



# Flupyradifurone

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# Global Perspectives and Approaches

- ❑ Provide solutions to customers, and support customers' needs
- ❑ Partner with leading experts to enhance/broaden strategic value in development, for example:
  - ❖ *IR-4 and PMC*
    - *Vast expertise and network in specialty crops and minor uses*
    - *Strategic vision extending to international collaborative activities, global minor uses, MRL harmonization, crop grouping, etc.*
- ❑ Customers need to be able to export their commodities from the crops treated with our products
  - ❖ *timely establishment of MRLs to facilitate trade*
- ❑ Seek Global Joint review and develop data accordingly





# Sivanto™

**as an example of our approaches to**

- Support specialty crops
- Global submissions for domestic uses and/or import MRLs
- Support for international trade of new Reduced Risk product





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# Example of *Early Global Project Planning*

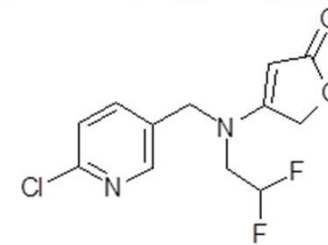
First tier submission (2012)		GJR					EU
	Submission dates	10/2012					5/2012
Crops on the label	Primary MRLs to be established	USA	CAN	MEX	AUS	BRA	EU
Coffee	coffee, bean	IT	IT			v	IT
Legume, pea and bean veg CG 6	CG 6	v	v		v		v
<i>green beans</i>							
Foliage of Legume veg CG 7	CG 7	v	v				
Fruiting veg CG 8-10	CG 8-10	v	v	v	v		v
Cucurbit veg CG 9	CG 9	v	v	v	v		v
Citrus fruits CG 10-10	CG 10-10, fruit	v	IT	v		v	IT
<i>citrus</i>							
Pome fruits CG 11-10	CG 11-10	v	v				v
Bushberry CSG 13-07B	CSG 13-07B	v	v	v			v
Small fruit vine climbing (except fuzzy kiwifruit) CSG 13-07F	CSG 13-07F	v	v	v			v
<i>grape</i>							
Low growing berry CSG 13-07G	CSG 13-07G	v	v				v
Tree nut CG 14	CG 14	v	v				IT

harmonized within NAFTA  
 globally harmonized GAP (within 25%, per OECD)



# Sivanto 200 SL

- Chemical code: BYI 02960
  - Common name: Flupyradifurone
  - Chemical class: Butenolide
  - Mode of action: IRAC Group 4D (Nicotinic acetylcholine receptor (nAChR) agonist)
- 
- Pest spectrum: Aphids, Leafhoppers, Whiteflies, Scales, Psyllids, *Scirtothrips*
  - Key crops: Tree Fruit, Nuts & Vine crops, Vegetables, Cotton, Sorghum
  - Application methods: Foliar and Soil





# Sivanto: Key Benefits

1. Flexible application window, including during bloom
  - ▶ *honey bee safety profile*
2. Compatible with Integrated Pest Management (IPM) systems
  - ▶ *minimal effects on major beneficial insects, when used as directed*
3. Provide effective disease mitigation due to:
  - ▶ *rapid feeding cessation*
  - ▶ *adult knockdown*
  - ▶ *control of immature stages*
4. Excellent control of NN-resistant aphid and whitefly populations





# Sivanto: Current Registration Status

## □ Global approval status for Sivanto 200 SL:

### ❖ Approved in 8 countries

- USA: approved 1/2015 (Reduced Risk)
- Mexico: approved 5/2015
- Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, S. Korea

### ❖ Pending approvals in Australia, Brazil, Canada, China, EU, India, Peru, South Africa, etc.





# Crops Registered (US)

## Foliar application

### Trees, Nuts & Vines

- ▶ Citrus Fruits (also soil)
- ▶ Pome Fruits
- ▶ Tree Nuts + pistachios (except almonds)
- ▶ Bushberry (**Blueberry**)
- ▶ Low Growing Berry
- ▶ Small Fruit Vine Climbing (except fuzzy kiwifruit); (also soil)
- ▶ Hop

### Broad Acre Crops

- ▶ Cotton
- ▶ Cereal Grains (except rice)
- ▶ Alfalfa, **Clover**
- ▶ Peanut

### Vegetables

- ▶ Fruiting Vegetables (also soil)
- ▶ Cucurbit Vegetables (also soil )
- ▶ Leafy Vegetables
- ▶ Brassica (Cole) Leafy Vegetables
- ▶ Root Vegetables
- ▶ Tuberous and Corm Vegetables
- ▶ Legume Vegetables (succulent, dried)
- ▶ **Prickly Pear/Cactus Pear/Pitaya**

**IR-4 and/or PMC projects**

- 14 Crop Groups/Subgroups and 6 individual crops
- Strategic contribution from IR-4 and PMC for specialty crops in Crop (sub)groups, and individual crops
- Blueberry in global residue program (26 locations in 9 countries)





## Blueberry



### GLOBAL RESIDUE STUDY-Blueberry



- 1 chemical
- 1 crop (blueberry)
- 26 locations in 9 countries
- Regulatory study conducted under one protocol (one GAP)

**The calculated MRL from the North America data sites (13 trials), was the same as when calculated with all 26 global sites.**

# New Crops/Uses Pending

## □ Additional food uses in the crop area

- ❖ Caneberry CSG 13-07A: blackberry (PMC)
- ❖ Stone fruits CG 12-12: peach, plum and cherry (BCS)
- ❖ “Tropical fruits CSG 24B”: pomegranate (IR-4) and avocado (BCS)
- ❖ Quinoa\* (IR-4)
- ❖ Kava\* (IR-4)
- ❖ Cilantro\* (IR-4)

\*: extrapolate from existing data

## □ Greenhouse use on vegetables:

- ❖ Tomato, pepper, cucumber (IR-4), lettuce (PMC)

Disclaimer: Sivanto is not yet registered for sale or use on these crops. Always read and follow label directions





# Key Considerations

- ❑ Partner with IR-4 and PMC early
- ❑ Be mindful about the needs in specialty crop area by
  - ❖ *Registration of Crop groups*
  - ❖ *Extrapolation based on existing data*
- ❑ Participate in Global residue program
- ❑ Support the revision of crop groups and flexibility of representative crops, and where possible, harmonization of CGs definition among jurisdictions
- ❑ Advocate/encourage JMPR to support new initiatives to improve efficiency for MRL harmonization, such as;
  - ❖ *Pilot of "Achieving timely and globally harmonized MRLs through Codex"*





# Trade and MRLs

## □ Always a challenge

- ❖ Early project planning to identify MRL needs (for trade enable)
- ❖ MRL establishment *via*
  - Global joint review, *also possible to request for import MRLs in North America*
  - Individual country/region application (domestic uses and MRLs, import MRLs)
  - Codex MRLs

## □ Uncertainties

- ❖ Residue definition
- ❖ MRL values
- ❖ Timing of MRL establishment



# Sivanto and MRL Timelines



Codex



Mexico



US



Canada



Australia



Japan



Taiwan



Hong Kong



South Korea



EU



H1 '15



H2 '15



H1 '16



H2 '16



2017

Registered also in Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, and S. Korea

Disclaimer: Projections only; regulatory and MRL timelines are subject to change



# We Have a Dream

- ❑ If some day,
  - ❖ Export countries and import countries are in GJR
  - ❖ All countries receive the same data package
  - ❖ All agree to also establish import MRLs (for the crops not grown locally) at the time of approvals

❑ NO MORE trade/MRL issue





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# A Single MRL Timeline



US



Mexico



Canada



Australia



Japan



Codex



Taiwan



South Korea



EU



Hong Kong





**Thank you**

