri-food chain in Argentina.

[8] FAO 1995 Codex Alimentarius (FAO), Vol. 3, Section 3

Within the framework of the GAP, the responsible management of crop protection products plays a fundamental role since its objective is to achieve the responsible management and use of these products throughout their life cycle: from their discovery and development, to their distribution and use in the field, and their final disposition and/or discontinuation.

Here are the stages of the life cycle where Responsible Management is exercised:

1. Research and Development: the data generated at this stage, which takes approximately 10 years for each new active substance, generate toxicological and ecotoxicological studies that are taken as a basis for assessment and authorization by SENASA.
2. Manufacturing: at this stage the Good Manufacturing Practices, the Program for Responsible Care for the Environment, and other undertakings of the type are applied with a view to reducing the greenhouse gas emissions, waste and accidents at work and to optimize the use of energy and water.
3. Transport, Storage and Distribution: various laws and regulations locally regulate this stage.
4. Responsible Application and Integrated Pest Management (IPM): responsible management at this stage is of the utmost importance because the release to the environment of the pesticide occurs and increases the risk of contact with the operator, rural populations and the environment.
IPM is defined by FAO as "the careful consideration of all available pest control techniques and their integration into appropriate measures that discourage the development of pest populations and keep the phytosanitary at economically justified levels, reducing and minimizing risks to human health and the environment. "
5. Handling of empty containers: The crop science Industry promotes the final disposal or safe recycling of used containers. The AgroLimpio program of the Chamber of Agricultural Health and Fertilizers (CASAFE) in Argentina promotes the technique of triple washing or pressure washing of used containers, perforation and subsequent collection of them for their transformation into useful and safe products.
6. Management of obsolete stocks: in Argentina, the industry, together with various authorities, provides assistance to individuals who request assistance in this area.

At all these stages, compliance with the FAO Code of Conduct for the distribution and use of crop protection products (November 2002) is promoted.

Additionally, the Network of Good Agricultural Practices (GAP) in Argentina was established following an inter-institutional dialogue between the main public and private entities in Argentina that develop various activities in relation to GAP. MAIZAR is a member of the GAP Network together with 80 other institutions in the sector.

The members of the Network understand that GAP constitutes a strategic instrument to adequately address the challenges of quantitative and qualitative growth of national and global demand for agroindustry products. The objective is to integrate availability, quality and safety and sustainability of agro-industrial production.

The GAP Network was created to have a mechanism for information exchange, inter-institutional dialogue and cooperation among its members, to comprehensively address the different dimensions of this issue. Having this platform, the Network pursues the objectives of promoting the implementation of GAP and communicating to society about the importance of such implementation and the relevance of agricultural activity in general.

Pesticide Regulations in Argentina

Law No. 3489/1958 establishes the control of the Secretary of Agriculture for the sale of chemical and biological products used for the treatment of pests. [9] It establishes the obligation to register the products, under the conditions stipulated in the regulations. It establishes sanctions in case of non-compliance. Decree No. 5769/1959 implements the previous law and establishes the requirements for registration, an essential condition for sale of crop protection products throughout the country.

SENASA, the National Service of Agrifood Health and Quality, is the regulatory agency responsible for the assessment of applications for the authorization of crop protection products. It does this on the basis of Resolution 350-1999 which provides for the procedures, criteria and

[9] Decreto Ley Nacional-3489-1958-SENASA - Servicio Nacional de Sanidad y Calidad Agroalimentaria, http://www.senasa.gob.ar/normativas/decreto-ley-nacional-3489-1958-senasa-servicio-nacional-de-sanidad-y-calidad-agroalimentaria

scope for the registration of crop protection products in Argentina.[10] This Resolution was based on the Manual on the Development and Use of Crop Protection Products, developed by FAO. SENASA is responsible for ensuring that the evaluation of crop protection products is based on sufficient scientific data and demonstrates that the product is effective for its intended purpose and does not entail undue risks to health and the environment.

SENASA also establishes MRLs of crop protection products in agricultural products , as laid down in Resolution 934-2010.[11] The MRLs are contained in the annexes of that Resolution.

Approaches to Setting International MRLs

Crop protection companies are responsible for submitting applications for either an MRL for domestic use or for an Import Tolerance, in the case that the substance is not used domestically but is important for imported products. An Import Tolerance is similar to an MRL in that it sets a trade enabling level for residues on products. However, unlike an MRL, the Import Tolerance only applies to imported products and not to domestically cultivated products. Import Tolerances are most often used for substances that are not applicable to a domestic market; otherwise, it is often the case that the MRL would be the same for both domestic and imported food products.

Some countries have a national system in which they set their own MRLs, like the United States' system described above, while others may choose to adopt the MRLs set by an external market or an international body like Codex Alimentarius.

Codex is an internationally recognized set of standards. However, the process for having an MRL approved at Codex can lead to a considerable lag in timelines, due to both capacity challenges and other important considerations. For example, in order to apply for a Codex MRL, an MRL must first be established in another market. From a high-level perspective, it is possible that Codex may be missing an MRL for a substance that is already being used to combat pest and disease issues in a market. This case of missing MRLs may last for several years, or until Codex

[10] Resolución-350-1999-SENASA - Servicio Nacional de Sanidad y Calidad Agroalimentaria, http://www.senasa.gob.ar/normativas/resolucion-350-1999-senasa-servicio-nacional-de-sanidad-y-calidad-agroalimentaria

[11] Resolución-934-2010-SENASA - Servicio Nacional de Sanidad y Calidad Agroalimentaria, http://www.senasa.gob.ar/normativas/resolucion-934-2010-senasa-servicio-nacional-de-sanidad-y-calidad-agroalimentaria

is able to set and approve its MRL. During this time, any residue above 0.00 would trigger an MRL violation in a country that defaults to the Codex MRL.

However, missing MRLs are not only restricted to those that default to Codex. This situation may also occur when defaulting to a specific country and its respective national system. Likewise, it is possible for an MRL to be established but to be set at a different level than the exporting country's MRL. Each of these systems, whether through Codex or a national system, has a unique process for calculating the appropriate MRL. Therefore, it is possible that each system may arrive at a different conclusion on where to set the MRL for the substance.

In recent years, we have seen a rise of national MRL systems. While there are cases to be made for the autonomy that such a system can provide, it can also cause serious disruptions for global trade, particularly for bulk commodities. As each new system sets its own MRL for a substance via its own considerations and processes, it becomes even more complicated and cumbersome for exporters to reconcile the differences in these levels and approaches to establishing testing levels.

Resources and capacity must be spent to gain a technical understanding of what misaligned or missing MRLs could mean. This includes understanding when and why a substance is used, how it breaks down and the likelihood that a residue above the MRL might appear. All of these considerations must be taken into account for any substance that is important for domestic farmers to respond to pest and disease pressures but does not have a matching MRL in the export market for which a vessel is intended.

Perhaps most worrisome, though, is the potential for a national MRL system to serve as a non-tariff trade barrier.

National MRL Systems and Market Access Challenges

With the rise of national MRL systems, we have experienced both positive examples of trade facilitation, as well as more concerning approaches.

As an example, Japan, a mature market for U.S. corn products, was among the first in recent years to establish its own national MRL system with a default of 0.01 parts per million. During the process of establishing their Positive List System, the Japanese and U.S. governments collaborated closely and held ongoing consultations with U.S. industry to address areas of concern.

The Japanese MRL system still represents challenges for exporters. For example, changes to MRLs occur frequently and notifications are rarely, if ever, translated to English. Likewise, the process for establishing a new MRL can take years to complete, which can lead to domestic issues in adopting new compounds to combat disease and pest pressures. The Japanese system is also among the strictest in the world, often requiring 60 consecutive clean tests after a violation. However, in total, the Japanese system does represent a science-based approach that is not dissimilar to that of the United States and could be considered a positive example of how governments and industries can address potential trade challenges together.

Much like the Japanese system, Korea's implementation of its Positive List System included a multi-year process of ongoing consultations between government and industry. Extensive analysis of crop and chemical combinations were relayed to the Ministry of Food and Drug Safety to work towards MRL harmonization. Through coordination with crop protection industry representatives, timely applications for Import Tolerances were requested and many of the U.S. grain industry's trade risk issues were resolved before the system went into effect.

We could consider the implementation of the Japanese and Korean systems to be among the positive examples of trade facilitation work. However, even with strong coordination, national MRL systems create uncertainty and potential market access risks. Considerable resources by U.S. exporters must be devoted to analyzing the crop and chemical combinations and the potential for residue violations.

The timing of submissions, differences in data packages, residue definitions, soil types, climate, and field trials, as well as different dietary and cultural preferences or different criteria and legal authority for setting MRLs can all impact the implemented MRL. These differences are costly and time consuming to explore and place a heavy burden on export groups. As more of these national systems emerge, the impact on exporters to stay abreast of changes and potential risks can be

overwhelming and incredibly complex. Furthermore, the changes to each MRL must constantly be monitored and tracked, as MRLs can change often and present immediate challenges.

A more concerning example of an MRL setting process would be Thailand's recently proposed ban on glyphosate, paraquat and chlorpyrifos. The proposed ban, which impacts imports as well as domestic use, would be nearly impossible for exporters to comply with. These substances are commonly used around the world in global corn production and have MRLs established in many national systems as well as within Codex. When MRLs are set at zero, an impossible standard, risk and liability for grain traders becomes too high, effectively shutting off a market to exporting countries. In such examples, we see MRLs being used as non-tariff trade barriers to keep competition for domestic markets at bay.

Industry Advocacy Efforts

The U.S. Grains Council actively monitors many of the top substances used in corn, barley and sorghum production in the United States, which enables us to respond to any questions or concerns from importing countries and, when necessary, to advocate for sound and fair enforcement mechanisms. An understanding of where MRLs are harmonized minimizes the risk of residue samples exceeding the trade enabling levels and ensures that products can enter a market.

In recent years, challenges related to MRLs have begun to appear more frequently, not just for corn producers and exporters from the United States but for our counterparts in South America, as well. MAIZALL and its farmer directors from Brazil, Argentina and the United States began to recognize that MRLs were being used as non-tariff trade barriers, with low or missing MRLs used to keep foreign products out of a market or to make it more challenging for exporters to compete.

Building on lessons learned from an asynchronous biotechnology regulatory environment and its impact on global grain trade, the MAIZALL directors determined that it was necessary to engage in global dialogues related to MRLs as well. The directors were most alarmed by the MRL policies being established in the European Union (EU). In addition to the potential impact that the its MRL policies may have on corn exports from the Americas to the EU market, the European Union exerts considerable influence on the development of policy and legislation in many countries around the world. In 2018, MAIZALL engaged in educational outreach focused on the European

Union's MRL policies at the World Trade Organization (WTO), at the FAO and at the European Commission in Brussels.

One example of our involvement was a presentation that MAIZALL's current President, provided at a Thematic Session on Approval Procedures of the Sanitary and Phytosanitary Committee (SPS) of the WTO on November 5, 2019. MAIZALL's President, a corn producer in Argentina, discussed his farming operations and the crucial role of agricultural technologies (such as biotech crops and the responsible use of crop protection products) in producing his crop sustainably. MAIZALL was one of two private sector organizations that was invited to speak in front of more than 250 WTO member country officials.

Through MAIZALL's advocacy efforts in the last few years and feedback from government and industry contacts, it has become clear that MAIZALL is uniquely positioned to offer the farmers' voice on challenging regulatory obstacles, such as reduced MRLs. The farmer's voice has not been previously included enough in policymaking fora on this topic, despite the significant implications for farmers' ability to operate. The topic of MRLs will continue to be a major focus for MAIZALL's efforts in the next two years.

IV. EU: Ground Zero

Concerns About the EU's Policies

Developments in EU policies and regulations pertaining to crop protection products have the potential to negatively impact grains exports to the EU in the future. A hazard-based approach to renewing the authorization of existing crop protection products in Europe has resulted in an increasing number of active ingredients losing their authorization. This may lead to the reduction or removal of MRLs of long-used products. Products that have approval in producing countries but not in the EU risk becoming subject to an MRL of 0.01 mg/kg default or lower at the Level of Detection (LOD). Companies and exporting country governments will continue to have the ability to submit applications for an Import Tolerance if the MRL has been reduced to the LOD, but there are uncertainties regarding the timelines and exact criteria that will be used.

EU legislation, Regulation (EC) No. 1107/2009, governs the registration of crop protection products in the EU. While the initial EU legislation on the authorization of plant protection products was based on a risk assessment, Regulation 1107/2009 introduced hazard-based criteria, requiring active substances to be approved only if they comply with both the hazard criteria as well as the risk assessment criteria. A number of widely used substances have not been reapproved due to these hazard "cut-off" criteria (Carcinogenic/Mutagenic/Toxic to Reproduction, Category 1 or Endocrine Disruptor under Regulation (1107/2009) after their current registrations expired). This trend is likely to continue.

EU Regulators establish MRLs and import tolerances under separate legislation, Regulation (EC) No. 396/2005. The regulatory decision-making process under this regulation is nominally risk-based. However, a May 2018 European Commission policy document (endorsed by the Standing Committee of Member States representatives in June 2019) states that when an active substance is not renewed because it triggered the hazard-based cut-off criteria, the existing MRL will be reduced to the default level of 0.01 mg/kg or to a lower LOD (defined as "the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods.")

The May 2018 document stipulated that applications for new Import Tolerances would continue to be considered, using the risk assessment approach (i.e. an assessment by EFSA). However, it also states that the granting of the Import Tolerance will be considered on a case-by-case basis, taking into account, 'where appropriate, other legitimate factors as well the precautionary principle'. What such legitimate factors are is not defined anywhere in the legislation and leaves the European Commission with considerable scope for maneuver and leaves a considerable degree of uncertainty.

With this position the Commission would apply a hazard-based approach to the MRL/IT process (which is supposed to be risk-based as per the EU's own legislation). It would run counter to the WTO Agreement on the Application of SPS language in Article 5:1:

> 'Members shall ensure that their sanitary and phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal, or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.'

Whereas the hazard-based cut-off criteria for authorization of CPPs only effect the EU itself, applying these criteria to MRLs/ITs of these active substances to imports could affect trade and run counter to the WTO SPS agreement. Additionally, most third countries have a risk-based regulatory system for authorizing crop protection products (in conformance with the WTO SPS requirements), which creates the variation between registered products in the EU and those that can be utilized in trading partners.

There are also concerns about the uncertainties associated with the EU's procedures and timelines for the withdrawal of MRLs (after an active substance has been banned) and the consideration and approval of Import Tolerances. There could be gaps between the removal of an MRL and the approval of an Import Tolerance. An added complication is that the European Parliament has the right to veto European Commission proposals for MRLs and Import Tolerances, of which there is precedent (March 2019). The increasingly political nature of the European Parliament debates on crop protection products does not bode well.

The new policy for MRLs and Import Tolerances will be applied regardless of whether the company submits an application for the renewal of EU authorization of the active substance or does not seek such renewal in the EU.

Potential Substances at Near-Term Risk

Among the substances under immediate threat for corn are glyphosate, malathion, propiconazole and lambda-cyhalothrin, as well as glufosinate.

Glyphosate

Glyphosate is a critical substance for row crop production in the U.S., including corn production. Glyphosate is one of the most-tested pesticides anywhere in the world and continues to be regarded as one of the safest weed control options by science-based governments around the world. It is generally regarded as a less-toxic alternative to many pesticides previously used in corn and row crop production. As a non-selective herbicide it is a critical tool for helping farmers manage weeds, particularly in conservation tillage systems. Without the use of products like glyphosate, these methods and better farming practices would be difficult for farmers to adopt. In total, glyphosate represents the most commonly used substance for corn, barley and sorghum

production and is often the most highly used substance for other crops grown in the United States and around the world.

While glyphosate does not meet the EU's cut-off criteria, the renewal of the authorization of glyphosate in the EU after 2022 will be particularly challenging. It has become a highly political issue in the light of the controversial IARC report, the court cases in the U.S. and the horse-trading over the last EU renewal. NGOs have been relentless in their pressure and several European governments have adopted policies to phase out or ban the use of the substance in their territories.

Malathion

Another substance of concern is malathion, an insecticide often used in grain storage. As previously explained, the current commodity bulk system functions well because its ability to source grain from large geographic areas over the course of several months. Products like malathion may be used to protect stored grain, extending the ability for U.S. farmers and grain traders to transport high-quality grain to the export customer as needed.

This substance triggered the cut-off criteria due to environmental risk to birds, causing significant concerns over likely residue detections. Oftentimes, crop protection products applied post-harvest are at higher risk for residue detections due to the late stage of application. The same challenges also exist for lambda-cyhalothrin, a broad-spectrum insecticide, which also tends to show residues.

Propiconazole

Propiconazole is another widely-used fungicide that triggered cut-off criteria due to health concerns. Propiconazole is an important product used by corn farmers to control diseases that impact farmers each season. As mentioned previously, few options exist for corn farmers to protect their crop against diseases. Effective fungicides like propiconazole are essential for corn farmers when a disease shows up in their fields.

Glufosinate

Glufosinate is another important herbicide for U.S. row crop production. It is an essential tool for farmer management of weeds, especially as more farmers must deal with issues of herbicide resistance. Glufosinate-tolerant crops represent a significant portion of row crops grown each year and are often used in rotation with other tolerant crops to decrease the selection pressure in the most commonly-used herbicides.

The registrant of glufosinate has elected not to submit a reregistration request to the European Union for the product. This decision was made after indications that the request would likely be denied. The Commission's 2018 policy document states that MRLs for substances falling under the cut-off criteria the approval of which is not renewed will be deleted on the basis of Article 17 of Regulation (EC) No 396/2005. This legal basis allows for deletion of MRLs without seeking the opinion of EFSA. To date, the European Commission has not yet proposed the removal of glufosinate's MRL.

If the MRL is removed, and the EU does not grant any future application for an import tolerance, U.S. farmers may have a challenge meeting the level of determination thresholds for grain residues in all shipments. It is feasible that farmers could phase out their use of the product, and associated tolerant crops, though this process will take several years. But ceasing use of this product will only increase the pressure put on other herbicides, decreasing a farmer's ability to manage herbicide resistance and likely resulting in an increase of applied overall product.

V. Impacts

In terms of estimating impacts on restrictive policies of crop protection products, among the most comprehensive and definitive studies was the **Estimation of Potentially Affected Imports Due to EU Hazard-Based Regulation of Plant Protection Products by Bryant Christie Inc.,**[12] in 2017. The report broadly identified the universe of worldwide agricultural exports to the EU that could be affected by EU hazard-based cut-offs for crop protection active substances.

[12] Bryant Christie (2017); Estimation of Potentially Affected Agricultural Imports due to hazard-based criteria in the EU Regulation of Plant Protection Products (http://www.ecpa.eu/reports_infographics/bryant-christie-report-estimation-affected-imports-through-hazard-criteria)

It should be noted that the Commission's policy has changed since this study was published in 2017. At the time, the policy suggested that Import Tolerances would not be considered. Since 2018, we interpret the Commission's position to include the case-by-case consideration of Import Tolerances. However, we still believe that these Import Tolerances will be difficult to obtain, making the impacts even more challenging to estimate. That said, the Bryant Christie study does provide a relevant snapshot of the impacts of the EU's policies.

The analysis suggested that agricultural imports with a total value of €70 billion in 2016 might be adversely affected by a loss of MRLs resulting from hazard-based non-approval of 58 active substances. This represented over 60 percent of the estimated total value of all agricultural imports into the EU in 2016.

Fruits and nuts compromise over one quarter of the value of potentially affected commodities. Oilseed and groundnuts account for over 14 percent of the total value and animal feed ingredients, primarily consisting of soybean products, account for an additional 11 percent. Other commodity groups such as cocoa and coffee, tea, and spices are significant both in their possible exposure to the risk of MRL revocation and in their role as leading exports for less wealthy export countries.

The potential impact also varies across trading partners. Among the nine world regions examined in this report, the Central and South American region has the greatest exposure to potential trade impacts from hazard-based cut-off criteria under EC Regulation 1107/2009. This region shipped €23.9 billion of the potentially impacted EU imports in 2016 – over one third of the global total value of potentially affected commodities; and almost three quarters of all agricultural products exported to the EU from the region.

A separate study in early 2019 by **CASAFE/Globaltecnos**[13] detailed the potential impact of the EU's policy on the non-renewal of the authorization of active substances related to Argentina, specifically. Assuming that 33 active substances that have not been renewed or will not be renewed after their existing authorization expires and that the MRL for those substances will be

[13] CASAFE (Cámara de Sanidad Agropecuaria y Fertilizantes) 2019: Documento elaborado en base al listado apéndice de "Estimation of Potentially Affected Agricultural Imports Due to Hazard-Based Criteria in the EU Regulation of Plant Protection Products – by Bryant Christie Inc. Las moléculas allí listadas fueron filtradas con el estudio de mercado privado de Pampas Group para identificar las usadas en Argentina y luego Globaltecnos evaluó su impacto económico por cultivo a nivel país.

reduced to the level of determination, the negative impact on Argentinian agricultural exports to the EU could amount to $4.5 billion.

Sub-Saharan Africa, too, has significant exports that are at risk of disruption. The total value of potentially impacted commodities from this region is less than half that of Central and South America; however Sub-Saharan Africa has a similarly high proportion of its total agricultural exports that could be impacted (75 percent). Cocoa is the largest value commodity that could be affected, at €5.8 billion in 2016, and also represents almost 85 percent of the EU's cocoa imports.

North America and the Caribbean accounted for 13.5 percent of potentially affected imports into the EU in 2016, and 65 percent of the region's total agricultural exports to the EU could be impacted by hazard-based cut-offs. Two commodity groups – fruits and nuts, and oilseeds and groundnuts – represent the bulk of the region's €9.4 billion export value, at €3.4 billion each. The EU also imported over €1 billion of cereal grains, including 60 percent of total wheat imports.

Southeast Asia supplied the EU with €5.9 billion of commodities in 2016 that are potentially affected by hazard-based cut-off criteria under EC Regulation 1107/2009. Vegetable oils – primarily palm, but also coconut – comprise one third of this total value, and also represent one third of all EU imports of vegetable oils. Coffee exports accounted for fully 25 percent of total regional exports of potentially affected commodities.

European countries outside the EU and EFTA exported €7.5 billion of potentially affected commodities to the EU in 2016. This included €2.5 billion of fruits and nuts, almost one third of which was the value of tree nuts from Turkey. The region also supplied almost half of the EU's total imports of stone fruit (valued at €178 million); and one third of all cereal grain imports (€1.7 billion). Exports of crude sunflower seed oil from Ukraine totaled €989, accounting for 98 percent of EU imports of the commodity and 82 percent of the region's total vegetable oil exports.

East and South Asia supplied the EU with €4.3 billion of potentially affected commodities in 2016, approximately 8.4 percent of the total value. Coffee, tea, and spices were the largest commodity group, with a total export value of €1.2 billion, divided almost evenly among the three named commodities.

North Africa and the Middle East exports of potentially affected agricultural commodities in 2016

totaled €4.3 billion. Seventy five percent comprised exports of fruit and nuts (€1.7 billion) and vegetables (€1.5 billion). Morocco was the primary supplier of both categories, with total potentially affected exports of €1.7 billion.

Oceania's exports of potentially affected commodities totaled only €1.9 billion in 2016. The primary commodity group, oilseeds, was comprised predominantly of rapeseed exports from Australia. Similarly, the second largest commodity group, fruits and nuts, includes primarily strawberries, apples, and pears from New Zealand and nuts from Australia.

The Central Asian region has the smallest value of potentially impacted commodities at just €1.4 billion. Russia alone provides 75 percent of the region's exports to the EU within the relevant commodity groups. Half of all relevant exports are comprised of cereals and animal feed ingredients.

North American and the Caribbean

North America and the Caribbean supply the EU with €9.4 billion of commodities that are potentially affected by cut-off criteria under EC Regulation 1107/2009 – 13.5 percent of the global total. The graphs below present the 2016 value of EU imports of potentially impacted goods on a country-by- country basis and provide regional totals for major commodity groups. EU imports from the region are dominated by oilseeds, soy products, cereals, fruits, nuts, and legumes.

The United States is the EU's second largest foreign supplier of the commodities potentially effected by regulation 1107/2009. In 2016, the EU imported €6.3 billion of the relevant commodities from the U.S. Among the potentially affected commodities, the top U.S. exports to the EU were tree nuts/almonds (€2.4 billion), soybeans (€2 billion), and wheat (€208 million).

In 2016, the North America and Caribbean region produced 33.6 percent of Europe's supply of imported oilseeds and groundnuts. The region provided €2.4 billion worth of soybeans – 45 percent of the total imported into the EU globally. €2 billion worth of soybeans were imported from the U.S. The remaining €436 million in soybeans were imported from Canada. The region supplies the EU with many oilseeds/groundnuts beyond soybeans. The United States is a leading supplier of sunflower seeds (22.8 percent of global total), while Canada is a significant supplier of rapeseed (19.6 percent of global total).

The North America and Caribbean region is also a major exporter to the EU of cereals, fruits, nuts and legumes, all of which could be impacted by EC Regulation 1107/2009. The EU sources about 60 percent of its wheat imports, valued at €1.25 billion, from North America. Canada alone ships 38 percent (€484 million) of the EU's total wheat imports.

A complimentary study—**The Challenges Facing Agriculture and the Plant Science Industry in the EU**[14] noted that the political environment in the EU and related regulatory and policy decisions have led to reduced access to modern agricultural tools, such as plant biotechnology and crop protection products, contributing to stagnating agricultural productivity and economic development.

The cost of innovation has significantly increased over the past decade, while the number of crop protection products has decreased, and GM technology is largely not available in the EU. This is driven by an EU regulatory system which is increasingly based on perceived hazard rather than risk and does not provide the predictability that businesses (both farmers and agrichemical companies) require to operate and innovate effectively.

Further diversion of regulatory standards between the EU and its key trading partners could have a significant adverse impact on trade. Given the EU is reliant on agricultural imports, any regulatory obstacles could have negative implications for EU consumers and farmers.

The EU is dependent on imports, especially for feed. While the EU has a positive trade balance for meat, this would not be possible without imported protein-rich feed, as shown by EU Commission statistics. Moreover, the EU has a trade deficit for several crops and relies on imports from other continents for food.

The hazard-based setting of Import Tolerances in the EU is regarded by many as non-compliant with WTO rules and is expected to create trade distortions as well as problems with production processes in countries exporting to the EU. This threatens the trade in arable produce that is required to be imported into the EU to meet food demand.

[14] AgbioInvester (2018): The Challenges Facing Agriculture and the Plant Science Industry in the EU

Impacts of Plant Science Registration Procedures on Trade

It is in the fruit and vegetables sector where the impact of the agrochemical registration procedure in the EU has a significant negative effect. Fruit and vegetables are a very diverse market with a high economic value, incorporating many different types of produce; as a result, the range of agrochemical products on individual crops is relatively limited. A significant number of products previously utilized in these sectors lost their registrations or were not supported in the EU re-registration process.

Since September 2015, minor uses, including crop protection use in specialty crops such as fruit and vegetables, is coordinated by the EU Minor Uses Co-ordination facility (MUCF) with crop requirements compiled into the European Minor Uses Database. As formulated products are registered on a country and crop level, minor uses are also granted on a country and crop basis to meet the needs of the minor and specialty crop producers; often minor use registrations are achieved by extending the registrations to include minor uses.

The EU re-registration process not only impacts EU growers but also growers importing their produce into the EU. One of the prerequisites to authorize a crop protection product in the EU is that potential residues in food and feed resulting from the intended use of the formulated product are covered by MRLs. When an authorization in the EU is not renewed, the MRL is lowered to the Limit of Quantification (LOQ). In principle, no residue of the unregistered product is allowed on crops produced in or imported into the EU. This effectively prohibits their use on crops in other world areas to be imported into the EU from trade partner countries.

There is however a system where interested parties, such as trading countries can apply for a modification of the EU-MRL, the so-called Import Tolerance, which is an MRL necessary to facilitate international trade. Once the Import Tolerance is granted, it allows usage of crop protection products not registered in the EU on crops to be sold into the region. However, trade disruptions for substances for which the MRL was lowered to the LOQ can be expected as procedures and timelines for establishing Import Tolerance are currently unclear and purchasing groups are reticent to purchase such produce. As a result, when a substance is not supported in the EU it has an effect on its global usage on all produce that is to be exported to the EU.

Much of this conflict arises from the EU regulatory system for crop protection products being regulated by hazard and the precautionary principle (Regulation EC 1107/2009) and the Residue regulation (Regulation EC 396/2005) following a risk-based approach. Additionally, most third countries have a risk-based regulatory system for authorizing crop protection products, which creates the variation between registered products in the EU and those that can be utilized in trading partners. The WTO Agreement on SPS Measures requires the assessment of risk to determine the appropriate level of sanitary or phytosanitary protection.

As the EU is becoming increasingly reliant on the import of animal feedstuffs, fruit and vegetable and coffee/tea/spices, the uncertainty created by the EU regulatory system is seen as restrictive to trade. However, the resulting possible loss of pesticide MRLs has the potential to adversely affect agricultural imports valued at almost €70 billion.

The Bryant Christie study shows that among the most affected commodities are fruits and nuts, but also vegetables. The EU relies heavily on imports of fruit and vegetables to satisfy local demand. It remains to be seen how this will develop. However, it is obvious that additional trade barriers are created for agricultural commodities which cannot be produced at the required amount in Europe and will have to be imported.