



Case Study: Way Forward to Accelerate Harmonized MRLs to Enable Trade Learning from Sivanto and Japan

Jamin Huang, Ph.D., Bayer CropScience, USA

Agenda



- 2013 MHLW Import MRL Policy Change
- Case study: Sivanto and Import MRLs in Japan
- Next Steps

心より感謝いたします



MHLW: Ministry of Health, Labor and Welfare

responsible for completeness check, dietary
exposure assessment, MRL establishment

FSC: Food Safety Commission

responsible for risk assessment, ADI establishment

心より感謝いたします



Mr. Kaoru Sasaki and Ms. Fumiko Sato
Tokyo, Japan

2013 MHLW Import MRL Policy Change

(May 14, 2013)

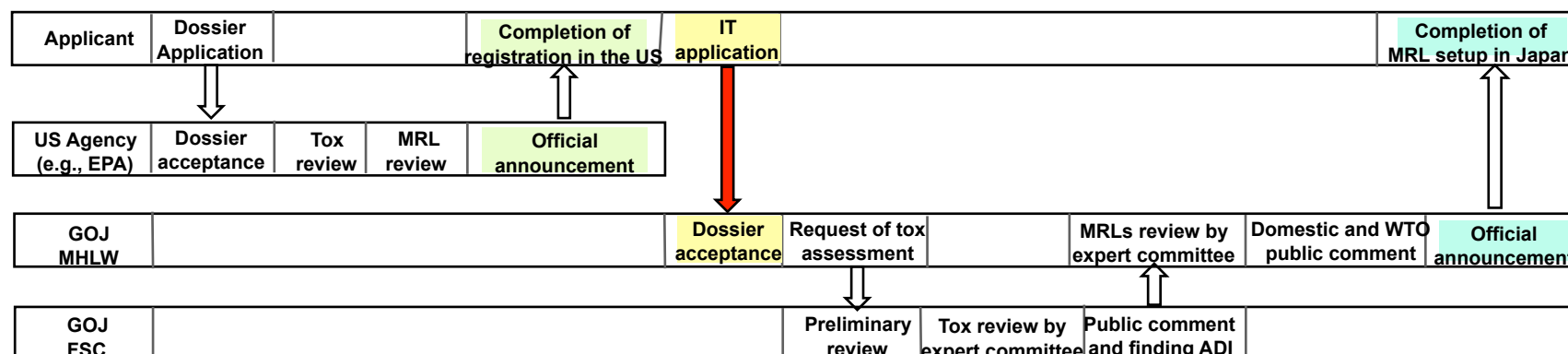


- Policy change initiated by MHLW
- MHLW would accept applications for import MRLs **before** the MRLs of the chemical are finalized in the export country
- MHLW requires that the MRLs in export country be officially finalized by the time FSC returns the application dossier back to MHLW for MRL review
- Previously, application accepted **only after** the MRL was officially finalized in the country where the substance would be used
- New policy would allow import MRL applications to start the review process in Japan **earlier** than in the previous system

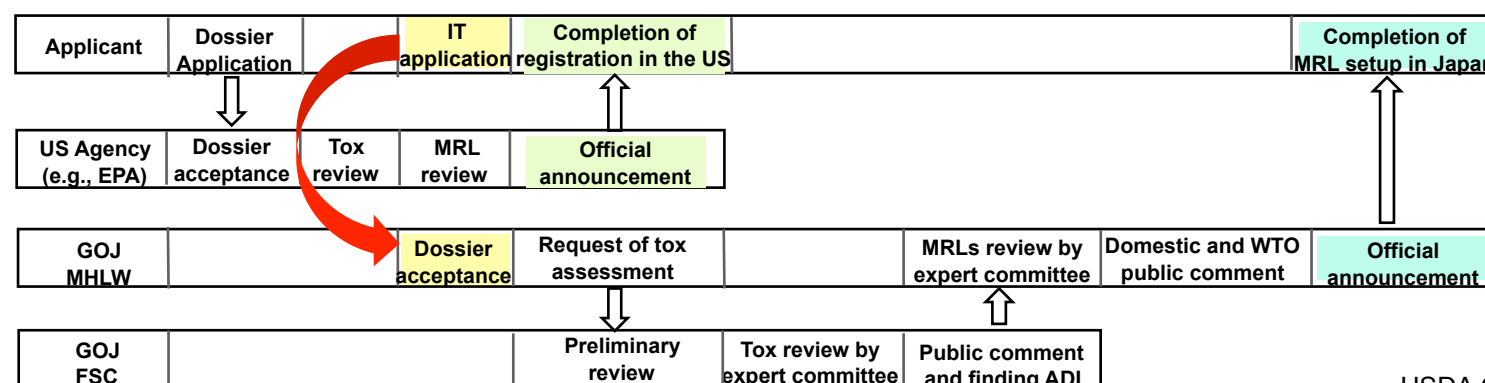


2013 MHLW Import MRL Policy Change

Before May 14, 2013



After May 14, 2013



USDA GAIN Report # JA3023
(June 27, 2013)



Anticipated Benefits from the MHLW Policy Change

- To export countries:
 - Reduce the time gap between the registration in the export country (such as, the US) and the import MRL establishment in Japan
 - Reduce problems for export country's agricultural trade to Japan
 - Allow an earlier adoption of new technology by growers in the export countries (if delay due to concern about violation of Japanese import regulations)
- To Japan:
 - Do not affect the Japan's stringent and robust food safety review process
 - Ensure food safety and food security

Case Study



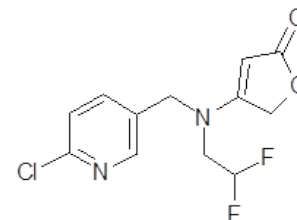
Sivanto and Import MRLs in Japan



Sivanto prime



- Chemical code: BYI 02960
- Common name: Flupyradifurone
- Chemical class: Butenolide
- Formulation: 200 SL
- Mode of action: IRAC Group 4D (Nicotinic acetylcholine receptor (nAChR))
- Pest spectrum: Aphids, Leafhoppers, Whiteflies, Scales, Psyllids,
- 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*
 - ▶ *control of adult and immature stages*
4. Excellent control of NN-resistant aphid and whitefly populations





Sivanto: Submissions and Reviews

1. First entry submission (2013)

- ▶ Global joint review: Australia, Canada, Mexico and the US (reduced risk)
 - ◆ Brazil and China as observers

2. Second entry submission (2015)

- ▶ Work share: Canada, Mexico and the US (reduced risk)

3. Partnership with IR-4 and PMC

- ▶ Support the needs of specialty crop growers in North America

4. With particular attention on MRL harmonization and trade





Sivanto: Current Registration Status

□ Global registration status for Sivanto prime:

❖ Registered in 11 countries/regions

- USA: registered 1/2015 (reduced risk)
- Mexico: registered 5/2015
- Canada: registered 11/2015
- EU: registered 11/2015 (Annex 1)
- Japan: registered 12/2015, including import MRLs
- Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, S. Korea

❖ Pending local registrations in Australia*, Brazil, China, India, Peru, South Africa, etc.

*: import MRLs established

Sivanto: Global MRL/iMRL Timelines



C O D E X
A L I M E N T A R I U S
International Food Standards

Codex



South Korea*



EU*

*: iMRL



Mexico



US



Japan*



Canada



Australia*



Taiwan*



Hong Kong*



H1 '15



H2 '15



H1 '16



H2 '16



2017

Up to now, iMRLs established are harmonized with local MRLs in North America

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





Sivanto: NAFTA and Japan

- ❑ Product registration and MRL setting (domestic and import) achieved in 2015, allowing a smooth trade
 - ❖ With harmonized residue definition and MRLs
 - ❖ Import MRLs in Japan available **11 months** after the US registration (benefited from the 2013 MHLW policy change)





Assessments: HMLW Policy Change (1 of 4)

- ☐ Is there a shorter time gap in MRL setting between US and Japan for new chemicals, as anticipated?
- ☐ Does this policy change affect the overall review time for new chemicals by FSC and MHLW?






Assessments: HMLW Policy Change (2 of 4)



❑ In the past 8 years, 71 new chemicals have been or are being through the reviews (for domestic and/or import MRL) in Japan.

- ❖ 15 are import MRL only
- ❖ 3 (domestic first, followed by import MRL)
- ❖ 2 (import MRL first, followed by domestic)
- ❖ 5 (import MRL and domestic concurrently)
- ❖ 46 (domestic only)





Assessments: HMLW Policy Change (3 of 4)



- ❑ Focus on 1) new chemicals, 2) import MRL only (based primarily on US MRLs), and 3) time gap in MRL setting between US and Japan
- ❖ Import MRL request **prior to** US MRL setting: *flupyradifurone (1st case)*, *benzovindiflupyr (in progress)*, *bicyclopyrone (in progress)*
- ❖ Import MRL request **after** US MRL setting: *fluxapyroxad*, *saflufenacil*, *spirotetramat* and *pyrasulfotole*

Assessments: HMLW Policy Change (4 of 4)



- The 2013 MHLW policy change does shorten the time gap between US MRL and Japan import MRL setting (333 days vs. average 968 days)
- The total review and MRL setting time in Japan remains similar (865 days vs. average 857 days), maintained the scheme and quality of scientific review

	US MRLs	Japan Import MRL Request	US MRLs	Japan Import MRLs	# of Days
Flupyradifurone		8/9/2013		12/22/2015	865
			1/23/2015		333
Fluxapyroxad		7/11/2012		10/3/2014	814
	5/14/2012				872
Saflufenacil		8/19/2010		3/12/2013	946
	9/22/2009				1,278
Spirotetramat		8/18/2008		10/20/2010	793
	7/9/2008				833
Pyrasulfotole		8/28/2007		1/18/2010	874
	8/15/2007				887





Case Study: Summary

- ❑ The 2013 MHLW policy change, initiated and implemented by FSC and MHLW of the Government of Japan, is highly commendable
- ❑ Flupyradifurone is the first new chemical to benefit from this new policy
- ❑ This policy works well, as intended
 - ❖ Shorter time gap in MRL setting between the export country and Japan (food security)
 - ❖ Maintain the high integrity and quality of the pesticide review and approval process in Japan (food safety)



Next Steps

- What could we do together to encourage more countries to consider adopting similar policy for import MRL establishment?



Thank you
