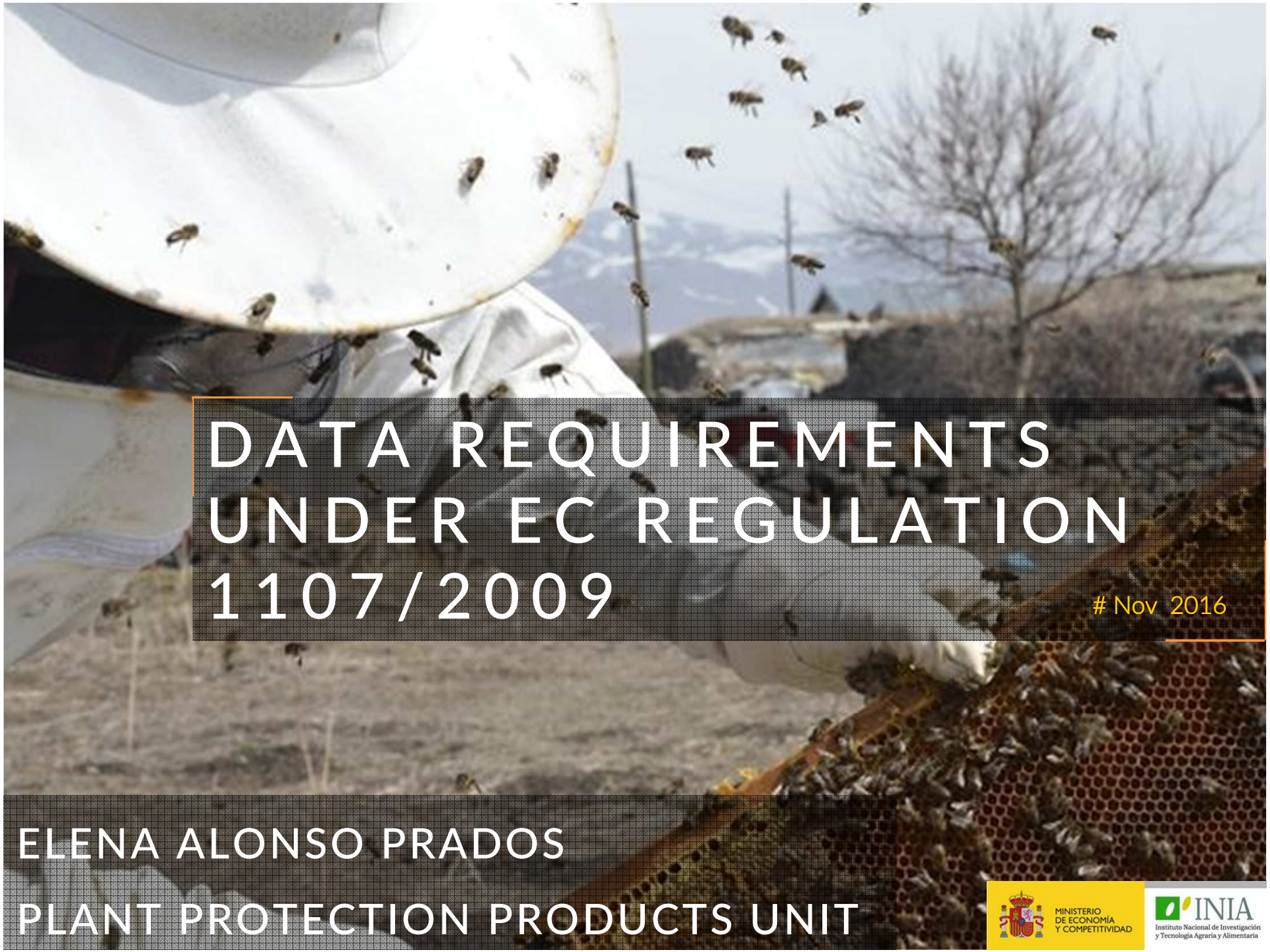


DATA REQUIREMENTS UNDER EC REGULATION 1107/2009

Nov 2016

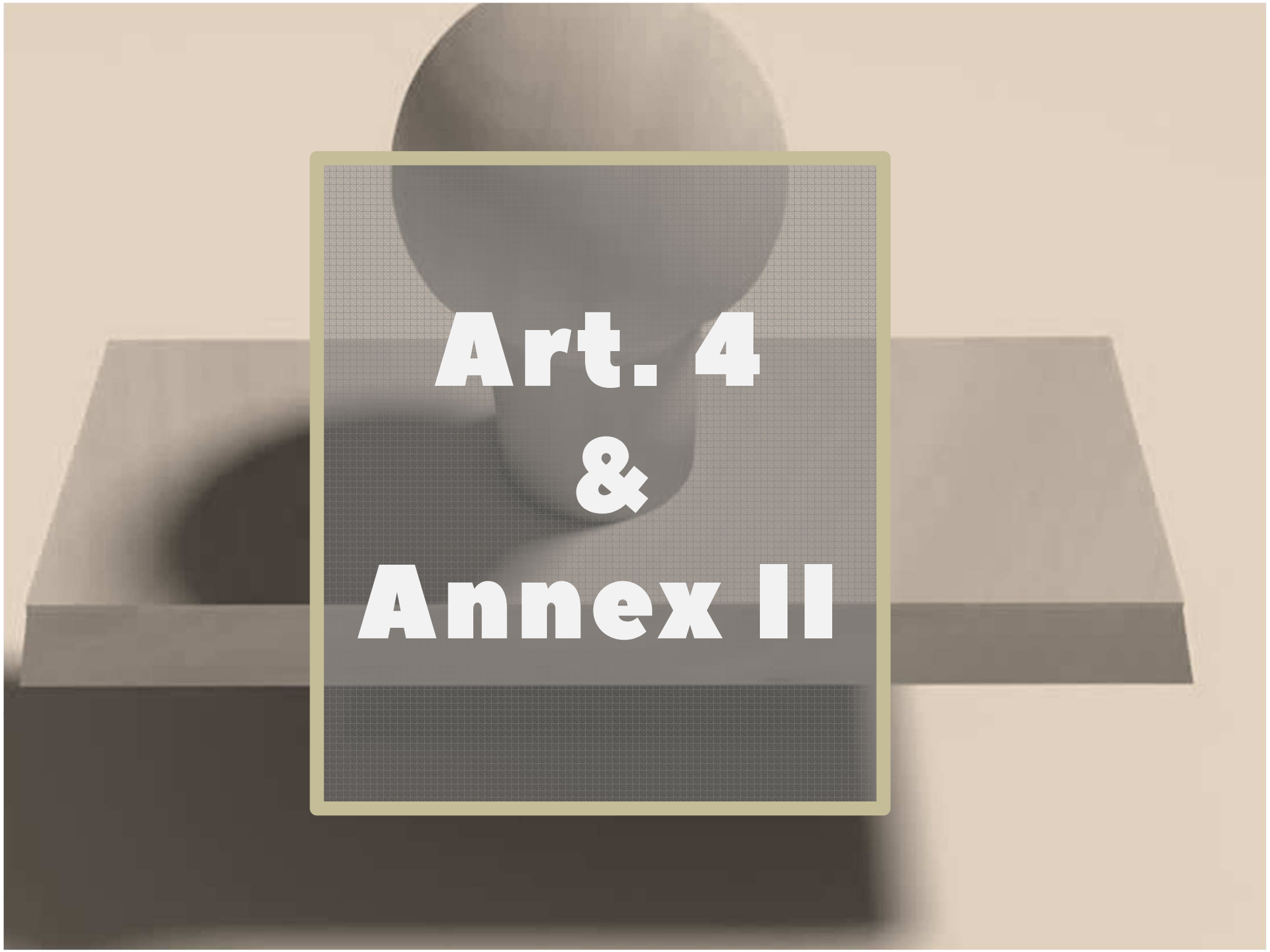
ELENA ALONSO PRADOS

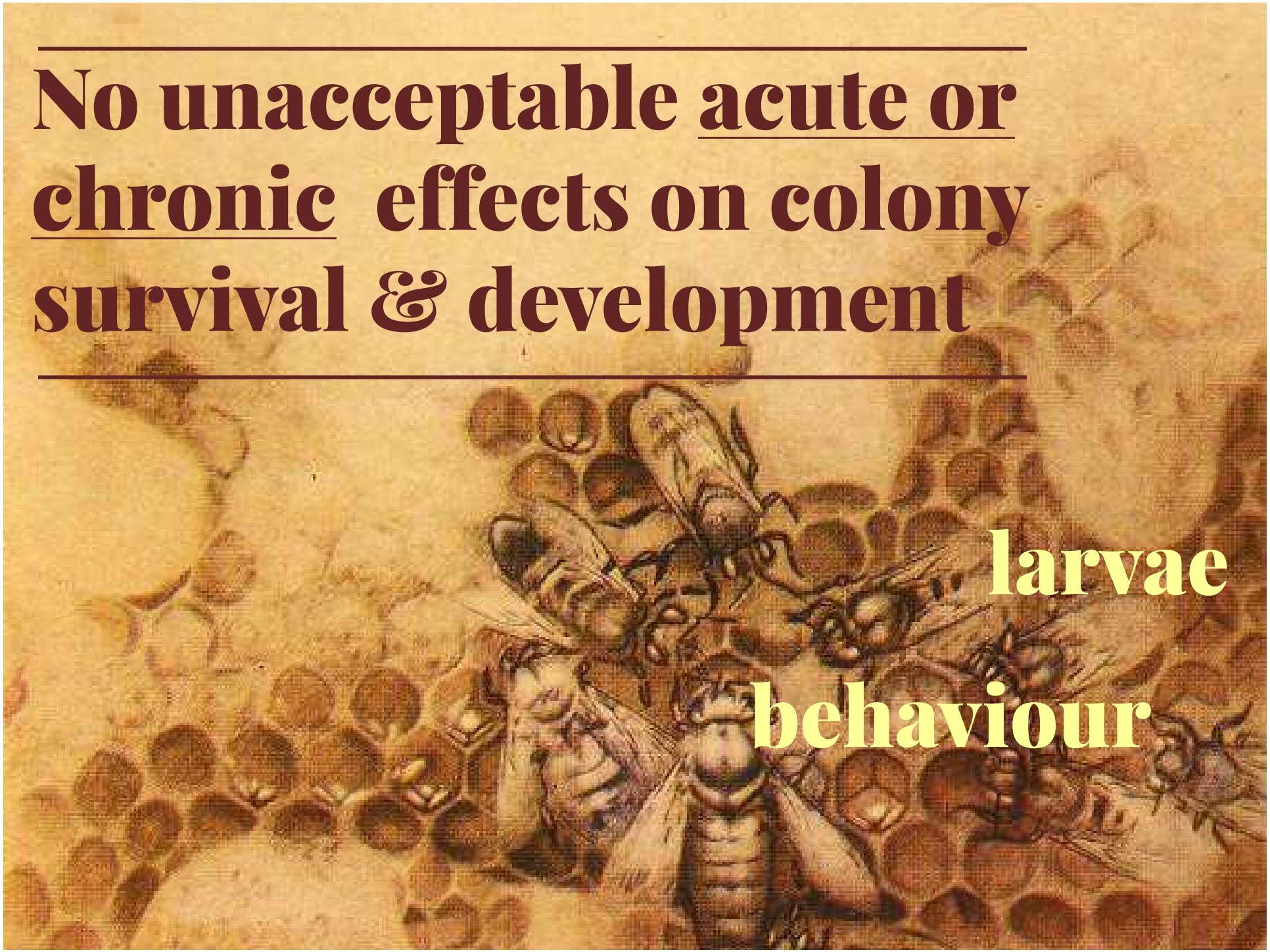
PLANT PROTECTION PRODUCTS UNIT

MINISTERIO DE ECONOMÍA Y COMPETITIVIDAD

INIA Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria


HIGH LEVEL OF
PROTECTION
HARMONIZATION
OF RULES
IMPROVING
AGRICULTUAL
PRODUCTION


Art. 4
&
Annex II


No unacceptable acute or chronic effects on colony survival & development
larvae
behaviour


Risk
Assessment
Risk
Managment
RISK ANALYSIS
Risk
comunication


Risk = F (Hazard, Exposure)


AGREED ASSESSMENT SCHEMES
GOOD AGRICULTURAL PRACTICES
PRECAUTION PRINCIPLE


THEORICAL
WORST CASE
REAL
WORST CASE

HAZARD CHARACTERIZATION

AGREED TEST GUIDELINES

(UE) 283/2013

Acute

Chronic

Development & Brood

Sublethal

(UE) 284/2013

lab toxicity test	HB	BB	SB
Acute oral	OECD 213 (LD50)	Validated Test methods not available: Proposal: modified OECD 213	Ring test ongoing futher work needed
Acute contact	OECD 214 (LD50)	Validated Test methods not available: Proposal: modified OECD 214	Ring test ongoing ready to be implemented
Chronic toxicity to adults	Draft (LC50): 10 d oral toxicity	Proposal: HB end point+safety factor	HB end point+safety factor
Toxicity to larvae	OECD draft GD (repeated exposure) up to pupal stage	No available Proposal: HB end point+safety factor	No available Proposal: HB end point+safety factor

lab toxicity test	HB	BB	SB
Acute oral	OECD 213 (LD50)	Validated Test methods not available: Proposal: modified OECD 213	Ring test ongoing futher work needed
Acute contact	OECD 214 (LD50)	Validated Test methods not available: Proposal: modified OECD 214	Ring test ongoing ready to be implemented
Chronic toxicity to adults	Draft (LC50): 10 d oral toxicity	Proposal: HB end point+safety factor	HB end point+safety factor
Toxicity to larvae	OECD draft GD (repeated exposure) up to pupal stage	No available Proposal: HB end point+safety factor	No available Proposal: HB end point+safety factor

Cage & Tunnel

Field

(UE) 284/2013

Higher tier studies	HB	BB	SB
Semi field	EPPO 2010 and OECD 2007 with further details as provided in Appendix O	Chapter 6.2.2 and Appendix P (with possibility for applicants to modify)	Futher work needed
Field studies	EPPO 2010 and OECD 2007 with further details as provided in Appendix O	Chapter 6.2.2 and Appendix P (with possibility for applicants to modify)	Futher work needed
Study with micro-colonies		Chapter 6.2.2 and Appendix P (with possibility for applicants to modify)	

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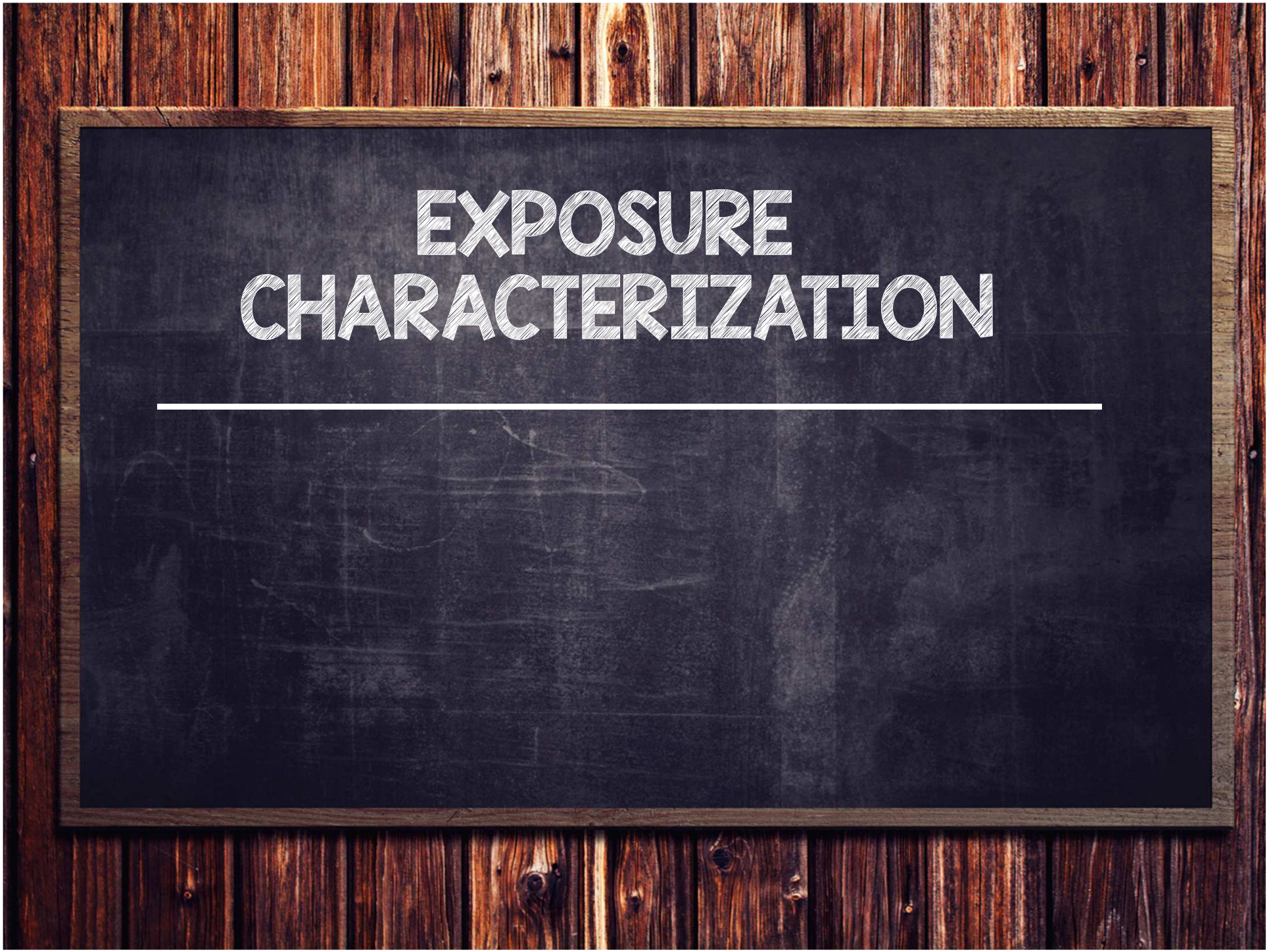
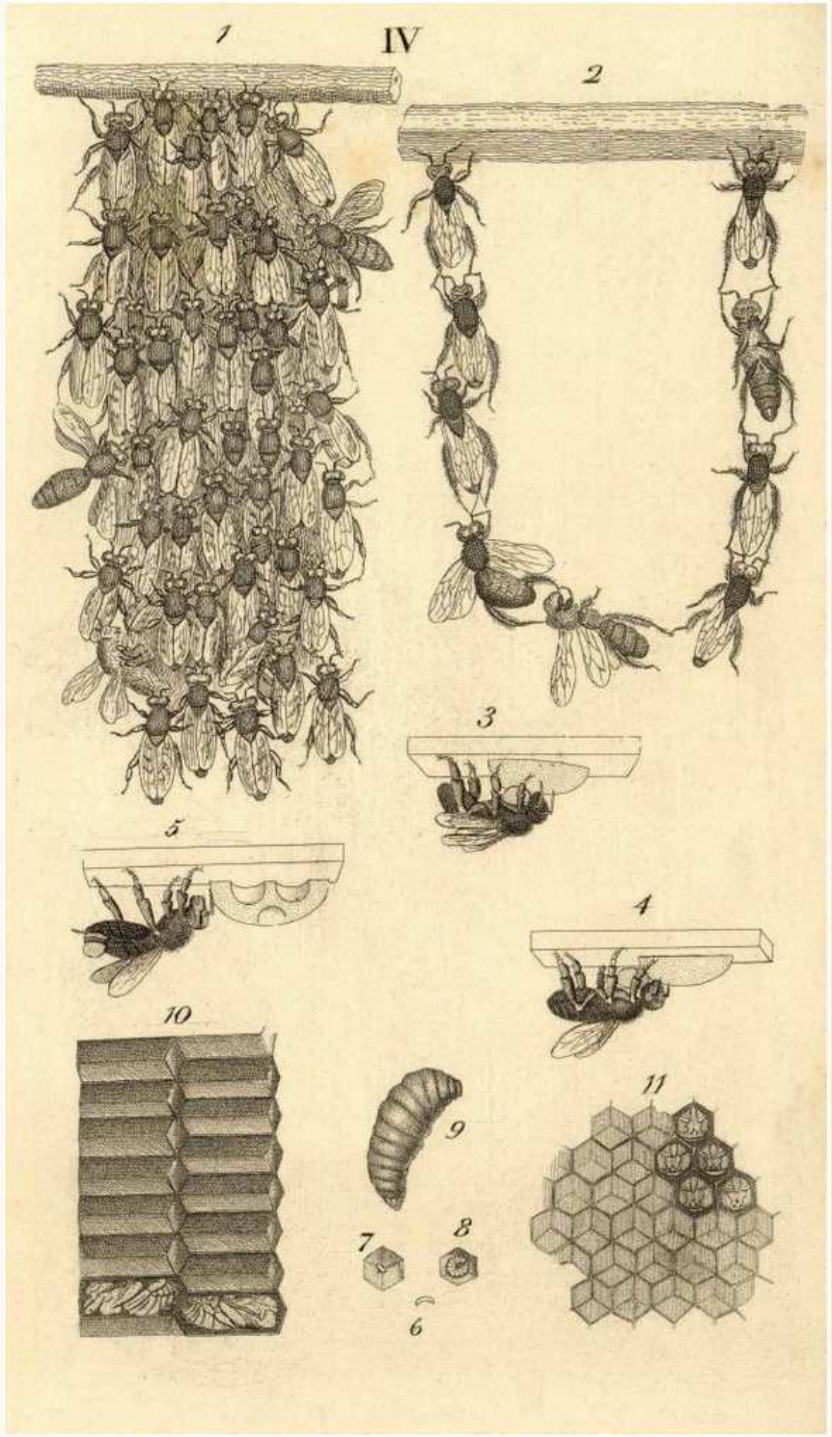
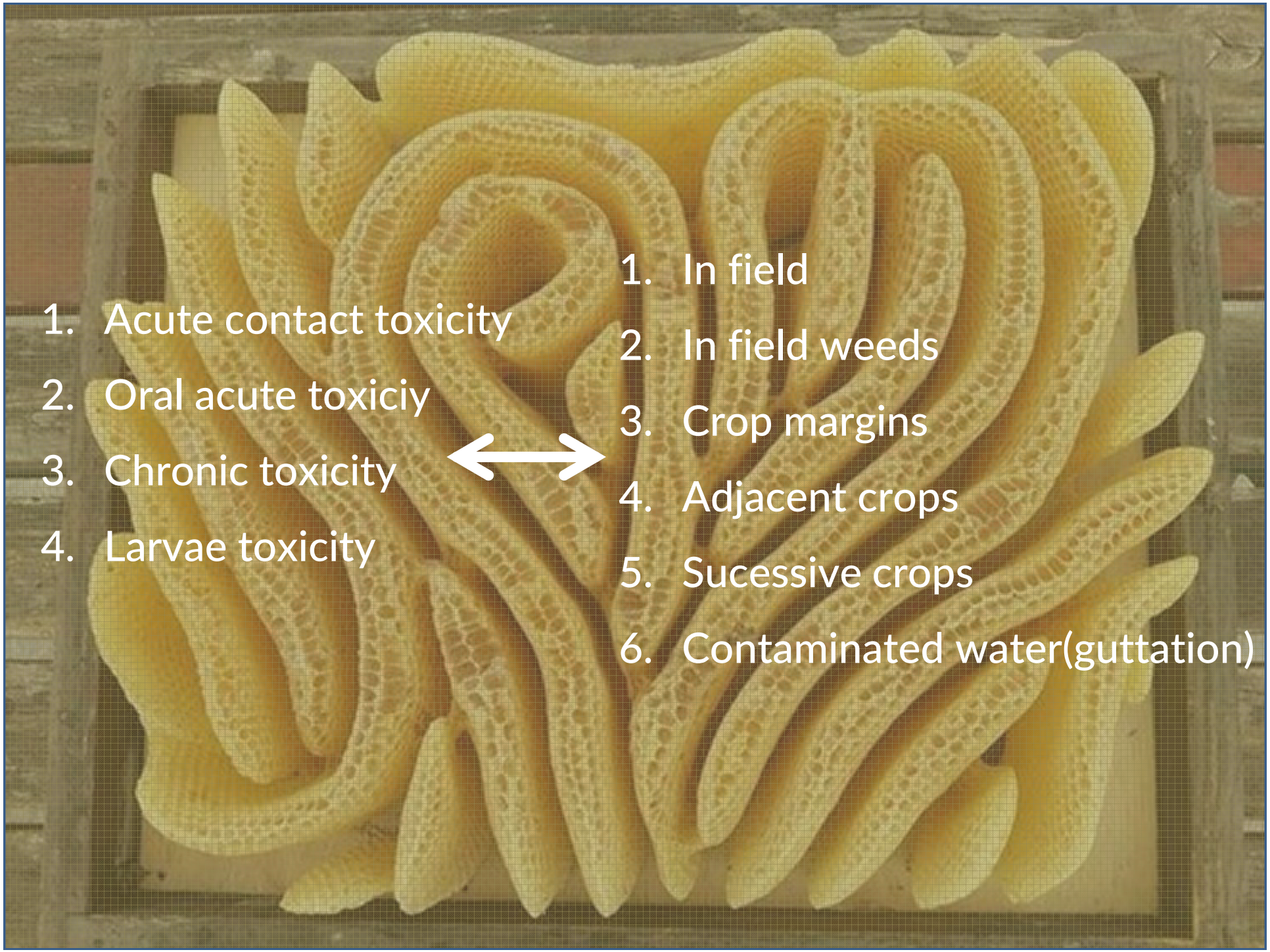

EXPOSURE
CHARACTERIZATION


(UE) 283/2013
Polen
Nectar
Water
Dust drift
(UE) 284/2013

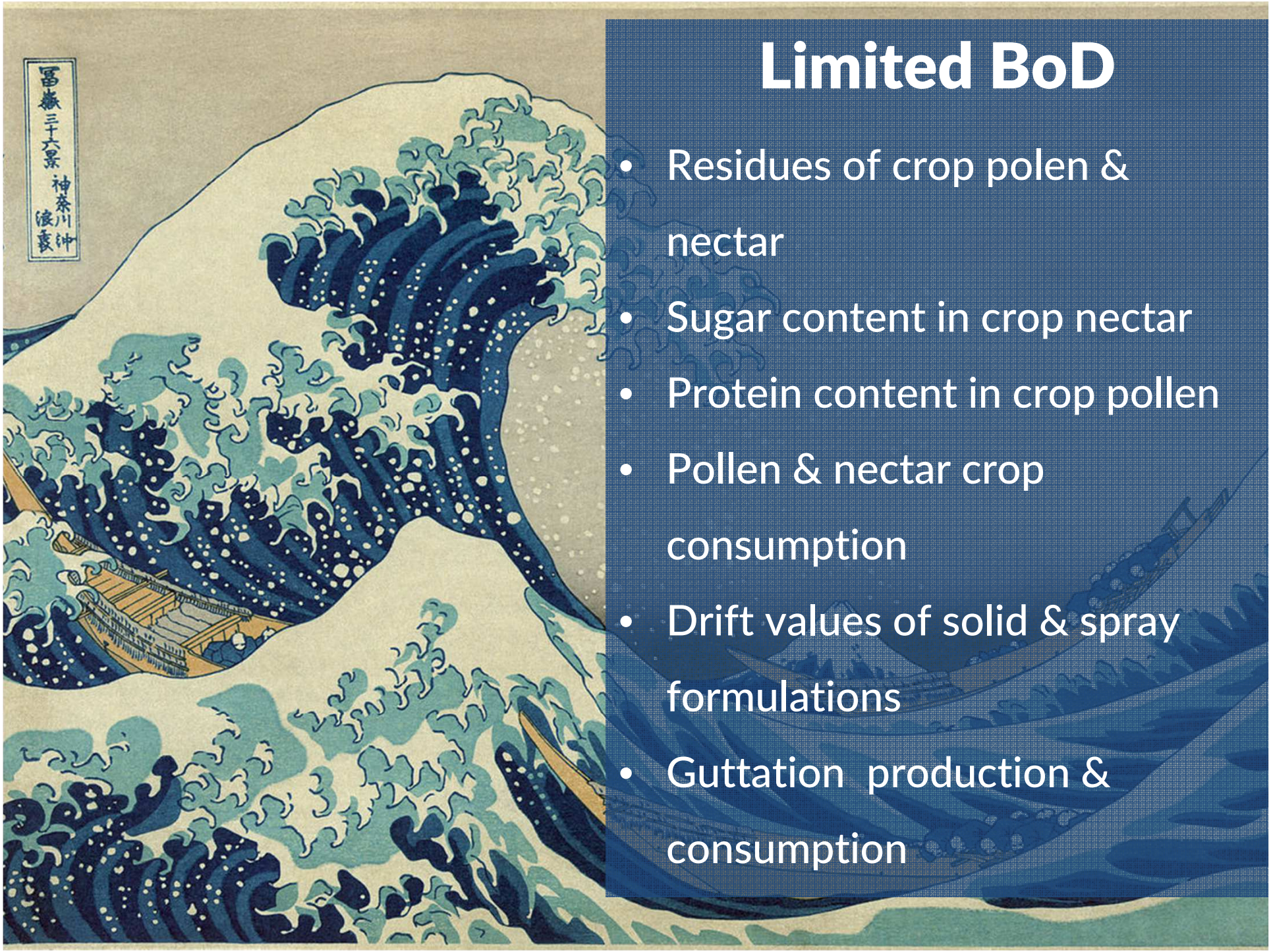
RISK CHARACTERIZATION



Not exceed 7% reduction in colony size


1. Acute contact toxicity
2. Oral acute toxiciy
3. Chronic toxicity
4. Larvae toxicity
1. In field
2. In field weeds
3. Crop margins
4. Adjacent crops
5. Sucessive crops
6. Contaminated water(guttation)


THEORICAL
WORST CASE
REAL
WORST CASE



Limited BoD

- Residues of crop polen & nectar
- Sugar content in crop nectar
- Protein content in crop pollen
- Pollen & nectar crop consumption
- Drift values of solid & spray formulations
- Guttation production & consumption

Field studies

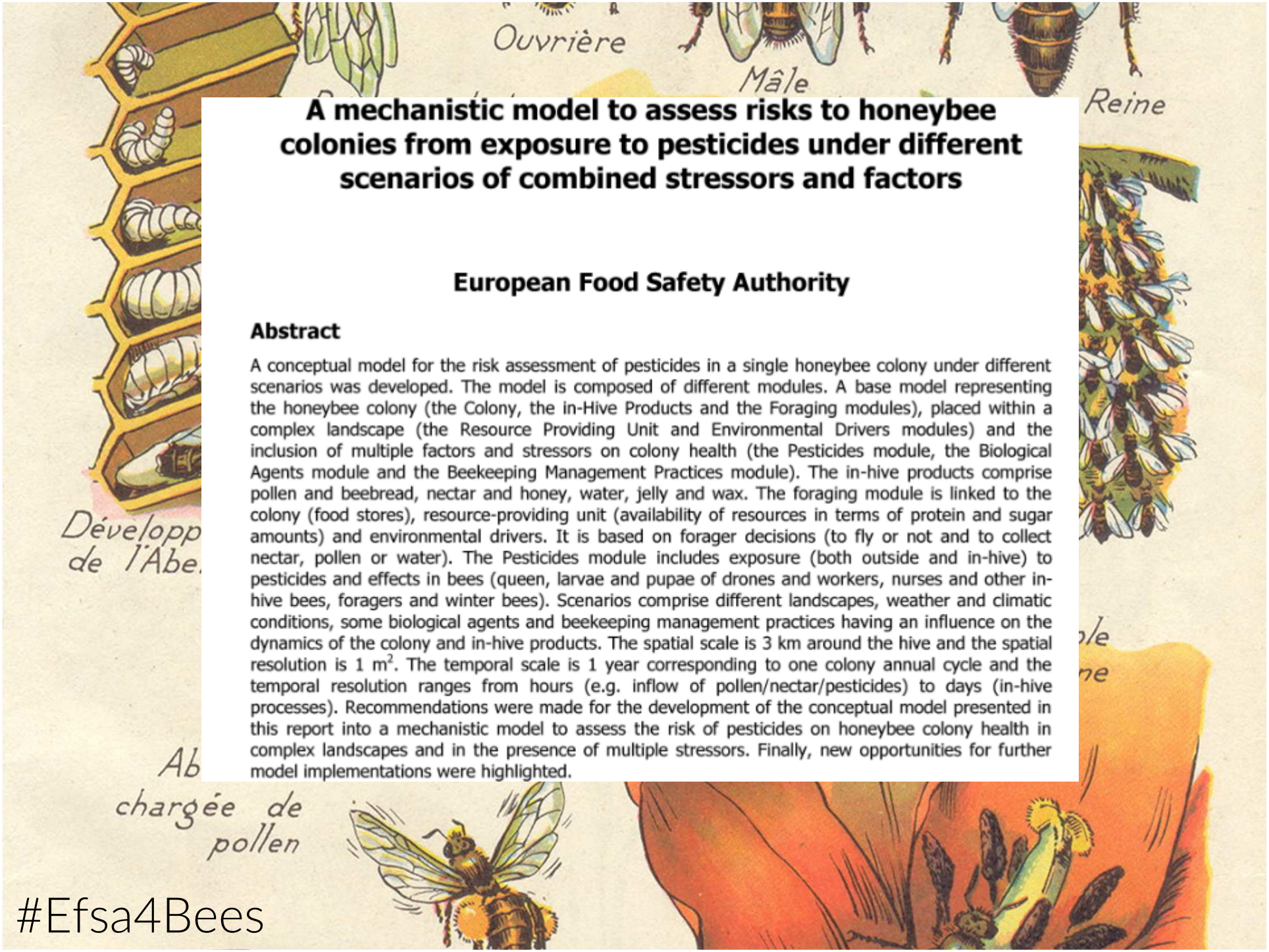
Design to compile with protection goals

Number of replicates

Distance to controls

Residues measurements.


Accumulative assessment
Sublethal effects
Protection goal.



A mechanistic model to assess risks to honeybee colonies from exposure to pesticides under different scenarios of combined stressors and factors

European Food Safety Authority

Abstract

A conceptual model for the risk assessment of pesticides in a single honeybee colony under different scenarios was developed. The model is composed of different modules. A base model representing the honeybee colony (the Colony, the in-Hive Products and the Foraging modules), placed within a complex landscape (the Resource Providing Unit and Environmental Drivers modules) and the inclusion of multiple factors and stressors on colony health (the Pesticides module, the Biological Agents module and the Beekeeping Management Practices module). The in-hive products comprise pollen and beebread, nectar and honey, water, jelly and wax. The foraging module is linked to the colony (food stores), resource-providing unit (availability of resources in terms of protein and sugar amounts) and environmental drivers. It is based on forager decisions (to fly or not and to collect nectar, pollen or water). The Pesticides module includes exposure (both outside and in-hive) to pesticides and effects in bees (queen, larvae and pupae of drones and workers, nurses and other in-hive bees, foragers and winter bees). Scenarios comprise different landscapes, weather and climatic conditions, some biological agents and beekeeping management practices having an influence on the dynamics of the colony and in-hive products. The spatial scale is 3 km around the hive and the spatial resolution is 1 m^2. The temporal scale is 1 year corresponding to one colony annual cycle and the temporal resolution ranges from hours (e.g. inflow of pollen/nectar/pesticides) to days (in-hive processes). Recommendations were made for the development of the conceptual model presented in this report into a mechanistic model to assess the risk of pesticides on honeybee colony health in complex landscapes and in the presence of multiple stressors. Finally, new opportunities for further model implementations were highlighted.

#Efsa4Bees