Supplemental Distributor Products

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Outline

1. Definition of Supplemental Distributor Products.
2. Why do registrants use Supplemental Distributors to market their products?
3. Why do companies choose to become Supplemental Distributors?
4. Supplemental Distributor Process.
5. Suggestions for the Future.

1 Definition of Supplemental Distributor Products

1. Definition

- Regulations allow the registrant to distribute or sell his registered product under another company’s name and address instead of (or in addition to) his own.
- Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "distributor product."
- The Distributor is considered an agent of the registrant.
- Distributor product labeling statements are identical to the reviewed and approved Basic registrants master label except for deleted claims or uses.

1 Definition of Supplemental Distributor Products

2. What a Supplemental Distributor IS NOT . . .

It is not Supplemental Labeling

- FIFRA Section 2 defines label and labeling.
  - Label: Written, printed or graphic matter affixed to container.
  - Labeling: All labels and all other written, printed or graphic matter.
- New approved uses not on current container label.
- Must refer to product label for complete directions and precautions.
- Supplemental Label must be in possession of the user.
- Supplemental labeling cannot conflict with existing container label.

1 Definition of Supplemental Distributor Products -- 8570-5 Form vs Label

EPA Registration Number of Product	Distributor Company Number
100-935	100-935-524
Note: Do not submit distributor product labels	
Name of Registered Product (*basic product name accepted by EPA*) Helix Xtra Insecticide with Fungicides	Distributor Product Name Acceleron IDL-810 Insecticide and Fungicides Seed Treatment

Name and Address of Distributor *(Type; include ZIP code)*

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

ACCELERON®
IDL-810
Insecticide and Fungicides
Seed Treatment

EPA Reg. No. 100-935-524 EPA Est. 46073-TN-003
Product of Canada

Packaged for: Monsanto Company • 800 N. Lindbergh Blvd.
St. Louis, Missouri 63167 • 1-314-694-4000

1 Definition of Supplemental Distributor Products -- Basic vs SupDist Labels

HelixXtra®

syngenta

Insecticide with Fungicides

A seed treatment product for control of certain insects and diseases of canola.
For use in commercial seed treatment facilities with closed transfer systems only. No open transfer.

Active Ingredients:	
Thiamethoxam*:	20.70%
Difenoconazole**:	1.25%
Mefenoxam***:	0.40%
Fludioxonil****:	0.13%
Other Ingredients:	77.52%
Total:	**100.00%**

*CAS No. 153719-23-4
**CAS No. 119446-68-3
***CAS Nos. 70630-17-0 and 69516-34-3
****CAS No. 131341-86-1

Helix XTra contains the following amounts of active ingredient per gallon: 2.23 lbs. thiamethoxam; 0.13 lbs. difenoconazole; 0.04 lbs. mefenoxam; 0.01 lbs. fludioxonil.

CAUTION **KEEP OUT OF REACH OF CHILDREN.**

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-935 EPA Est. 71478-CAN-001
Product of Canada

SCP 935A-L2F 0909
306098

30 gallons
Net Contents

ACCELERON®
IDL-810

Insecticide and Fungicides Seed Treatment

A seed treatment product for control of certain insects and diseases of canola.

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Acceleron IDL-810 Insecticide and Fungicides Seed Treatment contains the following amounts of active ingredient per gallon: 2.23 lbs. thiamethoxam; 0.13 lbs. difenoconazole; 0.04 lbs. mefenoxam; 0.01 lbs. fludioxonil.

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Product of Canada

KEEP OUT OF REACH OF CHILDREN
CAUTION

See additional precautionary statements and directions for use in booklet.

Net Contents:
30 gallons

401071.2-1
323808

Packaged for: Monsanto Company • 800 N. Lindbergh Blvd. St. Louis, Missouri 63167 • 1-314-694-4000

2 Why do registrants use Supplemental Distributors to market their products?

1. The Big Picture

- **Division of Labor** is the heart of the relationship between the basic registrant and the supplemental distributor.
- Each company does what they do well: **develop**, **manufacture** or **distribute** products.
- Supplemental Distributor products are often **better targeted and more economical** for end-users.

2 Why do registrants use Supplemental Distributors to market their products?

2. Marketing

- Strengthen **brand recognition** and fortify brand loyalty.
- Ability to **reach markets and customers** the basic registrant cannot by itself (especially for smaller manufacturers).
    - Distributor advertising
    - Distributor relationships, e.g., big box stores
    - Distributor sales force
    - Distributor warehouse network
- **Inclusion** in national or regional distributor branded product offerings.

2 Why do registrants use Supplemental Distributors to market their products?

- **Customize** product for special situations.
  - Customize label for **local needs**
  - Local **fertilizer** blends
  - **Packaging** preferences
  - Specialized **dispensing/application equipment** for specific markets (common in institutional/industrial biocides markets)
- Basic registrant has **more control** over how product is labeled and positioned in the marketplace compared to Me-Too.
- Leverage relationship with formulator to **expand** to other technical molecules/materials.
- Differentiates formulators who use **branded material vs. generic**, allowing branded material to extract more value.
- **Cost** advantage compared to alternatives.

2 Why do registrants use Supplemental Distributors to market their products?

3. State Registrations

- When the distributor is responsible for state registrations, it puts the decision making process closer to the market. It gives the distributor more **flexibility** to quickly apply for or cancel state registrations. Keeps a tighter control on costs.

4. Distributor Motivation

- Distributors are more motivated to sell products with distributor's name, distributor's product design.
- Product can be customized for distributor using alternate colors/fragrances.

2 Why do registrants use Supplemental Distributors to market their products?

5. Combination Products, e.g., Pesticide + Fertilizer

- Distributor brings manufacturing expertise, e.g., fertilizer, granules.
- Distributor brings biological expertise, e.g., fertilizer, granules, local biological factors.
- Distributor's physical location may reduce shipping/warehousing costs.

3 Why do companies choose to become Supplemental Distributors?

1. Speed to Market – by capitalizing on the Basic Registrant's product development, which includes:

- Regulatory Expertise
- State Registration Support
- Formulating and Manufacturing capabilities
- EHS and Product Safety guidance
- Availability of Cooperative Marketing Funds
- Access to Technical Training, 800 Line, Product Training
- Favorable Financial Terms

3 Why do companies choose to become Supplemental Distributors?

2. Access to niche products/markets

- Expand product line without large cost investment.
- Market flexibility, add/drop products with less cost.
- Market recognition and brand loyalty.

3. Distributor/End-User relationship

- Relationship with distributor sales rep.
- End-use has ability to "price-shop" for same active ingredient within private label product at multiple distributors.
- Proven performance with a certain distributor’s private label product.
- Rebate/loyalty program with certain distributor.
- Resources available from certain distributor/corresponding primary registrant.

3 Why do companies choose to become Supplemental Distributors?

4. The alternatives aren't great

- Maintaining a Federal Registration often requires hiring regulatory staff or a consultant and requires funds to purchase data.
- Me-Too alternative: PRIA Fees are $1,506 to $1,806.
- Annual EPA Maintenance Fees: $3,575 per year.

Although there are some advantages too . . .

- A Me-Too registrant has freedom to control label design, branding, etc. within the constraints of citing the basic registrant's **data**.
- A Me-Too registrant can incorporate any branding that may have conflicted with constraints of a Supplemental Distributor product label.
- From a basic registrant's viewpoint: a Me-Too means less upkeep/maintenance for basic registrant's regulatory personnel.
- A Me-Too decreases compliance risk for the basic registrant.

4 Supplemental Distributor Process

1. Registrant Registration Requirements

- **40 CFR 152.132; Pesticide Registration Manual Chapter 9**
  http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered
- **Label Review Manual; Chapters 3, 4, 12, 14, 15:**
  http://www2.epa.gov/pesticide-registration/label-review-manual
- **FIFRA Section 3 Product Information Files:**
  http://www.epa.gov/pesticides/PPISdata/

Distributor Product Labeling Statements Identical to EPA Reviewed & Approved Basic Master Label Except for Deleted Claims or Uses

4 Supplemental Distributor Process

2. Registrant Distributor Agreements

Registration Agreement

- Identifies a Specific EPA Registration
- Commercial Brand Name
- Distributor Company Name, Address, EPA Company Number
- Includes Provisions for FIFRA 6(a)(2) Reporting Obligations
- Defines Responsibilities & Terms

Manufacturing, Formulating, Packaging Agreements

- Identify EPA Registered Pesticide Production Establishments Approved to Formulate and/or Package
- Production Allowed at Multiple EPA Approved Locations

4 Supplemental Distributor Process

3. Registrant Responsibilities

Basic Registrant

- Controls EPA Master Label
- Submits Form 8570-5
- Review & Approves Labeling
- Label & EPA Accepted Master Match Except for Any Deleted Claims & Uses
- Issue Letter of Authorization
- Notify Transfer Agreements

Supplemental Distributor

- Proposes Label Language
- Manages State Registration
- Label Reflects EPA Accepted Changes in Same Timeframe as Basic
- Same Effective Dates to Cancel or for Existing Stocks
- Distributorships Do Not Transfer New 8570-5 Form Required

4 Supplemental Distributor Process

1. State Role

- State registration
  - New product application + fee
  - Market place product label
  - EPA stamped master label, 8570-5 Form, Letter of authorization, CSF, New York certification statement
- Product compliance inspections (producer establishment & marketplace)
  - State registration
  - Federal registration
  - Misbranding
  - Adulteration

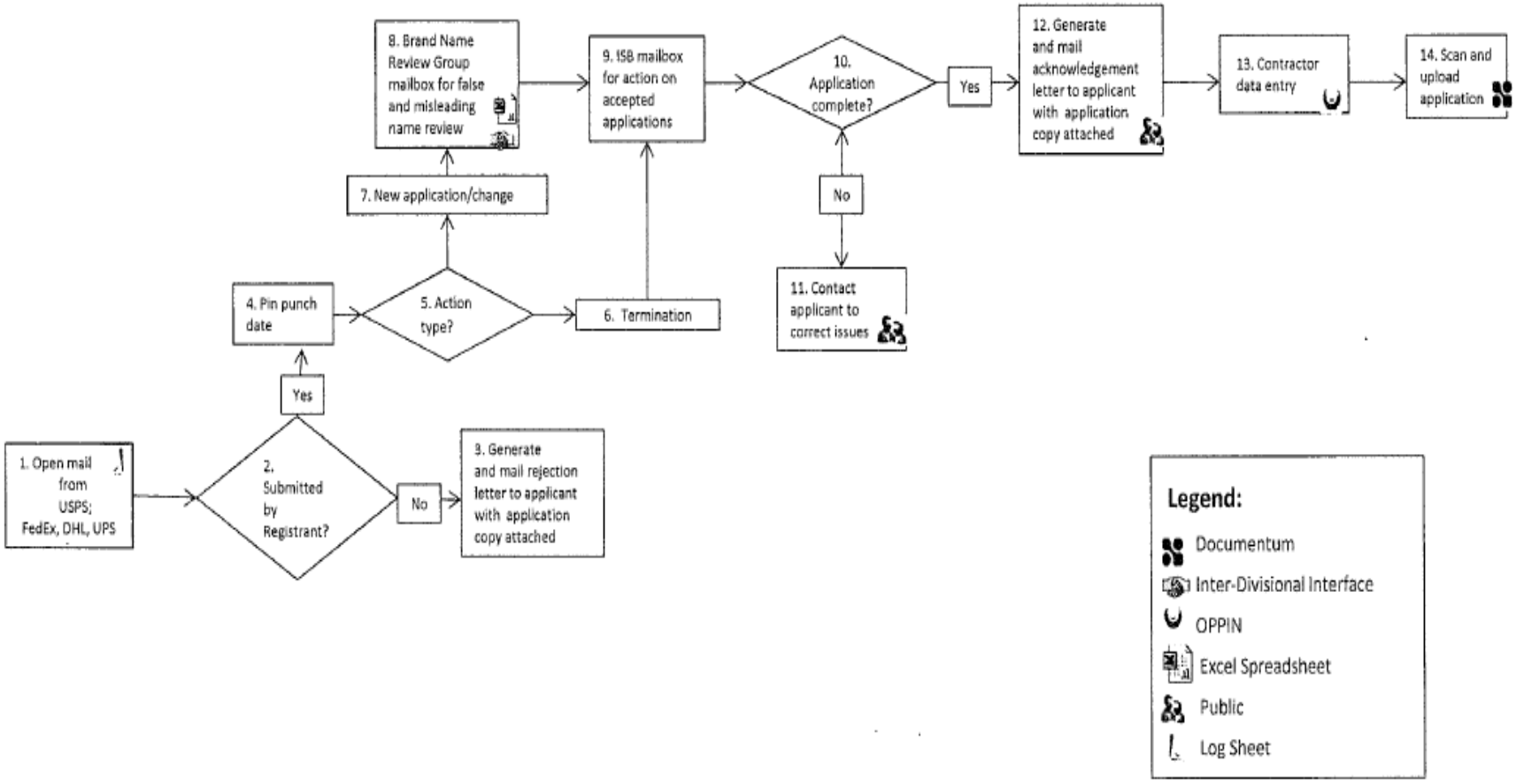
4 Supplemental Distributor Process

2. Compliance Issues

- EPA (OPP) focuses on basic registrations & labels
- Most states operate in a market label world
    - Primary product
    - Alternative brand names
    - Distributor registrations
    - Supplemental labels
- State compliance relatively straight forward
- Federal compliance, not straight forward to SLAs
    - US EPA OPPIN (PPLS) database not terribly useful
    - Confidence in the 8570-5 Form process?

4 Supplemental Distributor Process

3. EPA Application Process



4 Supplemental Distributor Process

4. State Compliance Issues

- State registered but not federally registered…oops!
- Limited or no access to federal data during market place & producer establishment inspections
- Weak & slow market place compliance

5 Suggestions for the Future

1. States

- Improve timeliness & reliability of 8570-5 process.
- Include distributor registration data in accessible data.
- Include market place labels in accessible data.
- Make web accessible registration data straightforward.

5 Suggestions for the Future

2. Registrants

- Industry and State Regulators agree that improvements to processes and recordkeeping for Supplemental Distributors would aid in assuring compliance.
- In particular, ACC Biocide Panel members identified many discrepancies between what registrants had submitted and what was on file at EPA.
- The ACC Biocide Panel began meeting and discussing concerns with Information Technology and Resources Management Division (ITRMD) in May 2014 and looking at ways to improve the process.

5 Suggestions for the Future

- Some outcomes of ACC Biocide Panel's work with ITRMD include:
  - ITRMD began sending letters and pin-punch of the notice to the primary registrant to confirm acceptance of the supplemental product notification. Previously, the primary registrant did not typically receive the letter or pin-punch from EPA; EPA sent it only to the supplemental distributor, who did not know to inform the primary registrant.
  - Instructions in the Registration Manual (Chapter 9) were revised by EPA and then further revised (Dec 31, 2014) on the basis of suggestions from the Panel, to improve clarity in how to make changes.
  - The Panel is at the start of a project to have its members review and confirm what is on file at EPA and work with ITRMD one-on-one to make corrections. As part of that process, it is expected that we will be able to identify ways to minimize problems going forward.

5 Suggestions for the Future

- Some additional issues identified include:
  - ITRMD's current process for handling these notifications may make it difficult to confirm entries on short notice. It can take 4 to 6 weeks before an acceptable notification is entered into EPA's database. Those changes will not be made publicly accessible until EPA does its monthly release of the PPIS files, which could result in another 3 to 4 week delay before entries can be accessed.
  - ITRMD expects that an electronic portal approach will help in the future.

5 Suggestions for the Future

- Additional improvements suggested by AAPCO Industry Workgroup:
  - While based on the work of ACC with ITRMD, registrants are to receive a pin-punched copy of Form , this does not yet seem to be consistently occurring. Both registrant and distributor need to receive a copy.
  - While it is understood that Supplemental Distributor labels are not submitted to EPA, it would be helpful if a field listing active Supplemental Distributor product names could be added to PPLS for a given registration.
  - If such listing could also include Supplemental Distributor Registration numbers associated with those product names, it would be even more helpful.
  - Alternatively, if EPA could provide a searchable database of current active Supplemental Distributor products it would allow states to confirm they are active when processes state registration.