



EPPO WORKSHOP ON COMPARATIVE ASSESSMENT OF PLANT PROTECTION PRODUCTS

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COUNTRY RESPONSES TO THE EPPO QUESTIONNAIRE

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INTRODUCTORY QUESTIONS














1. ARE COMPARATIVE ASSESSMENTS PERFORMED IN YOUR COUNTRY?

- 19 EPPO Countries responded
- 16 EPPO countries confirmed they are performed:
 - Austria, Belgium, Denmark, France, Germany, Hungary, Italy, Latvia, Lithuania, Netherlands, Portugal, Slovenia, Spain, Sweden, Switzerland, UK
- 3 EPPO countries do not:
 - Bulgaria, Guernsey, Montenegro





How many products has your country performed comparative assessment on?

Country	Number	Country	Number
 Italy	Unknown	 Sweden	13
 Switzerland	1	 Belgium	14
 Netherlands	2-5	 Denmark	16
 Portugal	2-5	 Spain	23
 Hungary	6	 Austria	>30
 Latvia	6	 Germany	36
 Slovenia	9	 UK	70 (on-going/ complete)
 Lithuania	11	 France	46 (out of 141 on-going)



2) WHAT HAS BEEN THE OUTCOME OF THE COMPARATIVE ASSESSMENTS PERFORMED? (I)

- For those completed assessments, the PPP containing the active substance for substitution has been authorised
- Common reasons to authorise rather than substitution:
 - Minor uses
 - Resistance
 - Use in organic farming (Regulation (EC) No 834/2007)
 - Not significantly 'safer' (human/animal health, environment)
 - Does not have comparable efficacy





2) WHAT HAS BEEN THE OUTCOME OF THE COMPARATIVE ASSESSMENTS PERFORMED? (II)

- Article 50(3): A PPP containing a candidate for substitution may be authorised (for 5 years) without conducting a CA where it is necessary to acquire experience first through using that product in practice
- Mutual Recognition Applications with PPP containing an active candidate for substitution: Is the PPP necessary for the MS?
- Many assessments ongoing, indications are there may be either substitutions and/or label changes





















NATIONAL PROCEDURE FOR COMPARATIVE ASSESSMENTS





1. Is National Guidance available ?

NO (6)		YES (10)			
		Public		Internal	
	Austria		Belgium		Italy
	Denmark		France		Netherlands
	Hungary		Germany		Switzerland
	Latvia		Portugal		
	Lithuania		Slovenia		
	Sweden		Spain		
			UK		





2. OUTLINE OF THE PROCEDURE

- All respondents follow a tiered approach, focussing first on the availability of relevant alternatives
 - This step (along with consideration minor uses) is a common point to stop the comparative assessment
- Respondents encompass the steps of the EPPO 1/271 for efficacy aspects, with some differences in the order
- Commonly, Human/Animal and Environment risk management is the last step in the process
 - Relatively few assessments reach this step





3. HOW DO YOU TAKE ACCOUNT OF MINOR USES? (REQUIREMENT ARTICLE 50D)

- All respondents consider the consequences of substitution on Minor Uses (Article 51) authorisations
- A number of respondents stop the comparative assessment if the PPP supports at least one associated minor use
 - major uses not considered further
 - implications of unsustainable control for a minor use
- Germany - the assessment is stopped if:
 - minimum 5 minor uses, or 50% of all PPP uses are minor
 - an Article 53 Emergency authorisation can be avoided
- All exclude comparative assessment of a minor use





COMPARATIVE ASSESSMENT OF EFFICACY ASPECTS

Assessing chemical and
non-chemical alternatives





1, 2. USE OF EPPO PP 1/271

- EU SANCO 11507/2013(2) Guidance document on comparative assessment and substitution (1107/2009)
 - Step 1 - Identification of candidates
 - Step 2 - EPPO 1/271
 - Step 3 - Health and the Environment
- SANCO notes there may be reasons to consider some of the 1/271 steps earlier in the process (e.g. resistance)
- PP 1/271 is followed by all respondents, the majority adapt the order to reach an earlier conclusion
 - Commonest reasons relate to Minor uses and resistance considerations





3. FOR CHEMICAL ALTERNATIVES, WHAT INFORMATION ON EFFICACY IS CONSIDERED?

- Regulatory studies supporting PPP authorisations and authorised label uses provide the main source. Expert judgement, and detailed comparisons of the use
- Both UK and CH authorise differential levels of control, which can provide additional detail for an individual target
- Denmark: commercial decision making scheme for herbicides 'Crop Protection Online'
- France - National Institute of Agronomic Research (INRA) network; technical notes





4. IS INFORMATION ON EFFICACY OF NON-CHEMICAL ALTERNATIVES AVAILABLE: 8 (YES); 8 (NO)

- Expert judgement, research/advisory services, (Spain - IPM guidance; French Institutes on organic farming, harmful organisms)
 - Consideration of natural predators, integration in IPM programmes - efficacy and feasibility
- Published sources: 5 refer to the UK-DEFRA study:
 - reviewing available published information on non-chemical control methods (efficacy, and economic viability)
 - Expert Assessment on comparing efficacy
 - Possible adverse health or environmental consequences
- EPPO bulletin; PP 2 Good Plant Protection Practice





5. HOW DO YOU ASSESS THE IMPACT ON IPM OF CHEMICAL OR NON-CHEMICAL ALTERNATIVES?

- Limited direct assessments, particularly non-chemical impacts on IPM
- Covered generally by the previous steps comparing efficacy of available alternatives (chemical and non chemical)
- Existing environmental risk mitigation (PPP)
- Resistance





COMPARATIVE ASSESSMENT OF EFFICACY ASPECTS

Resistance





6, 7. INHERENT RESISTANCE RISK AND NATIONAL RESISTANCE MANAGEMENT

- PP 1/213 'Resistance Risk Analysis'
- Industry Resistance Action Committee ('RAC')
- National Advisory bodies, for example
 - French National Resistance Network (R4P)
 - UK Resistance Action Groups (UK-RAGs)
 - German Expert Committees on Pesticide Resistance (ECPR)
 - Italian Herbicide Resistance Group (GIRE)
- National Research Institutes; published sources
- Reference to regulatory studies





8. DO YOU FOLLOW THE RECOMMENDED NUMBER OF REQUIRED MODES OF ACTION (L/M/H RISK)?

- All respondents base the required modes of action on EPPO 1/271
- Most however simplify to a minimum threshold, rather than differentiate to Low/Medium/High
 - 6 respondents require 4 available MoA groups for resistance management (high risk)
 - 1 respondent generally has a minimum of 3 MoA groups
- Expert judgement based on National experience





COMPARATIVE ASSESSMENT OF EFFICACY ASPECTS

Assessing practical, economic
disadvantages and effects on minor uses





9, 10. SOURCES OF INFORMATION ON PRACTICAL, ECONOMIC IMPACTS OF ALTERNATIVES; LOSS OF ACTIVES ON MINOR USES

- Expert judgement, published studies (UK-DEFRA), published research, regulatory information (PPP)
- Impact of loss of an active substance on a minor use is usually not directly assessed:
 - If a product has associated minor uses, comparative assessment is usually stopped, and as one of the first steps
 - Comparative assessment is not conducted on a minor use





COMPARATIVE ASSESSMENT OF EFFICACY ASPECTS

General comments on using EPPO PP 1/271





11. Do you follow the order of the PP 1/271 steps for each assessment?

YES (4)



DENMARK



HUNGARY



SLOVENIA



SWEDEN

NO (10)



AUSTRIA



BELGIUM



FRANCE



GERMANY



ITALY



LATVIA



PORTUGAL



SPAIN



SWITZERLAND



UK





12. ARE ALL THE STEPS OF COMPARATIVE ASSESSMENT PROCESS IN PP 1/271 CLEAR (I)? (YES 10; NO 6)

- Defining 'significant' practical or other impacts
- Resistance (Impact of management strategy)
- Level of uncertainty in answering some of the steps, further clarification of explanatory notes
 - H - retaining a major use to maintain PPP supply
 - J - consider if other actives also 'at risk' of losing authorisation (non-renewal)





12. ARE ALL THE STEPS OF COMPARATIVE ASSESSMENT PROCESS IN PP 1/271 CLEAR (II)?

- Step 4 - anticipating new pest problems
- Step 5 - disruption of established IPM, prevent new IPM, negative impact on beneficials
- Step 14 - alternatives '*considerably more expensive*'
- Step 15 - wider consequences, for example:
 - quarantine, emerging pests,
 - Maintain diversity to minimize impacts on water quality and biodiversity





















13. SUGGESTED IMPROVEMENTS TO 1/271

- Change the order of the steps - Minor uses
- Add steps (aid clarity)
- Consider co-formulated mixtures
- Widely share available resources
- Develop examples, illustrate 'comparable' PPP



14. Are EPPPO codes used to define the uses?

YES (9)		NO (7)	
	Denmark		Austria
	Germany		Belgium
	Hungary		France
	Italy		Netherlands
	Latvia		Sweden
	Lithuania		Switzerland
	Portugal		UK
	Slovenia		
	Spain		



15. WHERE ARE THE MOST SIGNIFICANT KNOWLEDGE GAPS?

- Alternative non-chemical methods
 - Efficacy, economics, resistance management
- IPM programmes
- Target spectrum
- Comparing single actives with co-formulated products; tank mixtures
- Wider impacts, anticipating consequences

