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# Global Pesticide and Inert Ingredient Regulation

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**Summary:** Pesticides are one of the most regulated product types around the globe. This fact is not surprising considering the products are meant to be lethal to targeted pests. However, many of the active ingredients used in pesticides are also lethal to off-target organisms. Therefore, they must be handled carefully during production as well as during final application in the field. Countries usually require commercial pesticide products to go through a rigorous registration process. Many times there is a special branch of the government that deals specifically with pesticide registration. This body will assess a wide variety of potential human health and environmental effects associated with the use of the pesticide product before finally approving the registration. Both the active ingredient (a.i.) and the pesticide formulation must be registered. Many countries also maintain lists of approved inert ingredients that can be used to formulate the pesticide product. A summary of the pesticide registration process will be provided for the U.S.A., European Union, Brazil, India, Canada and Australia.

**Introduction:** The U.S. EPA defines "pesticide" as any of the following:

1) Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest,

2) Any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, or

3) Any nitrogen stabilizer. (Does not include fertilizers).

The definition of "pest" is: "Living organisms that occur where they are not wanted or that cause damage to crops or humans or other animals." Examples of pests are insects, mice, weeds, fungi, bacteria, viruses, and prions. The definition of "inert ingredient" is: "Any substance other than an active ingredient, which is intentionally included in a pesticide product." The term inert does not imply that the chemical is nontoxic.

**The United States of America:**

The regulatory body in the USA is the EPA: Environmental Protection Agency. The specific department that handles pesticide registration is the Registration Division (RD) of the Office of Pesticide Programs (OPP) within the Office of Chemical Safety and Pollution Prevention (OCSPP). The home page for the EPA pesticide registration process is located on the internet at: www.epa.gov/pesticide-registration. The EPA Pesticide Registration Manual is at: www.epa.gov/pesticide-registration/pesticide-registration-manual.

There are several statutes that cover pesticide regulation in the USA.

- FIFRA: Federal Insecticide, Fungicide and Rodenticide Act
  - Requires all pesticides sold or distributed in the United States (including imported pesticides) to be registered by EPA
  - Registration is based on evaluation of scientific data and assessment of risks and benefits of a product's use
- FFDCA: Federal Food, Drug and Cosmetic Act
  - Pesticide tolerances set for all pesticides used in or on food, or in a manner that will result in a residue in or on food or animal feed
  - A tolerance is the Maximum Residue Limit (MRL)
  - Provides for an exemption from the requirement for a tolerance for inert ingredients
- FQPA: Food Quality Protection Act, 1996
  - Amended both FIFRA and FFDCA
  - Requires "reasonable certainty of no harm"
  - Increased susceptibility to infants and children (10x safety factor)
  - Review each pesticide registration at least once every 15 years
  - Reassessment of all existing inerts
- PRIA: Pesticide Registration Improvement Act, 2003
  - Amended both FIFRA and FFDCA
  - PRIA2: Pesticide Registration Improvement Renewal Act of 2007

- PRIA3: Pesticide Registration Improvement Extension Act of 2012
- Companies must pay service fees
- EPA must meet decision review time periods
- PRIA4: Currently in development. In place by September 30, 2017

• ESA: Endangered Species Act

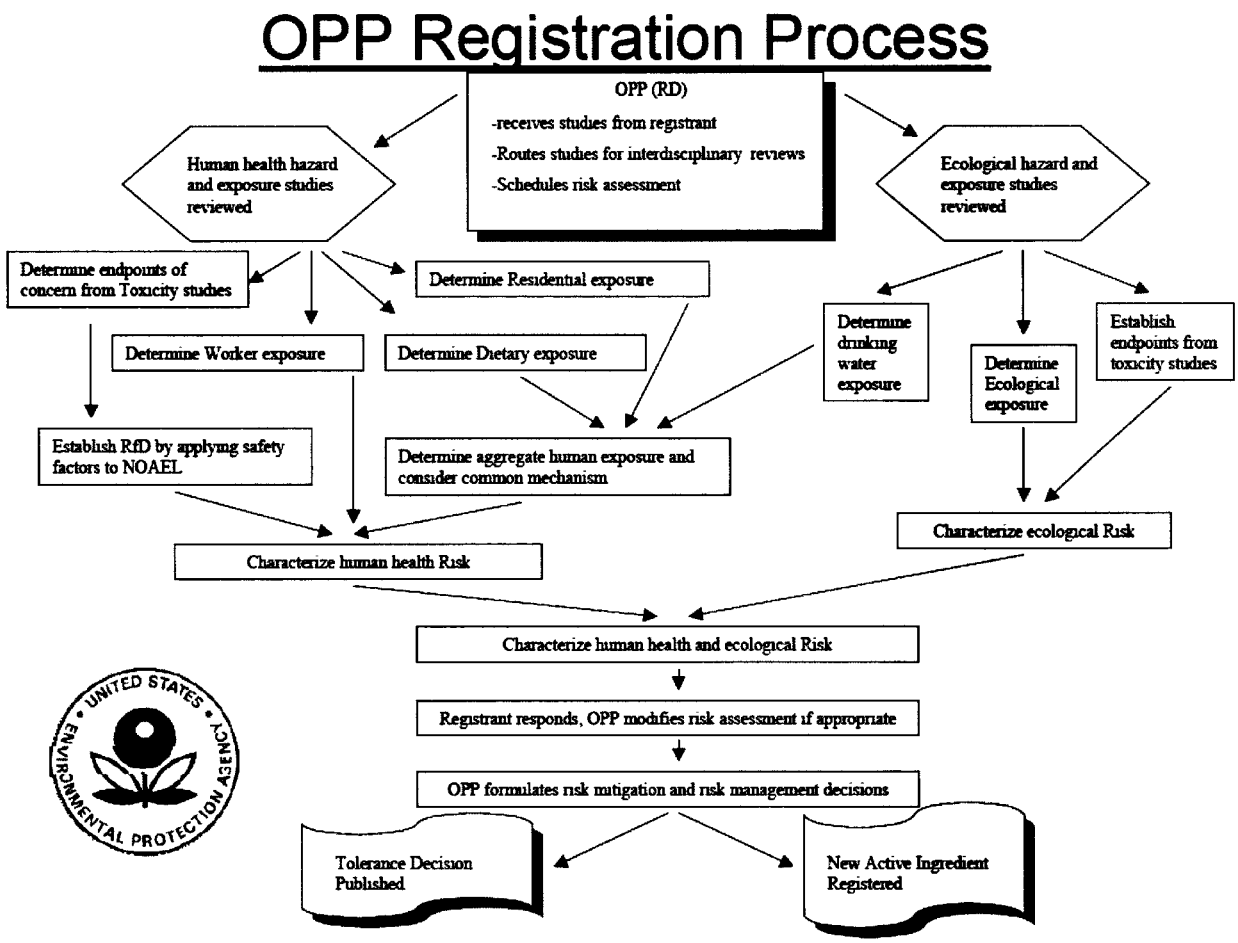


**Figure 1:** US EPA Pesticide Registration Process (Source: US EPA OPP)

The US EPA pesticide registration process is shown in Figure 1. After the Registration Division receives all required submissions it examines the ingredients of the pesticide formulation (CSF: Confidential Statement of Formula), the crop where it will be used, and the product's use, storage and disposal practices. The EPA assesses a wide variety of potential human health and environmental effects associated with use of the pesticide product. The registrant must provide data from studies that comply with EPA testing guidelines. Risk assessments are developed that evaluate the potential for harm to humans, wildlife, fish, and plants, including endangered species and non-target organisms. Contamination of surface water or ground water from leaching, runoff, and spray drift is also considered.

As shown on https://www.epa.gov/pesticide-registration/about-pesticide-registration, submissions include:

- Service fee(s) required by the Pesticide Registration Improvement Act (PRIA).
- Forms describing the requested action.
- The identity and quantity of all chemicals in the product. (The CSF)
- Data on potential risks to human health and the environment, including about the potential for pesticide residues on food (if applicable).
- Proof that the product manufacturing process is reliable.
- Labeling, including directions for use, contents, and appropriate warnings.
- Evidence of meeting all legal and financial obligations.

Pesticide Registration Improvement Acts have established fees and times for different petitions.

- Pesticide Product Petitions for a New Active Ingredient
  - R010: New Active Ingredient, Food Use: 24 Months, $627,568
  - R020: New A.I., Food Use, Reduced Risk: 18 Months, $627,568
  - R060: New A.I., Non-Food Use, Outdoor: 21 Months, $436,004
  - R110: New A.I., Non-Food Use, Indoor: 20 Months, $242,495
  - R123: New A.I., Seed Treatment Only: 18 Months, $471,861
- Existing Pesticide Product: Petition for New Uses
  - R150: First Food Use: 21 Months, $264,253
  - R160: First Food Use, Reduced Risk: 16 Months, $264,253
  - R170: Additional Food Use: 15 Months, $66,124
  - R260: New Use, Non-Food, Indoor: 12 Months, $12,764
- Pesticide Petitions: New Product of Existing A.I.
  - R300: New Product, Substantially Similar: 4 Months, $1,582
    - Must Have Data Rights
  - R314: New Combination Package Mix Product: 8 Months, $6,626
  - R320: New Product, New Physical Form: 12 Months, $13,266
- Pesticide Product Petitions: Amendments
  - R340: Amendment Requiring Data Review: 4 Months, $3,988
  - R351: Adding New Unregistered Source of A.I.: 8 Months, $13,226
- Pesticide Product Petitions: Antimicrobials
  - A380: Food Use, Establish Tolerance Exemption: 24 Months, $114,867
  - A390: Food Use, Establish Tolerance: 24 Months, $191,444
  - A420: Non-Food Use, Indoor; 18 Months, $63,816
- Pesticide Product Petitions: Biochemical
  - B580: New A.I., Food Use, with Tolerance: 19 Months, $51,053
  - B590: New A.I., Food Use, Tolerance Exemption: 17 Months, $31,910
  - B600: New A.I., Non-Food Use: 13 Months, $19,146
- Petitions: PIP: Plant Incorporated Protectants
  - B780: New PIP, Non-Food Use: 12 Months, $159,537
  - B820: New PIP, Food Use: 15 Months, $319,072
- Petitions: Inert Ingredients
  - I001: New Food Use Inert Ingredient: 12 Months, $19,845
  - I004: New Non-Food Use Inert Ingredient: 8 Months, $11,025
  - I008: New Food Use Polymer Inert Ingredient: 5 Months, $3,749
  - I009: New Non-Food Use Polymer Inert Ingredient: 4 Months, $3,087
  - I010: Add CASRNs, No New Data: 6 Months, $1,654

Inert ingredients contained in food-use pesticides must be approved on 40CFR180: CFR is the Code of Federal Regulations. Title 40 is Protection of Environment. Part 180 is Tolerances and Exemptions for Pesticide Chemical Residues in Food. This information can be found at www.ecfr.gov: (Select "Title 40", then select "Parts 150-189", then select "Part 180"). Subpart C contains specific A.I. tolerances.
Subpart D contains all inert ingredient exemptions from tolerances:

- §180.910 Inert ingredients used pre- and post-harvest
- §180.920 Inert ingredients used pre-harvest
- §180.930 Inert ingredients applied to animals
- §180.940 Active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)
- §180.950 Minimal risk active and inert ingredients (GRAS)
- §180.960 Polymers: Must Meet 40CFR723.250 Low-Risk Polymer Definition

As a result of the 1996 FQPA all inert ingredients had to undergo a new risk/hazard analysis that included a 10x safety factor considering exposure to infants and children. Everything had to be reassessed. EPA OPP IIAB (Inert Ingredient Assessment Board) started requiring CASRNs be listed for each chemistry. IIAB is now CITAB: Chemistry, Inerts and Toxicology Assessment Branch. Some chemistries had enough public tox data information available to make reassessment decisions. These chemistries were reapproved with

CASRNs in Decision Documents. Original CASRNs are listed in InertFinder but NOT on 40CFR180. Missing CASRNs were added by letter request to the EPA on 9/28/2012 for the following inert chemistries: BSA: Alkylbenzene Sulfonic Acids and Salts; Methyl Esters; PEG Esters; Quats; Sorbitan Derivatives; Alkyl Sulfates; Toluene Sulfonates and Xylene Sulfonates. While the new CASRNs are "Approved for Use," they are NOT on InertFinder or 40CFR180.

Many inert chemistries required new toxicity data to be reassessed. PRIA in combination with FFDCA established that data rights would be available for these new tox tests when the inert was used in a pesticide for food-use applications. Data compensation had long been used for active ingredients, but would now be applicable for inert ingredients for the first time. Data rights are valid for 15 years from submission of coverable data. Exclusive use is usually granted for 10 years after approval, but decisions were made to allow any company to pay data compensation without waiting for any exclusive period to expire.

A Joint Inert Task Force (JITF) was formed to handle inert reassessments that required new toxicology testing. Many individual inert chemistry listings that existed on 40CFR180 were combined into clusters, or groupings of similar chemistries. Companies got together to form Cluster Support Teams (CSTs). There were 17 CSTs formed. There is an old PDF document version circulating dated 12-01-2010 that has the original company agents listed. The most up-to-date version is dated 5-17-2012. Each CST has a Data Compensation Agent. Curtis Elsik is the CST1 and CST2 Data Compensation Agent. InertFinder should report when data rights exist for a specific CASRN. The EPA RD audits CSFs for registration submissions to see if data rights exist for any formulation component. If it does, then the company submitting the CSF for registration or the company that supplies the inert ingredient covered by data rights has to own rights to the data. If they do not, then either company needs to send an Offer To Pay (OTP) to the Cluster Agent. Payments are made to original member companies. The EPA is trying to make the Cluster Company Member Lists more visible. Here is detailed information on JITF CST1:

- JITF CST1: Chemistry: Alcohol Alkoxylates
  - Original I001 Petition: 89 CASRNs added to 40CFR180.910/930/940a/960
    - α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons
    - Submitted 4/15/2009 (Data Rights till 4/15/2024)
    - Allowed 8/5/2009 (No "Exclusive" Use: Anybody Can Pay)
  - EPA Company #84913: 19 Original Members:
    - Air Products, AkzoNobel, BASF, Bayer, Clariant, Cognis, Croda, Dow, Drexel, DuPont, Huntsman, ISK, Monsanto, Nufarm, Omnichem, Solvay, Stepan, Syngenta, Valent
    - 8 New Companies Have Paid Data Comp: $56,016.12
      - Oxiteno, Lamberti (Conlen), Ethox, Tanatex, Sasol, Harcros, Baker Petrolite, Shell
    - 1 OTP: Kolb; 1 Has Asked About Process: Kao

What does membership mean? Customers/Producers that are members can buy from any source, even if the source is not a member. Suppliers that are members can sell to any formulator, even if the customer is not a member. Producers and suppliers that aren't members don't have to pay if they buy from a member company. Any other combination and one of the companies has to submit an OTP and pay data compensation to gain rights to use that inert chemistry in a food-use pesticide.

A missing CASRN petition was submitted for CST1 on 7/19/2013. It was a PRIA3 I010 with target approval time of 6 months, and a FY14/15 cost of $1575. The 76 new CASRNs were approved 2/3/2014. The new CASRNs are in 40CFR180, but the new CASRNs are not in InertFinder. There are currently 165 CASRNs on 40CFR180. If there is a need for any new petitions to add missing CASRNs, then the company needing to add the CASRN should work through the Data Compensation Agent. That way all member companies can be solicited to see if they also have any CASRNs to add. The PRIA3 Petition I010 which takes 6 months and costs $1654 (FY16/17) does not have any limits on the number of CASRNs added. There will be limits placed on the number of CASRNs under the new PRIA4 statute in development.

Here is detailed information on JITF CST2:

- JITF CST2: Chemistry: Alcohol Alkoxylate Phosphates and Sulfates
  - Original I001 Petition: 34P/15S CASRNs added to 40CFR180.920/930
    - α-alkyl (minimum C6 linear, branched, saturated and/or unsaturated)-ω-hydroxypolyoxyethylene polymer with or without polyoxypropylene, mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; minimum oxyethylene content is 2 moles; minimum oxypropylene content is 0 moles
    - α-alkyl(C6- C15)-ω-hydroxypoly(oxyethylene)sulfate, and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts, poly(oxyethylene) content averages 2-4 moles
    - Submitted 4/15/2009 (Data Rights till 4/15/2024)
    - Allowed 7/29/2009 (No "Exclusive" Use: Any Company can Pay)
  - EPA Company #84914: 16 Original Members
    - AkzoNobel, BASF, Bayer, Clariant, Cognis, Croda, Dow, DuPont, FMC, Huntsman, Monsanto, Nufarm, Omnichem, Solvay, Stepan, Syngenta
  - 3 New Companies Have Paid Data Comp: $80,500.00
    - Oxiteno, Ethox, Harcros
  - 40CFR180.920 Listing was Expanded to 910

A missing CASRN I010 Petition was submitted on 6/5/13. Approximately 118 new Phosphate and 58 new Sulfate CASRNs were approved for use on 2/21/2014. The new CASRNs are not in InertFinder but they are on 40CFR180. There are currently 203 Phosphate and 72 Sulfate CASRNs listed on 40CFR180. The complete list of JITF CSTs is shown in the table below. All of these chemistries have data rights.

| JITF CST | Inert Chemistry |
|---|---|
| 1 | Alcohol Alkoxylates |
| 2 | Alcohol Alkoxylate Phosphate and Sulfate Derivatives |
| 4 | Alkylamine Polyalkoxylates |
| 5 | Octylphenol Ethoxylates |
| 7 | Alkyl Ammonium Chloride Salts |
| 8 | Amine Salts of Alkyl Benzene Sulfonic Acid |
| 9 | Nonylphenol Ethoxylate Phosphate and Sulfate Derivatives |
| 10 | Sodium Alkyl Naphthalene Sulfonate |
| 11 | Naphthalene Sulfonate Formaldehyde Condensates |
| 13 | Sodium 1,4-Dialkyl Sulfosuccinates |
| 14 | Sodium Salts of Alkyl Iminoproprionic Acid |
| 15 | Tetrakis Hydroxpropyl Ethylenediamine |
| 19 | Ethoxylated Acetylenic Diols |
| 20 | Ethoxylated/Propoxylated di-sec Butylphenyl Ether |
| 23 | Polyglyceryl Phthalate Ester of Coconut Oil Fatty Acids |
| 24 | Sodium *N*-Oleoyl-*N*-Methyl Taurine |

InertFinder is the new EPA on-line Search Engine for CASRNs. It is available at:
https://iaspub.epa.gov/apex/pesticides/f?p=101:1:
InertFinder should confirm if an inert ingredient is approved for use in a pesticide formulation in the U.S. It will have information pertaining to Food and Non-Food Use. Note as mentioned before, not all Food-Use CASRNs are loaded into InertFinder. InertFinder should also report if Data Rights exist for that chemistry. InertFinder is the only current source to check for approvals of Non-Food Use CASRNs.

Pesticide Registrations are also required on the State level. Information is available at:
http://npic.orst.edu/reg/state_agencies.html

For example, California has the California Department of Pesticide Regulation (CDPR) and Washington has the Washington State Department of Agriculture (WSDA).

Recent regulatory activity in the U.S.A.:

1) Adjuvants: Have No Effect on Pesticide A.I. Residue Levels
2) Nanomaterials: Getting Extra Scrutiny Due to Potential Hazards

TSCA (Toxic Substances Control Act) covers inert ingredients made or transported in U.S.A. This act is currently being modified:

- The Frank R. Lautenberg Chemical Safety for the 21st Century Act
  - President Obama Signed into Law June 22, 2016
  - EPA will have broader, more flexible authority to use Consent Orders and test rules to require toxicity/ecotoxity test data for new and/or existing chemicals
  - EPA can take expedited action when new information suggests that a chemical presents a significant risk to human health
  - EPA must designate a chemical as "high priority" or "low priority" for risk evaluation
  - Industry required to substantiate claims for confidentiality
  - Inventory Reset: Active vs. Inactive Chemicals

**The European Union (EU):**

ECHA: The European Chemicals Agency is the governing regulatory body. Pesticide registrations are covered under the following statutes:

- PPP: Plant Protection Products
  - 2011: Regulation (EC) No 1107/2009
  - EC: European Commission (Governing Body of EU)
- BPR: Biocidal Products Regulation
  - 2013: Regulation (EU) No 528/2012
- REACH: Registration, Evaluation, Authorization and Restriction of Chemicals
  - 2007: Regulation (EC) No 1907/2006
- CLP: Classification, Labelling and Packaging
  - 2009: Regulation (EC) No 1272/2008
  - UN GHS: Globally Harmonized System
  - Global Update of SDS: Safety Data Sheets Conform to GHS
  - Pictograms Used to Convey Hazards on the SDS

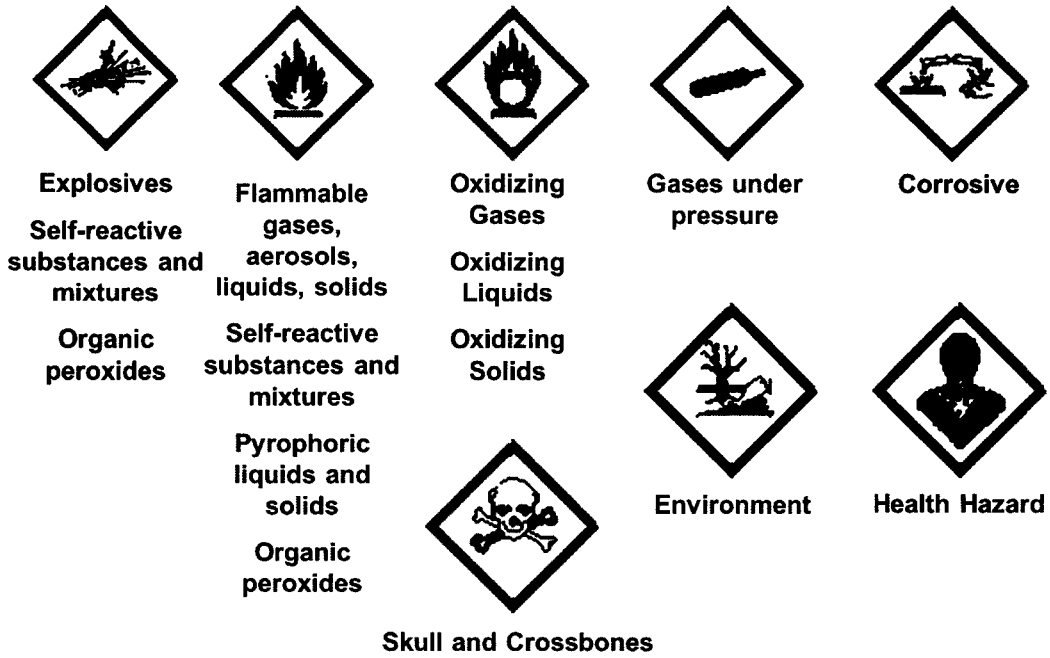


**Figure 2:** Pictograms Used to Convey Hazards on the GHS SDS

- Approval of Active Ingredients covered in 2011 by Regulation (EC) No 1107/2009:
  - Application made to a representative EU country: Rapporteur Member State (RMS)
  - RMS verifies if the application is admissible
  - RMS prepares a draft assessment report
  - EFSA issues its conclusions (European Food Safety Authority)
  - Standing Committee for Food Chain and Animal Health votes on approval or non-approval
  - Commission Adopts the Petition
  - Publication of a Regulation in the EU Official Journal
- Timing: 2.5 to 3.5 years
- Example RMS: Germany National Authority: BVL
  - Das Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
  - The Federal Office of Consumer Protection and Food Safety

- Approval of Plant Protection Product
  - Plant Protection Products Application Management System (PPPAMS, On-Line)
  - Zonal system of authorization
    - North, Central, and South Zones
    - Obligatory mutual recognition within Zone
  - Zonal Rapporteur Member State (zRMS)
    - Can Apply to Several zRMS at Same Time
    - Other States are Concerned Member States cMS
  - Work can be shared between Member States
  - All applications made as a draft Registration Report (dRR)
    - Part A – risk management
    - Part B – data evaluation and risk assessment
    - Part C – confidential information
- Timing: 12 to 18 months
- Fees for Germany: 7000 – 136000 €
- One Zone Exceptions
  - Greenhouses, Post-Harvest, Seed Treatment

Guidelines on Active Substance & Plant Protection Product Petitions:
1) Technical Guidance includes Phys-Chem, Toxicity, Efficacy, Residues, and Ecotox data.
2) Procedural guidance includes Dossier and Draft Assessment Report and Issues
3) Available on the internet at:
   - ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents/active_substances_en.htm

FAO, WHO, CIPAC, ASTM, and OECD are examples of the bodies that issue specifications, analytical and QC test methods that are required for data submission.

REACH has been the most important recent regulatory activity in the European Union. REACH is the Registration, Evaluation, Authorization and Restriction of Chemicals. It was established in 2007 by Regulation (EC) No 1907/2006.

- Registration
  - Every Chemical has to be Registered if Volume > 1 tonne/yr
  - Tiered Timing Tied to Volume (Registration > 100 tonnes/yr Completed)
  - Last to Register: 1-100 tonnes/yr by May 31, 2018
- Evaluation
  - Toxicity/Ecotoxicity Data: Hazards Evaluated for Humans and the Environment
  - SIEF: Substance Information Exchange Forums
    - Competitors Work Together for Similar Chemistry
    - One Company Takes Lead Role
    - Minimizes Duplicate Tox Testing
- Authorization and Restriction
  - Ban SVHC: Substances with Very High Concern
  - Isolate Bad Substances, Encourage Substitution

- Exemptions From Registration
  - Polymers (OECD): Monomers/Reactants Have to be Registered
  - Some Annex IV Products
    - $CO_2$, $N_2$, $H_2O$, Fatty Acid Methyl Esters
  - Some Annex V Product Groups
    - $H_2$, $O_2$, Fatty Acids and Their Salts, Minerals, By-Products
- REACH Registration Number: RRN
  - Customers Ask: "What is REACH Status of a Product?"
    - It DOES NOT MATTER!
    - Each Legal Entity (LE) Has to do a Registration
  - Importers of Products into EU have to Register
    - Even if Product Already has RRN
    - Importer Has to Obtain Their Own Registration
    - Supplier Can Act as "Only Representative" (OR)
- Formulations Don't Need REACH Registration
  - All Components Have to be REACH Registered
- Situation Where Product is Manufactured in EU
  - Products are REACH Compliant as Manufactured
    - Buy and Formulate (Blend) in EU: No Additional Registration
    - Export, Blend, Re-Import into EU: Track Batch Number
      - No Chemical Reactions Allowed; Track All Components
- Situation Where Product is Manufactured Outside EU
  - Products are NOT REACH Compliant
    - REACH Does Not Apply Outside EU
    - REACH Requirement is Triggered When Product is Brought Into EU
    - Importer Has to Obtain Their Own Registration
      - Join SIEF if Chemistry Registered; New Registration if Not
    - Supplier Can Act as "Only Representative" (OR)
      - If Chemistry Matches Product Registered by Supplier

**Brazil:**

There are three Federal Agencies that are involved with pesticide registration in Brazil:

- MAPA: Ministry of Agriculture, Livestock and Food Supply (1934)
  - Evaluates the Bioefficacy of Pesticides
  - Issues the Certificate of Registration
  - http://www.agricultura.gov.br/
- ANVISA: Ministry of Health (1976)
  - Performs Toxicological Assessment
  - Classification of Health Hazards of Pesticides
  - MRL Establishment
  - http://portal.anvisa.gov.br/
- IBAMA: Ministry of Environment (1989)
  - Environmental Assessment
  - Classification of Potential Environmental Hazards
  - Including Pesticides
  - http://www.ibama.gov.br/
- Law is in Force at Federal, State and Federal District Levels
  - Provides for research, experimentation, production, packaging and labeling, transportation, storage, marketing, commercial advertising, use, importation, exportation, final disposal of residues and packaging, registration, classification, control, inspection and oversight of pesticides
- Time Required for Registration
  - Typical 5 Years
  - Can be up to 6 Years

It is recommended that registrants file in triplicate simultaneously to all three agencies. Each agency can then perform their respective assessments simultaneously. All three agencies have to authorize the registration before it gains final approval. This process can take 5-6 years for approval.

Recent regulatory activity in Brazil:

- Considering a New System for Pesticide Registration
  - Current System Outdated and Slow
  - Brazil's Chamber of Deputies Looking to Make Changes
  - May Be Similar to U.S.A./Canada
- MRL: Maximum Residue Limit
  - New Regulation: INC 01/2010
  - MRLs Extrapolation for Minor Crops
  - Inclusion of Crops on Pesticide Monographs
- SDSs Have to be FISPQ Compliant
  - Ficha de Informações de Segurança de Produtos Químicos
- Brazil Government Auditing Existing Formulation CSFs
  - Do NOT Be Out of Compliance: In One Case a $5 Million Fine was levied on a Company
  - CASRNs of Alternate Raw Materials Have to Match CSF

**India:**

- Pesticide Regulations in India
  - The Insecticides Act, 1968: http://cibrc.nic.in/insecticides_act.htm
  - Insecticide Rules, 1971: http://cibrc.nic.in/insecticides_rules.htm
  - Regulate the import, registration process, manufacture, sale, transport, distribution and use of insecticides (all pesticides)
- Central Insecticides Board & Registration Committee
  - CIB & RC: http://cibrc.nic.in/
  - Computerized Registration of Pesticides (CROP)
  - Registration Procedure: http://cibrc.nic.in/reg_procedure.htm
  - Guidelines: http://cibrc.nic.in/guidelines.htm
  - Registration Certificate
- Indian Pest Control Association
  - http://ipca.org.in/pesticide-regulations/

**Canada:**

- Health Canada: General Regulatory Agency in Canada
  - www.hc-sc.gc.ca
  - www.hc-sc.gc.ca/cps-spc/alt_formats/pdf/pubs/pest/_fact-fiche/regulation-Pesticides-reglementation-eng.pdf
  - Pest Control Products Act (PCPA)
  - MRLs: Food and Drugs Act
- Pest Management Regulatory Agency (PMRA)
  - PMRA is Branch that is responsible for Federal Pesticide Registration
  - www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/index-eng.php
  - Human Health, Environment, Bioefficacy, Compliance, Enforcement
- Provincial/Territorial Responsibilities:
  - Transportation, Sale, Use, Storage, Disposal
- Inert Ingredients: PMRA List of Formulants
  - If Not on This List, Should be on U.S. EPA 40CFR180

**Australia:**

- Australian Pesticides and Veterinary Medicines Authority (APVMA)
  - Agricultural and Veterinary Chemicals Code Act 1994
  - Pesticide Registration: http://apvma.gov.au/
  - On-Line Application for Approvals
  - Active Constituents, Pesticide Products, Labels

  - Veterinary Products: GMP: Good Manufacturing Practice
- APVMA: Active Constituents Not Requiring Evaluation
  - List of Approved Chemistries
  - Chemistry Evaluation May Not Be Necessary
  - Other Stages of Registration Must Still Proceed as Normal
  - http://apvma.gov.au/node/4176
- Recent Regulatory Activity
  - Looking at Adjuvant Effects on Residue Levels

**Conclusions:**

Pesticides are the most regulated product type globally. Every country requires pesticide registration including both active ingredients and the pesticide product formulation. Specific regulatory departments that specialize in pesticides are usually established within or separately from the main regulatory agency. Usually there are additional requirements for compliance of the inert ingredients of the pesticide formulation. In the USA inerts have to be TSCA-Listed until they are included in the pesticide product. In the EU all components have to be REACH registered. Most countries have on-line procedures and electronic application systems. Most countries require significant fees and require significant time for approval.

**References:**


**The United States of America:**

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www.epa.gov/pesticide-registration/pesticide-registration-manual
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**The European Union (EU):**

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cibrc.nic.in/insecticides_rules.htm
cibrc.nic.in/
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ipca.org.in/pesticide-regulations/

**Canada:**

www.hc-sc.gc.ca
www.hc-sc.gc.ca/cps-spc/alt_formats/pdf/pubs/pest/_fact-fiche/regulation-Pesticides-reglementation-eng.pdf
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**Australia:**

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