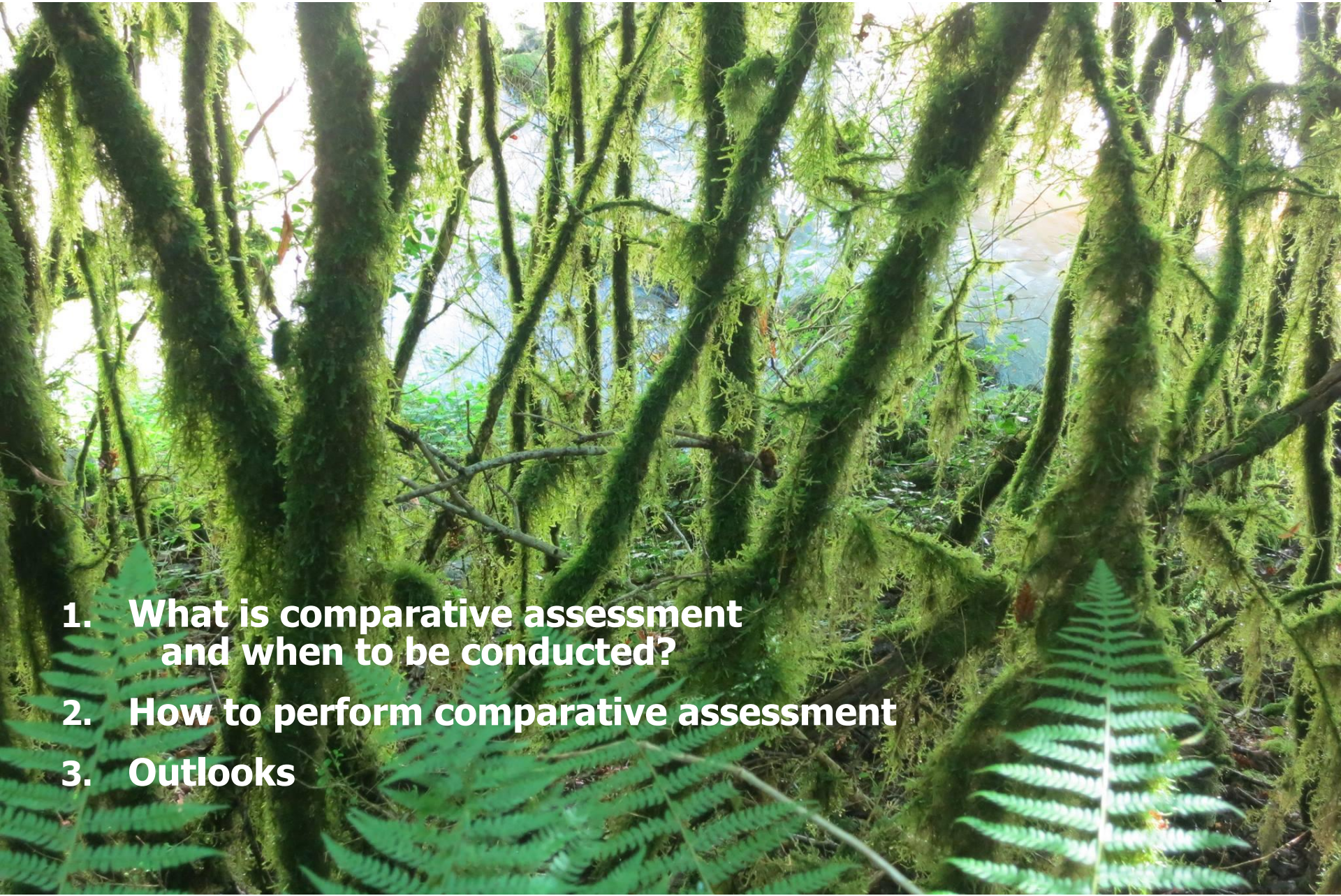


Comparative Assessment and Candidates for Substitution

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- 1. What is comparative assessment and when to be conducted?**
- 2. How to perform comparative assessment**
- 3. Outlooks**

1- What is comparative assessment and when to be conducted?



General Considerations:

- introduced by **Regulation 1107/2009**
- **candidates for substitution: substances** meeting specific requirements
- products containing a candidate for substitution to be considered in a **comparative assessment**

1- What is comparative assessment and when to be conducted?



Criteria for candidates for substitution are *hazard* based!
(Annex II of Reg (EG)1107/2009)

(Active substance/PPP evaluation is *risk* based!)

- ADI, ARfD or AOEL significantly lower than others in the same group
- Satisfies 2 PBT criteria
- Reasons for concern: nature of critical effects even with mitigation
- Significant proportion of non-active isomers
- Cat 1a or 1b Carcinogen or reprotox (if not already excluded)
- Endocrine effects

1- What is comparative assessment and when to be conducted?



List of candidates for substitution (CfS)

- 1st list of substances (approved before January 2013)
78 substances; to be published
- 2nd list of substances (approved after January 2013 onwards)
still to be addressed

1- What is comparative assessment and when to be conducted?

Outlined in GD SANCO/11507/2013

Aim of the comparative assessment:

Replacement of a product, which contains a candidate for substitution by methods and products of plant protection of **lesser concern** in order to benefit the protection of human or animal health and the environment **while minimizing** the economic and practical disadvantages for agriculture



1- What is comparative assessment and when to be conducted?



- Comparative assessment to be performed by **individual MS** (not at zonal level)
- Obligatory comparative assessment: for PPP containing a candidate for substitution
- Optional comparative assessment: may be performed for PPP which do not contain candidate for substitution

1- What is comparative assessment and when to be conducted?

- **“existing”** PPP: comparative assessment at the next legal step (i.e. renewal of the product according to Article 43)
- amendment (additional crop)
 - only the new/amended uses to be considered (comparative assessment and substitution); existing uses at the next legal step!
- **“new”** PPP: comparative assessment 5 years after first authorisation at the latest

Remark: “new” products means **new use**; if the active/crop combination had been previously considered – experience to be expected for this combination



Comparison with alternative has to be done at the level of uses

2- How to perform comparative assessment

- **SANCO/11507/2013** incorporates EPPO guidance
- **stepwise approach** recommended, options to start or finish the comparative assessment at any step to reduce resource needed



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2- How to perform comparative assessment

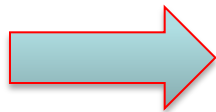
General:



Focus on PPP without a candidate for substitution

But also possibility to compare with:

- PPP containing **a different candidate for substitution** (according to REG 1107/2009 not excluded)
- PPP containing **the same candidate for substitution** (e.g. the compared product contains an additional active and the amount of candidate for substitution to be applied is reduced)



Alternative must show “**significantly**” lower risk

2- How to perform comparative assessment

 Tiered approach:

STEP 1

Product contains a candidate for substitution

Yes



Step 2



No



End

Source: SurfGard

2- How to perform comparative assessment

STEP 2

- Compare with chemical and non chemical alternatives for every use of the product containing a candidate for substitution
- Resistance (a minimum of four different chemical modes of action are used to reduce the risk of resistance)
- Economic effects
- Impact on „minor uses“



EPPO standard PP 1/271

2- How to perform comparative assessment

STEP 2

Substitution of the product by chemical and/or non chemical methods possible

Yes



Step 3



No



End

2- How to perform comparative assessment

STEP 3



- Comparison for health and the environment of the product (containing a candidate for substitution) with alternative products
- Focus on the specific criterion that defines an active as a candidate for substitution
 - e.g. ADI judged to be „significantly low“ as criterion for the substance being a candidate -> compare consumer risk only
- To be considered: risk assessments may be different over the time due to new guidance documents
- Risk mitigation measures?

2- How to perform comparative assessment

STEP 3

Alternative product is a better choice from the perspective of health or the environment

Yes



Step 4?



Source: LORD MOON

No



End

2- How to perform comparative assessment



STEP 4

- Comparison for health and the environment of the product (containing a candidate for substitution) with alternative products considering other aspects than the specific criterion that defines an active as a candidate for substitution

e.g. ADI regarded as „significantly low“ as criterion for the substance being a candidate -> comparison of the consumer risk indicated lower risk of the alternative product, but higher risk with regard to aquatic

2- How to perform comparative assessment

STEP 4

- Weighting of different areas of risk assessment?
- Substitution not appropriate

Are there significant risks to health or the environment identified in other aspects of the risk assessment (other aspects than the specific criterion that defines an active as a candidate for substitution)

Yes



End (i.e. no substitution)

2- How to perform comparative assessment

Documentation of the comparative assessment:

- clear and appropriate documentation (all relevant steps to be clearly presented) – format proposal mentioned in GD SANCO/11507/2013=> **clear conclusion**
- **no zonal procedure** => national addendum (Part A of the RR)



up to the applicant/authorisation holder to provide a proposal for comparative assessment

GD on renewal, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 SANCO/2010/13170 rev 7:

"The applicant should add to his application a proposal for comparative assessment, the concerned products (product applied for and alternatives). Such based on his knowledge of proposal should address the criteria foreseen in Article 50(1)"

3- Outlooks



Source: Sud-ouest.fr

- ESTIMATION:
20% of all products might be subject to comparative assessment?
5% to be considered in step 3?
2% will be substituted?
- Fungicides, insecticides: comparative assessment ends at step 2?
Herbicides: for the same weed control more alternatives – to be further considered at step3/4
- **Parallel trade permits**: Considered along with the identical reference product
- **Home and garden use products**: to be excluded from comparative assessment ? – *in discussion*

3- Outlooks

How to deal with *minor use*?

- to be **excluded** from comparative assessment?
- "*major uses*" are the ones for which alternatives to be considered
- no substitution of a product with one "minor use" only?



3- Outlooks



- If substitution necessary:
 - **Amendment/restriction**
 - **application refusal** } **of the authorisation of the PPP containing a candidate for substitution**

?? Comments of the authorisation holder/applicant in case of substitution: Time schedule??

- For “new” product the comparative assessment has to be performed 5 years after the 1st authorisation at the latest
 - comparative assessment has to be finalised after 5 years at the latest ??
 - kind of application/procedure ?? – to be considered and nationally regulated by each MS

3- Outlooks



Harmonisation

- Procedure? GD is a harmonisation tool
 - general issues to be harmonised
 - how to handle minor uses
 - how to handle home and garden uses
 -
- Possible? Registration status varies between MS
- Mutual recognition (possible to rely on the comparative assessment of the reference MS as well?)
- Pilot projects by NL, UK, AT (planned) and EPPO – information exchange (harmonisation?)



Thank you for your attention