Presentation
July 8, 2014

CERTIS

The Biopesticide Company

CERTIS

Certis USA
A Global Leader in Biological

- **Biological Product Development**
  - screening, formulation, and field development
- **Dedicated Manufacturing Base**
  - fermentation, formulation, plant extraction
- **Global Registrations**
- **Global Sale Channels**

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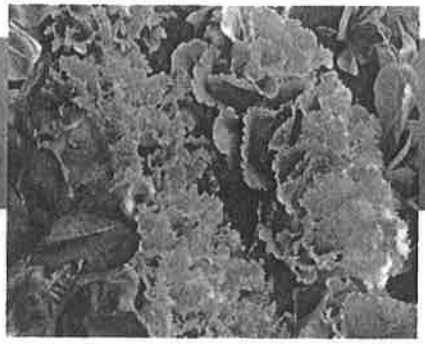
Value of Biological Pesticides



Current Concepts:

Use microbes or biochemicals to control insects and diseases

- ➢ Residue and Harvest Management
- ➢ Resistance Management
- ➢ Worker Safety
- ➢ Preserving beneficial insects and pollinators
- ➢ Food safety and Consumer Perception
- ➢ Sustainability Programs

Future Concepts:

Natural products that improve plant health, increase resistance, or reduce stress.

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Market Drivers For Biological Pesticides

US: Increasing organic acreage and acceptance of IPM practices.

Europe: Restrictions of EU Annex I and food chain traceability.

Japan: "Positive List" started in May 2006 and food chain traceability.

Residue and Resistance Management Tool

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AgriScience Operation

- ***Mitsui & Co. Ltd.***
  - Trading activities : Representing specialty manufacturers (mainly Japanese)
  - Supply Chain Managements (logistics)
  - Toll manufacturing activities
  - Supporting alliances and licensing products
  - Acquisition of IPs
- ***Operational Subsidiaries***
  - Distribution set up for key suppliers (mainly Japanese R&D) in Europe and USA
  - Biological products (Development, Registration, Manufacturing, Sales)

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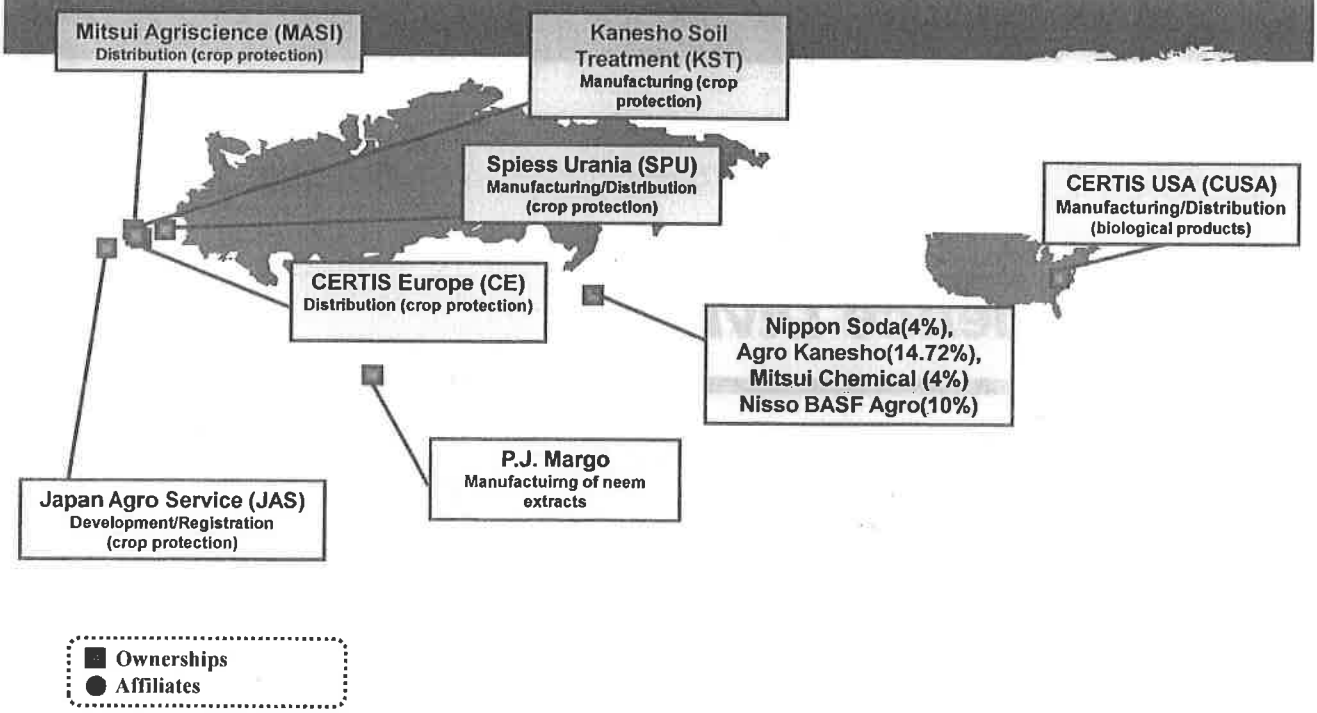
Key Investments in Crop Protection Sector



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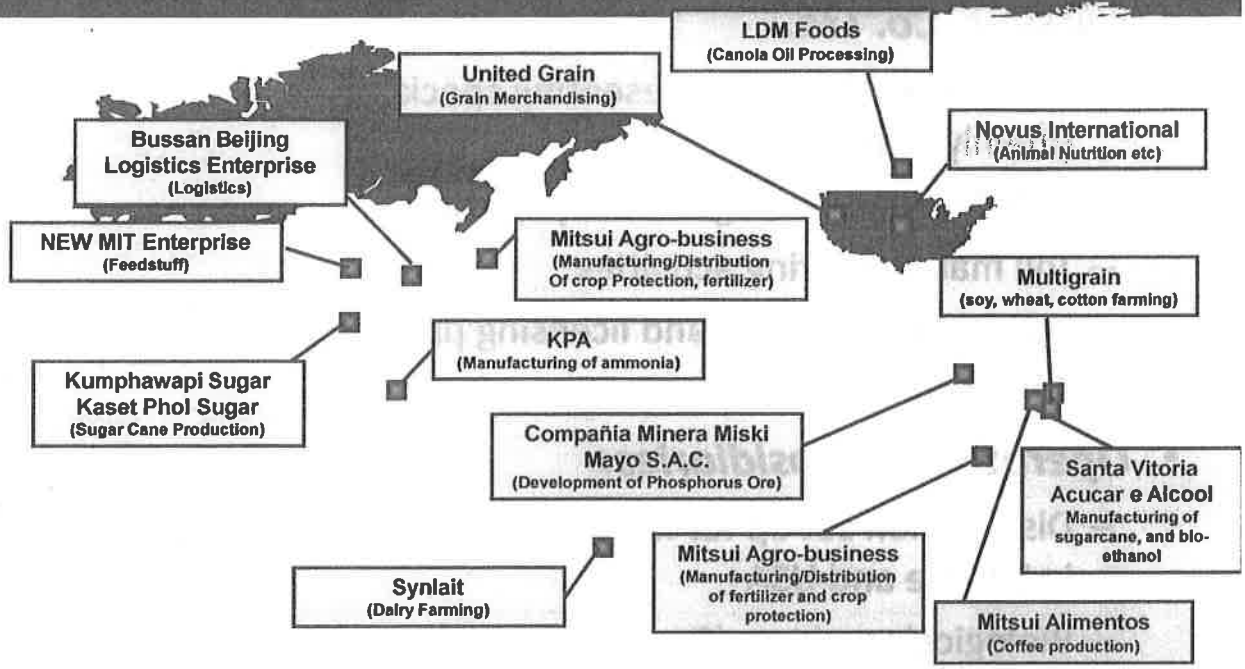
Key Investments in Agricultural Sector



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AgriScience Division

Chemical segment

Mitsui's Organization – by Business Unit

as of July 1, 2011

- Iron & Steel Product (ex. pipeline)
- Energy I / Energy II (ex. oil & gas)
- Mineral & Metal Resources (ex. mining)
- Food and Retail (ex.demand chain management)
- Infrastructure Project (ex. IPP projects, trains)
- Consumer Service (ex. apparel)
- Motor Vehicles (ex. automobiles)
- IT (ex. e-commerce, IT)
- Marine & Aerospace (ex. ships, airplanes)
- Financial Markets (ex. VC, commodity trading)
- Basic Chemicals
- Transportation Logistics (ex. shipping)
- Performance Chemicals

14 Business Units

3 Regional BU

- Americas BU
- EMEA BU
- Asia Pacific BU ex. Taiwan, Korea, China, Russia

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Performance Chemical Organization

Performance Chemical

Marketing Platform	Performance Materials	Environmental Chemicals	Agricultural Chemicals SBU	Advanced Materials SBU
3 Subsidiaries of marketing platform	Automobiles Home Appliances Inorganic Chemicals	Solar Energy Green Chemicals Specialty Chemicals	Agrochemicals Animal Nutrition Fertilizer (NPK) Ammonia and Sulphur	FPD Parts Semi-conductors SCM Service

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The Numbers Tell It All - Mitsui & Co., Ltd.

(Fiscal year ended March 31, 2012)

Total Assets: US$ 109.9 billion

Shareholders' Equity: US$ 32.2 billion

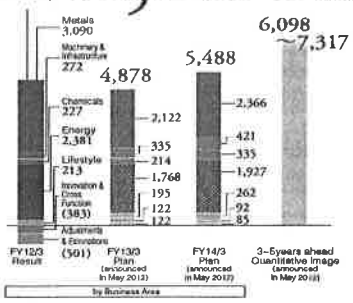
Revenues: US$ 64.0 billion

Investments and Loans Result: US$ 7.9 billion

Net Income Attributable to Mitsui & Co., Ltd.

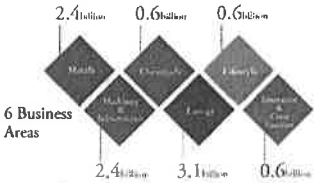
by Business Area (Reference)(¥ billion)

US$ 5,299 million



Medium-Term Management Plan Investments and Loans (FY13/3 Plan)

US$ 9.7 billion



We develop a wide range of businesses in six core areas: Metals, Machinery & Infrastructure, Chemicals, Energy, Lifestyle, and Innovation & Cross-Function.

The U.S. dollar amounts represent translations of the Japanese yen amounts at the rate of ¥82.00=U.S. $1, the approximate rate of exchange on March 31, 2012.

Mitsui at a Glance

The Numbers Tell It All - Mitsui & Co., Ltd.

(Fiscal year ended March 31, 2012)

Global Network (as of February 1, 2013):

67 countries/ regions

Number of Offices and Overseas Trading Subsidiaries (as of February 1, 2013):

151

Number of Employees (consolidated):

44,805

Number of Subsidiaries and Associated Companies:

413

A Total of 136 years since establishment

Former Mitsui & Co.* established in 1876.

*Legally speaking, there has been no continuation between the former Mitsui & Co. and the current Mitsui & Co.

(As of March 31, 2012)

THE GLOBAL COMPACT WE SUPPORT

Source : UNIC

FTSE4Good

Dow Jones Sustainability Indexes

sam 2012 bronze class

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Mitsui & Co., Ltd.

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Corporate Profile

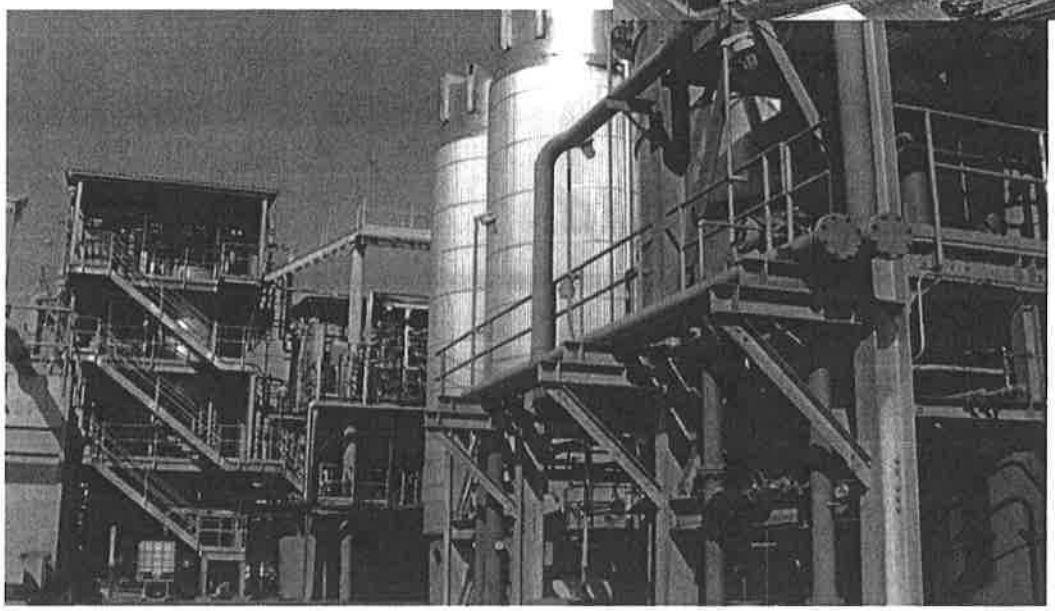
MITSUI & CO., LTD.

Company Name	MITSUI & CO., LTD.
Date of Establishment	July 25, 1947
Representative	Masami Iijima, Representative Director, President and Chief Executive Officer
Common Stock	JPY 341,481,648,946
Number of Employees	6,136 (44,805 on consolidated basis)
Number of Offices and Overseas Trading Subsidiaries (As of April 1, 2012)	154 offices in 69 countries/regions Japan: 12 offices Overseas: 142 offices in 68 countries/regions
Head Office	2-1, Ohtemachi 1-chome, Chiyoda-ku, Tokyo 100-0004, Japan TEL: 81(3)3285-1111 FAX: 81(3)3285-9819 URL: http://www.mitsui.com/jp/en/
Number of Subsidiaries and Associated Companies	Subsidiaries: Japan 76 Overseas 187 Associated Companies: Japan 41 Overseas 109 Total 413
Stock Information	Stock Exchange Listings: Tokyo, Osaka, Nagoya, Sapporo, Fukuoka Number of Shares Authorized: 2,500,000,000 shares Common Stock Issued: 1,829,153,527 shares Number of Shareholders: 210,164 shareholders

(As of March 31, 2012)

Mitsui & Co.'s Head Office

Fermentation Plant
Wasco, California



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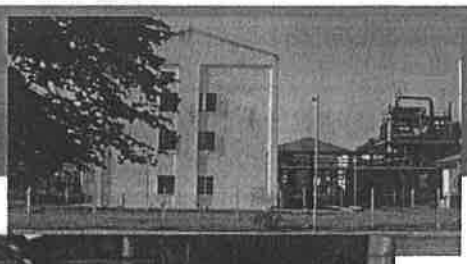
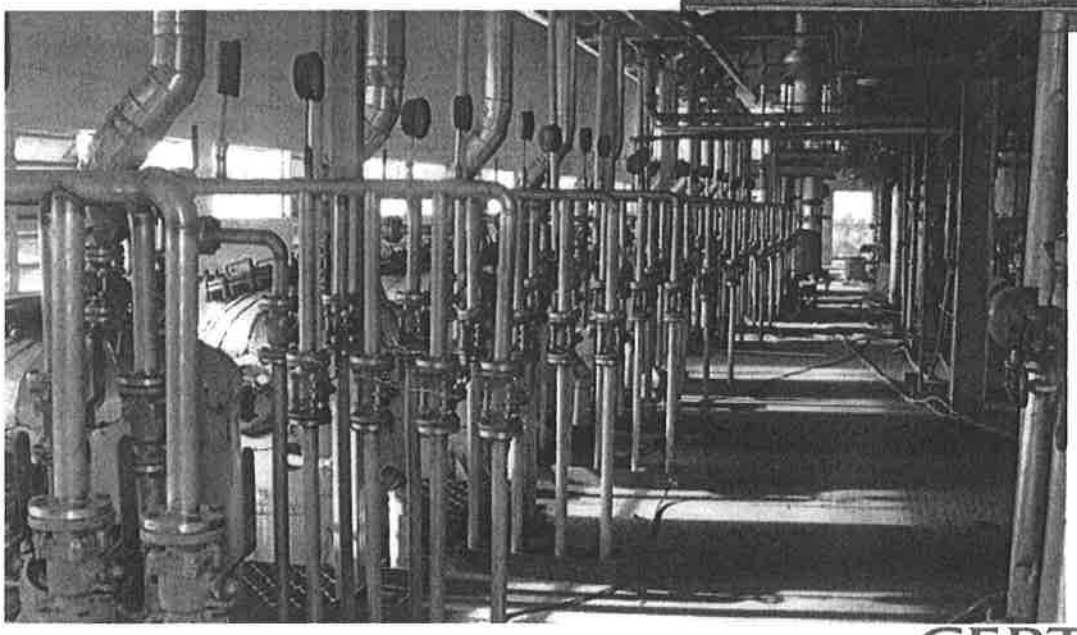
Neem Extraction Plant
Bangalore, India





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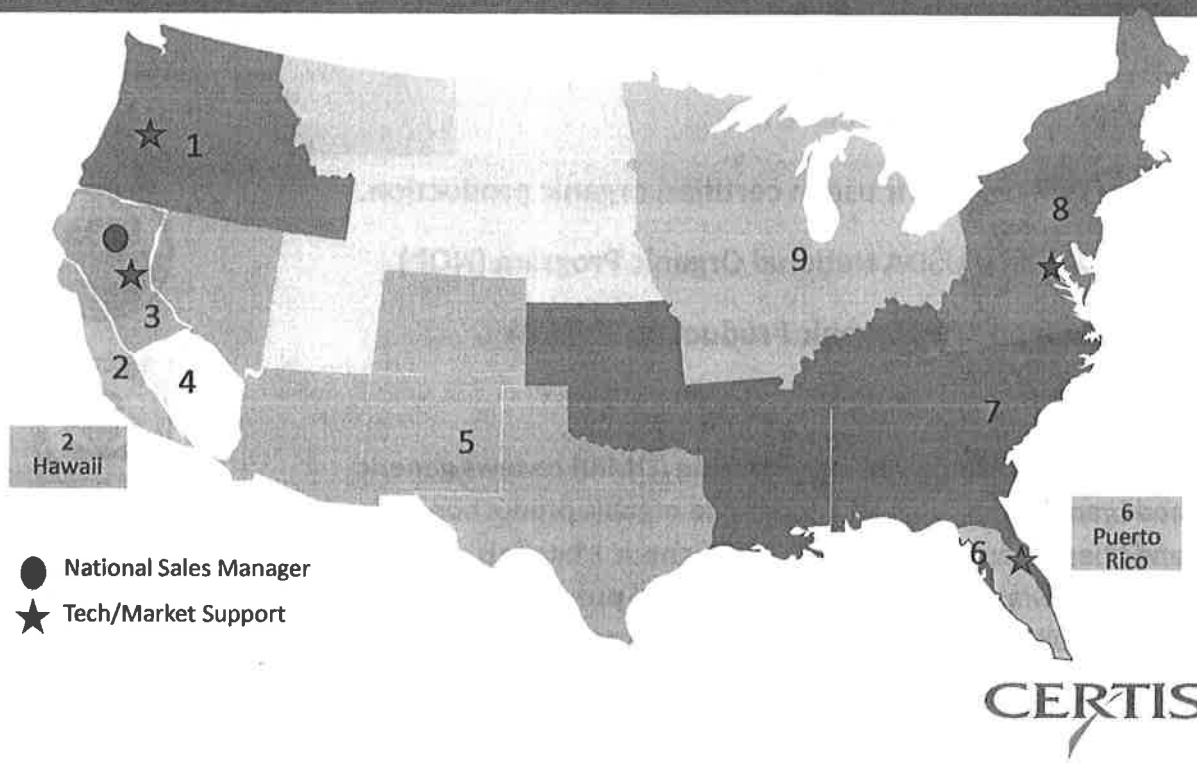
Certis US Field Sales Team Services High Value Crops



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Global Development and Sales Network

- Export to 45+ countries
- Network of local distributors specialized in biological product registration and development.
- Strong positions in US and Europe.

  Under-represented in South America and Asia

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Certis USA Products are NOP and OMRI Listed

Most Certis products are:

- ➢ **OMRI listed for use in certified organic production.**
- ➢ **Listed by USDA National Organic Program (NOP)**
- ➢ **Labeled "For Organic Production" by EPA**

The Organic Materials Review Institute (OMRI) reviews generic and brand name products used in the organic production of food and fiber. As publisher of the OMRI Generic Materials List and the OMRI Brand Name Product List, OMRI provides guidance on the suitability of material inputs in U.S. organic production.

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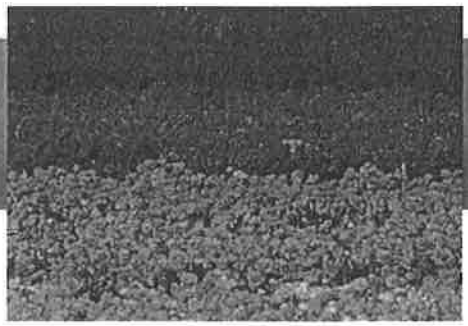
Global Market Positions



- ➢ **Market Focus:**
  - ➢ Agriculture: Specialty Crops, Fruits/Vegetables, Organic Farms
  - ➢ Turf and Ornamental: Greenhouse/nursery, landscape, golf courses
  - ➢ Consumer/Home Garden: Re-packager/formulators
  - ➢ Pull-Through Marketing Strategy
  - ➢ Toll Fermentation
- ➢ Broadest OMRI/NOP certified biological offering in the industry
- ➢ Worldwide top 2 positions in Bt, neem, and virus products
- ➢ Growing portfolio with new fungicides/bactericides and low impact OMRI certified biochemicals

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Certis USA Product Line:
OMRI Biochemicals (3rd party Products)

Polyoxin-D:

Tavano® and OSO ® Bio-Fungicides
(Fermentation product from *Streptomyces cacaoi.* Chitin Inhibitor)

Soap Technologies:

DES-X® (potassium salts of fatty acids): contact insecticide
Cueva® (copper octanoate soap): fungicide/bactericide
Final-san-O (herbicidal soap): herbicide

Bait Technologies:

Seduce® (Spinosad insecticidal bait): various soil insects
Sluggo® (iron phosphate bait): control snail and slugs
Bug-N-Sluggo (combination bait): Broad spectrum

Heat Stress Technology: **Screen-Duo**

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Residue Exempt

Bt Biolarvicides
Agree® WG
CryMax® WDG
Deliver®
Javelin® WG
Lepinox® WDG

Insect Growth Regulators
Neemazad® 1% EC
Neemix® 4.5 EC

Insecticidal Viruses
CYD-X®
Gemstar® LC
Spod-X®

Insecticidal Soaps
DES-X®

Insecticidal Baits
Sluggo®
(Eastern U.S. only)

Biofungicides
SoilGard®
Trilogy®

Biochemicals
Cueva™
Sil-MATRIX®

Miticides (Acaricides)
Trilogy®
Sil-MATRIX®

Bionematicides
MeloCon® WDG

1-800-250-5024
www.CertisUSA.com

Certis USA Product Line:
New Technologies Under Development

- Foliar and soil fungicides and bactericides based on new microbes and biochemicals

- Disease control agents through systematically induced resistance - Bacillus *mycoides* technology with Montana State University

- Heat stress technologies based on dicarboxylic acids – with CMM

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Certis USA Product Line:
Botanical Extracts

Azadirachtin (neem seed extract):

Neemix®, Azatin®

Natural insect growth regulator controlling sucking and piercing insect pests

Clarified hydrophobic extract of neem oil:

Trilogy®, Triact®

Controls mites, diseases, soft bodied insects

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Certis USA Product Line: *Bacillus thuringiensis* (Bt)

Bt kurstaki:

Javelin®, Delfin® *(SA-11)*

Deliver®, CoStar® *(SA-12)*

Crymax® (*EG7841*), Lepinox® *(EQ7826*)

Condor (EG2348)

Bt aizawai:

Agree®, Turex®, Jackpot®

Control a wide range of Lepidopteran species for specific cropping situations

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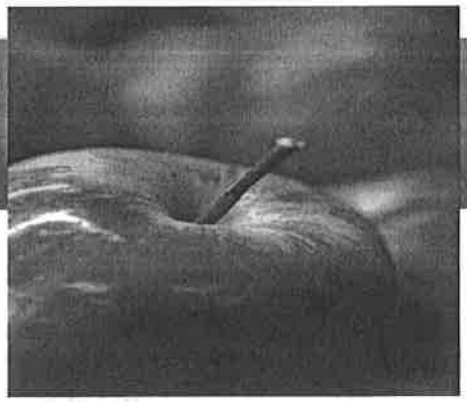
Certis USA Product Line: Insecticidal Virus



CYD-X HP®: *(Cydia pomonella* GV)

Controls codling moth larvae

MADEX HP®: *(Cydia pomonel* GV)

Controls oriental fruit moth larvae (3rd party product)

Gemstar®: *(Helicoverpa zea NPV)*

Controls Heliothis species such as corn earworm, tomato fruitworm, tobacco budworm

Spod-X®: *(Spodoptera exigua NPV)*

Controls beet armyworm

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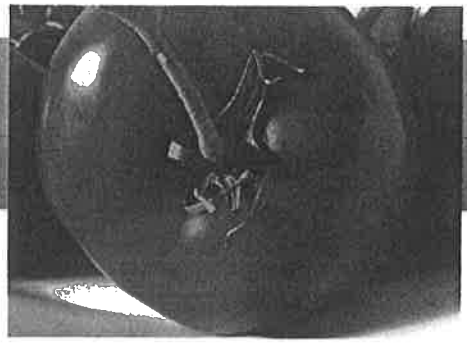
Certis USA Product Line: Fungi Based Products



SoilGard® (*Gliocladium virens* GL-21):
Broad spectrum soil disease fungicide

MeloCon® (*Paecilomyces lilacinus*):
Controls multiple species of nematodes (3rd party product)

PFR-97® *(Paecilomyces fumosoroseus)*:
Broad spectrum soil and foliar insecticide

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Certis USA Product Line: Bacterial Fungicides:

Amylo-X® (Bacillus *amyloliquefaciens*):

Broad spectrum foliar and soil disease control fungicides and bactericides

Collaboration with Kumiai Chemicals .

Worldwide registration and development

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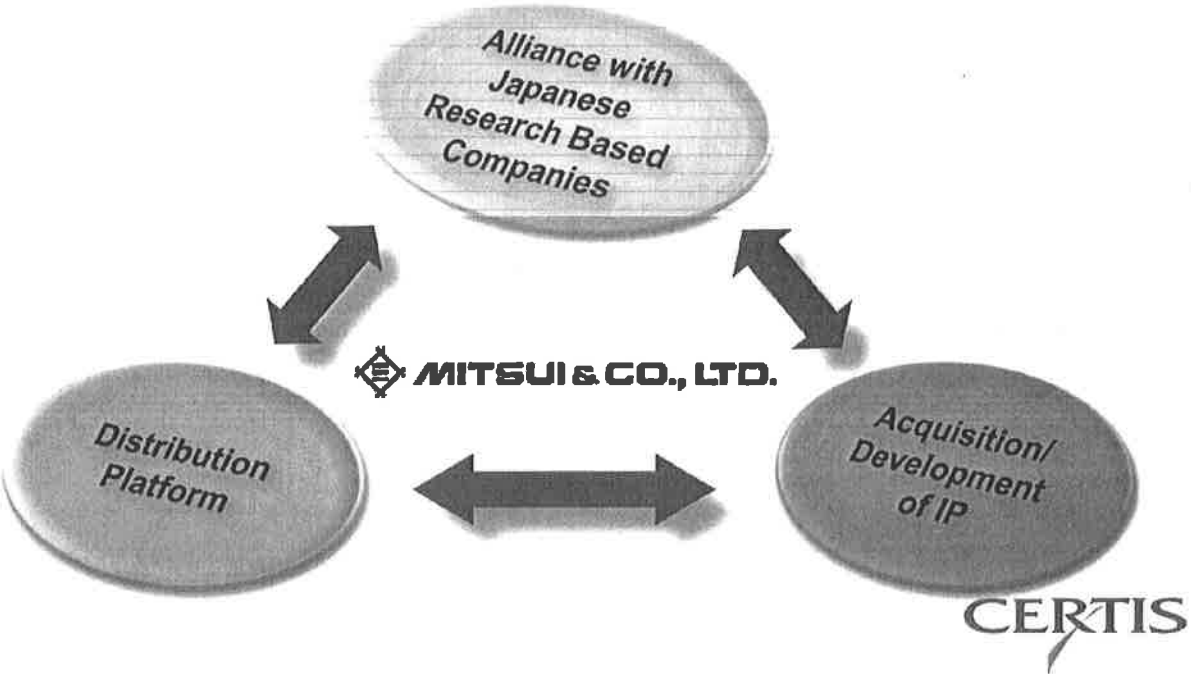
Mitsui's Business Concept in Crop Protection Industry

Mitsui's direction is to expand and strengthen global distribution platform by creating an unique product portfolio under the IPM concept through alliance with Japanese Research based companies and IP acquisition/development



Thank You
End of Presentation

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The Biopesticide Company

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CERTIS USA

	Active Ingredient	Pest Controlled	OMRI Listed	NOP Appr.	Residue Exempt	REI	PHI	Interval*	Bee Safe
INSECTICIDES									
Bt Biolarvicides									
Agree® WG	*Bt aizawai*	Lepidoptera (caterpillar) pests	✔	✔	✔	4 hrs.	0	3-14 days	✔
CryMax® WDG	*Bt kurstaki* strain EG7841	Lepidoptera (caterpillar) pests	—	—	✔	4 hrs.	0	3-14 days	✔
Deliver®	*Bt kurstaki*	Lepidoptera (caterpillar) pests	✔	✔	✔	4 hrs.	0	3-14 days	✔
Javelin® WG	*Bt kurstaki*	Lepidoptera (caterpillar) pests	✔	✔	✔	4 hrs.	0	3-14 days	✔
Bioinsecticides									
PFR-97™	*Paecilomyces fumosoroseus*	Aphids, whiteflies, thrips, mites, psyllids	✔	✔	✔	4 hrs.	0	7-10 days	**
Insect Growth Regulators									
Neemazad® 1% EC	Azadirachtin	Leafminers, whiteflies, aphids	✔	✔	✔	4 hrs.	0	7-21 days	✔
Neemix® 4.5 EC	Azadirachtin	Leafminers, whiteflies, aphids	✔	✔	✔	4 hrs.	0	7-21 days	✔
Insecticidal Viruses									
CYD-X® HP	*Cydia pomonella* GV	Codling moth larvae	✔	✔	✔	4 hrs.	0	7-14 days	✔
Gemstar® LC	*Helicoverpa zea* NPV	Corn earworm larvae	✔	✔	✔	4 hrs.	0	7-14 days	✔
Madex® HP	*Cydia pomonella* CpGV V-22	Codling moth, oriental fruit moth larvae	✔	✔	✔	4 hrs.	0	7-14 days	✔
Insecticidal Soaps									
DES-X®	Potassium salts of fatty acids	Aphids, whiteflies	✔	✔	✔	12 hrs.	0	7-21 days	✔
Insecticidal Baits									
Bug-N-Sluggo®	Spinosad, iron phosphate	Earwigs, cutworms, slugs, snails	✔	✔	—	4 hrs.	Varies	14-28 days	✔
Seduce	Spinosad	Earwigs, cutworms	✔	✔	—	4 hrs.	Varies	14-28 days	✔
Sluggo® (Eastern U.S. only)	Iron phosphate	Slugs, snails	✔	✔	✔	0 hrs.	0	14-28 days	✔
FUNGICIDES and/or BACTERICIDES									
Biofungicides									
Double Nickel 55®	*Bacillus amyloliquefaciens* strain D747 (Ba D747)	Powdery mildew, *Botrytis*, bacterial disorders	✔	✔	✔	4 hrs.	0	7-10 days	✔
Double Nickel® LC	*Bacillus amyloliquefaciens* strain D747 (Ba D747)	Powdery mildew, *Botrytis*, bacterial disorders	✔	✔	✔	4 hrs.	0	7-10 days	✔
OSO® 5% SC	Polyoxin D zinc salt	*Alternaria*, early/late blight, powdery mildew, black scurf, gray/white mold, *Botrytis*, anthracnose	—	—	✔	4 hrs.	0	7-14 days	✔
SoilGard®	*Gliocladium virens* GL-21	Damping off and other soil-borne diseases	✔	✔	✔	0 hrs.	0	7-28 days	✔
Tavano® 5% SC	Polyoxin D zinc salt	*Alternaria* leaf spot, leaf blotch, powdery mildew, scab, *Botrytis* blossom blight, septoria spot	—	—	✔	4 hrs.	0	7-14 days	✔
Trilogy®	Clarified hydrophobic extract of neem oil	Powdery mildew, rust, black spot	✔	✔	✔	4 hrs.	0	7-14 days	**
Biochemicals									
Cueva®	Copper octanoate	Bacterial disorders, downy mildew, powdery mildew	✔	✔	✔	4 hrs.	0	7-10 days	✔
Rendition®	Peroxyacetic acid 5%	Bactericide/fungicide	—	—	✔	0/1 hr.	0	5-14 days	**
Sil-MATRIX®	Potassium silicate	Powdery mildew, *Botrytis*, mites, aphids	✔	✔	✔	4 hrs.	0	7-10 days	✔
MITICIDES (Acaricides)									
Trilogy®	Clarified hydrophobic extract of neem oil	Spider mites, broad mites, rust mites	✔	✔	✔	4 hrs.	0	7-21 days	✔
Sil-MATRIX®	Potassium silicate	Mites	✔	✔	✔	4 hrs.	0	7-10 days	✔
NEMATICIDES									
MeloCon® WDG	*Paecilomyces lilacinus*	Plant parasitic nematodes, including root knot, burrowing, cyst, root lesion, false root knot and sting nematodes	✔	✔	✔	4 hrs.	0	4-6 weeks	✔
HERBICIDES									
Final-San-O™	Ammoniated soap of fatty acids	Grasses and broadleaf weeds	✔***	✔	✔	24 hrs.	0	14-21 days	✔
ABIOTIC STRESS MANAGEMENT									
SCREEN™ Duo	Enhanced kaolin blend	Heat stress and sunburn management	—	—	✔	0 hrs.	0	7-14 days	✔

OMRI LISTED For Organic Use | 50 | Residue Exempt | SoilSolution | BEE SAFE

1-800-250-5024
www.CertisUSA.com

*These intervals are for general information purposes. Actual use patterns may vary according to pest pressure, crop growth stage, and other circumstances. All applications must be consistent with label use instructions.

**Do not apply when bees are actively foraging.

***OMRI Listed with Conditions.

55 Double Nickel

BIOFUNGICIDE

A fungicide with 5 modes of action.

Double Nickel 55®. A new generation fungicide and bactericide. For control of foliar and soil-borne diseases. Double Nickel employs five modes of action. Provides excellent control at low rates. Has no resistance or residue issues. And offers fast worker reentry. From the roots of your crop to all its plant surfaces, Double Nickel helps keep your plants clean and disease-free.

Double Nickel. Multiple modes of action.

Residue Exempt

4 hr. REI
0 PHI

CERTIS USA

1-800-250-5034

Did you know?

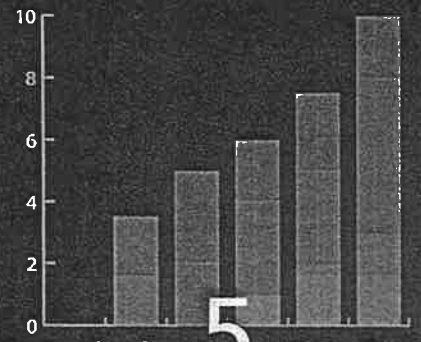
Approximately **100** **Employees are based at Certis USA headquarters in Maryland, manufacturing plant in California and throughout the U.S.**

17 **sales and marketing employees steward products in the NAFTA region.**

Certis USA owns and operates **2** dedicated production plants. One manufactures **microbial** products and one is for plant extraction of **neem** based products.

MITSUI & CO., LTD.

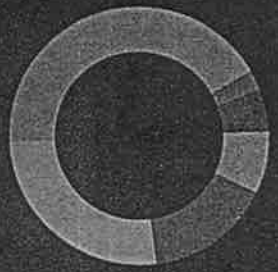
We are owned by Mitsui & Co., Ltd. one of the world's most diversified trading, investment and services companies. It has a global network of 150 offices in 67 countries, as well as about 320 associated companies worldwide.



Over the last **5** years, Certis USA business has grown in the double digits each year.

Certis USA features the broadest OMRI-listed biological offerings in the industry. About **30** products.

And most are Residue Exempt.



Our core competencies are screening, formulation, fermentation and registrations of microbial or biochemical products.

CERTIS USA

1-800-250-5024 • www.CertisUSA.com

Visit to the U.S. Environmental Protection Agency Office of Pesticide Programs
by Dr. Su-San Chang, Director General
Bureau of Animal and Plant Health Inspection and Quarantine
Council of Agriculture, Taiwan

July 7, 2014, 2:00 – 4:00
EPA Conference Room Potomac Yards 11621

Agenda

2:00 to 2:10	Introductions – Meeting Hosts Robert McNally, Director Biopesticides & Pollution Prevention Division Brian Frazer, Acting Director Field and External Affairs Division
2:10 to 2:50	Registration of Conventional Pesticides Lois Rossi, Director Registration Division
2:50 to 3:30	Registration of Biopesticides Chris Wozniak, Ph.D., Special Assistant on Biotechnology Biopesticides and Pollution Prevention Division Sheryl Reilly PhD., Senior Advisor for Regulatory Policy and Science Biopesticides and Pollution Prevention Division
3:30 to 3:50	Discussion of Drift Related Issues Jay Ellenberger, Associate Director Field and External Affairs Division
3:50 to 4:00	Discussion and Adjournment Jack Housenger, Director, Office of Pesticide Programs Director General Chang

Products for Export Only - Licensed products

Types of products

- Vaccines for foreign animal disease
- Diagnostic products that are restricted to official use in the US
- Other products, when requested by firm

Studies

- Firm must fulfill all requirements for licensure: Master Seeds, efficacy, safety
- Field safety study for vaccines may be conducted outside of the US
- Samples used to demonstrate the sensitivity and specificity of diagnostic products may be obtained outside of the US

Outlines and Labels

- Product has an approved Outline of Production and approved labeling
- Labels for exported product do not need to meet all of the criteria that must be met for product used in the US
  - Labels that meet the US criteria are accepted with an English translation
  - Labels that do not meet the US criteria - the firm must submit an English translation AND documentation that the foreign government has approved the labeling

Other considerations

- Firms may send samples overseas for testing prior to release by the CVB

Products for Export Only - Unlicensed products (FDA-EREA)

Types of products

- Products that the firm does not want to market in the US
- The product must be different from any of the firm's licensed products
- The firm must provide documentation that a foreign regulatory authority (usually Europe or Japan) has granted marketing authorization for the product
- Manufacture must not pose a threat to any licensed products

Studies

- No studies are submitted; CVB does not review any data

Outlines and Labels

- An Outline of Production and labeling are on file but neither are reviewed
- The Establishment Number cannot be on the labeling

US EPA's Pesticide Registration Process

Lois Rossi
Director, Registration Division
Office of Pesticide Programs
July 7, 2014

Overview of Topics

1. Goals of Pesticide Registration in the U.S.
2. Federal Pesticide Laws
3. Organizational Structure
4. Overview of the Pesticide Review Process
5. Data Requirements
6. Types of Registration Applications
7. Registration Fees
8. Pesticide Labeling
9. Additional Information Resources

What is a Pesticide?

- In the US, a pesticide is defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.
- Examples:

insecticides	herbicides
fungicides	nematicides
rodenticides	miticides
plant growth regulators	defoliants
thinning agents	dessicants
antimicrobials	fumigants

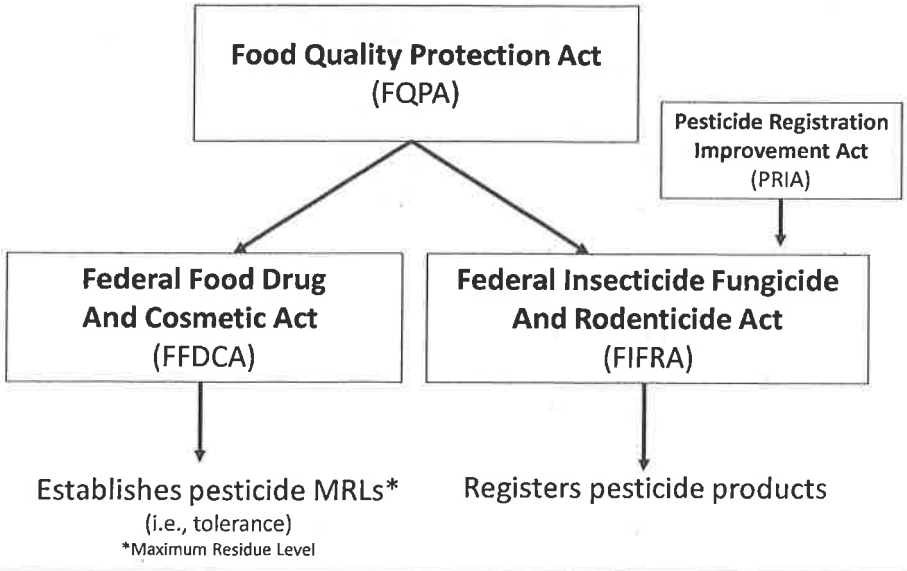
EPA's Registration Program

- By law, EPA must act on all pesticide registration applications that it receives.
- In addition to meeting this requirement, EPA's Office of Pesticide Programs (OPP) has designed a pesticide registration process that also:
  - Protects human health
  - Protects the environment
  - Provides benefits for society

US Pesticide Laws

- Major Statutes:
  - **FIFRA:** Federal Insecticide, Fungicide & Rodenticide Act, 1947
  - **FFDCA:** Federal Food, Drug and Cosmetic Act [Section 408]
  - **FQPA:** Food Quality Protection Act, 1996
  - **PRIA:** Pesticide Registration Improvement Act, 2003

US Pesticide Laws



Scope of US Pesticide Registrations

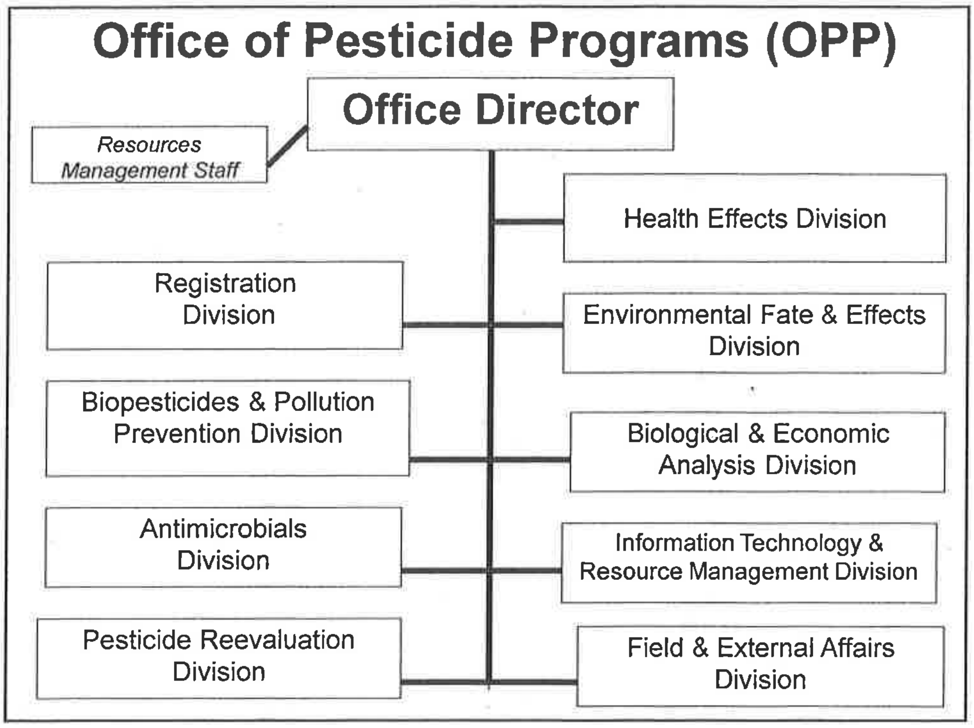
- Over **1,200** active ingredients
- Over **18,000** pesticide products
- Over **10,000** tolerances (i.e., MRLs)

Pesticide Categories

- EPA separates pesticides into three general categories:

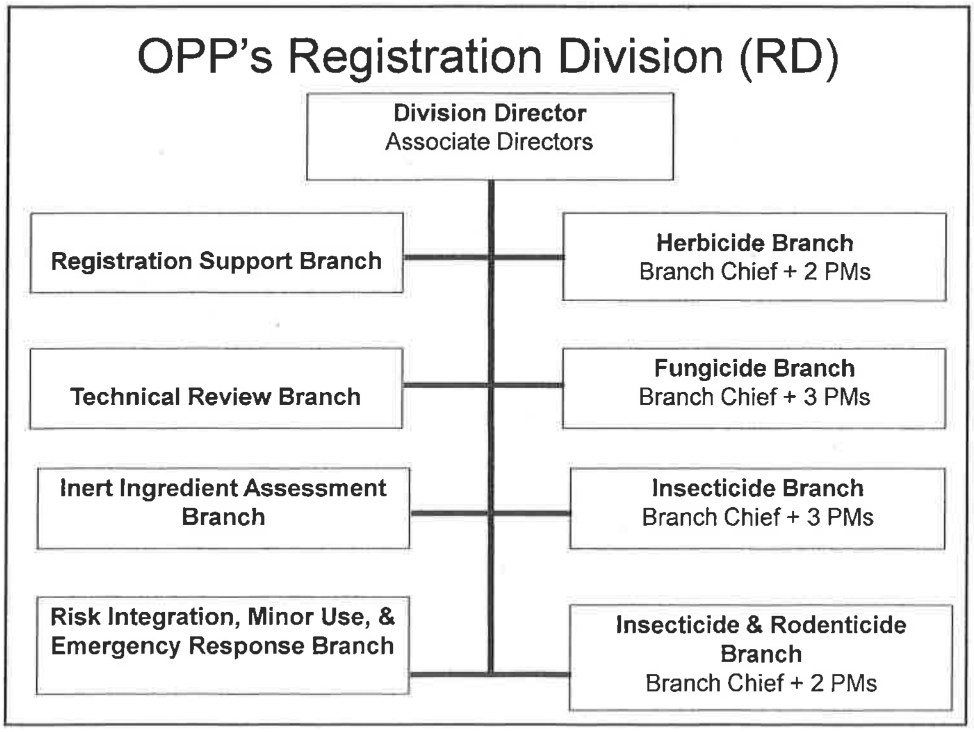
  1. Conventional Chemical Pesticides
  2. Antimicrobial Pesticides
  3. Bio-Pesticides

- Depending on the type of pesticide under review, different Divisions of OPP will evaluate the action, and the data requirements for registration will vary.



Inert Ingredients

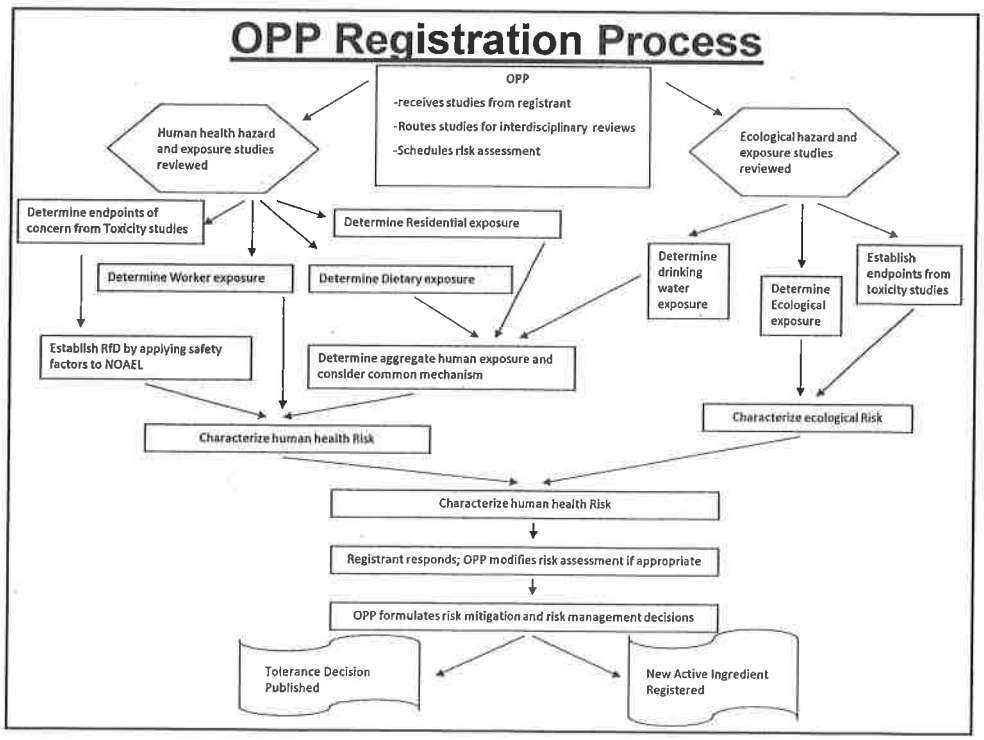
MRLs



OPP Registration Process: Risk Assessment & Risk Management

1. Registrant develops a pesticide, conducts studies, and submits a registration application.
2. OPP scientists review studies to assess the risk of a pesticide.
3. OPP risk managers make the decision to register a pesticide or change a registration based on the study reviews, benefits, and any adverse incident information.
4. Decision includes product labeling, packaging, and directions for use, and any limitations on where, how, and when a pesticide may be applied.

Each pesticide decision is unique …
although the approach is generally the same.



Transparency and Public Process

- Transparency and public participation are important aspects of EPA's Pesticide Program.
- The public can review and comment on the risk assessments and proposed registration decisions for certain pesticide registration actions.
- Public input informs the risk assessment and risk management processes associated with registration.

Pesticide Data Requirements

- Data/information requirements depend on the proposed use(s) of the active ingredient / pesticide product:
  - More data required to register new food use pesticide than one with no food uses
  - Antimicrobials, biopesticides, and conventional pesticides each have different data requirements
- Up to 150 different studies may be required to register a pesticide, including:
  - Product Chemistry
  - Toxicology and Health Effects
  - Applicator and Post-Application Exposure
  - Residue Chemistry
  - Environmental Fate
  - Ecotoxicity
  - Efficacy

crop groups

Product Chemistry

- Identity and composition
  - Identify the active material
  - Identify impurities (especially impurities of concern)
  - Identify co-formulants (i.e., inert ingredients)
- Manufacturing process
  - Identify the potential for impurities
- Physical and chemical properties
  - Identify physical and chemical hazards (e.g., flammability)
- Analytical methods

Inert Ingredients

- Any substance, other than an active ingredient, which is intentionally included in a pesticide product, such as:

Solvents	Fragrances
Carriers	Dyes
Propellants	Preservatives
Diluents	Stabilizer
Thickeners	Antifoamers

Inert Ingredients

- All inert ingredients must be cleared by the Agency.
- EPA regulates the entire product formulation; not just the active ingredient. Therefore, the entire formula, including the inert ingredients, must meet the standard for registration.
- Inert ingredients in pesticide products used on food and feed crops, agricultural commodities, or livestock must have a tolerance or tolerance exemption.

Additional Information Resources for Inert Ingredients

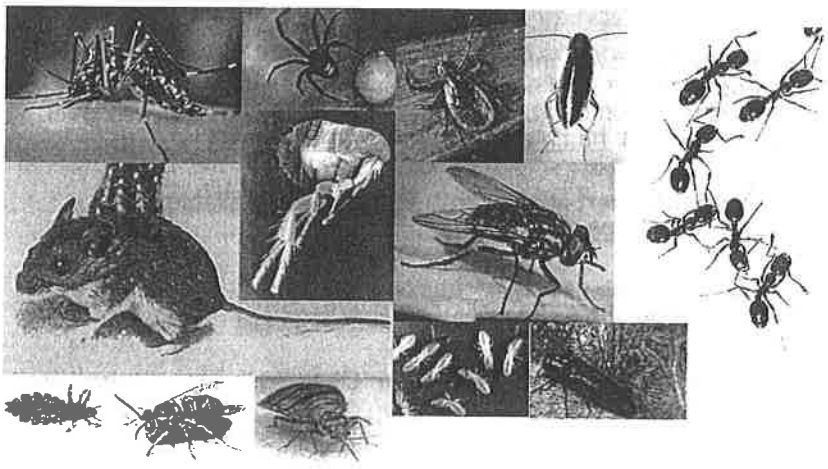
- **InertFinder:** An online database that provides information on the approval status of substances used as inert ingredients for use in food use, nonfood use and fragrance use pesticide products. Available at: http://iaspub.epa.gov/apex/pesticides/f?p=901:1:
- **Pesticide Inert Ingredients Webpage.** Available at: http://www.epa.gov/opprd001/inerts/
- **Inert Ingredient FAQs.** Available at: http://www.epa.gov/opprd001/inerts/faqs.pdf
- **Pesticide Registration Manual: Chapter 8 – Inert Ingredients.** Available at: http://www.epa.gov/pesticides/bluebook/chapter8.html

Efficacy

(Product Performance)

- Ensures that the pesticide product works as intended.
- For products with public health implications, the Agency does require applicants to submit product performance data.
- Efficacy requirements are typically waived for other products; however registrants are expected to have data on record for all pests listed on the label, and the Agency may request to review the data.

Pests for Which Efficacy Data are Required



Pests of Significant Public Health Importance

- Pests Identified as:
  - Injurious (e.g., Biting, Stinging, or Allergen source)
  - Disease vectors
  - Pathogen carriers
  - Quarantine
  - Structural
- The most common public health pests are listed in Pesticide Registration (PR) Notice 2002-1, and include:
  - Invertebrates (*e.g.*, Mosquitoes, Fire ants, Ticks)
  - Vertebrates (*e.g.*, Geese, Rattlesnakes, Bats, Rats)
  - Bacteria (*e.g.*,*Bacillus anthracis*, *E. coli*, *Salmonella* spp.)
  - Fungi (*e.g.*, spp. causing: ringworm, histoplasmosis)
  - Protozoa (*e.g.*, spp. causing: dysentery, diarrhea)
  - Viruses (*e.g.*, Herpes, Poliovirus, Hepatitis, Ebola)
  - Prions (*e.g.*, Bovine Spongiform, Kuru, scrapie)

Adverse Effects Data

- **FIFRA §6(a)(2):** "If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information…"
- Additional information on adverse effects data is available at: http://www.epa.gov/pesticides/fifra6a2/

Additional Information Resources for Data Requirements

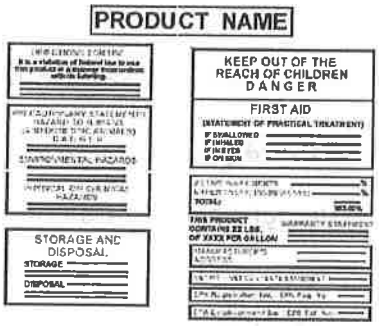
- Data requirements for conventional pesticides, antimicrobial pesticides, and biopesticides are in Title 40 of the Code of Federal Regulations (CFR) Part 158.
  - Available at: http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40cfr158_main_02.tpl

Additional Information Resources for Pesticide Registration Applications

- **Pesticide Registration Kit & Forms.** Available at: http://www.epa.gov/pesticides/registrationkit/
- **Pesticide Registration Manual (Blue Book).** Available at: http://www.epa.gov/pesticides/bluebook/
- **PRIA Information** (fee schedule, fee determination, waivers, refunds). Available at: http://www.epa.gov/pesticides/fees/
- **Data Requirements Checklist.** Available at: http://www.epa.gov/pesticides/fees/data_require_check.html
- **Examples of Completed Registration Forms.** Available at: http://www.epa.gov/pesticides/bluebook/appendix-d.html

Pesticide Labels

The Label is the Law



- EPA Registration Number
- Establishment Number
- Directions for Use
- Signal Word
- First Aid
- Ingredients Statement
- Precautionary Statements
- Hazards Statements
- Environmental Hazards
- Physical or Chemical Hazards
- Storage and Disposal
- Warranty Statement
- Net Contents

Labeling requirements are product-specific, and are informed by the data.

Pesticide Labeling

- When a new product registration application is submitted, it must include a draft/proposed label.
- OPP reviews the label in conjunction with the submitted data to ensure that every statement on the label is reflective of and supported by the data.

The label must be accurate – it must make sense and be clear to the user – and it must contain language that is enforceable.

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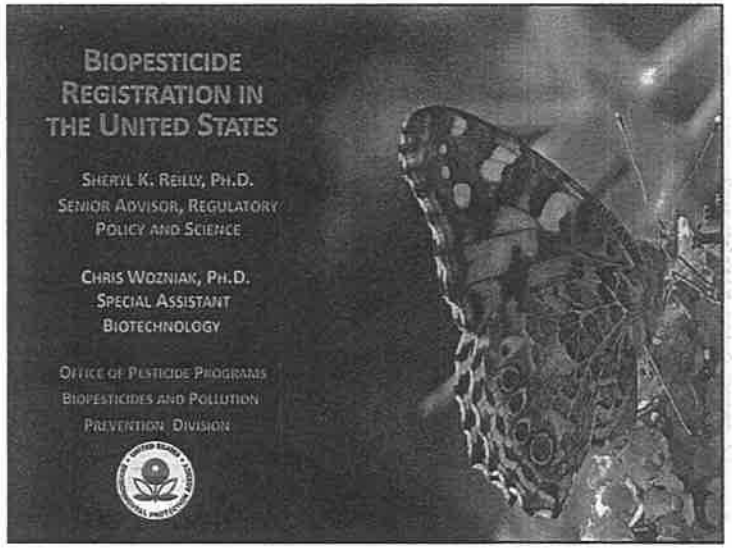
Additional Information Resources for Labeling

- **Label Review Manual.**
  - Available at: http://www.epa.gov/oppfead1/labeling/lrm/
- **Pesticide Product Labels Webpage.**
  - Available at: http://www.epa.gov/pesticides/regulating/labels/product-labels.htm
- **Pesticide Registration (PR) Notices.**
  - Available at: http://www.epa.gov/PR_Notices/index.htm

Thank you!

Questions?



STATUTORY AND REGULATORY AUTHORITIES

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

WHEN USED IN ACCORDANCE WITH WIDESPREAD AND COMMONLY RECOGNIZED PRACTICE, THE PRODUCT WILL NOT GENERALLY CAUSE UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT.

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA)

THERE IS A REASONABLE CERTAINTY THAT NO HARM WILL RESULT FROM AGGREGATE EXPOSURE TO THE PESTICIDE CHEMICAL RESIDUE, INCLUDING ALL ANTICIPATED DIETARY EXPOSURES AND ALL OTHER EXPOSURES FOR WHICH THERE IS RELIABLE INFORMATION.

2

STATUTORY AND REGULATORY AUTHORITIES

- FIFRA SECTION 3(C)(5), SECTION 3(C)(7) – REGISTRATIONS, AMENDMENTS
- FIFRA SECTION 5 – EXPERIMENTAL USE PERMITS (EUPS)
- FIFRA SECTION 33 – REGISTRATION FEES, TIME FRAMES
- FFDCA SECTION 408 – ESTABLISH TOLERANCES, TOLERANCE EXEMPTIONS FOR RESIDUES IN FOOD/FEED COMMODITIES
- 40 CFR PARTS 150-180 – REGULATIONS
- ENDANGERED SPECIES ACT

3

STATUTORY AND REGULATORY AUTHORITIES

Pesticide Registration Improvement Act (PRIA)

- Allows EPA to Collect Fees to Register Pesticides
- Actions Given a Decision* Time Frame
- Assumes Submitted Application is Complete
  - Administrative Documents
  - All Data Requirements are Addressed
  - Fees are Paid, or
  - 25% (or 50%) of Fees Paid if a Small Business Fee Waiver Is Requested

** Decision may be to register, not grant, or deny*

4

Statutory and Regulatory Authorities

Pesticide Registration Improvement Act (PRIA)

- Gives EPA 21 days to screen applications for completeness before decision time frame begins
- Gives EPA 45 – 90 days to screen application for technical completeness (e.g., all data requirements addressed)
- Decision time frames may be negotiated for:
  - Deficiencies (incomplete or missing data)
  - Risks discovered during risk assessment

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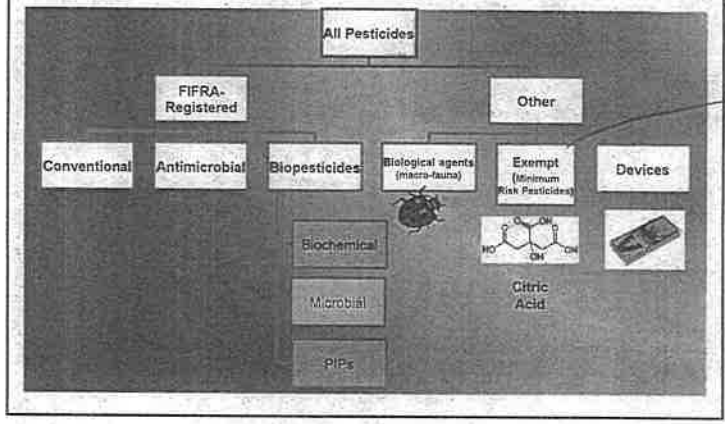
Pesticide Universe



EPA's Office of Pesticide Programs
Registering Divisions

- Registration Division - Conventional Pesticides
- Antimicrobials Division - Antimicrobial Pesticides
- Biopesticides & Pollution Prevention Division
  - Microbial Pesticides Branch
    - Microorganisms
    - Plant Incorporated Protectants (PIPs) — BT
  - Biochemical Pesticides Branch
    - Naturally Occurring
    - Non-Toxic Mode of Action

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Biopesticides vs. Conventional Pesticides

Similarities

= Standard for registration (FIFRA)
= Safety standard for food residues (FFDCA)
= Submission format and criteria
= Science-based decision process
= Labels and labeling

Differences

≠ Data requirements
≠ Fees, processing time
≠ Tolerance exempt vs. tolerance
≠ Toxicity
≠ Target specificity
≠ Environmental Persistence

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Biopesticides vs. Conventional Pesticides

Conventional Data Requirements (Not Tiered)

Human Health - Food Use Pesticide

- Acute Toxicity/Irritation/Sensitization "6-pack"
- Acute Neurotoxicity (rat)
- 90 day Oral Tox – rodent
- 90-day Oral Tox – non-rodent
- 21/28 day Dermal
- 90-day Neurotoxicity – rat
- Chronic Oral toxicity – rodent
- Carcinogenicity – 2 rodent species (rat & mouse preferred)
- Developmental tox – 2 species (rat & rabbit preferred)
- Reproduction and fertility effects
- Mutagenicity Testing (3)

Reference: 40 CFR 158.500

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Biopesticides vs. Conventional Pesticides

Biopesticide Data Requirements (Tiered)

Human Health Tier I (Food Uses) – Biochemicals

- Acute Toxicity/Irritation/Sensitization "6-pack"
- Subchronic (90 day) Oral Tox
- Mutagenicity (reverse mutation, in vitro mammalian cell assay)
- Developmental tox (Rat)

References: 40 CFR 158.2050 and 40 CFR 158.2140

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Biopesticides vs. Conventional Pesticides

Biopesticide Data Requirements (Tiered)

Human Health Tier I – Microbials

- Acute oral tox/path
- Acute pulmonary tox/path
- Acute injection (intraperitoneal or intravenous) tox/path
- Acute tox "6-pack"
- Cell Culture

References: 40 CFR 158.2050 and 40 CFR 158.2140

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What are Biopesticides?

Biochemical Pesticides  Example: Lepidopteran pheromones

Microbial Pesticides  Microorganisms *(Bacillus thuringiensis)*

Plant-Incorporated Protectants (PIPs)  Bt Cry Proteins

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Biochemical Pesticides

- Naturally Occurring Substances
- Non-Toxic Mode of Action
- Low Exposure to Non-Targets, Including Humans
  - Pheromones
  - Plant regulators
  - Repellents and attractants
  - Use nontoxic control such as suffocation

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Microbial Pesticides

- Naturally Occurring & Genetically Engineered Microorganisms
  - Bacteria, fungi, viruses
- Control/Suppress Insects, Plant Diseases, Weeds
- Modes of Action Against Pest
  - Competition or Inhibition (Non-Toxic)
  - Toxic (Kills)
- Data Requirements for Infectivity and Pathogenicity to Non-Targets is Unique to Microbial Pesticides

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Plant Incorporated Protectants (PIPs)

- Produced by Biotechnology
- Pesticidal Substance and the Genetic Material (from a Microbial Source) Needed to Make the Pesticide
- Most are Bt Crops (Control Insects)
- Resistant to Viral Pathogens
- Data Requirements are Similar to Microbial Pesticides
- Regulation is Coordinated with USDA and FDA

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Common Problems

- Incorrect fee category chosen
- Incomplete fee payment
- Incomplete submissions
- Deficient data submissions
  - Missing/Inadequate
  - Study quality, poor reporting
  - Product Identity
- Unexpected Hazard or Risk
- Label mistakes
- Unsupported claims

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Solutions

- Have a Pre-Submission Meeting with BPPD
  - Clarify Data Needs, Petition (When Food Tolerance Exemption Needed), Forms, Formats, Time Frames, Fees
- Submit Your Applications Well in Advance of the Planned Use Season
  - Allow Extra Time to Address Problems Identified During Screen and Review
  - Allow Extra Time for State Registrations

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Resources

PRIA Decision Tree (How to find your Fee Category):
http://www.epa.gov/pesticides/fees/tool/decisiontree/main.htm

Fee Categories for Pesticide Registration Actions:
http://www.epa.gov/pesticides/fees/tool/category-table.html#bppd

REDs and BRADs:
http://www.epa.gov/pesticides/biopesticides/ingredients/

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Resources

Online Code of Federal Regulations:
http://www.gpoaccess.gov/ecfr/

Data Requirements: **40 CFR part 158**

Online Pesticide Registration Manual:
http://www.epa.gov/pesticides/bluebook/

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Resources: Pesticide Registration Manual (the "Blue Book")

Chapter 3:	Biopesticides
Chapter 5:	Registration Fees
Chapter 11:	Tolerance Petitions
Chapter 14:	Obtaining an EPA Establishment Number
Chapter 15:	Submitting Data, Confidential Business Information
Chapter 20:	Forms & How to Obtain Them

http://www.epa.gov/pesticides/bluebook/

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PESTICIDE REGISTRATION MANUAL
(AKA "BLUE BOOK")

CHAPTER 21:	SUBMITTING APPLICATIONS, CONTACTING EPA
CHAPTER 11:	TOLERANCE PETITIONS
APPENDIX A:	GUIDANCE DOCUMENTS
APPENDIX B:	REGISTRANT DOCUMENTS
APPENDIX C:	FORMS OVERVIEW TABLE
APPENDIX D:	EXAMPLES OF COMPLETED FORMS

http://www.epa.gov/pesticides/bluebook/

11

COMMISSION IMPLEMENTING DIRECTIVE ../.../EU

of XXX

amending Annexes I, II, III, IV and V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community[1], and in particular points (c) and (d) of the second paragraph of Article 14 thereof,

After consulting the Member States concerned,

Whereas:

(1) In view of increased international trade and in order to protect plants, plant products and other objects, it is technically justified, consistent with the pest risk involved, to add the harmful organisms *Agrilus anxius* Gory and *Anthonomus eugenii* Cano to Section I of Part A of Annex I to Directive 2000/29/EC.

(2) In order to protect the production and the trade of plants, plant products and other objects, it is technically justified, consistent with the pest risk involved, to delete the harmful organisms *Agrilus planipennis* Fairmaire, Citrus greening bacterium and *Diaphorina citri* Kuway from Section I of Part A of Annex II of Directive 2000/29/EC and to add them to Section I of Part A of Annex I to Directive 2000/29/EC.

(3) The presence of the harmful organisms *Bursaphelenchus xylophilus* (Steiner and Bührer) Nickle *et al.* and *Trioza erytreae* Del Guercio poses an unacceptable risk to the production and the trade of plants, plant products and other objects. Therefore, it is technically justified, consistent with the pest risk involved, to move those harmful organisms, from Annex II to Directive 2000/29/EC to Annex I thereto. Information submitted by Portugal shows that those harmful organisms are now known to occur within the Union. Consequently, they should be added to Section II of Part A of Annex I to Directive 2000/29/EC.

(4) It is technically justified, consistent with the pest risk involved to delete the harmful organism *Monilinia fructicola* (Winter) Honey from Section I of Part A of Annex I and *Ciborinia camelliae* Kohn from Section I of Part A of Annex II to Directive 2000/29/EC since those harmful organisms have spread and are established within a

[1] OJ L 169, 10.7.2000, p. 1.

large part of the Union, and no measures are feasible to eradicate them or contain their further spread.

(5) It is technically justified, consistent with the pest risk involved to delete the organism Citrus vein enation woody gall from Section II of Part A of Annex II to Directive 2000/29/EC since it no longer fulfils the criteria to be regulated as a harmful organism due its observed low impact.

(6) Certain plants, plant products and other objects are likely to host the following harmful organisms *Agrilus anxius* Gory, *Agrilus planipennis* Fairmaire, *Amauromyza maculosa* (Malloch), *Anthonomus eugenii* Cano, *Bemisia tabaci* Genn. (non-European populations), *Bursaphelenchus xylophilus* (Steiner and Bührer) Nickle *et al.*, Citrus greening bacterium, *Diaphorina citri* Kuway, *Ditylenchus dipsaci* (Kühn) Filipjev, *Helicoverpa armigera* (Hübner), *Liriomyza huidobrensis* (Blanchard), *Liriomyza sativae* (Blanchard), *Liriomyza trifolii* (Burgess), *Spodoptera eridiana* Cramer, *Spodoptera frugiperda* Smith, *Spodoptera litura* (Fabricius), *Spodoptera littoralis* (Boisd.) and *Trioza erytreae* Del Guercio which are listed or are to be listed in Part A of Annexes I or II to Directive 2000/29/EC. Developments in scientific and technical knowledge, show that the special requirements set out in Part A of Annex IV to Directive 2000/29/EC are inadequate to reduce to an acceptable level, the phytosanitary risk caused by the introduction of those plants, plant products and other objects into the Union, and their movement within the Union. Therefore it is necessary to amend those special requirements and to add additional special requirements. In the case of *Bursaphelenchus xylophilus* (Steiner and Bührer) Nickle *et al.*, the special requirements set out in Section I of Part A of Annex IV to Directive 2000/29/EC should also be amended to align them with Union rules on internal movement against this harmful organism.

(7) As regards certain plants, plant products and other objects not listed in Part A of Annex IV to Directive 2000/29/EC, developments in scientific and technical knowledge, show that their introduction into the Union, and their movement within the Union may pose an unacceptable phytosanitary risk due to their likelihood to host the harmful organisms referred to in recital 5. Therefore it is necessary that those plants, plant products and other objects should be listed in Part A of Annex IV.

(8) In addition, the plants, plant products or other objects referred to in recital 6 should be subject to plant health inspections before being introduced, or moved within, the Union. Therefore, those plants, plant products and other objects should be listed in Parts A and B of Annex V to Directive 2000/29/EC.

(9) Frequent interceptions at import of *Manihot esculenta* Crantz, of *Limnophila* L. and *Eryngium* L., and of *Capsicum* L have shown that the leaves of *Manihot esculenta* Crantz, the leafy vegetables of *Limnophila* L. and *Eryngium* L., and the fruits of *Capsicum* L are likely to host harmful organisms listed in Annexes I and II to Directive 2000/29/EC. Therefore those plants should be subject to a plant health inspection before being introduced into the Union and their introduction should only be permitted if they are accompanied by a phytosanitary certificate. Consequently, they should be listed in Section I of Part B of Annex V.

(10) Taking into account the revised FAO International Standard for Phytosanitary Measures No. 15 "Regulation of wood packaging material in international trade" it is considered that the current approach in Directive 2000/29/EC to impose different requirements, depending on whether the wood packaging material is actually in use or not, should be abandoned, since this approach is not anymore technically justified.

Section I of Part A of Annex IV to Directive 2000/29/EC should be amended accordingly.

(11) Similarly, wood used to wedge or support all types of cargo should be considered a type of wood packaging material, in line with the definitions in the International Standard for Phytosanitary Measures No. 15, since there is no technical justification anymore for regulating it separately from other types of wood packaging material. Section I of Part A of Annex IV to Directive 2000/29/EC should be amended accordingly

(12) It is considered that the formulation of the phytosanitary requirements based on a heat treatment of wood and isolated bark need to be amended to clarify that the requested heating time refers to continuous minutes, and that the requested temperature needs to be achieved throughout the entire profile of the wood or isolated bark in order to reach successful elimination of wood-infesting harmful organisms. Section I of Part A of Annex IV to Directive 2000/29/EC should be amended accordingly.

(13) The CN codes for coniferous wood need to be updated in Part B of Annex V to Directive 2000/29/EC, to cover coniferous wood of a thickness not exceeding 6 mm, which according to a recent pest risk analysis also poses a risk for the introduction of *Bursaphelenchus xylophilus* (Steiner and Bührer) Nickle *et al.*.

(14) The names of *Pseudomonas solanacearum* (Smith) Smith, *Lycopersicon lycopersicum* (L.) Karsten ex Farw. and citrus greening bacterium should be amended in line with the revised scientific denomination of those organism. *Pseudomonas solanacearum* (Smith) Smith should be referred to as *Ralstonia solanacearum* (Smith) Yabuuchi *et al.*. *Lycopersicon lycopersicum* (L.) Karsten ex Farw. should be referred to as *Solanum lycopersicum* L.. The, Citrus greening bacterium should be referred to as *Candidatus* Liberibacter spp., causal agent of Huanglongbing disease of citrus/citrus greening.

(15) Council Directive 2007/33/EC[2] establishes measures to be taken against European populations of potato cyst nematodes (*Globodera pallida* (Stone) Behrens and *Globodera rostochiensis* (Wollenweber) Behrens) in order to determine their distribution, to prevent their spread and to control them. The current provisions of Directive 2000/29/EC concerning potato cyst nematodes (*Globodera pallida* (Stone) Behrens and *Globodera rostochiensis* (Wollenweber) Behrens) should be updated to align with the requirements of Directive 2007/33/EC. Annexes IV and V to Directive 2000/29/EC should therefore be amended accordingly.

(16) By Commission Regulation (EC) No 690/2008[3], certain zones are recognised as protected zones in respect of various harmful organisms. Regulation (EC) No 690/2008 has been amended to take account of the latest developments with regard to the protected zones within the Union and the following harmful organisms: Citrus tristeza virus (European strains), *Erwinia amylovora* (Burr.) Winsl. *et al.* and Grapevine flavescence dorée MLO. It is therefore necessary to amend Annexes I to V to Directive 2000/29/EC accordingly, to ensure that the requirements concerning protected zones with regard to the respective harmful organisms are consistent.

(17) Moreover, several areas within the Union which have been recognised as protected zones with regard to certain harmful organisms, no longer fulfil the requirements

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2 Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/464/EEC, OJ L 156, 16.6.2007, p. 12.

3 Commission Regulation (EC) No 690/2008 of 4 July 2008 recognising protected zones exposed to particular plant health risks in the Community, OJ L 193, 22.7.2008, p. 1.

because those harmful organisms are now established there. Those areas are the following: the autonomous communities of Castilla la Mancha, Murcia, Navarra and La Rioja, and the Comarca of the Community of Calatayud (Aragon) and the province of Guipuzcoa (Basque Country) (Spain), Friuli-Venezia Giulia and the province of Sondrio (Lombardy) (Italy), the communes of Ohrady, Topoľníky and Trhová Hradská (Slovakia) with regard to *Erwinia amylovora* (Burr.) Winsl. *et al.*; the Regional Unit of Argolida and Chania (Greece), Corsica (France) and Algarve (Portugal) with regard to Citrus tristeza virus (European strains). Part B of Annex II, Part B of Annex III and Part B of Annex IV to Directive 2000/29/EC should be amended accordingly.

(18) From a recent pest risk analysis carried out by France it emerges that *Ips amitinus* Eichhof does not pose an unacceptable phytosanitary risk in Corsica (France). Therefore Corsica should be removed from the list of protected zones with regard to this harmful organism. Part B of Annex II and Part B of Annex IV to Directive 2000/29/EC should be amended accordingly.

(19) From information provided by the United Kingdom it appears that *Cryphonectria parasitica* (Murrill) Barr is not present in the Isle of Man, and that the Isle of Man fulfils the conditions set out in point (h) of Article 2(1) of Directive 2000/29/EC for the establishment of a protected zone with respect to that harmful organism. Part B of Annex II and Part B of Annex IV to Directive 2000/29/EC should be amended accordingly.

(20) In order to protect the production and trade of plants, plant products and other objects, it is technically justified, consistent with the pest risk involved, to add the harmful organisms *Dryocosmus kuriphilus* Yasumatsu and *Thaumatopoea processionea* L. to Part B of Annex I to Directive 2000/29/EC.

(21) From information provided by Ireland, Portugal and the United Kingdom it appears that the territories of these countries are free from *Dryocosmus kuriphilus* Yasumatsu, and that those territories fulfil the conditions set out in point (h) of Article 2(1) of Directive 2000/29/EC for the establishment of a protected zone with respect to that harmful organism. Part B of Annex I and Part B of Annex IV to Directive 2000/29/EC should be amended accordingly. Similarly, Part B of Annex IV and Part A of Annex V to Directive 2000/29/EC should be amended to introduce requirements for the movement of certain plants, plant products and other objects into the protected zones.

(22) From information provided by Ireland and the United Kingdom it appears that the territory of Ireland and part of the territory of the United Kingdom are free from *Thaumatopoea processionea* L., and that those areas fulfil the conditions set out in point (h) of Article 2(1) of Directive 2000/29/EC for the establishment of a protected zone with respect to that harmful organism. Part B of Annex I and Part B of Annex IV to Directive 2000/29/EC should be amended accordingly. Similarly, Part B of Annex IV and Part A of Annex V to Directive 2000/29/EC should be amended to introduce requirements for the movement of certain plants, plant products and other objects into the protected zones.

(23) From information provided by France and Italy, it appears that Picardie (département de l'Aisne) and Ile de France (communes de Citry, Nanteuil-sur-Marne et Saâcy-sur-Marne) and Apulia are free from Grapevine flavescence dorée MLO, and they fulfil the conditions set out in point (h) of Article 2(1) of Directive 2000/29/EC for the establishment of a protected zone with respect to that harmful organism. Part B of

Annex II and Part B of Annex IV to Directive 2000/29/EC should be amended accordingly.

(24) From information provided by Switzerland it appears that Switzerland (except the Canton of Ticino and the Misox Valley) is free from Grapevine flavescence dorée MLO. It is therefore appropriate to include Switzerland (except the Canton of Ticino and the Misox Valley) as an area wherefrom plants of *Vitis* L. may be introduced into protected zones in respect of the organism. Part B of Annex IV to Directive 2000/29/EC should be amended accordingly.

(25) A recent pest risk analyses shows that the current requirements for introduction into, and movement within, certain protected zones of plants, plant products and other objects with regard to *Cryphonectria parasitica* (Murrill) Barr are inadequate to reduce the phytosanitary risk in question to acceptable levels. Those requirements should be updated. Part B of Annex II, Part B of Annex IV, Section II of Part A of Annex V and Section II of Part B of Annex V to Directive 2000/29/EC should be amended accordingly.

(26) Directive 2000/29/EC should therefore be amended accordingly.

(27) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes I, II, III, IV and V to Directive 2000/29/EC are amended in accordance with the Annex to this Directive.

Article 2

Member States shall adopt and publish, by (...) [*Office of Publications, please insert the date of the last day of the second month following the month of the entry into force of this Directive*] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from (...)[*Office of Publications, please insert the date of the day next to the above*].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the third day following that of its publication in the *Official Journal of the European Union.*

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
The President
[...]

Annex

Annexes I, II, III, IV and V to Directive 2000/29/EC are amended as follows:

(1) Annex I is amended as follows:

(a) Part A is amended as follows:

(i) Section I is amended as follows:

(-) In heading (a), the following point 1.1 is inserted after point 1:

"1.1. *Agrilus anxius* Gory"

(-) In heading (a), the following point 1.2 is inserted after point 1.1:

"1.2. *Agrilus planipennis* Fairmaire"

(-) In heading (a), the following point 1.3 is inserted after point 1.2:

"1.3. *Anthonomus eugenii* Cano"

(-) In heading (a), the following point 10.5 is inserted after point 10.4:

"10.5. *Diaphorina citri* Kuway"

(-) In heading (b), the following point 0.1 is inserted before point 1:

"0.1.*Candidatus* Liberibacter spp., causal agent of Huanglongbing disease of citrus/citrus greening"

(-) In heading (c), point 9 is deleted.

(ii) Section II is amended as follows:

(-) In heading (a) , the following point 0.01 is inserted before point 0.1:

"0.01. *Bursaphelenchus xylophilus* (Steiner and Bührer) Nickle *et al.*"

(-) In heading (a) , the following point 10 is inserted after point 9:

"10. *Trioza erytreae* Del Guercio"

(-) In heading (b), in point 2 the text "*Pseudomonas solanacearum* (Smith) Smith " is replaced by "*Ralstonia solanacearum* (Smith) Yabuuchi *et al.*"

(b) Heading (a) of Part B, is amended as follows:

(i) The following point 1.2 is inserted after point 1.1:

"1.2.	*Dryocosmus kuriphilus* Yasumatsu	IRL, P, UK"

(ii) The following point 5 is inserted after point 4:

"5.	*Thaumatopoea processionea* L.	IRL, UK (excluding the local authority areas of Barnet; Brent; Bromley; Camden; City of London; City of Westminster; Croydon; Ealing; Elmbridge District; Epsom and Ewell District; Hackney; Hammersmith & Fulham; Haringey; Harrow; Hillingdon; Hounslow; Islington; Kensington & Chelsea; Kingston upon Thames; Lambeth; Lewisham; Merton; Reading; Richmond Upon Thames; Runnymede District; Slough; South Oxfordshire; Southwark; Spelthorne District; Sutton; Tower Hamlets; Wandsworth and West Berkshire)"

(2) Annex II, is amended as follows:

(a) Part A is amended as follows:

(i) Section I is amended as follows:

(-) Heading (a) is amended as follows:

(-) Point 1.1 is deleted,

(-) Point 8 is deleted,

(-) Point 10 is deleted,

(-) Point 31 is deleted.

(-) In heading (b) point 1 is deleted.

(-) In heading (c), point 7 is deleted.

(-) In point 5.1, of heading (d), the text in the right hand column, "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." is replaced by "*Solanum lycopersicum* L."

(ii) Section II is amended as follows:

(-) Heading (b) is amended as follows:

(-) In point 2, the text in the right hand column, "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." is replaced by "*Solanum lycopersicum* L."

(-) In point 9, the text in the right hand column, "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." is replaced by "*Solanum lycopersicum* L."

(-) Heading (d) is amended as follows:

(-) Point 5 is deleted.

(-) In point 15, the text in the right hand column, "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." is replaced by "*Solanum lycopersicum* L."

(-) In point 16, the text in the right hand column, "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." is replaced by "*Solanum lycopersicum* L."

(b) Part B is amended as follows:

(i) In point 6(a) of heading (a), the text in the third column, protected zone(s), is replaced by the following:

"EL, IRL, UK".

(ii) In point 2 of heading (b), the text in the third column, protected zone(s), is replaced by the following:

"E (except the autonomous communities of Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja, and the Comarca of the Community of Calatayud (Aragon) and the province of Guipuzcoa (Basque Country)), EE, F (Corsica), IRL, I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua and Sondrio), Marche, Molise, Piedmont, Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto

(except the provinces of Rovigo and Venice, the communes Castelbaldo, Barbona, Boara Pisani, Masi, Piacenza d'Adige, S. Urbano, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT, P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska), SK (except the communes of Blahová, Horné Mýto, Ohrady, Okoč, Topoľníky and Trhová Hradská (Dunajská Streda County), Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málinec (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuše and Zatín (Trebišov County)), FI, UK (Northern Ireland, Isle of Man and Channel Islands).".

(iii) Point 0.1 of heading (c) is replaced by the following:

"0.1. *Cryphonectria parasitica* (Murrill.) Barr.	Wood, excluding wood which is bark-free, isolated bark, and plants intended for planting of *Castanea* Mill.	CZ, IRL, S, UK"

(iv) Heading (d) is amended as follows:

(-) In point 1, the text in the third column, protected zone(s), is replaced by the following:

'EL (except the Regional Units of Argolida and Chania), M, P (except Algarve and Madeira)';

(-) In point 2, the text in the third column, protected zone(s), is replaced by the following:

'CZ, FR (Alsace, Champagne-Ardenne, Picardie (département de l'Aisne), Ile de France (communes de Citry, Nanteuil-sur-Marne et Saâcy-sur-Marne) and Lorraine), Italy (Apulia, Basilicata and Sardinia)'.

(3) Part B of Annex III, is amended as follows:

(a) In point 1, the text in the second column, protected zone(s), is replaced by the following:

"E (except the autonomous communities of Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja, and the Comarca of the Community of Calatayud (Aragon) and the province of Guipuzcoa (Basque Country)), EE, F (Corsica), IRL, I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua and Sondrio), Marche, Molise, Piedmont, Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Castelbaldo, Barbona, Boara Pisani, Masi, Piacenza d'Adige, S. Urbano, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT, P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska), SK (except the communes of Blahová, Horné Mýto, Ohrady, Okoč, Topoľníky and Trhová Hradská (Dunajská Streda County), Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málinec (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuše and Zatín (Trebišov County)), FI, UK (Northern Ireland, Isle of Man and Channel Islands).".

(b) In point 2, the text in the second column, protected zone(s), is replaced by the following:

"E (except the autonomous communities of Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja, and the Comarca of the Community of Calatayud (Aragon) and the province of Guipuzcoa (Basque Country)), EE, F (Corsica), IRL, I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua and Sondrio), Marche, Molise, Piedmont, Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Castelbaldo, Barbona, Boara Pisani, Masi, Piacenza d'Adige, S. Urbano, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT, P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska), SK (except the communes of Blahová, Horné Mýto, Ohrady, Okoč, Topoľníky and Trhová Hradská (Dunajská Streda County), Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málinec (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuše and Zatín (Trebišov County)), FI, UK (Northern Ireland, Isle of Man and Channel Islands).".

(4) Annex IV is amended as follows:

(a) Part A is amended as follows:

(i) Section I is amended as follows:

(-) Point 1.1 is replaced by the following:

"1.1. Whether or not listed among the CN codes in Annex V, Part B, wood of conifers (Coniferales), except that of *Thuja* L. and *Taxus* L., other than in the form of: – chips, particles, sawdust, shavings, wood waste and scrap obtained in whole or part from these conifers, – wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment, – wood of *Libocedrus decurrens* Torr. where there is evidence that the wood has been processed or manufactured for pencils using heat treatment to achieve a minimum temperature of 82 °C for a seven to eight-day period, but including that which has not kept its natural round surface, originating in Canada, China, Japan, the Republic of Korea, Mexico, Taiwan and the USA, where *Bursaphelenchus xylophilus* (Steiner et Bührer) Nickle *et al.* is known to occur.	Official statement that the wood has undergone an appropriate: (a) heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 continuous minutes throughout the entire profile of the wood (including at its core). There shall be evidence thereof by a mark 'HT' put on the wood or on any wrapping in accordance with current usage, and on the certificates referred to in Article 13.1.(ii), or (b) fumigation to a specification approved in accordance with the procedure laid down in Article 18.2. There shall be evidence thereof by indicating on the certificates referred to in Article 13.1.(ii), the active ingredient, the minimum wood temperature, the rate (g/m 3) and the exposure time (h), or (c) chemical pressure impregnation with a product approved in accordance with the procedure laid down in Article 18.2. There shall be evidence thereof by indicating on the certificates referred to in Article 13.1.(ii), the active ingredient, the pressure (psi or kPa) and the concentration (%) and official statement that subsequent to its treatment the wood was transported until leaving the country issuing that statement outside of the flight season of the vector *Monochamus*, taking into account a safety margin of four additional weeks at the beginning and at the end of the expected flight season, or, except in the case of wood free from any bark, with a protective covering ensuring that infestation with *Bursaphelenchus xylophilus* (Steiner et Bührer) Nickle *et al.* or its vector cannot occur."

(-) Point 1.2 is is replaced by the following:

"1.2. Whether or not listed among the CN codes in Annex V, Part B, wood of conifers (Coniferales) in the form of: — chips, particles, sawdust, shavings, wood waste and scrap obtained in whole or part from these conifers, originating in Canada, China, Japan, the Republic of Korea, Mexico, Taiwan and the USA, where *Bursaphelenchus xylophilus* (Steiner et Bührer) Nickle et al. is known to occur.	Official statement that the wood has undergone an appropriate: (a) heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 continuous minutes throughout the entire profile of the wood (including at its core), the latter to be indicated on the certificates referred to in Article 13.1.(ii), or (b) fumigation to a specification approved in accordance with the procedure laid down in Article 18.2. There shall be evidence thereof by indicating on the certificates referred to in Article 13.1.(ii), the active ingredient, the minimum wood temperature, the rate (g/m 3) and the exposure time (h), and official statement that subsequent to its treatment the wood was transported until leaving the country issuing that statement outside of the flight season of the vector *Monochamus*, taking into account a safety margin of four additional weeks at the beginning and at the end of the expected flight season, or, except in the case of wood free from any bark, with a protective covering ensuring that infestation with *Bursaphelenchus xylophilus* (Steiner et Bührer) Nickle *et al.* or its vector cannot occur."

(-) Point 1.3 is replaced by the following:

"1.3 Whether or not listed among the CN codes in Annex V, Part B, wood of *Thuja* L. and *Taxus* L., other than in the form of: – chips, particles, sawdust, shavings, wood waste and scrap obtained in whole or part from these conifers, – wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment, but including wood which has not kept its natural round surface, originating in Canada, China, Japan, the Republic of Korea, Mexico, Taiwan and the USA, where *Bursaphelenchus xylophilus* (Steiner et Bührer) Nickle *et al.* is known to occur.	Official statement that the wood: (a) is bark-free, or (b) has undergone kiln-drying to below 20 % moisture content, expressed as a percentage of dry matter, achieved through an appropriate time/temperature schedule. There shall be evidence thereof by a mark 'kiln-dried' or 'K.D.' or another internationally recognised mark, put on the wood or on any wrapping in accordance with current usage, or (c) has undergone an appropriate heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 continuous minutes throughout the entire profile of the wood (including at its core). There shall be evidence thereof by a mark 'HT' put on the wood or on any wrapping in accordance with current usage, and on the certificates referred to in Article 13.1.(ii), or (d) has undergone an appropriate fumigation to a specification approved in accordance with the procedure laid down in Article 18.2. There shall be evidence thereof by indicating on the certificates referred to in Article 13.1.(ii), the active ingredient, the minimum wood temperature, the rate (g/m 3) and the exposure time (h), or (e) has undergone an appropriate chemical pressure impregnation with a product approved in accordance with the procedure laid down in Article 18.2. There shall be evidence thereof by indicating on the certificates referred to in Article 13.1.(ii), the active ingredient, the pressure (psi or kPa) and the concentration (%)."

(-) Point 1.4 is deleted,

(-) Point 1.5 is replaced by the following:

"1.5 Whether or not listed among the CN codes in Annex V, Part B, wood of conifers (Coniferales), other than in the form of: – chips, particles, sawdust, shavings, wood waste and scrap obtained in whole or part from these conifers, – wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether actually in use or not in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment, but including that which has not kept its natural round surface, originating in Russia, Kazakhstan and Turkey. –	Official statement that the wood: (a) originates in areas known to be free from: — *Monochamus* spp. (non-European) — *Pissodes* spp. (non-European) — *Scolytidae* spp. (non-European) The area shall be mentioned on the certificates referred to in Article 13.1.(ii), under the rubric 'place of origin,' or (b) is bark-free and free from grub holes, caused by the genus *Monochamus* spp. (non-European), defined for this purpose as those which are larger than 3 mm across, or (c) has undergone kiln-drying to below 20 % moisture content, expressed as a percentage of dry matter, achieved through an appropriate time/temperature schedule. There shall be evidence thereof by a mark 'kiln-dried' or 'K.D'. or another internationally recognised mark, put on the wood or on any wrapping in accordance with the current usage, or (d) has undergone an appropriate heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 continuous minutes throughout the entire profile of the wood (including at its core). There shall be evidence thereof by a mark 'HT' put on the wood or on any wrapping in accordance with current usage, and on the certificates referred to in Article 13.1.(ii), or (e) has undergone an appropriate fumigation to a specification approved in accordance with the procedure laid down in Article 18.2. There shall be evidence thereof by indicating on the certificates referred to in Article 13.1.(ii), the active ingredient, the minimum wood temperature, the rate (g/m 3) and the exposure time (h), or (f) has undergone an appropriate chemical pressure impregnation with a product approved in accordance with the procedure laid down in Article 18.2. There shall be evidence thereof by indicating on the certificates referred to in Article 13.1.(ii), the active ingredient, the pressure (psi or kPa) and the concentration (%)."

(-) Point 1.6, is replaced by the following:

"1.6 Whether or not listed among the CN codes in Annex V, Part B, wood of conifers (Coniferales), other than in the form of: – chips, particles, sawdust, shavings, wood waste and scrap obtained in whole or part from these conifers, – wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether actually in use or not in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment, but including that which has not kept its natural round surface, originating in third countries, other than: — Russia, Kazakhstan and Turkey, — European countries, — Canada, China, Japan, the Republic of Korea, Mexico, Taiwan and the USA, where *Bursaphelenchus xylophilus* (Steiner et Bührer) Nickle et al. is known to occur.	Official statement that the wood: (a) is bark-free and free from grub holes, caused by the genus *Monochamus* spp. (non-European), defined for this purpose as those which are larger than 3 mm across, or (b) has undergone kiln-drying to below 20 % moisture content, expressed as a percentage of dry matter, achieved through an appropriate time/temperature schedule. There shall be evidence thereof by a mark 'kiln-dried' or 'K.D' or another internationally recognised mark, put on the wood or on any wrapping in accordance with current usage, or (c) has undergone an appropriate fumigation to a specification approved in accordance with the procedure laid down in Article 18.2. There shall be evidence thereof by indicating on the certificates referred to in Article 13.1.(ii), the active ingredient, the minimum wood temperature, the rate (g/m 3) and the exposure time (h), or (d) has undergone an appropriate chemical pressure impregnation with a product approved in accordance with the procedure laid down in Article 18.2. There shall be evidence thereof by indicating on the certificates referred to in Article 13.1.(ii), the active ingredient, the pressure (psi or kPa) and the concentration (%), or (e) has undergone an appropriate heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 continuous minutes throughout the entire profile of the wood (including at its core). There shall be evidence thereof by a mark 'HT' put on the wood or on any wrapping in accordance with current usage, and on the certificates referred to in Article 13.1.(ii)."

(-) In the right hand column of point 1.7, heading (e) is replaced by the following:

"(e) has undergone an appropriate heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 continuous minutes throughout the entire profile of the wood (including at its core), the latter to be indicated on the certificates referred to in Article 13.1.(ii).";

(-) Point 2 is replaced by the following:

" 2.	Wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except raw wood of 6 mm thickness or less, and processed wood produced by glue, heat and pressure, or a combination thereof, and dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment, coming from third countries, except Switzerland.	The wood packaging material shall: - be subject to one of the approved treatments as specified in Annex I to FAO International Standard for Phytosanitary Measures No 15 on Regulation of wood packaging material in international trade, and - display a mark as specified in Annex II to that International standard, indicating that the wood packaging material has been subjected to an approved phytosanitary treatment in accordance with this standard."

(-) In point 2.1, the text in the left hand column, is replaced by the following:

" Wood of *Acer saccharum* Marsh., including wood which has not kept its natural round surface, other than in the form of:

– wood intended for the production of veneer sheets,

– chips, particles, sawdust, shavings, wood waste and scrap,

– wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment,

originating in the USA and Canada."

(-) Point 2.3 is replaced by the following:

2.3.	Whether or not listed among CN codes in Annex V, Part B, wood of *Fraxinus* L., *Juglans ailantifolia* Carr., *Juglans mandshurica* Maxim., *Ulmus davidiana* Planch. and *Pterocarya rhoifolia* Siebold & Zucc., other than in the form of – chips, particles, sawdust, shavings, wood waste and scrap, obtained in whole or part from these trees, – wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type	Official statement that: (a) the wood originates in an area recognised as being free from *Agrilus planipennis* Fairmaire in accordance with the procedure referred to in Article 18(2). The name of the area shall be mentioned on the certificates referred to in Article 13.1.(ii); or (b) the bark and at least 2.5 cm of the outer sapwood are removed in a facility authorised and supervised by the national plant protection organisation; or (c) the wood has undergone ionizing irradiation to achieve a minimum absorbed dose of 1 kGy throughout the wood.

	and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment, but including wood which has not kept its natural round surface, and furniture and other objects made of untreated wood, originating in Canada, China, Democratic People's Republic of Korea, Japan, Mongolia, Republic of Korea, Russia, Taiwan and USA	

(-) Point 2.4 is replaced by the following:

2.4.	Whether or not listed among CN codes in Annex V, Part B, wood in the form of chips, particles, sawdust, shavings, wood waste and scrap obtained in whole or in part from *Fraxinus* L., *Juglans ailantifolia* Carr., *Juglans mandshurica* Maxim., *Ulmus davidiana* Planch. and *Pterocarya rhoifolia* Siebold & Zucc. originating in Canada, China, Democratic People's Republic of Korea, Japan, Mongolia, Republic of Korea, Russia, Taiwan and USA	Official statement that the wood originates in an area recognised as being free from *Agrilus planipennis* Fairmaire in accordance with the procedure referred to in Article 18(2). The name of the area shall be mentioned on the certificates referred to in Article 13.1.(ii)

(-) Point 2.5 is replaced by the following:

2.5.	Whether or not listed among CN codes in Annex V, Part B, isolated bark and objects made of bark of *Fraxinus* L., *Juglans ailantifolia* Carr., *Juglans mandshurica* Maxim., *Ulmus davidiana* Planch. and *Pterocarya rhoifolia* Siebold & Zucc. originating in Canada, China, Democratic People's Republic of Korea, Japan, Mongolia, Republic of Korea, Russia, Taiwan and USA	Official statement that the bark originates in an area recognised as being free from *Agrilus planipennis* Fairmaire in accordance with the procedure referred to in Article 18(2). The name of the area shall be mentioned on the certificates referred to in Article 13.1.(ii)

(-) In point 3, the text in the left hand column, is replaced by the following:

" Wood of *Quercus* L., other than in the form of:

- chips, particles, sawdust, shavings, wood waste and scrap,
- casks, barrels, vats, tubs and other coopers' products and parts thereof, of wood, including staves where there is documented evidence that the wood has been produced or manufactured using heat treatment to achieve a minimum temperature of 176 °C for 20 minutes
- Wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type

and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment,

but including wood which has not kept its natural round surface, originating in the USA."

(-) The following points 4.1, 4.2 and 4.3 are inserted after point 3:

" 4.1	Whether or not listed among CN codes in Annex V, Part B, wood of *Betula* L., other than in the form of – chips, particles, sawdust, shavings, wood waste and scrap obtained in whole or part from these trees, – wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment, but including wood which has not kept its natural round surface, and furniture and other objects made of untreated wood, originating in Canada and the USA where *Agrilus anxius* Gory is known to occur.	Official statement that: (a) the bark and at least 2.5 cm of the outer sapwood are removed in a facility authorised and supervised by the national plant protection organisation; or (b) the wood has undergone ionizing irradiation to achieve a minimum absorbed dose of 1 kGy throughout the wood."
" 4.2	Whether or not listed among CN codes in Annex V, Part B, wood chips, particles, sawdust, shavings, wood waste and scrap obtained in whole or in part from *Betula* L.	Official statement that the wood originates in a country known to be free of *Agrilus anxius* Gory."
" 4.3	Whether or not listed among CN codes in Annex V, Part B, bark and objects made of bark of *Betula*, originating in Canada and the USA where *Agrilus anxius* Gory is known to occur.	Official statement that the bark is free from wood."

(-) In point 5, the text in the left hand column, is replaced by the following:

" Wood of *Platanus* L., except that in the form of:

– chips, particles, sawdust, shavings, wood waste and scrap,

– wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment,

but including wood which has not kept its natural round surface, originating in the USA or Armenia."

(-) In point 6, the text in the left hand column, is replaced by the following:

"Wood of *Populus* L., except that in the form of:

- chips, particles, sawdust, shavings, wood waste and scrap,
- wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment,

but including wood which has not kept its natural round surface, originating in countries of the American continent."

(-) In the right hand column of point 7.1, heading (d) is replaced by the following:

"(d) has undergone an appropriate heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 continuous minutes throughout the entire profile of the wood (including at its core), the latter to be indicated on the certificates referred to in Article 13.1.(ii).";

(-) In the right hand column of point 7.2, heading (c) is replaced by the following:

"(c) has undergone an appropriate heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 continuous minutes throughout the entire profile of the wood (including at its core), the latter to be indicated on the certificates referred to in Article 13.1.(ii).";

(-) In point 7.3, the text in the right hand column, is replaced by the following:

"Official statement that the isolated bark:

(a) has been subjected to an appropriate fumigation with a fumigant approved in accordance with the procedure laid down in Article 18.2. There shall be evidence thereof by indicating on the certificates referred to in Article 13.1.(ii), the active ingredient, the minimum bark temperature, the rate (g/m 3) and the exposure time (h),

or

(b) has undergone an appropriate heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 continuous minutes throughout the entire profile of the bark (including at its core), the latter to be indicated on the certificates referred to in Article 13.1.(ii).",

and

official statement that subsequent to its treatment the bark was transported until leaving the country issuing that statement outside of the flight season of the vector *Monochamus*, taking into account a safety margin of four additional weeks at the beginning and at the end of the expected flight season, or with a protective covering ensuring that infestation with *Bursaphelenchus xylophilus* (Steiner et Bührer) Nickle *et al.* or its vector cannot occur."

(-) Point 8 is deleted,

(-) Point 11.4 is replaced by the following:

11.4.	Plants of *Fraxinus* L., *Juglans ailantifolia* Carr., *Juglans mandshurica* Maxim., *Ulmus davidiana* Planch. and *Pterocarya rhoifolia* Siebold & Zucc., other than fruit and seeds, but including cut branches with or without foliage, originating in Canada, China, Democratic People's Republic of Korea, Japan, Mongolia, Republic of Korea, Russia, Taiwan and USA	Official statement that the plants originate in an area recognised as being free from *Agrilus planipennis* Fairmaire in accordance with the procedure referred to in Article 18(2). The name of the area shall be mentioned on the certificates referred to in Article 13.1.(ii)

(-) The following point 11.5 is inserted after point 11.4:

" 11.5	Plants of *Betula* L., other than fruit and seeds, but including cut branches of *Betula* L. with or without foliage	Official statement that the plants originate in a country known to be free of *Agrilus anxius* Gory."

(-) Points 15 and 16 are deleted,

(-) The following points 18.1,18.2 and 18.3 are inserted after point 18:

"18.1	Plants of *Aegle* Corrêa, *Aeglopsis* Swingle, *Afraegle* Engl, *Atalantia* Corrêa, *Balsamocitrus* Stapf, *Burkillanthus* Swingle, *Calodendrum* Thunb., *Choisya* Kunth, *Clausena* Burm. f., *Limonia* L., *Microcitrus* Swingle., *Murraya* J. Koenig ex L., *Pamburus* Swingle, *Severinia* Ten., *Swinglea* Merr., *Triphasia* Lour. and *Vepris* Comm., other than fruit (but including seeds); and seeds of *Citrus* L., *Fortunella* Swingle and *Poncirus* Raf., and their hybrids, originating in third countries	Without prejudice to the provisions applicable to the plants in Annex IV(A)(I)(18.2) and (18.3), official statement that the plants originate in a country recognised as being free from *Candidatus* Liberibacter spp., causal agent of Huanglongbing disease of citrus/citrus greening, in accordance with the procedure referred to in Article 18 (2)
18.2.	Plants of *Casimiroa* La Llave, *Clausena* Burm. f., *Vepris* Comm, *Zanthoxylum* L., other than fruit and seed, originating in third countries	Without prejudice to the provisions applicable to the plants in Annex IV(A)I(18.1) and (18.3), official statement that: (a) the plants originate in a country in which *Trioza erytreae* Del Guercio is known not to occur or (b) the plants originate in an area free from *Trioza erytreae* Del Guercio, established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures, and which is mentioned on the certificates referred to in Article 13.1 (ii) of this Directive under the rubric 'Additional declaration'.

18.3.	Plants of *Aegle* Corrêa, *Aeglopsis* Swingle, *Afraegle* Engl., *Amyris* P. Browne, *Atalantia* Corrêa, *Balsamocitrus* Stapf, *Choisya* Kunth, *Citropsis* Swingle & Kellerman, *Clausena* Burm. f., *Eremocitrus* Swingle, *Esenbeckia* Kunth., *Glycosmis* Corrêa, *Limonia* L., *Merrillia* Swingle, *Microcitrus* Swingle, *Murraya* J. Koenig ex L., *Naringi* Adans., *Pamburus* Swingle, *Severinia* Ten., *Swinglea* Merr., *Tetradium* Lour., *Toddalia* Juss., *Triphasia* Lour., *Vepris* Comm., *Zanthoxylum* L., other than fruit and seed, originating in third countries	Without prejudice to the provisions applicable to the plants in Annex IV(A)I(18.1) and (18.2), official statement that: (a) the plants originate in a country in which <u>*Diaphorina citri*</u> Kuway is known not to occur or (b) the plants originate in an area free from <u>*Diaphorina citri*</u> Kuway, established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures, and which is mentioned on the certificates referred to in Article 13.1 (ii) of this Directive under the rubric 'Additional declaration'. "

(-) In headings (aa) and (bb) of point 25.4, the words "*Pseudomonas solanacearum* (Smith) Smith" are replaced by "*Ralstonia solanacearum* (Smith) Yabuuchi *et al.*"

(-) In the right hand column of point 25.4.1, the words "*Pseudomonas solanacearum* (Smith) Smith" are replaced by "*Ralstonia solanacearum* (Smith) Yabuuchi *et al.*"

(-) In the left hand column of point 25.6, the words "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." are replaced by "*Solanum lycopersicum* L."

(-) Point 25.7 is replaced by the following:

"25.7 Plants of *Capsicum annuum* L., *Solanum lycopersicum* L., *Musa* L., *Nicotiana* L. and *Solanum melongena* L., intended for planting other than seeds, originating in countries where *Ralstonia solanacearum* (Smith) Yabuuchi *et al.* is known to occur	Without prejudice to the provisions applicable to the plants listed in Annex III(A)(11) and (13), and Annex IV(A)(I)(25.5) and (25.6), where appropriate, official statement that: (a) the plants originate in areas which have been found free from *Ralstonia solanacearum* (Smith) Yabuuchi *et al.*; or (b) no symptoms of *Ralstonia solanacearum* (Smith) Yabuuchi *et al.* have been observed on the plants at the place of production since the beginning of the last complete cycle of vegetation."

(-) Point 27.1 is replaced by the following:

"27.1	Plants of *Dendranthema* (DC.) Des Moul., *Dianthus* L. and *Pelargonium* l'Hérit. ex Ait., intended for planting, other than seeds	Official statement that: (aa) the plants originate in an area free from *Helicoverpa armigera* (Hübner) and *Spodoptera littoralis* (Boisd.), established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures or (a) no signs of *Helicoverpa armigera* (Hübner), or *Spodoptera littoralis* (Boisd.) have been observed at the place of production since the beginning of the last complete cycle of vegetation or (b) the plants have undergone appropriate treatment to protect them from the said organisms.

(-) Point 27.2 is replaced by the following:

"27.2	Plants of *Dendranthema* (DC.) Des Moul., *Dianthus* L. and *Pelargonium* l'Hérit. ex Ait., other than seeds	Without prejudice to the requirements applicable to the plants listed in Annex IV(A) (I)(27.1), official statement that: aa) the plants originate in an area free from *Spodoptera eridiana* Cramer, *Spodoptera frugiperda* Smith and *Spodoptera litura* (Fabricius), established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures or (a) no signs of *Spodoptera eridiana* Cramer, *Spodoptera frugiperda* Smith, or *Spodoptera litura* (Fabricius) have been observed at the place of production since the beginning of the last complete cycle of vegetation or (b) the plants have undergone appropriate treatment to protect them from the said organisms.

(-) In the left hand column of point 28.1, the words, "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." are replaced by "*Solanum lycopersicum* L."

(-) In the right hand column of point 32.1, the following heading (d) is added after heading (c):

32.1

"or (d) originate from plant material (explant) which is free from *Liriomyza sativae* (Blanchard) and *Amauromyza maculosa* (Malloch); are grown *in vitro* in a sterile medium under sterile conditions that preclude the possibility of infestation with *Liriomyza sativae* (Blanchard) and *Amauromyza maculosa* (Malloch); and are shipped in transparent containers under sterile conditions."

(-) In the right hand column of point 32.3, the following heading (d) is added after heading (c):

32.3

"or (d) the plants originate from plant material (explant) which is free from *Liriomyza huidobrensis* (Blanchard) and *Liriomyza trifolii* (Burgess); are grown *in vitro* in a sterile medium under sterile conditions that preclude the possibility of infestation with *Liriomyza huidobrensis* (Blanchard) and *Liriomyza trifolii* (Burgess); and are shipped in transparent containers under sterile conditions."

(-) Point 33 is replaced by the following:

"33.	Plants with roots, planted or intended for planting, grown in the open air	Official statement that: (a) the place of production is known to be free from *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis *et al.* and *Synchytrium endobioticum* (Schilbersky) Percival. and (b) the plants originate from a field known to be free from *Globodera pallida* (Stone) Behrens and *Globodera rostochiensis* (Wollenweber) Behrens."

(-) In the right hand column of point 36.1, in, the following heading (d) is added after heading (c):

38.1

"or (d) originate from plant material (explant) which is free from *Thrips palmi* Karny; are grown *in vitro* in a sterile medium under sterile conditions that preclude the possibility of infestation with *Thrips palmi* Karny; and are shipped in transparent containers under sterile conditions."

(-) The following point 36.3 is inserted after point 36.2:

"36.3	Fruits of *Capsicum* L. originating in Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Nicaragua, Panama, Puerto Rico, USA and French Polynesia where *Anthonomus eugenii* Cano is known to occur	Official statement that the fruits: (a) originate in an area free from *Anthonomus eugenii* Cano, established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures, and which is mentioned on the certificates referred to in Article 13.1 (ii) of this Directive under the rubric 'Additional declaration' or (b) originate in a place of production, established in the country of export by the national plant protection organisation in that country, as being free from *Anthonomus eugenii* Cano, in accordance with relevant International Standards for Phytosanitary Measures, and which is mentioned on the certificates referred to in Article 13.1 (ii) of this Directive under the rubric 'Additional declaration', and declared free from *Anthonomus eugenii* Cano on official inspections carried out at least monthly during the two months prior to export, at the place of production and its immediate vicinity"

(-) Point 38.1 is deleted.

(-) In the right hand column of point 45.1, the following heading (d) is added after heading (c):

45.1

"or (d) originate from plant material (explant) which is free from *Bemisia tabaci* Genn. (non-European populations); are grown *in vitro* in a sterile medium under sterile conditions that preclude the possibility of infestation with *Bemisia tabaci* Genn. (non-European populations); and are shipped in transparent containers under sterile conditions."

(-) In the left hand column of point 45.3, the words "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." are replaced by "*Solanum lycopersicum* L."

(-) In the right hand column of point 46, the following heading (d) is added after heading (c):

46

"or (d) the plants originate from plant material (explant) which is free from *Bemisia tabaci* Genn. (non-European populations) and which did not show any symptoms of the relevant harmful organisms; are grown *in vitro* in a sterile medium under sterile conditions that preclude the possibility of infestation with *Bemisia tabaci* Genn. (non-European populations); and are shipped in transparent containers under sterile conditions."

(-) In the left hand column of point 48, the words "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." are replaced by "*Solanum lycopersicum* L."

(-) In the right hand column of point 49.1, the following heading (c) is added after heading (b):

"or (c) the seeds have been subjected to an appropriate physical treatment against *Ditylenchus dipsaci* (Kühn) Filipjev and have been found to be free of this harmful organism after laboratory tests on a representative sample."

(5) Annex IV, Part A, Section II is amended as follows:

(-) Point 10 is replaced by the following:

"10.	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., and their hybrids, other than fruit and seeds	Official statement that: (a) the plants originate in areas known to be free from *Spiroplasma citri* Saglio *et al.*, *Phoma tracheiphila* (Petri), Kanchaveli and Gikashvili and *Citrus* tristeza virus (European strains); or (b) the plants derive from a certification scheme requiring them to be derived in direct line from material which has been maintained under appropriate conditions and has been subjected to official individual testing for, at least, *Citrus tristeza* virus (European strains), using appropriate tests or methods in line with international standards, and have been growing permanently in an insectproof glasshouse or in an isolated cage on which no symptoms of *Spiroplasma citri* Saglio *et al.*, *Phoma tracheiphila* (Pandri) Kanchaveli and Gikashvili and *Citrus tristeza* virus (European strains) have been observed; or (c) the plants: – have been derived from a certification scheme requiring them to be derived in direct line from material which has been maintained under appropriate conditions and has been subjected to official individual testing for, at least *Citrus tristeza* virus (European strains), using appropriate tests or methods in line with international standards, and has been found in these tests, free from *Citrus tristeza* virus (European strains), and certified free from at least *Citrus tristeza* virus (European strains) in official individual tests carried out according to the methods mentioned in this indent, and – have been inspected and no symptoms of *Spiroplasma citri* Saglio *et al.*, *Phoma tracheiphila* (Pandri) Kanchaveli et Gikashvili, and *Citrus tristeza* virus (European strains) have been observed since the beginning of the last complete cycle of vegetation."

(-) The following point 10.1 is inserted after point 10:

"10.1.	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., and their hybrids *and Casimiroa* La Llave, *Clausena* Burm f., *Vepris* Comm., *Zanthoxylum* L., other than fruit and seed.	Official statement that the plants originate in an area free from *Trioza erytreae* Del Guercio, established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures"

(-) Point 18.1 is replaced by the following:

"18.1. Tubers of *Solanum tuberosum* L., intended for planting	Official statement that: (a) the Community provisions to combat *Synchytrium endobioticum* (Schilbersky) Percival have been complied with; and (b) either the tubers originate in an area known to be free from *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis *et al.* or the Community provisions to combat *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis *et al.* have been complied with; and (d) (aa) either, the tubers originate in areas in which *Ralstonia solanacearum* (Smith) Yabuuchi *et al.* is known not to occur; or (bb) in areas where *Ralstonia solanacearum* (Smith) Yabuuchi *et al.* is known to occur, the tubers originate from a place of production found free from *Ralstonia solanacearum* (Smith) Yabuuchi *et al.*, or considered to be free thereof, as a consequence of the implementation of an appropriate procedure aiming at eradicating *Ralstonia solanacearum* (Smith) Yabuuchi *et al.*; and (e) either, the tubers originate in areas in which *Meloidogyne chitwoodi* Golden *et al.* (all populations) and *Meloidogyne fallax* Karssen are known not to occur, or in areas where *Meloidogyne chitwoodi* Golden *et al.* (all populations) and *Meloidogyne fallax* Karssen are known to occur: — either, the tubers originate from a place of production which has been found free from *Meloidogyne chitwoodi* Golden *et al.* (all populations) and *Meloidogyne fallax* Karssen based on an annual survey of host crops by visual inspection of host plants at appropriate times and by visual inspection both externally and by cutting of tubers after harvest from potato crops grown at the place of production, or — the tubers after harvest have been randomly sampled and, either checked for the presence of symptoms after an appropriate method to induce symptoms or laboratory tested, as well as inspected visually both externally and by cutting the tubers, at appropriate times and in all cases at the time of closing of the packages or containers before marketing according to the provisions on closing in Council Directive 66/403/EEC, and no symptoms of *Meloidogyne chitwoodi* Golden *et al.* (all populations) and *Meloidogyne fallax* Karssen have been found.

(-) The following point 18.1.1 is inserted after point 18.1:

"18.1.1	Tubers of *Solanum tuberosum* L., intended for planting, other than those to be planted in accordance with Article 4.4(b) of Council Directive 2007/33/EC	Without prejudice to the requirements applicable to the tubers of *Solanum tuberosum* L., intended for planting in Annex IV, Part A, Section II (18.1), official statement that the Union provisions to combat *Globodera pallida* (Stone) Behrens and *Globodera rostochiensis* (Wollenweber) Behrens are complied with"

(-) In the right hand column of point 18.3, the words "*Pseudomonas solanacearum* (Smith) Smith" are replaced by "*Ralstonia solanacearum* (Smith) Yabuuchi *et al.*"

(-) Point 18.5 is replaced by the following:

'18.5	Tubers of *Solanum tuberosum* L., other than those mentioned in Annex IV(A)(II)(18.1), (18.1.1), (18.2), (18.3) or (18.4)	There shall be evidence by a registration number put on the packaging, or in the case of loose-loaded potatoes transported in bulk, on the vehicle transporting the potatoes, that the potatoes have been grown by an officially registered producer, or originate from officially registered collective storage or dispatching centres located in the area of production, indicating that the tubers are free from *Ralstonia solanacearum* (Smith) Yabuuchi *et al.* and that (a) the Union provisions to combat *Synchytrium endobioticum* (Schilbersky) Percival; and (b) where appropriate, the Union provisions to combat *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis *et al.;* and (c) the Union provisions to combat *Globodera pallida* (Stone) Behrens and *Globodera rostochiensis* (Wollenweber) Behrens are complied with'

(-) The following point 18.6.1 is inserted after point 18.6:

'18.6.1	Plants with roots, intended for planting, of *Capsicum* spp., *Solanum lycopersicum* L. and *Solanum melongena* L. intended for planting, other than those to be planted in accordance with Article 4.4(a) of Council Directive 2007/33/EC.	Without prejudice to the requirements applicable to the plants in Annex IV, Part A, Section II (18.6) official statement that the Union provisions to combat *Globodera pallida* (Stone) Behrens and *Globodera rostochiensis* (Wollenweber) Behrens are complied with'

(a) (-) Point 18.7 is replaced by the following:

'18.7 Plants of *Capsicum annuum* L., *Solanum lycopersicum* L., *Musa* L., *Nicotiana* L., and *Solanum melongena* L., intended for planting, other than seeds	Without prejudice to the requirements applicable to the plants listed in Annex V(A)(II)(18.6) where appropriate, official statement that: (a) the plants originate in areas which have been found free from *Ralstonia solanacearum* (Smith) Yabuuchi *et al.*; or (b) no symptoms of *Ralstonia solanacearum* (Smith) Yabuuchi *et al.* have been observed on the plants at the place of production since the beginning of the last complete cycle of vegetation. '

(-) Point 20 is replaced by the following:

"20. Plants of *Dendranthema* (DC.) Des Moul., *Dianthus* L. and *Pelargonium* l'Hérit. ex Ait., intended for planting, other than seeds	Official statement that: (aa) the plants originate in an area free from *Helicoverpa armigera* (Hübner) and *Spodoptera littoralis* (Boisd.), established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures; or (a) no signs of *Helicoverpa armigera* (Hübner), or *Spodoptera littoralis* (Boisd.) have been observed at the place of production since the beginning of the last complete cycle of vegetation; or (b) the plants have undergone appropriate treatment to protect them from the said organisms.

(-) In the right hand column of point 23, the following heading (d) is added after heading (c):

"or (d) the plants originate from plant material (explant) which is free from *Liriomyza huidobrensis* (Blanchard) and *Liriomyza trifolii* (Burgess); are grown *in vitro* in a sterile medium under sterile conditions that preclude the possibility of infestation with *Liriomyza huidobrensis* (Blanchard) and *Liriomyza trifolii* (Burgess); and are shipped in transparent containers under sterile conditions."

(-) Point 24 is replaced by the following:

'24. Plants with roots, planted or intended for planting, grown in the open air	There shall be evidence that the place of production is known to be free from *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis *et al.* and *Synchytrium endobioticum* (Schilbersky) Percival.

(-) The following point 24.1 is inserted after point 24:

'24.1	Plants with roots, intended for planting, grown in the open air, of *Allium porrum* L., *Asparagus officinalis* L., *Beta vulgaris* L., *Brassica* spp. and *Fragaria* L. and bulbs, tubers and rhizomes, grown in the open air, of *Allium ascalonicum* L., *Allium cepa* L., *Dahlia* spp., *Gladiolus* Tourn. Ex L., *Hyacinthus* spp., *Iris* spp., *Lilium* spp., *Narcissus* L. and *Tulipa* L., other than those plants, bulbs, tubers and rhizomes to be planted in accordance with Article 4.4(a) or (c) of Council Directive 2007/33/EC.	Without prejudice to the requirements applicable to the plants in Annex IV, Part A, Section II (24) there shall be evidence that the Union provisions to combat *Globodera pallida* (Stone) Behrens and *Globodera rostochiensis* (Wollenweber) Behrens are complied with'

(-) In the left hand column of point 26.1 the words "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." are replaced by "*Solanum lycopersicum* L."

(-) In the left hand column of point 27, the words "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." are replaced by "*Solanum lycopersicum* L."

(-) In the right hand column of point 28.1, the following heading (c) is added after heading (b):

"or (c) the seeds have been subjected to an appropriate physical treatment against *Ditylenchus dipsaci* (Kühn) Filipjev and have been found to be free of this harmful organism after laboratory tests on a representative sample."

(b) Part B is amended as follows:

(i) In points 4, 10. and 14.2., the text in the third column, protected zone(s), is replaced by the following:

"EL, IRL, UK".

(ii) In points 6.3. and 14.9., the text in the third column, protected zone(s), is replaced by the following:

"CZ, IRL, S, UK".

(iii) The following point 19.1. is inserted after point 19:

"19.1.	Plants of *Castanea* Mill, intended for planting	Without prejudice to the provisions applicable to the plants listed in Annex III(A)(2) and IV(A)(I)(11.1), 11.2), official statement that: (a) the plants have been grown throughout their life in places of production in countries where *Cryphonectria parasitica* (Murrill) Barr is known not to occur; or (b) the plants have been grown throughout their life in an area free from *Cryphonectria parasitica* (Murrill) Barr, established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary measures or c) the plants have been grown throughout their life in the protected zones listed in the right-hand column	CZ, IRL, S, UK

(iv) Point 20.3 is replaced by the following:

'20.3.	Plants with roots, planted or intended for planting, grown in the open air	There shall be evidence that the plants originate from a field known to be free from *Globodera pallida* (Stone) Behrens.	FI, LV, SI, SK'

(v) In point 21, the text in the third column, protected zone(s), is replaced by the following:

"E (except the autonomous communities of Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja, and the Comarca of the Community of Calatayud (Aragon) and the province of Guipuzcoa (Basque Country)), EE, F (Corsica), IRL, I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua and Sondrio), Marche, Molise, Piedmont, Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Castelbaldo, Barbona, Boara Pisani, Masi, Piacenza d'Adige, S. Urbano, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT, P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska), SK (except the communes of Blahová, Horné Mýto, Ohrady, Okoč, Topoľníky and Trhová Hradská (Dunajská Streda County), Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málinec (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuše and Zatín (Trebišov County)), FI, UK (Northern Ireland, Isle of Man and Channel Islands).".

(vi) In point 21.3, the text in the third column, protected zone(s), is replaced by the following:

"E (except the autonomous communities of Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja, and the Comarca of the Community of Calatayud (Aragon) and the province of Guipuzcoa (Basque Country)), EE, F (Corsica), IRL, I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua and Sondrio), Marche, Molise, Piedmont, Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Castelbaldo, Barbona, Boara Pisani, Masi, Piacenza d'Adige, S. Urbano, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT, P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska), SK (except the communes of Blahová, Horné Mýto,

Ohrady, Okoč, Topoľníky and Trhová Hradská (Dunajská Streda County), Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málinec (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuše and Zatín (Trebišov County)), FI, UK (Northern Ireland, Isle of Man and Channel Islands).".

(vii) Point 31 is replaced by the following:

'31.	Fruits of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., and their hybrids originating in BG, HR, SI, EL (Regional Units of Argolida and Chania), P (Algarve and Madeira), E, F, CY and I	Without prejudice to the requirement in Annex IV Part A Section II point 30.1 that packaging should bear an origin mark: (a) the fruits shall be free from leaves and peduncles; or (b) in the case of fruits with leaves or peduncles, official statement that the fruits are packed in closed containers which have been officially sealed and shall remain sealed during their transport through a protected zone, recognised for these fruits, and shall bear a distinguishing mark to be reported on the passport.	EL (except the Regional Units of Argolida and Chania), M, P (except Algarve and Madeira)

(-) Point 32 is replaced by the following

'32. Plants of *Vitis* L., other than fruit and seeds.	Without prejudice to the provisions applicable to the plants listed in Annex III(A)(15), IVA(II)17, and IVB21.1, official statement that: (a) the plants originate and have been grown in a place of production in a country where Grapevine flavescence dorée MLO is not known to occur; or (b) the plants originate and have been grown in a place of production in an area free from Grapevine flavescence dorée MLO established by the national plant protection organisation in accordance with the relevant international standards; or (c) the plants originate and have been grown in either the Czech Republic, France (Alsace, Champagne-Ardenne, Picardie (département de l'Aisne), Ile de France (communes de Citry, Nanteuil-sur-Marne et Saâcy-sur-Marne) and Lorraine) or Italy (Apulia, Basilicata and Sardinia); or (cc) the plants originate and have been grown in Switzerland (except the Canton of Ticino and the Misox Valley); or (d) the plants originate and have been grown in a place of production where: (aa) no symptoms of Grapevine flavescence dorée MLO have been observed on the mother-stock plants since the beginning of the last two complete cycles of vegetation; and (bb) either (i) no symptoms of Grapevine flavescence dorée MLO have been found on the plants in the place of production; or, (ii) the plants have undergone hot water treatment of at least 50 ° C for 45 minutes in order to eliminate the presence of Grapevine flavescence dorée MLO.	CZ, FR (Alsace, Champagne-Ardenne, Picardie (département de l'Aisne), Ile de France (communes de Citry, Nanteuil-sur-Marne et Saâcy-sur-Marne) and Lorraine), Italy (Apulia, Basilicata and Sardinia)'

(-) The following point 33 is inserted after point 32:

"33.	Plants of *Castanea* Mill, other than plants in tissue culture, fruit and seeds	Without prejudice to the provisions applicable to the plants listed in Annex III(A)(2) and IV(A)(I)(11.1, 11.2), official statement that: (a) the plants have been grown throughout their life in places of production in countries where *Dryocosmus kuriphilus* Yasumatsu is known not to occur; or (b) the plants have been grown throughout their life in an area free from *Dryocosmus kuriphilus* Yasumatsu, established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures or c) the plants have been grown throughout their life in the protected zones listed in the right-hand column	IRL, P, UK

(6) Annex V is amended as follows:

(a) Part A is amended as follows:

(i) Section I is amended as follows:

(-) Point 1.4 is replaced by the following:

"1.4. Plants of *Fortunella* Swingle, *Poncirus* Raf., and their hybrids, *Casimiroa* La Llave, Clausena Burm f., Vepris Comm., Zanthoxylum L. and Vitis L., other than fruit and seeds."

(-) Point 2.1 is replaced by the following:

'2.1. Plants intended for planting, other than seeds, of the genera *Abies* Mill., *Apium graveolens* L., *Argyranthemum* spp., *Asparagus officinalis* L., *Aster* spp., *Brassica* spp., *Castanea* Mill., *Cucumis* spp., *Dendranthema* (DC) Des Moul., *Dianthus* L. and hybrids *Exacum* spp., *Fragaria* L., *Gerbera* Cass., *Gypsophila* L., all varieties of New Guinea hybrids of *Impatiens* L., *Lactuca* spp., *Larix* Mill., *Leucanthemum* L., *Lupinus* L., *Pelargonium* l'Hérit. ex Ait., *Picea* A. Dietr., *Pinus* L., *Platanus* L., *Populus* L., *Prunus laurocerasus* L., *Prunus lusitanica* L., *Pseudotsuga* Carr., *Quercus* L., *Rubus* L., *Spinacia* L., *Tanacetum* L., *Tsuga* Carr. , *Verbena* L. and other plants of herbaceous species, other than plants of the family Gramineae, intended for planting, and other than bulbs, corms, rhizomes, seeds and tubers'

(-) In the third indent of point 2.4, the words "*Lycopersicon lycopersicum* (L.) Karsten ex Farw." are replaced by "*Solanum lycopersicum* L."

(-) Point 3 is replaced by the following:

'3. Bulbs, corms, tubers and rhizomes intended for planting, produced by producers whose production and sale is authorised to persons professionally engaged in plant production, other than those plants, plant products and other objects which are prepared and ready for sale to the final consumer, and for which it is ensured by the responsible official bodies of the Member States, that the production thereof is clearly separate from that of other products of *Camassia* Lindl., *Chionodoxa* Boiss., *Crocus flavus* Weston 'Golden Yellow', *Dahlia* spp., *Galanthus* L., *Galtonia candicans* (Baker) Decne., miniature cultivars and their hybrids of the genus *Gladiolus* Tourn. ex L., such as *Gladiolus callianthus* Marais, *Gladiolus colvillei* Sweet, *Gladiolus nanus* hort., *Gladiolus ramosus* hort. and *Gladiolus tubergenii* hort., *Hyacinthus* L., *Iris* L., *Ismene* Herbert, *Lilium* spp., *Muscari* Miller, *Narcissus* L., *Ornithogalum* L., *Puschkinia* Adams, *Scilla* L. *Tigridia* Juss. and *Tulipa* L.'

(ii) Section II is amended as follows:

(-) Point 1.2 is replaced by the following:

"1.2. Plants intended for planting, other than seeds, of *Populus* L., *Beta vulgaris* L. and *Quercus* spp., other than *Quercus suber*"

(-) In point 1.3 the words ", Castanea Mill." are inserted after "*Amelanchier* Med."

(-) In point 1.8 the words ", *Castanea* Mill." are inserted after "*Beta vulgaris* L."

(b) Part B is amended as follows:

(i) Section I is amended as follows:

(-) Points 1 and 2 are replaced by the following

1. Plants, intended for planting, other than seeds but including seeds of *Cruciferae, Gramineae, Trifolium* spp., originating in Argentina, Australia, Bolivia, Chile, New Zealand and Uruguay, *genera Triticum, Secale* and *X Triticosecale* from Afghanistan, India, Iran, Iraq, Mexico, Nepal, Pakistan, South Africa and the USA, *Citrus* L., *Fortunella* Swingle and *Poncirus* Raf., and their hybrids, *Capsicum* spp., *Helianthus annuus* L., *Solanum lycopersicum* L., *Medicago sativa* L., *Prunus* L., *Rubus* L., *Oryza* spp., *Zea mays* L., *Allium ascalonicum* L., *Allium cepa* L., *Allium porrum* L., *Allium schoenoprasum* L. and *Phaseolus* L.

2. Parts of plants, other than fruits and seeds of:

— *Castanea* Mill., *Dendranthema* (DC) Des. Moul., *Dianthus* L., *Gypsophila* L., *Pelargonium* l'Herit. ex Ait, *Phoenix* spp., *Populus* L., *Quercus* L., *Solidago* L. and cut flowers of Orchidaceae,

— conifers (*Coniferales*),

— *Acer saccharum* Marsh., originating in the USA and Canada,

— *Prunus* L., originating in non-European countries,

— Cut flowers of *Aster* spp., *Eryngium* L., *Hypericum* L., *Lisianthus* L., *Rosa* L. and *Trachelium* L., originating in non-European countries,

— Leafy vegetables of *Apium graveolens* L., *Ocimum* L., *Limnophila* L. and *Eryngium* L,

—Leaves of *Manihot esculenta* Crantz,

--- Cut branches of *Betula* L. with or without foliage,

--- Cut branches of *Fraxinus* L., *Juglans ailantifolia* Carr, *Juglans mandshurica* Maxim., *Ulmus davidiana* Planch. and *Pterocarya rhoifolia* Siebold & Zucc., with or without foliage, originating in Canada, China, Democratic People's Republic of Korea, Japan, Mongolia, Republic of Korea, Russia, Taiwan and USA,

--- *Amiris* P. Browne, *Casimiroa* La Llave, *Citropsis* Swingle & Kellerman, *Eremocitrus* Swingle, *Esenbeckia* Kunth., *Glycosmis* Corrêa, *Merrillia* Swingle, *Naringi* Adans., *Tetradium* Lour., *Toddalia* Juss. and *Zanthoxylum* L..

(-) The following point 2.1 is inserted after point 2:

"2.1 Parts of plants, other than fruits but including seeds, of *Aegle* Corrêa, *Aeglopsis* Swingle, *Afraegle* Engl, *Atalantia* Corrêa, *Balsamocitrus* Stapf, *Burkillanthus* Swingle, *Calodendrum* Thunb., *Choisya* Kunth, *Clausena* Burm. f., *Limonia* L., *Microcitrus* Swingle., *Murraya* J. Koenig ex L., *Pamburus* Swingle, *Severinia* Ten., *Swinglea* Merr., *Triphasia* Lour and *Vepris* Comm..";

(-) In point 3 the following indent is added:

"—*Capsicum* L."

(-) Points 5 and 6 are replaced by the following:

5. Isolated bark of:

— conifers (Coniferales), originating in non-European countries,

— *Acer saccharum* Marsh, *Populus* L., and *Quercus* L. other than *Quercus suber* L.,

— *Fraxinus* L., *Juglans ailantifolia* Carr, *Juglans mandshurica* Maxim., *Ulmus davidiana* Planch. and *Pterocarya rhoifolia* Siebold & Zucc., originating in Canada, China, Democratic People's Republic of Korea, Japan, Mongolia, Republic of Korea, Russia, Taiwan and USA,

— *Betula* L., originating in Canada and the USA.

6. Wood within the meaning of the first subparagraph of Article 2(2), where it:

(a) has been obtained in whole or part from one of the order, genera or species as described hereafter, except wood packaging material defined in Annex IV, Part A, Section I, Point 2:

— *Quercus* L., including wood which has not kept its natural round surface, originating in the USA, except wood which meets the description referred to in (b) of CN code 4416 00 00 and where there is documented evidence that the wood has been processed or manufactured using a heat treatment to achieve a minimum temperature of 176 ° C for 20 minutes,

— *Platanus*, including wood which has not kept its natural round surface, originating in the USA or Armenia,

— *Populus* L., including wood which has not kept its natural round surface, originating in countries of the American continent,

— *Acer saccharum* Marsh., including wood which has not kept its natural round surface, originating in the USA and Canada,

— *Conifers* (Coniferales), including wood which has not kept its natural round surface, originating in non-European countries, Kazakhstan, Russia and Turkey,

— *Fraxinus* L., *Juglans ailantifolia* Carr, *Juglans mandshurica* Maxim., *Ulmus davidiana* Planch. and *Pterocarya rhoifolia* Siebold & Zucc., including wood which has not kept its natural round surface, originating in Canada, China, Democratic People's Republic of Korea, Japan, Mongolia, Republic of Korea, Russia, Taiwan and USA,

— *Betula* L., including wood which has not kept its natural round surface, originating in Canada and the USA;

and

(b) meets one of the following descriptions laid down in Annex I, Part two to Council Regulation (EEC) No 2

CN code	Description
4401 10 00	Fuel wood, in logs, in billets, in twigs, in faggots or in similar forms
4401 21 00	Coniferous wood, in chips or particles
4401 22 00	Non-coniferous wood, in chips or particles
ex 4401 30 40	Sawdust, not agglomerated in logs, briquettes, pellets or similar forms
ex 4401 30 80	Other wood waste and scrap, not agglomerated in logs, briquettes, pellets or similar forms
4403 10 00	Wood in the rough, treated with paint, stains, creosote or other preservatives, not stripped of bark or sapwood, or roughly squared

4403 20	Coniferous wood in the rough, other than treated with paint, stains, creosote or other preservatives, whether or not stripped of bark or sapwood, or roughly squared
4403 91	Oak wood (*Quercus* spp.) in the rough, other than treated with paint, stains, creosote or other preservatives, whether or not stripped of bark of sapwood, or roughly squared
ex 4403 99	Non-coniferous wood (other than tropical wood specified in subheading note 1 to Chapter 44 or other tropical wood, oak (*Quercus* spp.), beech (*Fagus* spp.) or birch (*Betula* L.)), in the rough, whether or not stripped of bark or sapwood, or roughly squared, not treated with paint, stains, creosote or other preservatives
4403 99 51	Sawlogs of birch (*Betula* L.) in the rough, whether or not stripped of bark or sapwood, or roughly squared
4403 99 52	Wood of birch (*Betula* L.) in the rough, whether or not stripped of bark or sapwood, or roughly squared, other than sawlogs
ex 4404	Split poles; piles, pickets and stakes of wood, pointed but not sawn lengthwise
4406	Railway or tramway sleepers (cross-ties) of wood
4407 10	Coniferous wood, sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm
4407 91	Oak wood (*Quercus* spp.), sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm
ex 4407 93	Wood of *Acer saccharum* Marsh, sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm
4407 95	Wood of ash (*Fraxinus* spp.) sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm
ex 4407 99	Non-coniferous wood (other than tropical wood specified in subheading note 1 to Chapter 44 or other tropical wood, oak (*Quercus* spp.), beech (*Fagus* spp.), maple (*Acer* spp.), cherry (*Prunus* spp.) or ash (*Fraxinus* spp.)), sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm
4408 10	Coniferous sheets for veneering (including those obtained by slicing laminated wood), for plywood or for similar laminated wood and other wood, sawn lengthwise, sliced or peeled, whether or not planed, sanded, spliced or end-jointed, of a thickness not exceeding 6 mm
4416 00 00	Casks, barrels, vats, tubs and other coopers' products and parts thereof, of wood, including staves

ex 4418	Builders' joinery and carpentry of wood of birch (*Betula* L.) or ash (*Fraxinus* L.), including shingles and shakes
9406 00 20	Prefabricated buildings of wood

(ii) In point 5 of Section II, the words "*Castanea* Mill.," are inserted before "*Dolichos* Jacq.".

http://www.epa.gov/pesticides/factsheets/spraydrift.htm
Last updated on Wednesday, May 28, 2014

Pesticides: Topical & Chemical Fact Sheets

Pesticide Drift

Current as of May 2014

On this page:

Quick Resources

- 5/28/14: Pesticide Spray Drift Reduction Technologies
- 3/31/14: EPA Response to "Pesticides in the Air – Kids at Risk: Petition to EPA to Protect Children form Pesticide Drift" (PDF) (45 pp, 5.30 MB, about PDF)
- 3/28/14: EPA Seeks Public Comment on Draft Guidance for Pesticide Volatilization Screening Methodology for Human Health Risk Assessments
- Public Comment Period Extended on Draft Guidance Documents for Evaluating Pesticide Spray Drift EPA-HQ-OPP-2013-0676
- Pesticide issues in the works: pesticide volatilization
- Worker risk assessment

Questions on Pesticides?

- National Pesticide Information Center (NPIC) 1-800-858-7378 (EXIT Disclaimer)

About Pesticide Drift

Pesticide drift is the movement of pesticide dust or droplets through the air at the time of application or soon after, to any site other than the area intended. Pesticide droplets are produced by spray nozzles used in application equipment for spraying pesticides on crops, forests, turf and home gardens. Some other pesticides are formulated as dusts with very fine particles.

Droplets and dust particles can be carried by the wind some distance from the application site and be deposited on other areas, exposing people (such as nearby farmworkers and residents), wildlife, and plants to pesticides that can affect their health and the environment and cause property damage.

Agency Actions to Address Pesticide Drift

We are actively engaged in several initiatives to help minimize pesticide drift problems:

- In collaboration with experts at USDA, universities, industry and our state and international partners, we are examining new studies and improving scientific models and methods for estimating pesticide drift, potential exposure and risks from drift.
- As we assess new pesticides and re-evaluate older pesticides, we are improving the clarity and enforceability of product label directions and drift management restrictions to protect people and the environment.
- We are facilitating the use of drift reduction technologies and best management practices to minimize drift.

- We are promoting applicator education and training programs.

Pesticide Drift in Human Health and Ecological Risk Assessments

We evaluate potential for pesticide drift as a routine part of our human health and ecological pesticide risk assessments. We are adjusting our current method for estimating off-target pesticide drift from the use of standard percentages of application rates stated on pesticide labels using scientific peer reviewed models. We are reviewing public comments on two draft guidance documents that describe how off-site spray drift will be evaluated for ecological and human health risk assessments for pesticides and will make appropriate modifications to these policies and finalize them for use in pesticide risk assessments.

These proposed approaches are available in Docket # EPA-HQ-OPP-2013-0676 at www.regulations.gov. The public comment period for these draft documents closed on March 31, 2014.

Labeling to Avoid Pesticide Drift

As a routine part of registration review (the required re-evaluation of all pesticides every 15 years), we evaluate the potential for each pesticide to drift and strengthen labeling as needed. Pesticide labeling may include buffer zone requirements and other application use restrictions to manage drift, such as minimum and maximum wind speeds during application.

In 2009, following extensive public outreach, we issued for public comment draft guidance to improve drift management for application of agricultural and residential pesticides. Specifically, we proposed guidance on labeling statements to improve instructions to applicators and, as a result, to improve protection of people, non-target plants and animals, and sites from potential harm that may be caused by pesticide drift. We included guidance to help enforcement officials interpret label instructions when they investigate alleged drift incidents. Many of the issues of drift management are complex, and we received many comments with diverse opinions on our proposals. We are considering the comments.

Applicator Training and Education

We support and encourage private and commercial pesticide applicators to take continual education and training on spray drift management.

- We provide annual funds to states for pesticide applicator training programs, many of which include educational material on drift management.
- We contributed to the National Coalition on Drift Minimization educational video and CD-ROM.
- We support the development of the National Pesticide Applicator Certification Core Manual, which contains a module on minimizing pesticide drift.
- We provide funds to the National Agricultural Aviation Association's Professional Aerial Applicator Support System (PAASS) for their training and education programs to reduce drift incidents. The PAASS has educational programs that enhance the

commercial aerial applicator profession by improving the understanding of human factors, enhancing critical aeronautical decision-making skills, and inducing positive behavioral change.

Drift Reduction Technology Program

Through a Federal Register Notice, we are requesting public comment on the information collection activities for a Drift Reduction Technology (DRT) Program and announcing that the required Information Collection Request (ICR)* has been sent to the Office of Management and Budget for approval. Upon approval, we plan to launch a new voluntary Drift Reduction Technology (DRT) Program that will offer incentives to the agricultural sector (industry and pesticide applicators) to manufacture, market and use spray application technologies and equipment that has been scientifically verified to significantly reduce pesticide drift.

- We would seek voluntary submission of information to verify the effectiveness of application technologies for agricultural pesticide sprays (including spray nozzles, shrouds and nozzle-drift reduction adjuvant chemical combinations) for aerial or ground boom applications to row and field crops.
- We believe that over time, the DRT Program will move the agricultural sector toward the widespread use of verified low drift technologies. A robust adoption of this voluntary program by equipment and pesticide manufacturers and by pesticide applicators will provide many benefits, including keeping more of the applied pesticide on the intended crop or site, improving pest control, reducing costs and improving environmental protection.
- We expect to initiate the DRT Program in 2014. We will encourage manufacturers to test their technologies to measure their drift reduction potential, pesticide registrants to include label directions to apply their products with verified technologies, and applicators to use these technologies.
- Documents describing the DRT program, including the Information Collection Request, our guidance to industry for participating in the program, the standard protocol for testing technologies, and the draft webpage, are available in the docket (EPA-HQ-OPP-2012-0631) at www.regulations.gov. Comments are requested on our ICR by June 27, 2014. Submit comments to that docket.

  * Under the Paperwork Reduction Act, whenever we ask people to submit information (whether voluntary or mandatory), we must obtain approval of an Information Collection Request (ICR).

What about Volatilization?

In addition to our initiatives to address spray and dust drift, we consider the risks posed when pesticides volatilize during or after application. The movement of vapors through the air is not the same as pesticide movement by spray drift, erosion, or windblown soil particles. Volatilization depends on a number of physical and chemical properties, weather conditions, and other factors. Once off-target, pesticide volatilization can result in inhalation exposure to people such as farm workers and bystanders.

For more information about volatilization see: Pesticide issues in the works: pesticide

volatilization.

Report Pesticide Drift Problems

If you believe that you have been exposed to pesticide spray or dust drift and have health-related questions, contact your physician, local poison control center, or health department for assistance. You can also contact the National Pesticide Information Center (NPIC) at 1-800-858-7378. EXIT Disclaimer

Tell your state pesticide regulatory agency EXIT Disclaimer about pesticide activities that are of concern or may be may be illegal.

Additional Information

For information on pesticides and pesticide exposure, contact the National Pesticide Information Center (NPIC) EXIT Disclaimer at 1-800-858-7378 (toll free) or through its Web site. NPIC, supported in part by EPA, provides pesticide information to any caller in the United States, Puerto Rico, or the Virgin Islands.

Draft Guidances; Availability: Consideration of Spray Drift in Pesticide Risk Assessment

View all documents and comments in this Docket

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Action

Notice.

Summary

EPA is announcing the availability of two draft guidance documents for public comment. These documents describe how off-site spray drift will be evaluated for ecological and human health risk assessments for pesticides. Once final, these guidance documents will be posted on EPA's Web site, to ensure consistent risk assessment practices and provide transparency for pesticide registrants and other interested stakeholders.

Dates

Comments must be received on or before March 31, 2014.

Addresses

Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2013-0676, by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.
Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

For Further Information Contact

For the ecological risk assessment guidance document, Faruque Khan, Environmental Fate and Effects Division, (7507P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-6127; email address: *khan.faruque@epa.gov.*
For the human health risk assessment guidance document, Jeff Dawson, Health Effects Division, (7509P), same address; telephone number: (703) 305-7329; email address: *dawson.jeff.@epa.gov.*

Supplementary Information

I. General Information

A. What is the Agency's authority for taking this action?

Pesticides are regulated under both the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et. seq.,* and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. 346a.

B. Does this action apply to me?

You may be potentially affected by this action if you are a producer of pesticide products (NAICS 32532), importers of such products, or any person or company who seeks to obtain a tolerance for such a pesticide. The North American Industrial Classification System (NAICS) code is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Other types of entities not listed could also be affected.

C. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading,Federal Register date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

D. What action is the Agency taking?

Pesticide drift can be characterized as the physical movement of a pesticide through the air at the time of application or soon thereafter from the target site to any non- or off-target site. This does not include pesticide movements by erosion, migration, volatility, or windblown soil particles after application. Drift is dependent on the design of application equipment, size of spray droplets or dry particles, weather conditions, and other factors.

Once off-target, pesticide drift can potentially deposit in unintended areas or directly onto people or nontarget species. To provide guidance to EPA staff and stakeholders, EPA has developed two documents describing EPA's approach to assessing pesticide drift in human health and ecological

risk assessments. Both documents are available in the docket for this action using the docket identifier EPA-HQ-OPP-2013-0676.

Guidance on Modeling Offsite Deposition of Pesticides via Spray Drift for Ecological and Drinking Water Assessments for the Environmental Fate and Effects Division (Draft dated 11/1/2013) (Ref. 1), and
Residential Exposure Assessment Standard Operating Procedures (SOPs), Addenda 1: Consideration of Spray Drift (Draft dated 11/1/2013) (Ref. 2).

The draft Ecological and Drinking Water Assessment Guidance provides information on estimating spray drift fractions of liquid sprays for modeling offsite deposition of a pesticide for ecological and drinking water assessment and on estimating distances from the treated field where adverse effects may be observed due to exposure to spray drift. The draft guidance also provides default assumptions for modeling inputs to use when estimating spray drift in terrestrial and aquatic assessments.
The Residential Exposure Addenda describes a screening approach for defining when assessments are needed and the methodology for estimating risks for indirect exposures to pesticide drift, such as children playing on a lawn that has pesticide residues that drifted from a nearby treated field. The draft guidance describes when quantitative risk assessments for spray drift are generally needed, and also provides the modeling inputs needed to complete the exposure and risk assessments.
EPA expects the model-generated values for spray drift fractions to provide realistic exposure and risk estimates for both ecological and human health assessments. These policies will promote consistency within EPA, as well as with other federal agencies and international regulatory partners that rely on predicted spray drift values.

II. Spray Drift Estimates Used for Risk Assessment

EPA uses two peer-reviewed spray drift models (AgDRIFT and AGDISP) to estimate the contribution of spray drift to ecological and human health risk assessments. Both models estimate drift fractions, as applicable to spray of liquid materials. In general, OPP uses the AgDRIFT model to assess spray drift from agricultural applications, whereas AGDISP is used for other types of pesticide applications, such as aerial application of mosquito adulticides. It is noted that AGDISP has limited capability to estimate drift fractions from dry materials application.
EPA has prepared a support document (Ref. 3), which is available in the docket for this action, explaining the scientific basis for AgDRIFT and AGDISP, and providing information on this harmonized approach for estimating spray drift fractions.

III. Consideration of Spray Drift in Ecological Risk Assessment

To enhance consistency and provide more realistic risk estimates, the Agency has developed the draft ecological guidance (Ref. 1) to apply a uniform approach for estimating drift fractions for all tiers of ecological risk assessments. Unit III. provides historical information on OPP's approach for estimation of spray drift.
Prior to the adoption of AgDRIFT and AGDISP, for aquatic exposure assessment purposes, default values of 5% were recommended to OPP for use as estimates for the spray drift loading from aerial

and air-blast applications to a pond (Ref. 4). However, beginning in the 1990s, OPP's practice was to use default drift values—developed using best professional judgement—of 5% (aerial application), 3% (air blast application), and 1% (ground application) in terrestrial and aquatic assessments. Then, to make more realistic calculations of exposure from spray drift deposition, EPA implemented the use of AgDRIFT model-generated values for spray drift fractions for:

Screening-level (Tier I) aquatic exposure model GENEEC (GENeric Estimated Exposure Concentration) for ecological exposure assessments, and
Tier I—FIRST (FQPA Index Reservoir Screening Tool) and Tier II—PRZM (Pesticide Root Zone Model)/EXAMS (Exposure Analysis Modeling System) for drinking water assessments.

However, the practice of using default drift values of 5% (aerial application), 3% (air blast application), and 1% (ground application) in terrestrial and Tier II aquatic assessments continued. In 2004, EPA staff performed a comparison study of these previously-specified, percentage-based default spray drift deposition levels and AgDRIFT predictions. The comparison indicated these default values can potentially underestimate off-site deposition of spray drift under certain scenarios when compared to model-predicted values (Ref. 5).
Based upon continued model refinements, EPA is now revising its approach for terrestrial and Tier II aquatic assessments. As a result of these revisions, EPA has developed default model input parameters to estimate the spray drift fraction for all tiers of aquatic and terrestrial exposure assessments. Use of these inputs in the AgDRIFT model should result in more realistic estimates of exposure from spray drift deposition for all terrestrial and aquatic environments.

IV. Consideration of Spray Drift in Human Health Risk Assessment

The draft guidance for considering spray drift in human health risk assessment has been developed as an addendum to the EPA's existing *SOPs For Residential Exposure Assessment (SOPs),* which are available at *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.* EPA routinely uses the SOPs as the basis for evaluating the risks associated with residential exposures to pesticides, including residential turf assessments.
The predominant sources of potential human health risks associated with spray drift is from direct contact with sprays and from contact with contaminated surfaces such as lawns in areas adjacent to pesticide applications. Direct contact with sprays is considered a violation of standard label language, and as applicable, EPA's Worker Protection Standard (40 CFR part 170). This means that direct contact is not evaluated in risk assessment but is addressed through enforcement action against persons not complying with label prohibitions/directions, through applicator education, and through other means. The primary focus on spray drift in the human health risk assessment process is through indirect contact with contaminated surfaces such as lawns. The draft guidance document describes scenarios for which quantitative risk assessments for spray drift would generally be appropriate, and provides the information needed to complete a residential turf assessment using spray drift fractions predicted by AgDRIFT.
Spray drift is governed by a variety of factors which govern how much of the pesticide application deposits on surfaces where contact with residues can eventually lead to indirect exposures (e.g., children playing on lawns that are next to treated fields and where residues have deposited). The

potential risk estimates from these residues can be calculated using drift modeling coupled with methods employed for residential risk assessments for turf products. There is a regulatory precedent for this approach as it has been used by the Agency in a number of previous situations that include:

Response to a petition to cancel 14 pesticides, (69 FR 30042; May 26, 2004; FRL-7355-7),
Development of buffer zone estimates for two organophosphate insecticides used on orchard crops in the Pacific Northwest, and
Development of a recent spray drift risk assessment for all uses of an organophosphate insecticide, available at *http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0105.*

Using default assumptions, the AgDRIFT model is used to predict spray drift estimates (similar to the ecological assessment process described in Unit III.) in the absence of application parameters such as droplet size spectrum, release height, wind speed, and percent of swath displacement (i.e., the same Tier 1 input parameters are used to compute drift fractions for both human health and ecological risk assessment). In the human health risk assessment process, deposition estimates are integrated over 50 feet wide lawns to account for the fact that small children can play anywhere on an impacted lawn. In the draft guidance document (Ref. 2), drift estimates are then used to adjust deposition values for the standard methods for evaluating children's exposure from treated turf. Small children are the focus of this methodology because they have the highest exposures. Values are calculated using lawns at different distances away from a treatment area—adjoining it to 300 feet away. Also, additional spray drift deposition values are included which account for more options available in the AgDRIFT model which allows for flexibility in the risk management process. These include:

All canopy types for orchard air blast sprayers,
All boom height and spray quality combinations available for groundboom sprayers, and
Different options for aircraft including consideration of helicopter use and differing spray qualities (e.g., coarse instead of fine to medium spray quality).

V. Request for Comment

EPA is providing an opportunity, through this notice, for the public to provide comments and input on any additional information that may impact the Agency's assessment of spray drift in pesticide risk assessments. Specifically included within the Agency's request for comments are the model-generated spray drift values as described in either or both of the draft guidance documents.
With regards to the Ecological and Drinking Water Assessment Guidance, as discussed in Unit III., EPA currently uses spray drift estimates, developed in the 1990s, using best professional judgement: 5% (aerial application), 3% (air-blast application) and 1% (ground application) in selected terrestrial and Tier II aquatic exposure assessments. Based upon continued model refinements, EPA is revising this approach and is beginning to incorporate AgDRIFT model estimates in all tiers for terrestrial and aquatic environments to estimate more realistic exposure from spray drift deposition. This approach is more consistent with current approaches throughout OPP. EPA is seeking comment on this approach.

While EPA does not intend to formally respond to all comments made, comments in response to this notice will be taken into consideration as EPA finalizes these guidance documents. If substantive comments are made that may substantially change the EPA's consideration of spray drift in pesticide risk assessment, EPA will notify the public of these comments and describe how EPA has responded to them.

VI. References

As indicated under ADDRESSES, a docket has been established for this notice under docket ID number EPA-HQ-OPP-2013-0676. The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the persons listed under FOR FURTHER INFORMATION CONTACT.

1. USEPA. Guidance on Modeling Offsite Deposition of Pesticides via Spray Drift for Ecological and Drinking Water Assessments for the Environmental Fate and Effects Division (Draft dated 11/1/2013).
2. USEPA. Residential Exposure Assessment Standard Operating Procedures (SOPs), Addenda 1: Consideration of Spray Drift (Draft dated 11/1/2013).
3. USEPA. Use of AgDRIFT and AGDISP in OPP Risk Assessments.
4. RESOLVE. 1992. Improving Aquatic Risk Assessment under FIFRA: Report of the Aquatic Effects Dialogue Group. Published by World Wildlife Fund, Suite 500, 1250 24th Street NW., Washington, DC 20037.
5. Birchfield N B. 2004. Pesticide spray drift and ecological risk assessment in the U.S. EPA: A comparison between current default spray drift deposition levels and AgDRIFT predictions in screening-level risk assessments. Aspects of Applied Biology 71: 125-131.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: January 13, 2014.

Steve Bradbury,

Director, Office of Pesticide Programs.

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http://www.epa.gov/pesticides/science/models_db.htm
Last updated on Thursday, May 29, 2014

Pesticides: Science and Policy

Models and Databases

Models

- **Aquatic Models**
  GENEEC, FIRST, KABAM, PRZM, EXAMS, EXPRESS, SWAMP, SCIGROW, SWIMODEL, Tier I Rice Model, PRZM-GW
- **Terrestrial Models**
  SIP, STIR, T-REX, TIM, T-HERPS, TerrPlant
- **Atmospheric Models**
  AgDRIFT, AgDISP, PERFUM (EXIT Disclaimer), SOFEA, FEMS
- **Health Effects Models**
  DEEM, CALENDEX, CARES, LifeLine™ Version 2.0, LifeLine™ Version 4.3, OPHED, OPPED, REx, SHEDS, PBPK/PD Residential SOPs

Databases

- **Environmental Effects Databases**
  ECOTOX Database, EXTOXNET (EXIT Disclaimer)
- **Water Databases**
  NAWQA Data Warehouse
- **Health Effects Databases**
  IRIS, NPIRS (EXIT Disclaimer), Toxicological Profiles, TOXNET
- **Regulatory Information Databases**
  Compendium of Pesticide Common Names (EXIT Disclaimer), Label Review Manual, NPIRS (EXIT Disclaimer), Pesticide Data Program, PDSL, PPIS, PPLS, Pesticide Products Databases (EXIT Disclaimer)

Impact of Different Nozzles/Droplet Sizes on Risk Assessment and Management – Aquatic Example