



## **UNDERSTANDING, MONITORING AND MEETING THE DIFFERING GLOBAL **MAXIMUM RESIDUE LIMITS (MRLS)** FOR PESTICIDES IN FOOD AND FEED PRODUCTS**

**AN INVESTIGATION INTO WHAT IS REQUIRED BY ORGANISATIONS SOURCING OR SELLING FOOD AND FEED PRODUCTS WITHIN THE EU, US, CHINA AND JAPAN MARKETS TO DEMONSTRATE COMPLIANCE AGAINST INTERNATIONAL PESTICIDE REGULATIONS**

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# ABSTRACT

The purpose of this white paper is to provide an overview on current thinking within the food industry for how best to manage pesticide residue risk in food products and supply chains. The aim is to promote an understanding of the origins of pesticide residues, and current industry challenges due to increasing regulations for the management and compliance of products destined for the EU, US, China and Japan. This paper is aimed equally at those organisations with established pesticide residues risk control and management plans as well as those considering development and implementation of risk protocols.

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# I. EXECUTIVE SUMMARY

The need to protect crops from pests and damage dates back millennia. In recent decades, pesticides have emerged as the most effective method of control. With pesticides use comes a need to manage their wider effects.

One key area of importance is ensuring that safe maximum residue levels (MRLs) are agreed on and monitored globally for food and feed products.

Governments setting MRLs have some way to go before any harmonised approach is implemented worldwide. Therefore it is imperative companies involved in food and feed goods are proactive and vigilant in understanding and meeting MRLs requirements in their chosen markets.



## II. PESTICIDE RESIDUES: A BRIEF HISTORY

Agriculture dates back almost 10,000 years to the Fertile Crescent of Mesopotamia. For as long as farming has existed, pests and disease have caused crop losses and famine. Insecticides were first recorded 4,500 years ago, when sulphur was used by the Sumerians to control insects and mites. Mercury, arsenic, tar, copper sulphate, lime, and smoking with fumes have all been tried as a solution to protect valuable crops. Up to as recently as the 1940s, sodium chlorate and sulphuric acid were still being employed as pest control.

It was not until the boom in synthetic pesticides late in the 1940s that products such as DDT, BHC, aldrin, dieldrin, endrin, chlordane, parathion, captan, and 2,4-D were developed and widely applied. These new products were inexpensive, effective and highly lauded: the discovery of DDT's

insecticidal properties won Dr Paul Muller the Nobel Prize in Medicine in 1949. Through the 1950s, cheap and available food continued an unabated rise in the need for and use of pesticides. Compared to arsenic and sulphuric acid in the 1940s, the new pesticides suddenly seemed much safer. All that changed in 1962 with the book 'Silent Spring' by Rachel Carson. It laid out the problems of indiscriminate pesticides use and the dangers to the environment, which prompted a shift in public perception and a rethink by governments on how to control pesticide use worldwide.

Pesticides research continued into the 1970s and 1980s, which led to many new products being invented including the world's greatest selling herbicide 'glyphosate', third-generation insecticides and new spray treatments.

The end of the 20th and beginning of the 21st century heralded development of entirely new families of agrochemicals. Advances in chemistry made these new pesticides safer, more selective and far friendlier to the environment, with usage rates only requiring grams rather than kilograms per hectare to be effective.

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**PESTICIDES IS AN ESTIMATED \$35 BILLION INDUSTRY ACCOUNTING FOR MORE THAN 2.5 MILLION TONNES OF CHEMICALS DEPOSITED INTO THE ENVIRONMENT ANNUALLY.**

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## WHAT IS A PESTICIDE?

The Food and Agriculture Organisation of the United Nations (FAO) Code of Conduct definition of a pesticide is as follows:

'Pesticide means any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.'

Some pesticide active ingredients upon application to the plant and environment can or purposely break down in a reaction generally with the insect or mite and produce chemicals commonly classified as metabolites. When developing MRLs the active pesticide and the metabolites are evaluated in establishing limits and sometimes limits are based on a sum of both active ingredient and metabolite.

Various types of pesticides exist for instance insecticides, acaricides, herbicides, fungicides, plant growth regulators, rodenticides, and biocides, which can be separated into two major groups:

### Chemical

- Organophosphate pesticides mostly insecticides which affect the nervous system by disrupting the enzyme that regulates acetylcholine, a neurotransmitter
- Carbamate pesticides work as above with the enzyme effects usually reversible; there are several subgroups within the carbamates
- Organochlorine insecticides were prevalent but many have now been removed from the market due to concerns (e.g. DDT and chlordane)
- Pyrethroid pesticides are a synthetic version of the naturally occurring pesticide pyrethrin, which is found in chrysanthemums, but modified to increase their stability in the environment

### Biological

- Microbial pesticides have a microorganism (e.g. bacterium, fungus, virus or protozoan) which acts as an active ingredient specifically targeting a certain group
- Plant incorporated protectants (PIPs) are pesticidal substances that plants produce from genetic material that have been added to the plant
- Biochemical pesticides are naturally occurring substances that control pests by non-toxic mechanisms (different to conventional pesticides which are often synthetic materials that directly kill or inactivate the pest)

# III. OVERVIEW OF PESTICIDES REGULATION

In this section, pesticides regulation for the EU, US, China and Japan are outlined.

## EU REGULATION

In the EU, legislation aimed at harmonising the registration of plant protection products – pesticides used to protect plant/crops from pests and diseases or control unwanted plants – falls under Regulation (EC) No 1107/2009 which entered into force on 14 June 2011 (replacing Council Directive 91/414/EEC). The new regulation includes two major developments from the older directive: the mutual recognition for pesticide registrations and cut-off criteria for risk assessments.

Mutual recognition for pesticide registrations

A new zonal registration approach has been introduced which should improve mutual recognition for pesticide registrations within the EU. The European and Mediterranean Plant Protection Organisation (EPPO) established three separate regions (i.e. 'Northern' Zone A, 'Central' Zone B, 'Southern' Zone) which are based on political boundaries instead of climatic zones. For registrations within

these zones a single Zonal Rapporteur Member State (Z-RMS) evaluates a given pesticide registration that can then be accepted or rejected by all other member states within that zone on the basis of the Z-RMS findings.

## REGULATORY UPDATE / EUROPEAN UNION

### EU 1107/2009 REGULATORY ZONES

#### ZONE A - NORTHERN ZONE

Denmark, Estonia, Latvia, Lithuania, Finland, Sweden

#### ZONE B - CENTRAL ZONE

Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom

#### ZONE C - SOUTHERN ZONE

Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal



#### The Zonal Approach

The European and Mediterranean Plant Protection Organisation (EPPO) has established three separate regions (i.e. 'Northern' Zone A, 'Central' Zone B, 'Southern' Zone) based on political boundaries instead of climatic zones, in order to improve mutual recognition for pesticide registrations within the EU.

Cut-off criteria for risk assessments

ANNEX II Chapter 3.7 of the directive introduces hazard-based cut-off criteria which states that if a compound (active, safener or synergist) is classified under one of the groups in Table 1, then no risk based evaluations will be conducted irrespective of exposure, risk or whether safe uses can be identified.

**TABLE 1. CRITERIA FOR APPROVAL OF ACTIVE SUBSTANCES\***

HUMAN HEALTH	ENVIRONMENTAL
Carcinogen CIA and CIB Mutagen MIA and MIB Toxic for Reproduction RIA and RIB Endocrine disruptor	PBT (Persistent, Bioaccumulative and Toxic) POP (Persistent Organic Pollutant) vPvB (very Persistent, very Bioaccumulative) Endocrine disruptor

*\*It is important to note that some questions remain over the interpretation of some of the criteria and the cut-off criteria will only take effect on renewal of each active substance (most taking place between 2016 and 2019).*

It should be noted that there are still questions over classification criteria interpretation and that the cut-off criteria will only come into effect at the time of renewal of active substances (i.e. for most between 2016-2019 as existing active substances already reviewed under Council Directive 91/414/EEC were granted automatic approval under Regulation (EC) No 1107/2009).

Maximum residue levels (MRLs)  
 Regulation (EC) No 396/2005 sets out the MRLs for pesticides, which are permitted in plant or animal origin products intended for human or animal consumption. MRLs are established at the legal upper level deemed to have the lowest impact on consumer exposure – quantified by a comprehensive risk assessment of the active substance intake at predetermined intake levels.

The regulation aims to harmonise EU MRLs for all foodstuffs and is the responsibility of the European Food Safety Authority (EFSA) Pesticides Unit. Ongoing is the collaboration of member states with the EFSA Pesticides Unit on the scientific review of existing

MRLs, their data compliance and safety in today's consumer landscape.

Annual report on pesticide residues  
 Member states must report to the European Commission, other member states and EFSA to comply with official EU monitoring controls on pesticide residues. This comprises 28 EU member states and 2 EFTA countries, Iceland and Norway, and includes the analysis of MRLs for 800 pesticides in over 60,000 food samples each year. In total, nearly 15 million determinations of pesticides are made annually, aiding the assessment of exposure risk to EU consumers from pesticide residues in foodstuffs.

**EU DATABASE OF APPROVED PESTICIDES**

Active substances approved by the EU are available to view via the website of the European Commission. Each substance can be searched for according to defined criteria and included is a reference to the relevant EU legislation with all toxicological information and MRLs in food and feed, exportable to Excel. The database can be found here [http://ec.europa.eu/sanco\\_pesticides/public/index.cfm](http://ec.europa.eu/sanco_pesticides/public/index.cfm)

## US REGULATION

In the US, prior to the sale or distribution of any pesticide the US Environmental Protection Agency (EPA) reviews and determines whether the pesticide presents an unreasonable risk to human health or the environment. On completion of EPA review, the pesticide is licensed or registered for use in strict accordance with its label directions.

Limits are established prior to use on foodstuffs for pesticides, including how much is incorporated into the growing and processing phases and the level remaining once the foodstuffs are sold to the consumer – governed by the Food Quality Protection Act of 1996. These levels are monitored via government inspectors who are also responsible for the enforcement of strict standards to protect workers from pesticide exposure risk.

The relevant sections of the Federal Food, Drug and Cosmetic Act (FFDCA) concerning food and feed containing pesticide residues are the sections 402, 408 and 409, expanded on below.

### Tolerances for pesticides

Tolerances for the maximum amount of a pesticide residue legally allowed to be present in or on a raw agricultural commodity are set out in Section 408. EPA is authorised to establish these tolerances or exempt a pesticide residue in a raw agricultural commodity from the requirement of a tolerance, as part of the registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for the use of a pesticide in food and feed production in the US.

However, registration is not a prerequisite for establishing a tolerance. In the case of experimental use of a non-registered pesticide, EPA may establish a temporary tolerance under section 408(j) or EPA may establish a tolerance for a pesticide residue

resulting from pesticide use in food or feed production in a foreign country.

### Food additive regulations for pesticides

Section 402(a)(2)(C) of the FFDCA concerns tolerances or tolerance exemptions for pesticide residues in the processed form of the commodity when ready to eat. If a pesticide concentrates during application and exceeds the tolerance level set for the raw agricultural commodity by the time it reaches the processed food or feed stage, then a food additive regulation is required. The maximum level is established under a food additive regulation under section 409 of the FFDCA, authorised by EPA.

### Enforcement of tolerances and food additive regulations for pesticides

Section 402(a)(2)(B) of the FFDCA grants the FDA responsibility for the enforcement of pesticide tolerances and food additive regulations established by EPA. Specifically, section 402 deems a raw agricultural commodity or a processed food or feed adulterated and subject to FDA enforcement action when:

- a) Pesticide residue is at a level greater than that specified by a tolerance or food additive regulation
- b) Pesticide residue has no tolerance, tolerance exemption, or food additive regulation

The exceptions to b) above under section 402 include 'action levels' for unavoidable pesticide residues (i.e. contamination by a pesticide that persists in the environment), and EPA emergency exemptions, should pesticides in the same chemical class combine to be above the lowest numerical tolerance of one of the pesticides being used.

### Imports

Domestic and imported food and feed found to contain pesticide residues must meet the same requirements of section 402 of the FFDCA. Imported food or feed must be in conformity with tolerances, tolerance exemptions, or food additive regulations established by EPA. In the case of an unavoidable pesticide residue, then action levels established by FDA apply.

### Maximum residue limits (MRLs)

EPA sets limits on the allowable amount of a pesticide residue for food and feed products, or commodities. Known as tolerances, pesticide residue limits can be found via the standardised name of agricultural food and feed products and commodities on the Electronic Code of Federal Regulations (eCFR). The preferred commodity term is the only term under which tolerances are listed in the eCFR. In addition, the International Maximum Residue Limit Database (IMRLD) contains MRLs for US specialty crops. The IMRLD is maintained by the Foreign Agricultural Service, Horticultural and Tropical Products Division of the US Department of Agriculture, and can be searched by crop or pesticide, in the US or 70 other countries.

## CHINA REGULATION

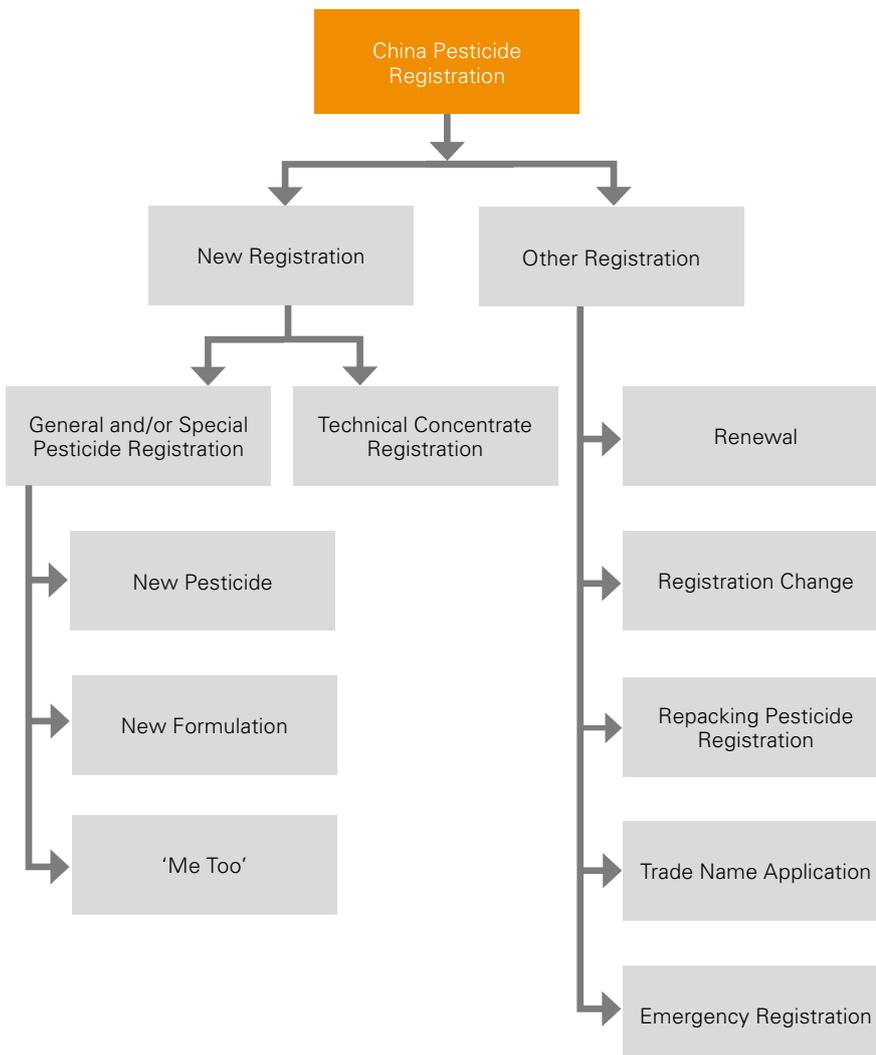
Established in 1963, the Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA) – affiliated to the Chinese Ministry of Agriculture (MOA) – is responsible for the pesticide registration, administration, quality control, bioassay and residue monitoring of pesticides, supervision of pesticide markets, information-sharing, international cooperation and other services. In 1978, the State Council reorganised the ICAMA, and on 20 April 1982, the MOA, Ministry of Forests (former), Ministry of Chemical

Industry (former), Ministry of Commerce (MOFCOM), and the environmental protection panel under the State Council issued two joint regulations: ‘Provision on Pesticide Registration’ and ‘Data Requirement on Pesticide Registration’. On 8 May 1997, the State Council issued the ‘Regulation on Pesticide Administration’ (also called ‘Regulation on the Control of Agrochemicals’), giving China its first comprehensive legislative and regulatory framework for the management of pesticides.

The ‘Regulation on Pesticide Administration’ is the latest regulation to come into force in China, including key updates which:

- Detail security and validity requirements
- Set out the duration of administrative review
- Require manufacturers to establish systems to record raw material import
- Require manufacturers to establish systems to record sale of pesticide products
- Establish strict quality controls for pesticide production
- Identify criteria for pesticide packaging and labeling
- Specify conditions and recording requirements for pesticide repacking, the foundry and addition of substances
- Require multiple organisations (e.g. agriculture technical services, pesticide manufacturers and distributors, and others) to provide technical assistance, and training for pesticide users

## TYPES OF PESTICIDE REGISTRATION IN CHINA (2011)



### Pesticide registration and distribution

Pesticide registration application is no longer restricted to pesticide companies. Any corporate enterprise may make an application for the registration of a new pesticide. However, temporary registration is not allowed under the new regulation. A new pesticide business license is now required and the new regulation establishes a mechanism for product traceability and pesticide recall.

Pesticide registration begins with determination of registration type as shown opposite and described on the following page.

## REGISTERING A PESTICIDE IN CHINA

Those wishing to register a pesticide must collect and determine the applicability of existing data and reports.

On completion the findings must then be compared against the 'Data Requirements of Pesticide Registration' and any data gaps identified and noted.

This process applies to the following pesticide product types:

- General chemical pesticide
- Public health pesticide
- Rodenticide
- Biochemical pesticide
- Microbial pesticide
- Botanical pesticide
- GMOs
- Natural enemies

Any field and residue studies must be undertaken in China and the laboratories used for analysis authorised by ICAMA. Final test reports need to include a full Chinese translation and be checked for validity before final dossier preparation, as some testing laboratories do not meet the acceptance criteria of the MOA.

When the dossier is finalised it should be submitted to ICAMA, containing the items listed below:

- Business license
- Illustration manual

- IP declaration
- MSDS
- Pesticide label
- Product chemical data
- Product summarisation
- Production process
- Registration application form
- Study reports, reports summarisation

### Maximum residue levels (MRLs)

Effective on 1 August 2014 the national food safety standard No 4/2014 establishes the MRLs for pesticides in food (GB 2763-2014 repealing GB 2763-2012). In total, 371 pesticide items and 3650 MRLs are defined, based on pesticide toxicity evaluation (i.e. acceptable daily intake: ADI), dietary structure (i.e. pesticide residues intake level), and actual residues on crops in farm produce (i.e. the monitoring data received on the field residues). MRLs are expanded to apply to 284 food groups which cover nearly all products (e.g. vegetables, fungi, fruits). The new standard is closely aligned with Codex Alimentarius Commission (CAC) standards, and at least 1811 MRLs in GB 2763-2014 are equal to or stricter than CAC standards.



## JAPAN REGULATION

The introduction of a positive list system by the Ministry of Health, Labour and Welfare (MHLW) came into force on 29 May 2006. The positive list system prohibits the distribution of foods that contain agricultural chemicals above set levels when MRLs have not been established.

Agricultural chemicals in scope include:

- Pesticides
- Feed additives
- Veterinary drugs

### Uniform limits

Prior to any agricultural chemical being authorised, uniform limits are established via discussions based on toxicity and other necessary matters. Restrictions are set for target crops and use amounts.

As a base toxicological threshold the MHLW use 1.5 µg/day to determine the uniform limit. This threshold is an acceptable exposure limit, in line with evaluations of flavouring agents by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and evaluations of indirect additives by the FDA; and the ADIs of chemicals previously evaluated by the Joint FAO/WHO Expert Meeting on Pesticide Residues (JMPR) or JECFA or in Japan.

As such, the uniform limit has been set at 0.01 ppm so that the estimated intake of agricultural chemicals to which the limit would be applied does not exceed 1.5 µg/day. This is calculated on consumption levels of the Japanese population. The MHLW accepts the limit as reasonable as this mirrors the EU levels of 2005.

### Non-detected limits

For chemicals with extremely low ADIs (as established by JMPR or JECFA), MRLs are based around non-detected levels (NDs) in place of uniform limits.

For those chemicals categorised in either of the following two types, NDs have been set instead of numerical limits:

- Genotoxic carcinogens
- Chemicals determined by JMPR or JECFA for which no ADI can be established

Separately from numerical limits, requirements/restrictions have been imposed on certain types of substances, including:

- Antibiotics
- Antibacterials
- Naturally occurring substances in foods

- Chemicals where standards are already set for food additive uses
- Applications of MRLs to processed foods

### Exempted substances

Exempted substances are those used during the production of crops and aquatic products, and substances which are produced by chemical changes of these agricultural chemicals in food, including:

- Pesticides
- Veterinary drugs
- Feed additives

Exempted substances are selected based on the agricultural chemicals themselves and whether their decomposition products could remain in food as a result of application in food production.

### Provisional MRLs

For chemicals without MRLs there are provisional MRLs in place to protect public health. The provisional MRLs are based on CAC standards and related information.

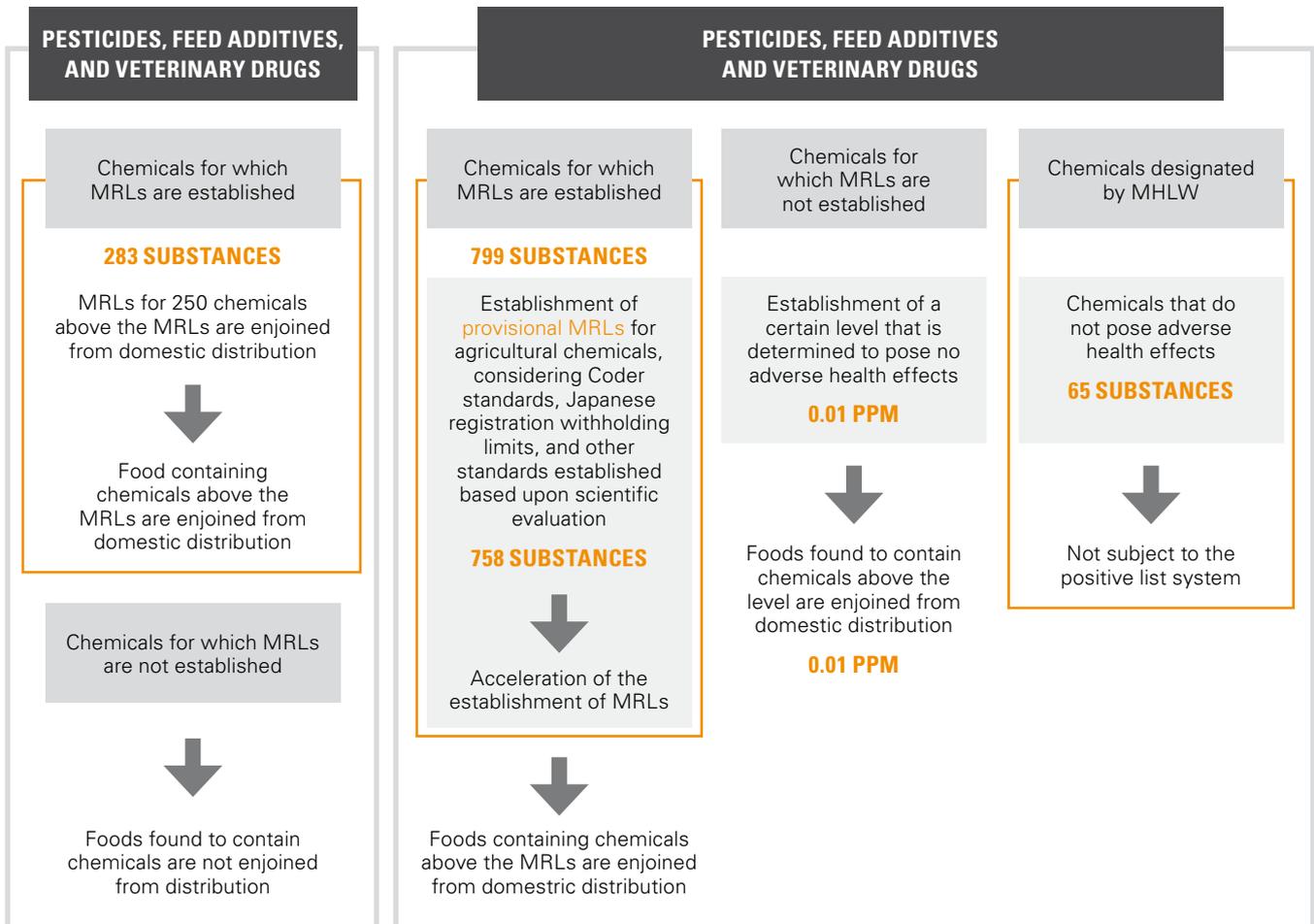




**OUTLINE OF POSITIVE LIST SYSTEM FOR AGRICULTURAL CHEMICAL RESIDUES**

Current Regulation

Enforcement of Positive List System - 29 May 2006



# IV. INDUSTRY CHALLENGES

## DIFFERING REGULATIONS

The biggest challenge to any manufacturer selling raw agricultural product or processed food around the globe is meeting the challenge of differing regulations concerning the MRLs within each region. International guidance on MRLs for specific food items or groups of food are set by the Codex Committee on Pesticide Residues (CCPR) based on scientific advice from the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). Codex member countries can then participate in CCPR and Codex Alimentarius Commission (CAC) sessions and adopt, if all in agreement, the proposed MRLs. The CAC has set over 2,400 MRLs to date.

However, from the preceding section it should already be clear that the MRLs from Codex are only 'recommended MRLs' as nations in most instances choose to exercise their sovereign right to set their own legally binding MRLs or tolerances. Countries establish different MRLs for the hundreds of pesticides in use and also for the hundreds of food products that may or may not end up contaminated by each specific pesticide. The resulting MRLs list ends up as literally thousands of MRLs for each individual country, which manufacturers have to consider whenever selling products into a specific region.

Presented in the global MRLs comparison table in section IV is a selection of the thousands of MRLs across the regions outlined in this white paper.

## OFFICIAL CONTROLS

In the EU, a key tool for enabling cross-border information on risks in the food chain is the Rapid Alert System for Food and Feed (RASFF). Since 1979, RASFF has provided a 365-day-a-year, round-the-clock portal for the collection and dissemination of urgent safety notifications between its members (EU-28 national food safety authorities, Commission, EFSA, ESA, Norway, Liechtenstein, Iceland and Switzerland).

In a single year, RASFF transmits around 3,000 original notifications (which in turn generate over 5,000 follow-up notifications). Anywhere in the region of 10%-15% of the original notifications can relate to alerts on exceeded MRLs. It should be noted that while the notifications from RASFF concern products entering or within the EU, the alerts directly linked to products exceeding MRLs of EU origin are normally less than 2% of the total number of original notifications.

In the US, the FDA samples approximately 7,000-8,000 domestic and imported food products each year, with tolerances found to be exceeded on average in less than 2% of the former and up to 4% of the latter. As has been noted previously, the Environment Protection Agency (EPA) is responsible for registering and establishing pesticides usages and tolerances for food crops. The Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA) monitors pesticides in meat, poultry and certain egg products; while the US Food and Drug Administration (FDA) ensures tolerances are met across domestic and imported food products. In addition, USDA's Agricultural Marketing Service (AMS) has carried out a Pesticide Data Program (PDP) since 1991 which samples and analyses pesticide residues under contract with certain US states.

## ORGANIC PRODUCTS

Under EU and US legislation organic production entails significant restrictions on the use of pesticides. It emphasises the use of natural resources over artificial inputs and is supported by strict regulations.

The majority of pest control materials permitted in organic agriculture are naturally derived from a plant (e.g. pyrethrum), microorganism (e.g. bacillus thuringiensis), or other natural sources. Organic standards prohibit the use of most synthetic substances – including most pesticides used in conventional

agriculture – for at least three years prior to the harvest of an organic crop. Per the USDA National Organic Program (NOP) and the European Commission Regulation (EC) No 889/2008 on production and labelling of organic products some synthetic pest control materials allowed in organic crop production include elemental sulfur, insecticidal soap, horticultural oils, and copper hydroxide.

Although many pesticides are prohibited in organic production, there can be inadvertent indirect contact from neighbouring conventional farms or shared handling facilities. To recognise that inadvertent or unavoidable contact with prohibited substances may occur, the USDA organic regulations allow residues of prohibited pesticides – up to five percent of the EPA tolerance level – if those residues are present due to unavoidable or inadvertent contact.

In the EU, organic regulation of MRLs for organic food commodities are identical to those for non-organic foods. If an organic producer used a prohibited pesticide or didn't take adequate steps to avoid contamination from it, any level of pesticide residues would be a violation of the organic standards. The practical challenge is to distinguish between pesticide findings resulting from unpredictable, unavoidable circumstances and application of non-permitted substances or technically avoidable contamination. The EU regulates both organic food and drink produced and/or processed within the EU and organic goods from elsewhere (Commission Regulation (EC) No. 1235/2008). These can readily be imported from non-EU countries whose rules on organic production and control are equivalent to the EU's (currently Argentina, Australia, Canada, Costa Rica, India, Israel, Japan, New Zealand, Tunisia, Switzerland and the US). For all other non-EU countries, importers can have their organic products certified for import into the EU by independent private control bodies approved by the European Commission.



## CASE STUDY

### **0.1PPM IN THE EU, 10PPM IN THE US – DIPHENYLAMINE (DPA) ON APPLES HIGHLIGHT THE GLOBAL BARRIER TO TRADE FROM NON-HARMONISED MRLs**

The way MRLs operate in different markets can create a serious barrier to global trade. For instance, the setting of MRLs at 0.1ppm by the European Union (EU) on diphenylamine (DPA) but the ongoing use of the chemical at 10ppm by US growers to keep apples fresh while in the storage has effectively 'banned' US apple exports into the EU.

Since 1962, DPA has been registered for use in the US so that growers can prevent 'storage scald' while apples are being stored. This ensures the produce is fresh and unblemished when it eventually goes on sale. The safety of DPA was re-evaluated by the EPA in 1997 and deemed to meet a 'reasonable certainty of no harm'. Yet the setting of MRLs in the EU for DPA at 0.1ppm is a direct response by European food authorities to the potential risk of DPA producing carcinogenic nitrosamines when interacting with other chemicals used for storage purposes. While the findings showed no established scientific risk for DPA, it was rather that data during the re-registration process failed to adequately meet EU standards. This illustrates the ongoing debate of the use of the Precautionary Principle in the EU and its effect on global trade – where the burden of proof for safety rests with the manufacturer of DPA not the European Commission.

What this means for growers and manufacturers of apple goods is that for any products of EU origin there is an outright ban on DPA, while for products such as US exports DPA must meet the 0.1ppm MRL. However, with most US apples being found to have DPA concentrations at an average of 0.4ppm and DPA present on 80% of US apples (based on the most recent research) the EU ruling blocks US export trade worth around \$1.5 million a year. It may also have consequences for any manufacturers of products which source US apples in the supply chain as a raw ingredient before a final processed product is successfully entered onto the EU market.



# IV. MRLs GLOBAL COMPARISON EXAMPLES

## COMMON PESTICIDES AND GLOBAL MRLs

PESTICIDE/ PRODUCT	CODEX	CHINA	EU	JAPAN	US
<b>ACETAMIPRID</b>					
Coconut	0.06	2	0.06	0.1	0.01
Wintergreen, Fresh Leaves	–	–	3	5	0.01
<b>ALDICARB</b>					
Potato	–	0.1	0.02	–	1
<b>AZOXYSTROBIN</b>					
Papaya	0.3	–	0.3	2	2
Watercress	–	–	0.05	70	3
<b>CAPTAN</b>					
Apple	15	15	3	5	25
Grape	25	5	0.02	5	25
<b>CARBARYL</b>					
Cucumber	–	1	0.01	3	3
Tangelo	15	–	0.01	7	10
<b>CARBENDAZIM AND BENOMYL</b>					
Orange	1	0.2	0.5	–	–
<b>CHLOROTHALONIL</b>					
Celery	20	–	20	10	15
Watermelon	–	5	1	5	–
<b>DIAZINON</b>					
Pineapple	0.1	0.1	0.3	0.1	0.5
Spinach	0.5	0.5	0.01	0.1	0.7
<b>DICHLORVOS</b>					
Mushroom	–	–	0.01	0.1	0.5
<b>DICOFOL</b>					
Eggplant	–	–	0.02	3	2*
Spearmint, Fresh	–	–	0.02	3	25*
<b>DIQUAT</b>					
Dill Seed	–	–	0.1	0.2	0.05
Okra	0.05	–	0.05	0.05	0.05
<b>DIURON</b>					
Asparagus	–	–	0.01	0.05	7
Peach	–	–	0.01	0.05	0.1
<b>ENDOSULFAN</b>					
Tea, Leaves	10	10*	30	30	24*
<b>GLYPHOSATE</b>					
Allspice	–	–	0.1	2	7
Basil, Fresh	–	–	0.1	0.2	0.2
Cantaloupe	–	0.01	0.1	0.5	–

<b>PESTICIDE/ PRODUCT</b>	<b>CODEX</b>	<b>CHINA</b>	<b>EU</b>	<b>JAPAN</b>	<b>US</b>
<b>IPRODIONE</b>					
Blackberry	30	–	10	12	25
Grape	10	10	10	25	60
<b>MALATHION</b>					
Corn, Sweet	0.02	0.5	0.02	2	2
Orange, Sweet	7	4	0.02	4	8
<b>MAELIC HYDRAZIDE</b>					
Garlic Bulb	15	–	15	50	15
Onion Bulb	15	–	15	20	15
<b>METHAMIDOPHOS</b>					
Bean, Kidney	1	0.05	0.01	0.3	1
Cauliflower	–	0.05	0.01	1	0.5
<b>METOLACHLOR</b>					
Soybean	–	0.5	0.5	0.2**	0.2
Tomato	–	–	0.5	0.1	0.1
<b>METRIBUZIN</b>					
Carrot	–	–	0.1	0.5	0.3
Soybean	–	0.05	0.1	0.1**	0.3
<b>PARAQUAT</b>					
Banana	0.01	0.02	0.02	0.05	0.05
Kale	0.07	0.05	0.02	0.05	0.05
<b>PERMETHRIN</b>					
Brussels Sprouts	1	0.05	0.05	5	1
Cherry, Tart	2	0.01	0.05	5	4
<b>PROPICONAZOLE</b>					
Kumquat	–	–	0.05	0.05	8
Pineapple	0.02	–	0.05	0.1	4.5
<b>THIABENDAZOLE</b>					
Lemon	7	10	5	10	10
Pear	3	–	5	3	5
<b>THIRAM+</b>					
Apple	5	5	5	5	7
Peach	7	–	3	7	7
<b>TRIFLURALIN</b>					
Cassava Root	–	–	0.01	0.05	0.05
Soybean	–	0.05	0.01	0.2**	0.05
<b>ZIRAM+</b>					
Nectarine	7	–	0.1	7	7
Tomato	2	–	0.1	5	7

\*time-limited

\*\*Dried

+Dithiocarbamates

# VI. VERIFICATION OF COMPLIANCE

## EU GUIDANCE ON METHODS AND PROCEDURES

For any manufacturer seeking verification of compliance to MRLs in the EU all laboratories involved in official control of pesticide residues in food and feed have clear guidance on methods and procedures from the Directorate-General for Health and Consumers (often abbreviated to SANCO). Method validation and analytical quality control (AQC) requirements for determining compliance with MRLs, enforcement actions, or assessment of consumer exposure to pesticides are clearly laid out for laboratories to follow in the documents SANCO/10684/2009 and Commission Decision 2002/657/EC, in tandem with the need for laboratories to be accredited to the ISO/IEC 17025 standard.

## US GUIDANCE ON METHODS AND PROCEDURES

The FDA publishes the Pesticide Analytical Manual (PAM) as a repository of the analytical methods used in

FDA laboratories to examine food for pesticide residues for regulatory purposes. PAM is split into two volumes: Volume 1 sets out the multi-residue methods (MRMs) that are used by FDA on a routine basis, due to their efficiency and broad applicability in analysing foods of unknown pesticide treatment history; and Volume 2 contains analysis methods of commodities for residues (most often used when the likely residue is known or cannot be determined by common MRMs) of only a single compound.

The EPA publishes the residue analytical methods (RAM) index, which lists most of the methods used (or extensively reviewed for use) by the EPA to monitor and regulate pesticide residue tolerances in food, feed, and animal commodities. For the methods, the RAM index also clarifies certain areas where improvements have been made to the method's performance or where more explanation is needed to remove ambiguity (in each case, an addendum is added to the method to explain the necessary clarifications).

## OTHER INTERNATIONAL GUIDANCE AND GUIDELINES

Other guidance on international and national guidelines for the requirements of analytical methods and validation protocols can be found in:

- Codex: CAC/GL 40-1993, Rev.2003, Amend 2010, 'Guidelines on Good Laboratory Practice in Pesticide Residue Analysis'
- OECD: ENV/JM/MONO(2007)17, 'Guidance Document on Pesticide Residue Analytical Methods'
- IUPAC: Pure Applied Chemistry, 2002, 74(5), p835-855, 'Harmonised Guidelines for Single Laboratory Validation of Method of Analysis'
- AOSIQ: GB/T 27404-2008, 'Criterion on Quality Control of Laboratories – Chemical Testing of Food'



## VII. CONCLUSION

Governments recognise the need for worldwide, uniform controls on pesticides but there is still some way to go before any homogeneous global limits are accepted and enforced.

Organisations such as Codex have had some success in this regard but the ongoing disparity between countries on maximum residue limits (MRLs) make it imperative that great care is taken when commodities used in manufacture are imported or final products exported.

With supply chains becoming ever more globalised, understanding the national differences in MRLs is key to ensuring speed to market for food manufacturers, traders and retailers.

For any final product, many different countries and respective MRLs can affect the supply chain. The risks of noncompliance with MRLs vary from growing region to growing region. This is dependent on a number of factors including local legislation/practices preferences, use of integrated crop and pest management techniques, Good Agriculture Practices, harvest interval and application withdrawal periods and others. How and where

the pesticide is applied can affect the residue level, for example pesticides applied to a product to suppress growth in long-term storage generally requires multiple applications and can create excess levels of a pesticide. It is imperative that the final product meets the regulatory compliance of the MRLs both allowed and not allowed or banned in the target market, including all individually sourced ingredients. This may not always be as simple a task as ensuring ingredients are sourced from countries corresponding to those MRLs, because the risk of pesticide residue contamination increases as the number of critical control points in the supply chain multiplies (e.g. storage, supplier plant machinery, transit).

To further complicate matters, the chemical industry is continually researching and developing ever safer and more effective pesticide alternatives. This requires anyone in the supply chain to be constantly vigilant and up-to-date on any new pesticides registered and marketed by the chemical industry.

Expert, trusted and independent third-party pesticides consultancy

can help to remove ambiguity and uncertainty around pesticides and MRLs. Testing and verification via state-of-the-art analytical methods for any given pesticide and any given matrix is essential for regulatory compliance.

Partnering with a global organisation that offers local representation is one of the most efficient and effective ways to access this capability and avoid costly product recalls or product bans, and the subsequent potential for damage to brand reputation.

Learn more about Pesticide MRLs\*:

<http://www.codexalimentarius.net/pestres/data/pesticides/index.html>

[http://ec.europa.eu/sanco\\_pesticides/public/](http://ec.europa.eu/sanco_pesticides/public/)

<http://www.epa.gov/pesticides/food/>

<http://www.m5.ws001.squarestart.ne.jp/foundation/search.html>

<http://www.foodsafety.govt.nz/industry/sectors/plant-products/pesticide-mrl/worldwide.htm>

*\*China: refer to regulation GB 2763-2014*



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James Cook received his Bachelor of Science in Chemical Engineering from the Newark College of Engineering in the United States of America. He has over 34 years of industry experience, serving as expert in areas of quality assurance, quality control, auditing, product inspection, laboratory management, and regulatory affairs within retail, distribution, manufacturing and contract testing service industries. He has extensive experience in food products, food packaging, cosmetics, personal care and household products and medical devices; and working knowledge of AOAC, SQF, HACCP, ServSafe, GMP, Six Sigma, and regulatory compliance. James chairs one technical committee for SGS and participates on two other technical committees.

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## ABOUT SGS

SGS is a leading independent third-party service provider offering efficient solutions to help safeguard against pesticides exceeding MRLs in consumer goods products and supply chains. SGS can fulfil all your testing, certification, technical assistance, audit, inspection and verification needs.

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 80,000 employees, SGS operates a network of over 1,650 offices and laboratories around the world.

Enhancing processes, systems and skills is fundamental to your ongoing success and sustained growth. We enable you to continuously improve, transforming your services and value chain by increasing performance, managing risks, better meeting stakeholder requirements and managing sustainability.

With a global presence, we have a history of successfully executing large-scale, complex international projects. Our people speak the language, understand the culture of the local market and operate globally in a consistent, reliable and effective manner. We have a harmonised approach to delivering services to our customers, leveraging the largest independent network of consumer product experts in the world.

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WHEN YOU NEED TO BE SURE

