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Principles of Risk Assessment in the EU Legislative Framework

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EFSA Consultative Workshop
Selection of comparators for the RA of GM plants
31 March 2011, Brussels

Directive 2001/18
Deliberate release of GMOs

ENVI

Risk

CULTIVATION

Import & processing

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Regulation 1829/2003
Integrated approach of the Food/Feed chain

GM SEEDS

ENVI

Risk

Food/Feed

Risk

GM FOOD
- containing or consisting of GMOs

-produced from GMOs

GM FEED
- containing or consisting of GMOs

- produced from GMOs

OTHER USES

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Environmental Risk Assessment

Annex II of Directive 2001/18

Decision 2002/623/EC

Environmental Risk Assessment Objective

To identify & evaluate potential adverse effects […] with a view to identifying if there is a need for risk management

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Environmental Risk Assessment General Principles

- ✓ Compare characteristics & use with non GM
  => definition of a baseline
- ✓ Scientifically sound:
  - ➢ Data based on Common methodology
  - ➢ Associated uncertainty
- ✓ Case by case basis
- ✓ Take into account new information

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Environmental Risk Assessment Methodology

Diagram 1: The six steps in the analysis of ERA

Step 1: *Identification of characteristics which may cause adverse effects*

Step 2: *Evaluation of the potential consequences of each adverse effect, if it occurs*

Step 3: *Evaluation of the likelihood of the occurrence of each identified potential adverse effect*

Step 4: *Estimation of the risk posed by each identified characteristic of the GMO(s)*

Step 5: *Application of management strategies for risks from the deliberate release or marketing of GMO(s)*

Step 6: *Determination of the overall risk of the GMO(s)*

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Environmental risk assessment Conclusions

- ✓9 points to be addressed
  - ➢Persistence/Invasiveness/gene transfer
  - ➢Target/Non-target organisms/Biogeochemical processes
  - ➢Human & Animal health

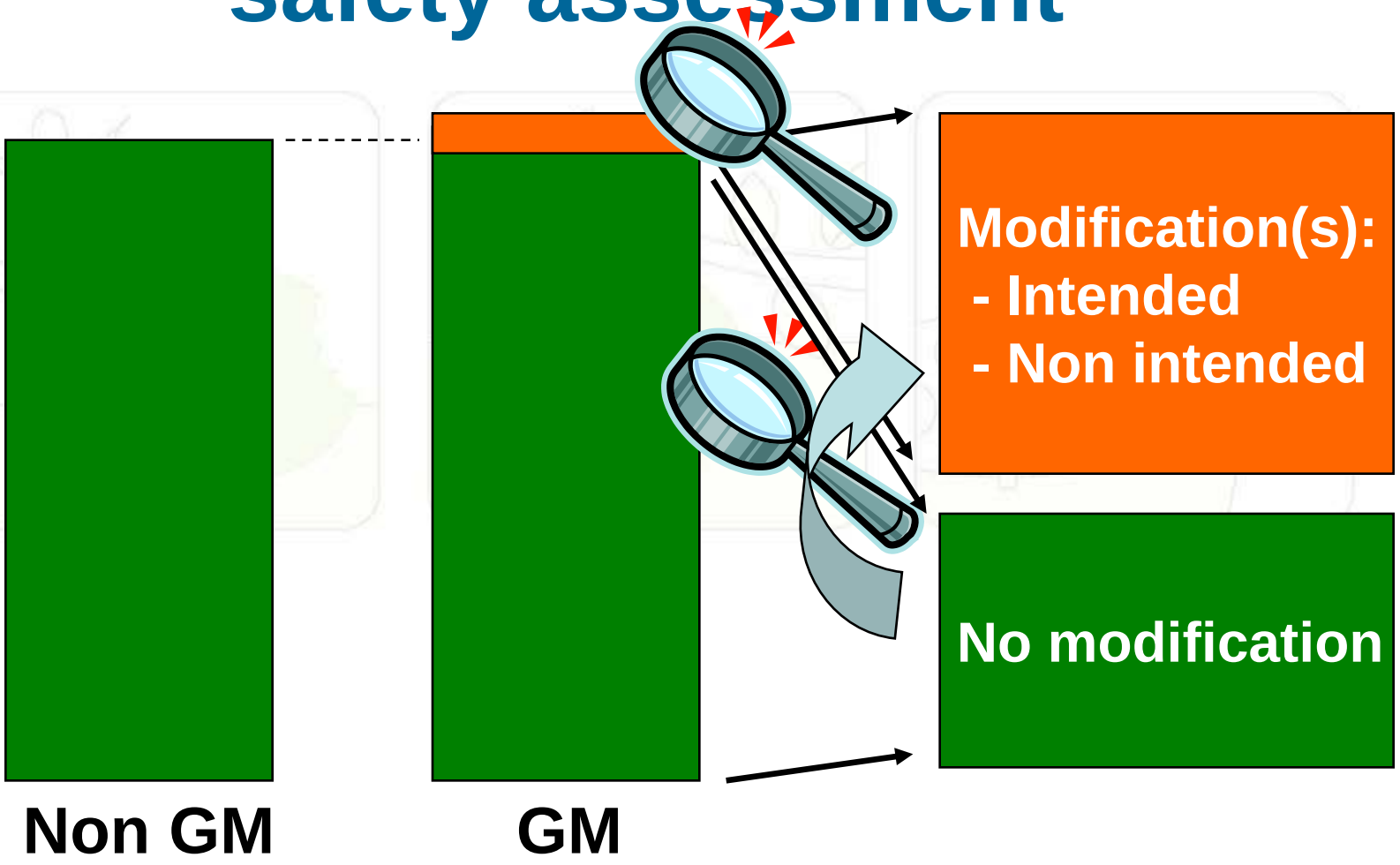
Food/Feed Safety Assessment Regulation on GM food/feed

- ✓ Food/Feed must NOT
  - ➢ have adverse effects
  - ➢ mislead the consumer
  - ➢ differ in a way that would be nutritionally disadvantageous

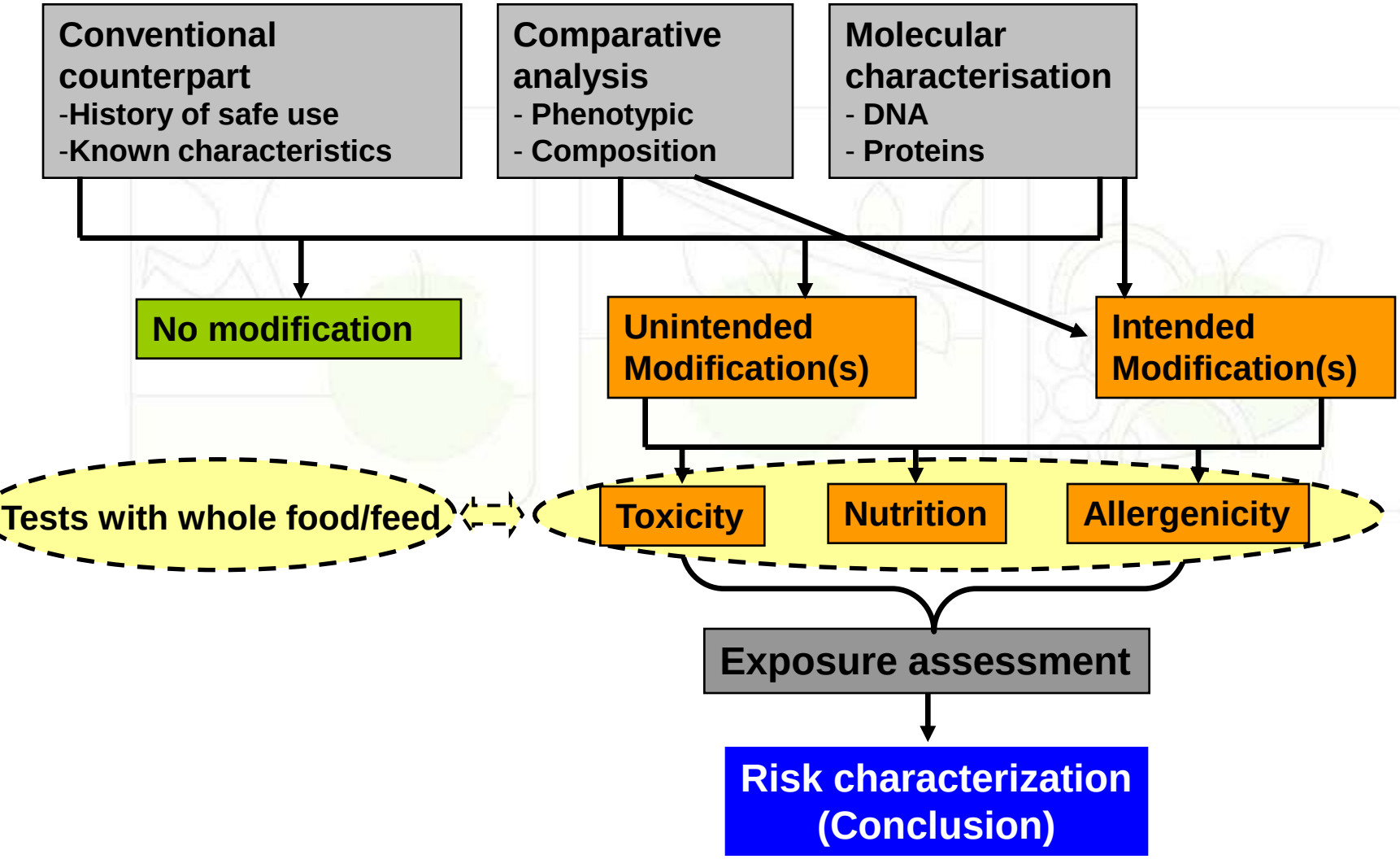
Conventional counterpart Definition

A similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use

Strategy of GM Food and Feed safety assessment



Strategy of safety assessment



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Consumer information Labelling

- ✓ In all cases: “genetically modified”
- ✓ In addition, when GM is different from conventional counterpart as regards:
  - ➢ Composition
  - ➢ Nutritional value or nutritional effects
  - ➢ Intended use of the food
  - ➢ Implications for the health of certain sections of the population

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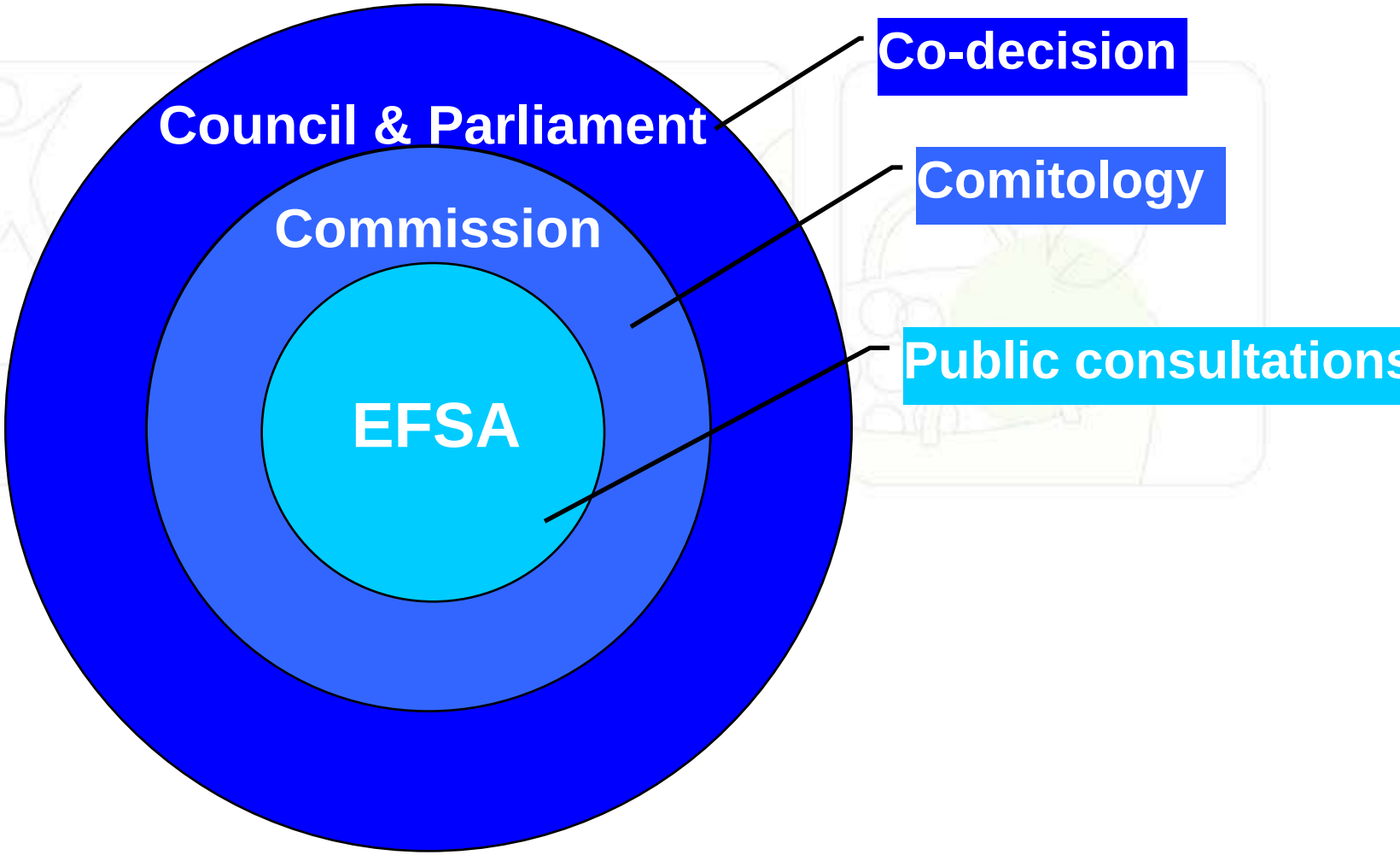
Adoption of additional rules through comitology

For Food/Feed (2011) & ERA (2012)

- More detailed requirements (e.g. inclusion of protocols)
- Increase the sense of ownership of Member States
- Improve the scientific and legal certainty

CCL: A comprehensive Risk Assessment Framework



Thank you!