

Implementation of comparative assessment

-Portuguese approach-



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Topics to be covered:

- Comparative assessment;
- Portuguese approach;
- Results;
- Concluding remarks.

Comparative assessment

- Comparative assessment (CA) shall be performed by Member States (MS) when evaluating an application for authorisation for a PPP containing an active substance approved as a candidate for substitution.



Article 24

- ✓ approved active substances meeting one or more of the conditions listed in point 4 of Annex II, of Regulation 1107/2009:

CfS - criteria	N. of active substances
Low ADI/ArfD/AOEL	18
Two PBT criteria	53
Non -active isomers	1
Toxic for reproduction 1B/1B	4
Endocrine disruption properties	5
Total	81

Comparative assessment

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Article 24

- ✓ have been evaluated and are approved for use in the EU in authorised PPP;
- ✓ Uses of PPP considered under the CA process:



have all been evaluated



all have an acceptable risk assessment
in accordance with Regulation
1107/2009.

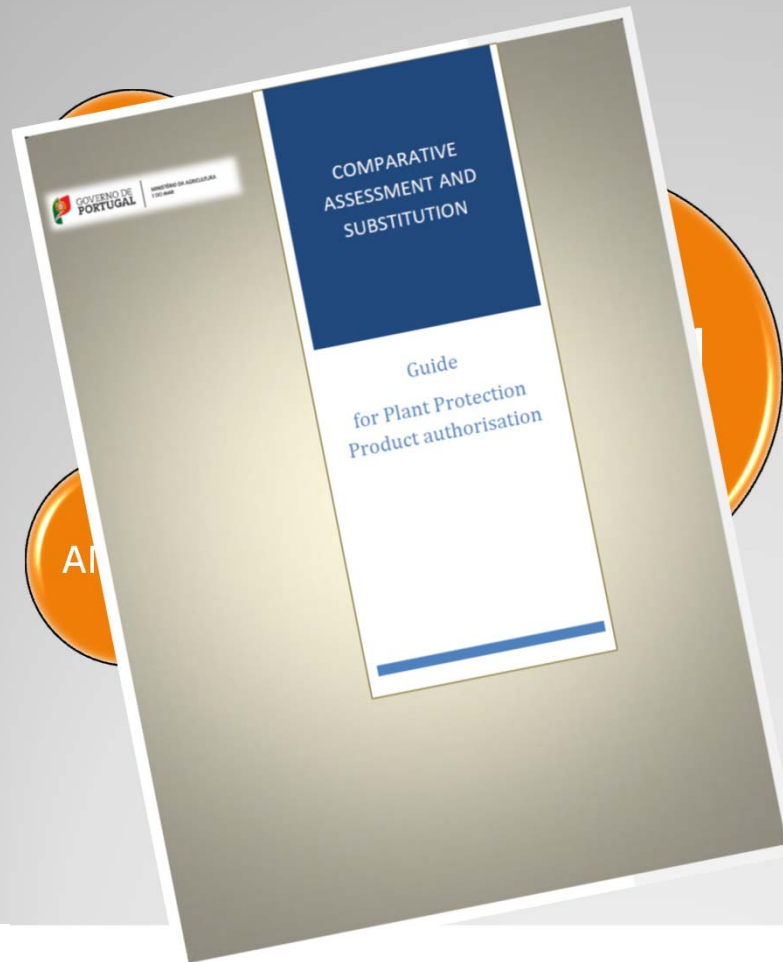
Comparative assessment

■ Guidances:



- ✓ **SANCO/11507/2013 (rev.12), 10th October 2014:** Guidance Document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) n.º 1107/2009 ;
- ✓ **EPPO standard PP 1/271:** EPPO Guidance on CA;
- ✓ **Guidance for UK applicants** for plant protection authorisations.

Portuguese approach



Tasked to 'sort out
how to deal with it'



Developed ideas and
procedures



PT guidance
(2015)

Comparative assessment

- Portuguese guidance -

- ➔ ■ When should be provide information for CA?
- ➔ ■ How should be provide information for CA?
- ➔ ■ What does the information needs to cover?
 - How to address CA for zonal applications?
 - Regulatory action in the end of CA
- ➔ ■ What if the availability of alternatives changes after a decision?
 - Final conclusion and Report



- Keep it as simple as possible;
- Involves applicants;
- Reach a conclusion at the earliest possible step.



Comparative assessment - Portuguese guidance -

When should be provide information for CA?

- EU guidance on comparative assessment came into force on 1 April 2015;
- The list of Candidates for Substitution came into force on 1 August 2015;
- Applicants need to provide information for comparative assessment from 1 August 2015 (submission date at ZRMS);
- Applicants need to provide the information in this guidance for:

new authorization, extension of authorization, renewal and mutual recognition

Comparative assessment

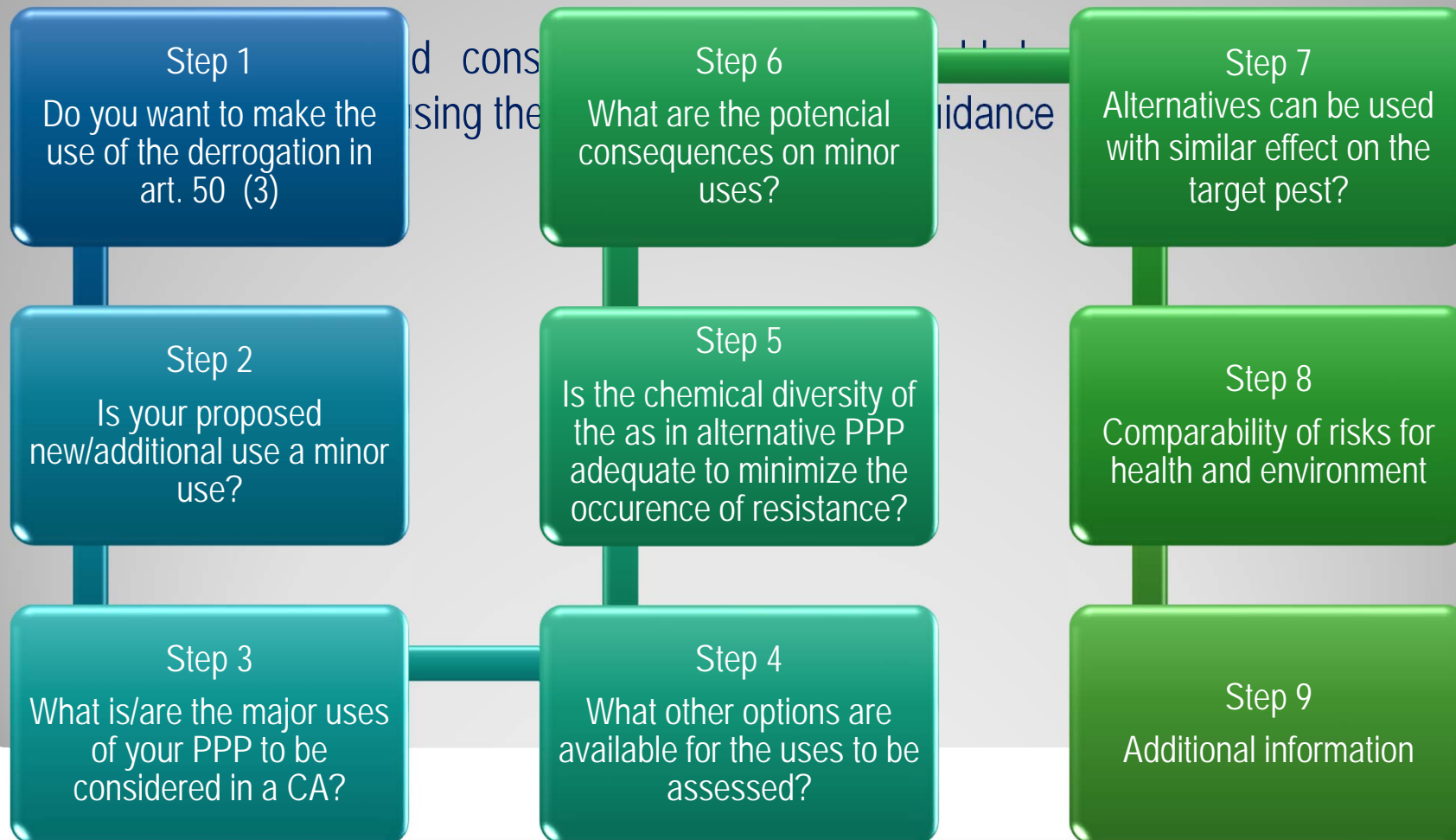
- Portuguese guidance -

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- CA portuguese guidance -

How should be provide information for CA?



Comparative assessment

- Portuguese guidance -

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Comparative assessment - Portuguese guidance -

What does the information needs to cover?

- Consider steps 1-9 of Annex 2 and decide which steps need to complete for the PPP;
- It is recommended to start the assessment in areas, where there might be a problem, e.g., development of resistance;
- CA shall be performed to additional use or uses, the previous authorized uses do not require comparative assessment;
- Any relevant conclusions will not be applied to other existing authorizations for products containing the same candidate for substitution.

Comparative assessment

- Portuguese guidance -

- When should be provide information for CA?
- How should be provide information for CA?
- What does the information needs to cover?
- How to address CA for zonal applications?
- Regulatory action in the end of CA
-  What if the availability of alternatives changes after a decision?
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Comparative assessment - Portuguese guidance -

What if the availability of alternatives changes after a decision?

- If the applicant believes that suitable significantly safer alternatives to the PPP are no longer available and a comparative assessment would not reach the conclusion that a substitution is appropriate:
 - ✓ may make an application for re-instatement of the product using the appropriate regular application route.
 - ✓ this application should include a new consideration for comparative assessment together with any other data or information that may be required for re-instatement at that time.

Comparative assessment - Portuguese guidance -

Results

Number of PPP with Cfs	PPP that have been substituted
6	0



Minor uses

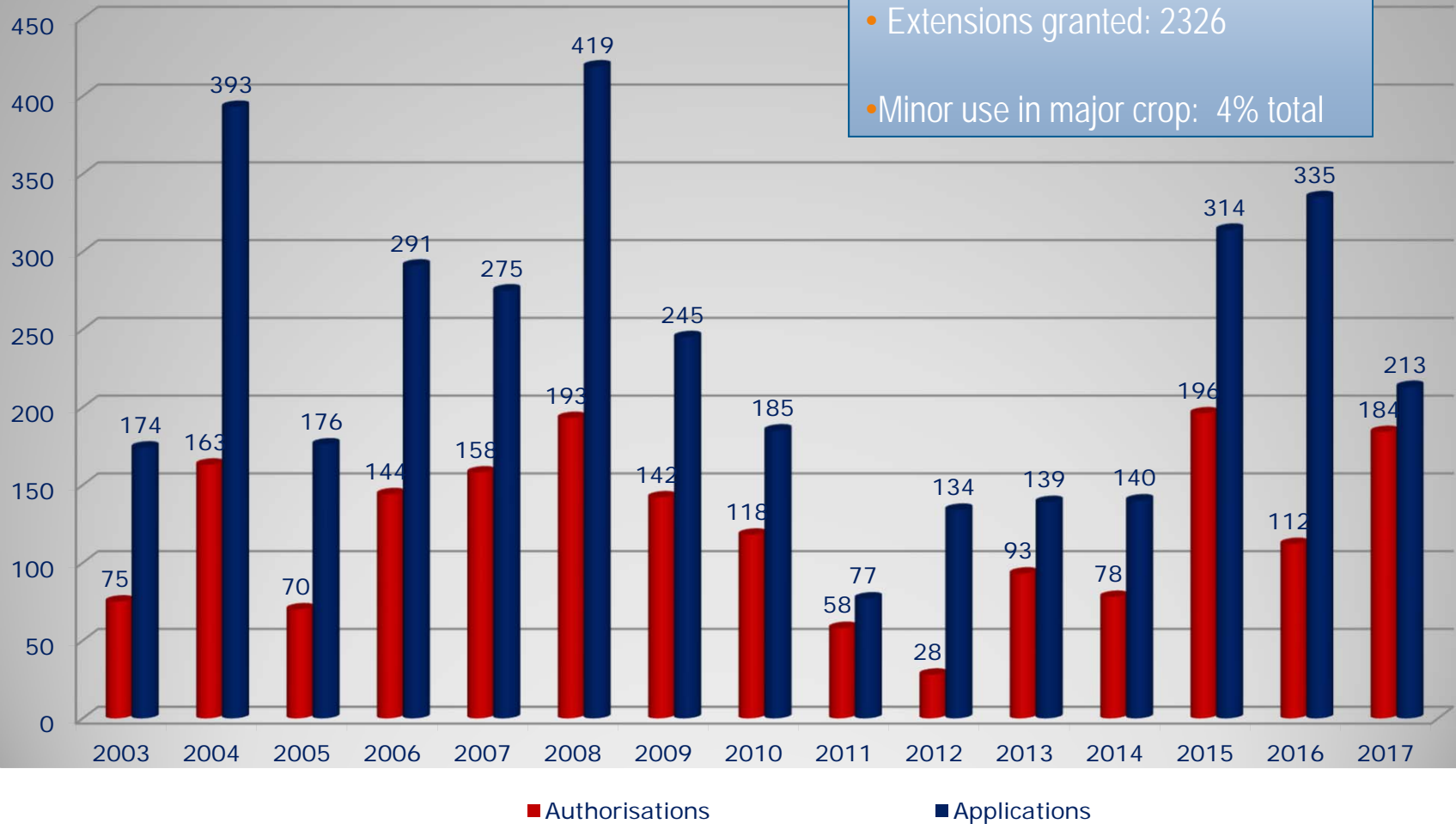
Step 2
Is your proposed
new/additional use a minor
use?

Step 6
What are the potential
consequences on minor
uses?



Importance of Minor uses in Portugal



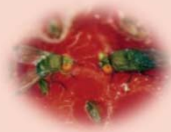
- Total of applications: 4478
- Extensions granted: 2326
- Minor use in major crop: 4% total





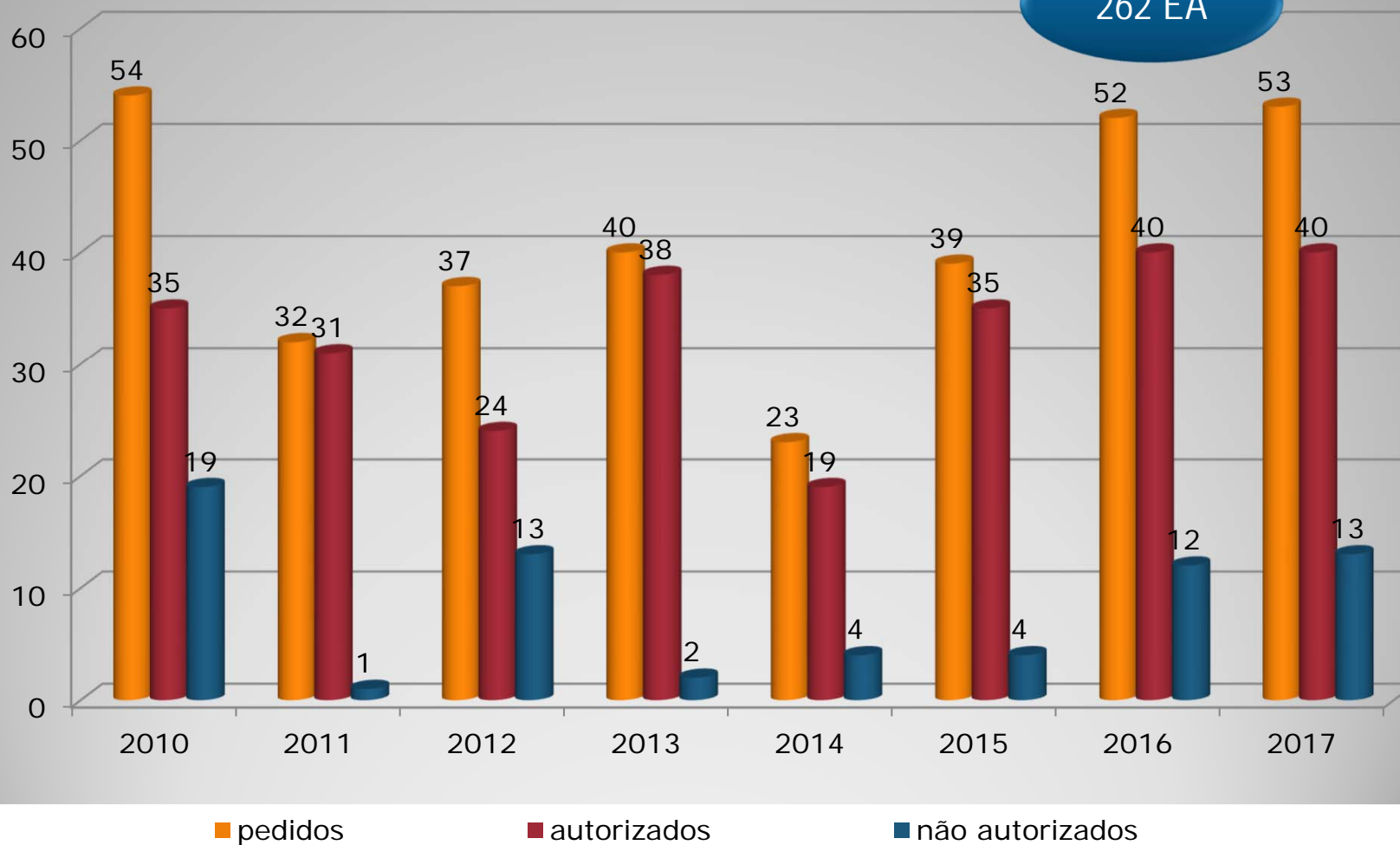
New pests every year

Southern Zone

Pest		Crop	Detected at	Losses (Estimation)
<i>Scaphoideus titanus</i>		vine	1999 (North of Portugal)	
<i>Tuta absoluta</i>		tomato	May 2009 (Algarve)	60-80% of the yield
<i>Drosophila suzukii</i>		cherry blackberries	July 2012 (Odemira)	10-80% of the yield



Emergency authorisations (art.º 53)



2010-2017

Concluding remarks

Comparative assessment



➤ Requires:

- A clear justification should be given for the conclusion of each step ;
- Clarifications (Cfs –mixture);
- More robust information about alternative methods; ;

➤ Offers the opportunity to:

- Share the experiences between applicants and CA;

Guidance will be updated in the light of experience (art. 53).



Thank you for your
attention!

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