anses
French agency for food, environmental and occupational health & safety
Investigate, evaluate, protect

Comparative Assessment
Feedback on Implementation in France

EPPO Workshop on comparative Assessment of Plant protection Products
Lisbon, 2018-10-24/25

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DAMM (Market Autorisation Department)_Decision Unit

PPPs Marketing Authorisations : Anses' organization

Roger GENET
Director General

Regulated Products Division

Managing Director General

- ✓signature of MA decisions
- ✓ Process coordination

Transmission of folder after admissibility

Regulated Products Assessment Department (DEPR)

Findings of the assessment

Market Authorisations Department (DAMM)

- ✓PPP Risk assessments implementation
- ✓Contribution to CA : steps related to risks comparison for health and environment

- ✓Administrative admissibility
- ✓Instruction of MA decisions
- ✓Contribution to CA : steps related to agronomic aspects

CA implementation in France

- **Preliminary work, consultations of**

  ✓ The Draft GD SANCO/11507/2013 rev. 12, 10 October 2014

  ✓ The PP 1/271 (1) Guidance on comparative assessment (EPPO, 2011)

  ✓ Other national Guidances : UK (published), EL and PT (draft in mid-2015)

  ✓ National experts working group

- **Approval of two documents** (July 2015)

  ✓ The "**Guidance document on the comparative assessment of plant protection products in France**" : Explains the modalities and the approach to be implemented at national level

  ✓ A **French Ministry of Agriculture's Order** : precise information and format to be submitted

Guidance document in France

- **Comparative assessment - conditions of implementation** :
  - ✓ **Applications covered** : new market authorizations (MA) applications, MA renewals, extension of use, mutual recognition
  - ✓ Elements relating to CA **should be included** in the dedicated section of dRR Part A of the dossier submitted by the applicant (if France is zRMS), or in a national addendum to Part A (if France is cMS)
  - ✓ Information should refer to **relevant publications** or any other reliable sources of information that have been identified
  - ✓ **Consequences** of comparative assessment if substitution is retained : refusal / withdrawal of authorization or limitation / modification of MA

Guidance document in France

- **The 2 European guidance documents available:**
  - ✓ Draft Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009 (SANCO/11507/2013 rev. 12, 10 octobre 2014)
  - ✓ PP 1/271 (1) Guidance on comparative assessment (EPPO, 2011)

➔ **Are use as basis of** the French guidance document on comparative assessment.

➔ Both specify a **step-by-step approach**

EPPO PP 1/271 (2) / Guidance document FR

❖ Assessing comparability regarding efficacy

↓

✓ Assessing comparability regarding the risk of developing resistance

↓

❑ Assessing practical or economical disadvantages
and
o effects on minor uses

and wider consequences :
(ex : quarantine/emerging bio-aggressors control)

✓ Assessing comparability regarding the risk of developing resistance

and

o effects on minors uses
and
quarantine/emerging bio-aggressors control

↓

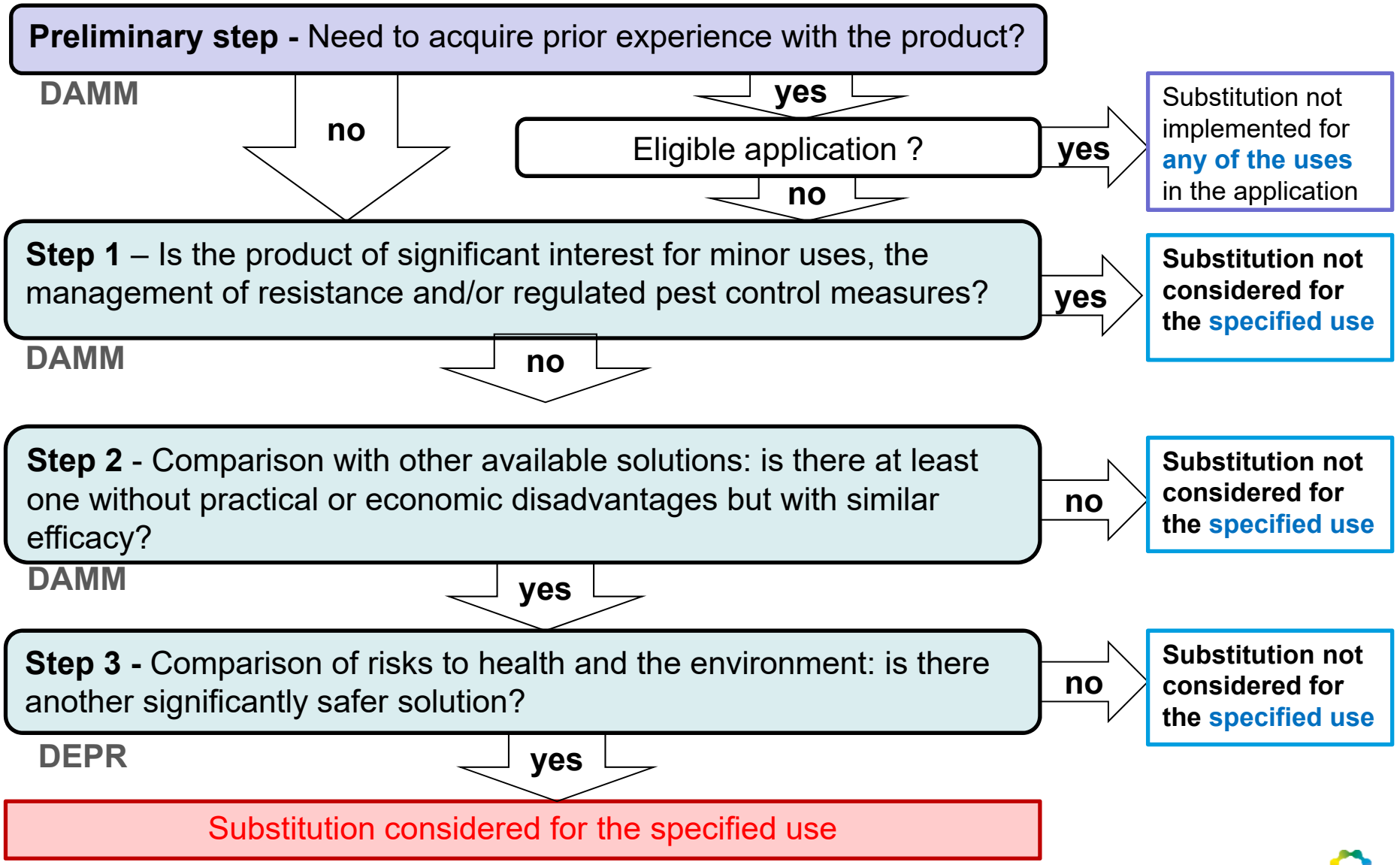
❖ Assessing comparability regarding efficacy

and

❑ Practical or economical disadvantages

➔ **Guidance document FR :** Resistance and minor use relating steps are seen earlier in the CA process to reduce or avoid the workload imposed by other steps

Guidance document FR : Steps of CA process



Guidance document FR : Steps of CA process

Step 1 – Is the product of significant interest for **minor uses**, the management of resistance and/or regulated pest control measures?

Substitution effects on minor uses

- It is considered that comparative assessment for minor uses has little relevance

➔ The substitution **will not be considered for minor uses**.

- Applicants must provide information about the potential consequences of substitution for the major uses covered by the comparative assessment on the minor uses of the product

➔ In practice, few information provided about commercial impact

Guidance document FR : Steps of CA process

Step 1 – Is the product of significant interest for minor uses, the management of **resistance** and/or regulated pest control measures?

Consideration of chemical diversity (number of available MOA/use and existence other PPPs with the same MOA) and the risk of resistance development

- Based on available information/reliable sources :
  - ✓ RAC / R4P (national network for reflection and research)
  - ✓ EPPO Standard PP 1/213
  - ✓ National expertise : technical notes or recommendations based on scientific research or monitoring data
  - ✓ Efficacy assessments performed by DEPR (efficacy unit)

➔ In case of lack of information **the risk of resistance development is considered as high** as a margin of safety (EPPO PP 1/271 (2), note f : at least 4 MOA needed).

Guidance document FR : Steps of CA process

Step 2 - Comparison with other available solutions: is there at least one without **practical or economic disadvantages** but with **similar efficacy**?

Efficacy (in the broad sense) of other available solutions

- ✓ Efficacy level and regularity / spectrum of action,
- ✓ adverse effects on crops,
- ✓ impact on integrated control systems

Major practical and economic disadvantages of other available solutions

- ✓ Operationality (costs, constraining use conditions, application window)
- ✓ Availability (products on the market, need of specialist equipment, structures or plant material)
- ✓ Sustainability

➔ There is no national guideline or method to integrate **cultural system level approach** in the CA process

Guidance document FR : Steps of CA process

Step 2 - Comparison with other available solutions: is there at least one without **practical or economic disadvantages** but with **similar efficacy**?

Identification and comparison of chemical and/or non chemical alternatives available in France

- based on available information/reliable sources that coming from:
  - ✓ Agricultural technical institutes (technical notes, consultation)
  - ✓ INRA (France's National Institute for Agricultural Research), specifically for non chemical methods (Works and publications)
  - ✓ Phytopharmacovigilance (national monitoring data of adverse effects related to the use of PPPs)
  - ✓ Efficacy comparison data, if submitted can be examined by DEPR (efficacy unit)
  - ✓ Consultation of national experts from the Ministry of agriculture and food

Balance sheet of the CA in France

On October, 2018

151 applications submitted after 1st august 2015 requiring the implementation of the CA procedure, which corresponds to :

- ✓ **57** ➔ substitution not retained in step 1
- ✓ **43** ➔ still in progress
- ✓ **21** ➔ eligible to Article 50(3) of Regulation (EU) N° 1107/2009
- ✓ **28** ➔ new applications for which CA was postponed to the renewal of the Cfs substance (similar products)
- ✓ **2** ➔ need analysis in step 3 (Comparison of risks to health and the environment)

Questions, still in progress…

Overall reflection about

- ❑ Feedback of the current CA process ? ➔ A lot of Cfs active substance and little possibility for substitution
- ❑ Sustainability of alternatives?
- ❑ How to implement the CA for similar products ? Procedure to be implemented in the context of MA renewals (Article 43) jointly for all products concerned ?

Methodological issues

- ❑ Specificity of herbicides➔ Reasoning at the specific weed spectrum
- ❑ Non chemical methods ➔ How to compare them to PPP ?
- ❑ Substitution consequences on minor uses ➔ What major use to preserve ? which criteria of choice ?
- ❑ Economic aspects ➔ Witch relevant references/indicators to consider?

THANK YOU FOR YOUR ATTENTION