

Efficacy for low-risk PPPs – an industry view, Efficacy workshop, Ede April 2016

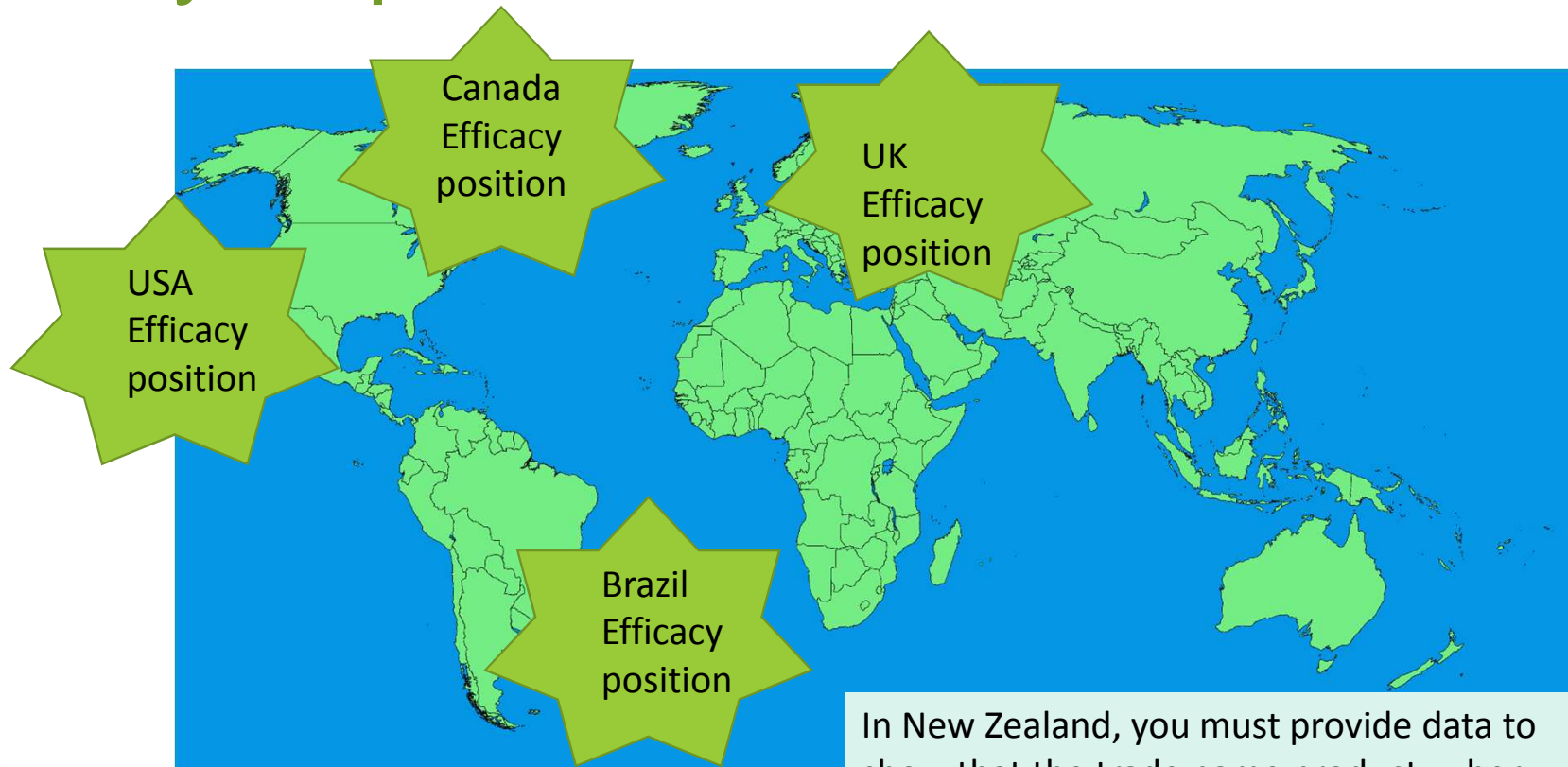
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Efficacy for stakeholders

- Farmer and Advisor – What the I-r PPP is capable / not capable of?
- IPM advisor – Can the I-r PPP contribute to an IPM programme?
- Manufacturer / Distributor – Do we manage expectations of the I-r PPP effectively?
- Regulator – Does the efficacy information package provided support the claims being made for the I-r PPP?

Efficacy requirements in different countries



In New Zealand, you must provide data to show that the trade name product, when used according to directions, is effective and safe for the purposes claimed in New Zealand under local conditions.

Concepts for I-r efficacy

- Mode of Action
- Critical parameters
- Worst case efficacy evaluations
- Minor Uses efficacy requirements
- Other relevant concepts

Mode of Action

- Describe as well as possible
- Multiple modes of action
- Extrapolation
- Frame in which activity can occur
- Justification of label claims

Parameters for efficacy of PPPs

- Crop and Target Pests / Disease
- Infestation level
- Development stages of crop and target
- Application equipment and method
- Application timing and intervals
- Efficacy levels and duration of activity
- Farming practices including IPM
- Field or indoor uses
- Climate and weather
- Comparative treatments – untreated / reference

What is / are the critical or limiting parameters for a I-r PPP for efficacy?

- Is the pest or disease present, reliable, at appropriate stage, etc..
- Are weather / climate conditions appropriate, challenging, etc..
- Is crop stage problematic, most challenging, etc..
- Is crop / variety more difficult due to growth habit, stage, attraction to pest / disease, etc...
- Do other farming practices interfere with control of a pest / disease?
- Is timing, application method, etc... optimal, sub-optimal?

Worst case efficacy situations

- Pheromones as an example
 - Mode of action
 - Extremely volatile substances
 - Temperature limiting duration
 - Higher number of generations in higher temperature conditions



What other worst case situations exist?

- Under protection – increased ventilation & entry of pest and pathogen
- Pathogens – increased humidity & incidence of rainfall
- Invasive pest – origin country of pest → more reliable test results
- Increased number of generations → higher pressure
- Location of pest / disease on plant
- Window of efficacy opportunity

Extrapolate from worst case to other uses

Justification required!



Minor Uses

- What are the efficacy requirements for minor uses for a PPP with major use label claims?
- What are the efficacy requirements for minor uses for a PPP with no major use label claims?
- Should efficacy be required for minor uses of I-r PPPs?
- An EU wide single zonal approach is required to be coordinated by the EU Minor Uses Facility

Should IPM be part of efficacy testing

- Concept of IPM is dynamic
- Practice of IPM is fluid
- Practice of IPM is local
- IPM Practice is holistic
- IPM practices used in trials can be redundant by time a PPP is brought to market
- IPM governance should not be part of efficacy evaluation



Other relevant concepts

- Crop Groupings
 - Some MS allow crop groupings
 - Other MS do not permit crop groupings
- More difference within many countries than between countries as confirmed by IR4 analysis
- Use of extrapolation
- Variable label claims
- Harmonised definition of major and minor crops / pests and uses

“Efficacy Light” Information package

- What should it contain?
- Detailed description of mode of action
- Literature, laboratory, Semi-field, Field data
- GEP or scientifically valid studies?
- Data generated in comparable external countries
- Good justification of information supplied including relevance

What does industry want in the EU?

- One regulatory zone for field and indoor use
- Fast track registration process
- “Efficacy Light” to justify label claims
- Extrapolation with guidance
- Single Zone classification of major and minor crops – EU wide EUMUDA
- Simplification
- Communication & co-operation between all stakeholders

**“Life is really simple, but we insist on making it complicated”
Confucius.**

Item/classification	Non low risk PPP	A. Low risk chemicals/botanicals/minerals	A. Low risk micro-organisms with direct MoA e.g. insect- and fungal pathogens and viruses	A. Low risk micro-organisms with indirect MoA e.g. host plants defense	A. Semiochemicals
Field use					
Reg./EPPO zones	3/4	1	1	1	1
New a.s./products					
Number of trials					
Major pest on major crop	10 (6-15)	?	?	?	?
Minor uses, pest	3 (2-6)				
Years	Min. 2	?	?	?	?
Indoor use					
Reg./EPPO zones	1	1	1	1	1
Number of trials					
Major pest	6 (4-8)	?	?	?	?
Years	Min. 2				
Formulation change	not defined, under review				
Efficacy levels	>80%	As per claim	As per claim	As per claim	As per claim
					15
Application scheme	Seasonal sequential				

What does industry want to result from this workshop?

- Harmonisation with no national requirements
- “Efficacy Light” dRR proving label claims with a quality checklist
- Guidance for “Efficacy Light” requirements
- Flexible efficacy levels & type of label claims
- Acceptance of extrapolation with justification
- Label claims to help farmers and advisors





Many thanks and let
us all make it a
productive workshop!

David Cary, Executive Director IBMA

