

# Implementation of comparative assessment

## -Portuguese Guidance -

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# Contents:

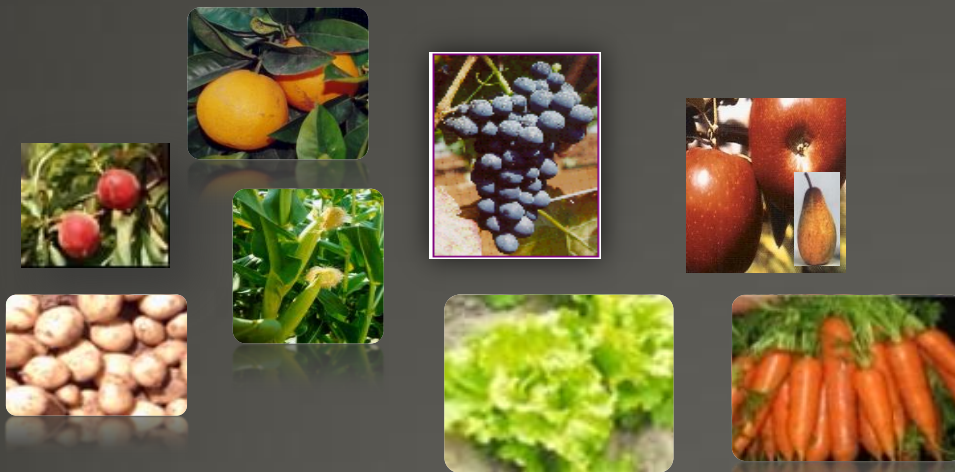
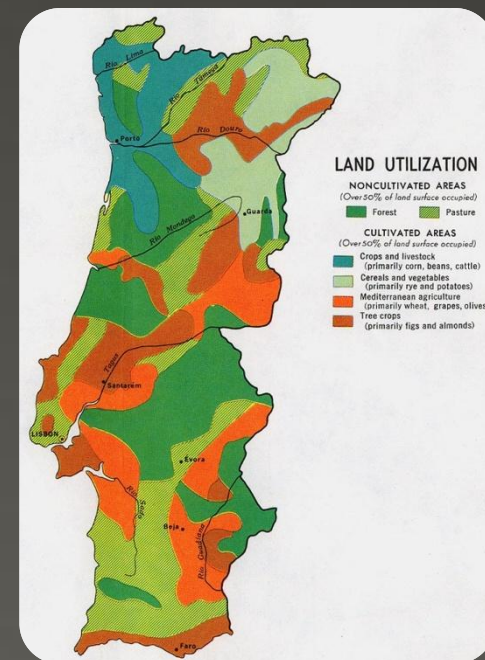
- Portuguese specificities;
- Sustainable Use Directive;
- Comparative assessment in the Southern Zone;
- Comparative assessment – Portuguese guidance;
- Concluding remarks.

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- The size of farms in Portugal is on average 5 hectares smaller than in the EU.
- PT produces a broad range of fruits and vegetables thanks to its varied climatic and topographic conditions;

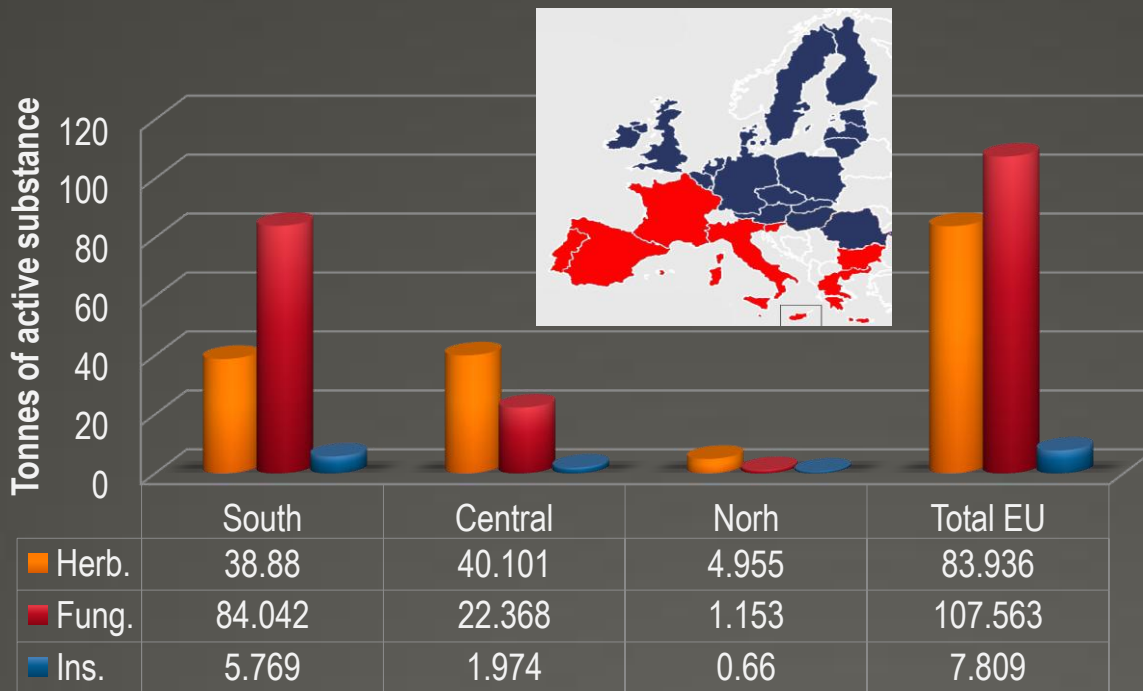


# SOUTHERN ZONE SPECIFICITIES

- High demand of pesticides to protect crop productions due:



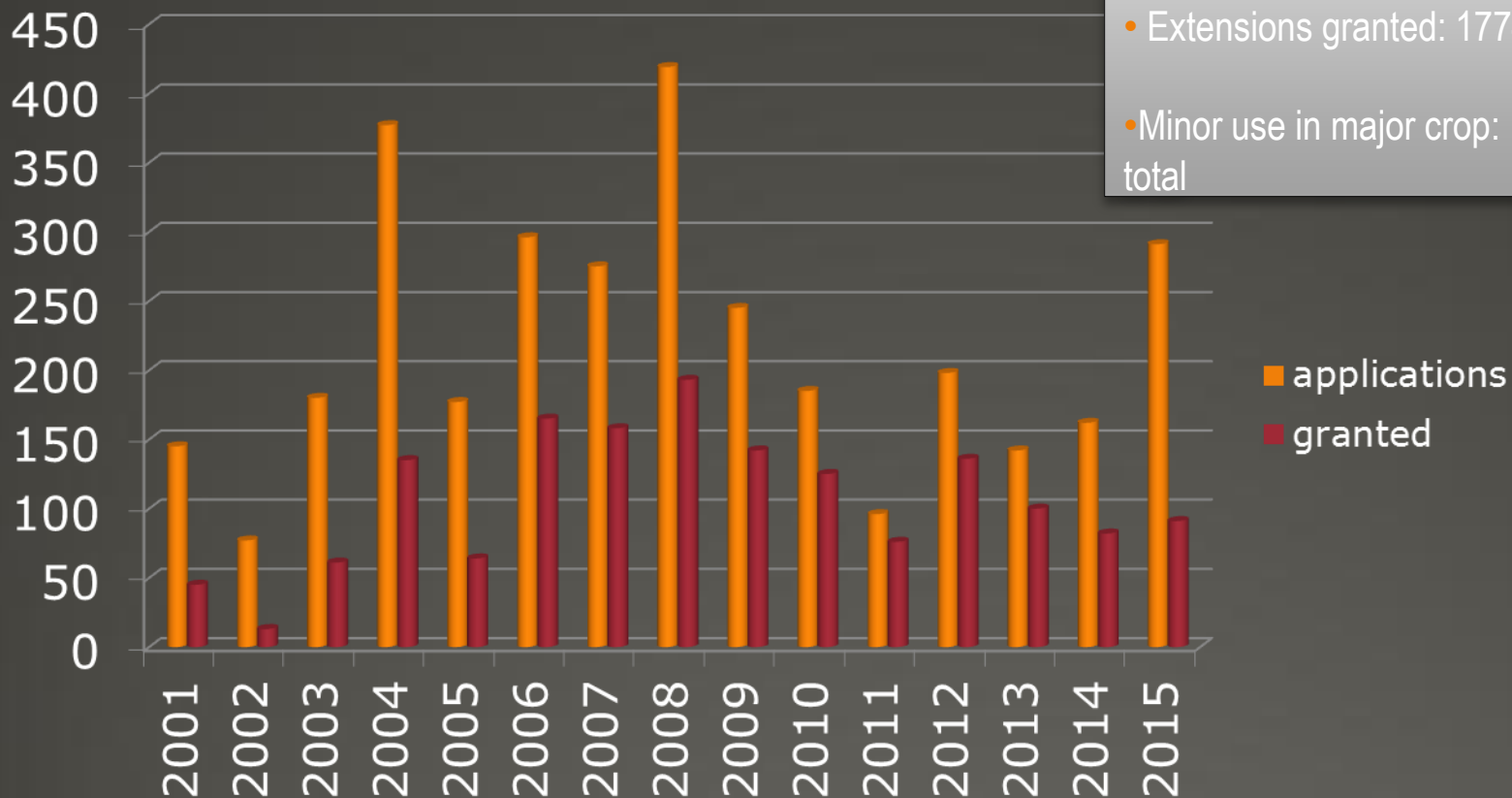
high number of pests raised by favourable climatic conditions

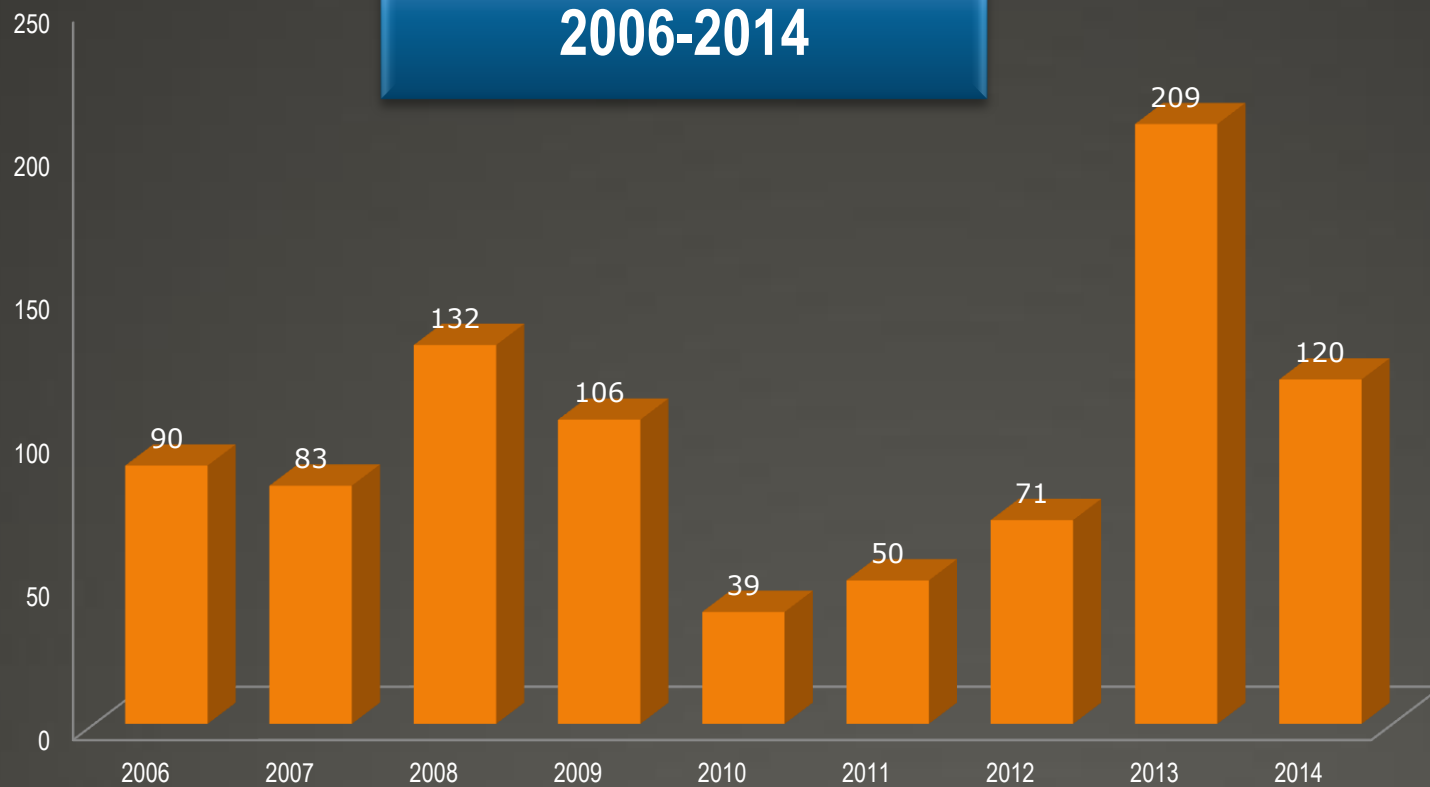


Eurostat (2005)

# Importance of Minor uses in Portugal

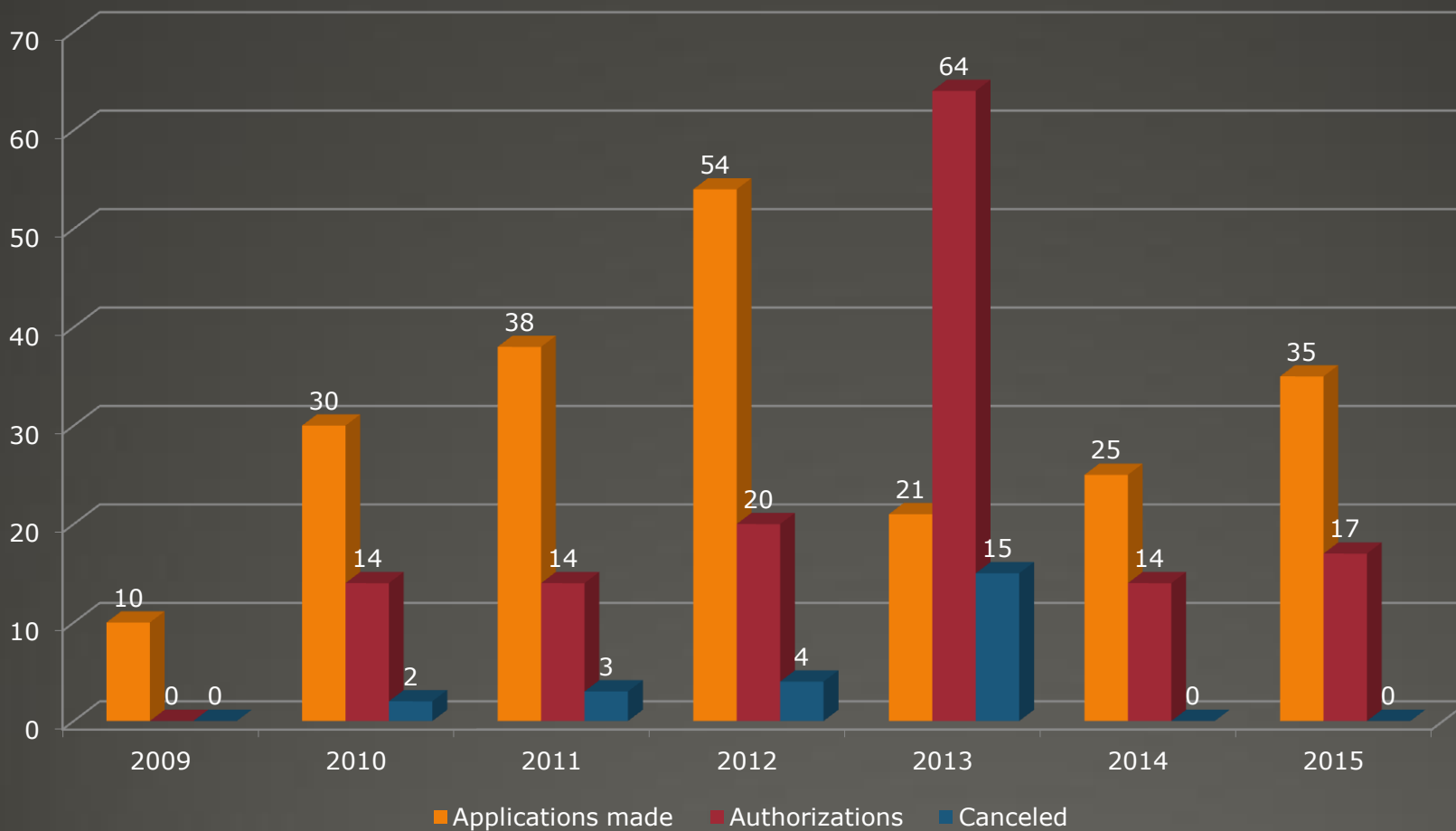
- Total of applications: 3284
- Extensions granted: 1774
- Minor use in major crop: 4% total





**Number of authorisations granted in Portugal**

# Mutual Recognition in Portugal



2009-2015



Ministry of Agriculture and Sea

dgav  
Direção Geral de Alimentação e Veterinária

General directorate of food and Veterinary

General Directorate....

Fitossanitary Department

.....

.....

Authorization of PPP Division



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**Risk Assessment**

**SUD** 2



**Equipment inspection** 1

**Risk Management** 6



**Plant Protection Products Authorisation Division**



**Integrated Pest Management** 1



**Minor Uses** 1



**Forecast Warning Service** 1



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# Sustainable Use Directive of pesticides (Directive 2009/128/CE, 21 st Octobre)

Establishing a framework for Community action to  
achieve the sustainable use of pesticides



Reducing the risks and impacts of pesticide  
use on human health and the environment



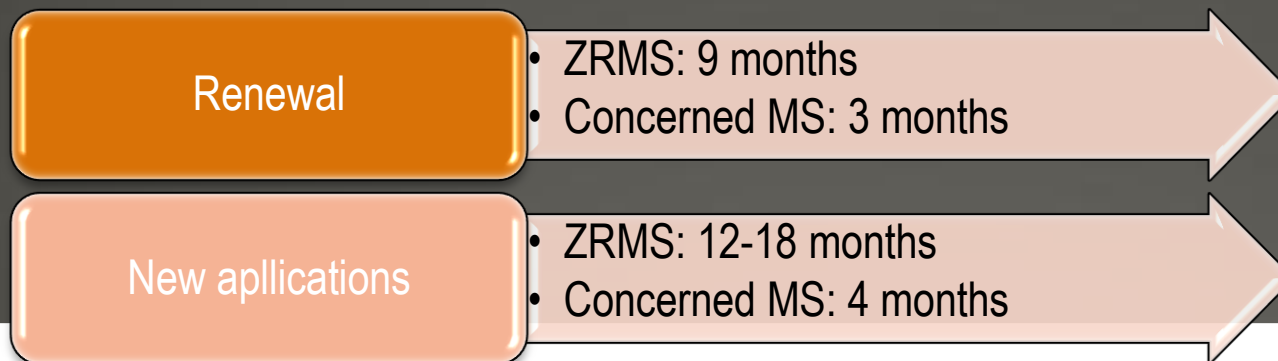
Promoting the use of IPM and alternative approaches or  
techniques such as non-chemical alternatives to pesticides.

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# Comparative assessment in Southern Zone

- CA should be done at Member State level;
- Depends on nationally available alternatives;
- EU GD allows a very restrictive or flexible interpretation – different approaches between MS;
- Restricted timelines:



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# Comparative assessment

- A 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 Annex II point 4 of Regulation 1107/2009.;
- ✓ have all been evaluated and are approved for use in the EU in authorised PPP;
- ✓ Uses of PPP considered under the CA process:



the approval may be renewed once or more for periods not exceeding 7 years



# Comparative assessment

- **Regulation (EU) 2015/408, 11 March 2015:** Establishes a list of candidate of substitution  77 active substances are candidates of substitution.
- **Guidances:**
  - ✓ **SANCO/11507/2013 (rev. 12), 10 the 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

# Comparative assessment - Portuguese guidance -

- This guidance is provided for applicants seeking authorisation of plant protection products in PT.
- Supplements the EU guidance for applicants.
- Explains:
  - ✓ what information is required for a CA;
  - ✓ when it should be submitted and;
  - ✓ how it should be presented.
- 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 -

## How should be provide information for CA?

- Applicants detailed consideration of this, should be provided as the supporting 'data'. using the form attached to the guidance  [Annex 2](#)
- The conclusion for comparative assessment and substitution should be included:



national addenda to the draft Registration Report (dRR)

# Comparative assessment - Portuguese guidance -

## What does the information needs to cover?

- Consider steps 1-10 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 -

## How to address CA for zonal applications?

- As comparative assessment and substitution is a Member State responsibility it cannot be considered appropriately by the zRMS;
- It remains the responsibility of the individual Member States and applicants should follow their advice and procedures;
- Applicants should include the PT comparative assessment information in their application in PT National addenda in both cases:
  - ✓ PT - Rapporteur Member State or;
  - ✓ PT - Concerned Member State.

# Comparative assessment - Portuguese guidance -

## Regulatory action in the end of CA

- If PT concludes that a substitution for any of the uses of the PPP is appropriate:
  - ✓ that withdrawal or amendment shall take effect 3 years after the decision
  - or
  - ✓ at the end of the approval period of the candidate for substitution where that period ends earlier.



# 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 -

## Final conclusion and Report

- All steps of CA should be appropriately documented in dRR;
- A clear justification should be given for the conclusion of each step;

Applicant information to support the  
CA

- The applicant should be given the possibility to comment.

# Concluding remarks



- We will have a lot to learn CA;
- Will need to share the experiences between applicants and CA;
- Expected that guidance will be updated in the light of experience!

## Thank you for your attention!

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