Risk Assessment and Risk Management for Plant Protection Products related to Honeybees

Technical Mission Brazil

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Risk Assessment and Management

Overview

i. Introduction

ii. Risk Assessment / Concepts and Principles

iii. Risk Mitigation / Labelling

iv. Post-registration Monitoring

v. Status Quo of Bee Keeping in Germany

vi. Conclusions

Introduction – The Value of Bees (FAO)

- It is estimated that about one third of all plants or plant products eaten by humans are directly or indirectly dependent on bee pollination.
- In Northern Europe, it is estimated that 75 percent of all wild blooming plants depend upon insect pollination, and most of the flowers are pollinated by honeybees and bumblebees.
- All the crops, fruit-trees and wild flowers blooming before midsummer are dependent from visits of bees to be able to develop their seeds, berries and fruits.
- Bee pollination not only results in a higher number of fruits, berries or seeds, it may also give a better quality of produce.
- The value of bee pollination in Western Europe is estimated to be 30-50 times the value of honey and wax harvests in this region (for Germany approx. 10-15 times, making 2 Billion € per year, and about 70 Billion US$ worldwide)

Introduction – Legal Background

- REGULATION (EC) No 1107/2009, ANNEX II, Point 3.8.3:
  An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:
  — will result in a negligible exposure of honeybees, or
  — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.

- COMMISSION REGULATIONS (EU) No 283/2013 and 284/2013

Risk Assessment for Honeybees

Different Concepts (1)

- **European and Mediterranean Plant Protection Organization (EPPO)**
  Implemented since 1991, several revisions of the original EPPO Risk Assessment Scheme PP 3/10(2) *Honeybees* and the test guideline PP1/170(4) *Side-effects on honeybees* have been undertaken in order to adopt a number of improvements**.**
  http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2338.2010.02376.x/full#b2
- **European Food Safety Authority (EFSA)**
  Published 2013. The EFSA Guidance Document is intended to provide guidance for notifiers and authorities in the context of the review of plant protection products (PPPs) and their active substances under Regulation (EC) 1107/2009 for bees (*Apis mellifera*, *Bombus* spp. and solitary bees).
  http://www.efsa.europa.eu/de/efsajournal/pub/3295.htm

Risk Assessment for Honeybees

Different Concepts (2)

- **International Commission on Plant Pollinator Relationships (ICPPR)**
  ICP-PR has developed the scientific process preceding decisions from European administrative authorities, EPPO and OECD. Operating through the EPPO honey bee sub-group, it has produced the testing methodology and risk assessment guidance currently used under Regulation (EC) 1107/2009.
  http://www.uoguelph.ca/icpbr/index.html
- **Organization for Economic Co-operation and Development (OECD) - OECD PEIP**
  Working Group established, chaired by US and Canada with input from EFSA, Germany, Netherlands and UK (Four sub-groups to investigate: Reporting of Pollinator Incidents/ Testing Requirements for Pollinators/ Regulatory Response to Potential Pollinator Risks/ Research). http://www.oecd.org/

Risk Assessment for Honeybees

Different Concepts (3)

- **US-Environmental Protection Agency**
  The guidance document provides guidance to risk assessors for evaluating the potential risk of pesticides to bees, particularly honey bees (*Apis mellifera*).
  http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

Risk Assessment and Management

Basic Principles

***Tier 1*: Laboratory tests**
Adults, larvae

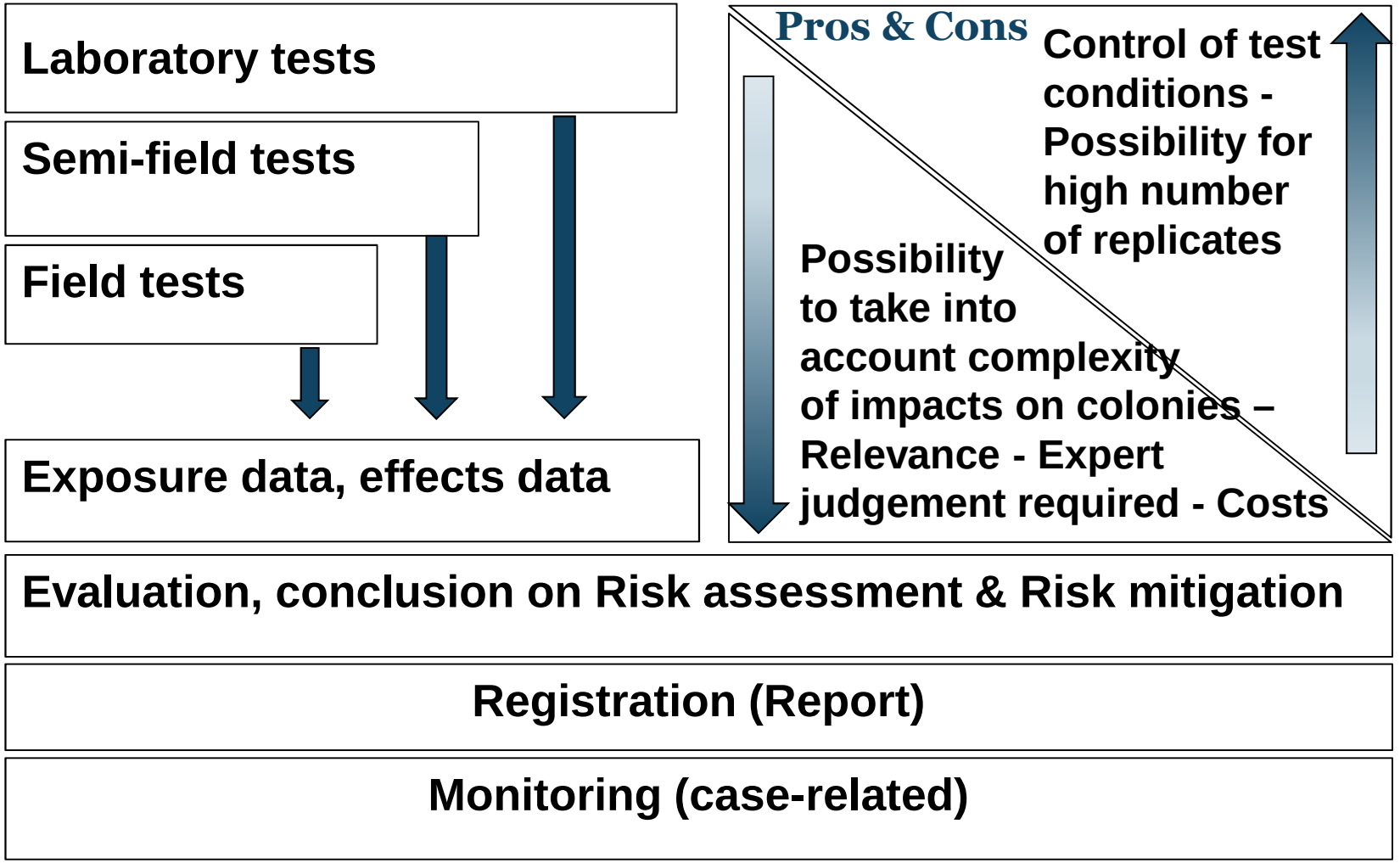
Mortality LD_{50} oral/contact

***Tier 2*: Semi-field tests**
Small colony, mortality, foraging activity, behavior, brood development

***Tier 3*: Field tests**
Colony, mortality, foraging activity, behavior, brood development, colony strength

Risk Assessment and Management

Basic Principles – Decision-Making



Basic Labels applied in Germany

Regulation (EU) No 547/2011 defines labelling requirements for PPPs:

- **SPe8** Dangerous to bees/To protect bees and pollinating insects do not apply (…)
  - *Depending on relevant national regulatory provisions, Member States may select the appropriate phrasing to mitigate the risk to bees*.
- **B1 - The product is classified as hazardous for bees (…)**
- **B2 - The product is classified as hazardous for bees except after the daily bee flight up to 23:00 (…)**
- **B3 - The product is not classified as hazardous for bees due to the intended uses (…)**
- **B4 - The product is not classified as hazardous for bees if the maximum application rate stipulated at the time of authorisation is not exceeded (…)**

Risk Management for Honeybees

Special Labels applied in Germany for Tank-Mixtures of B4-Pyrethroids and Triazole-Fungicides

- **NB6612- The product must not be used in combination with fungicides from the group of ergosterol-biosynthesis-blockers on plants which are in flower or which are visited by bees. (…)**

- **NB6622 - In combination with fungicides from the group of ergosterol-biosynthesis-blockers, the product may only be used in the evening after the end of the daily bee flight until 11 p.m on plants which are in flower or which are visited by bees. (…)**

Special Labels applied in Germany for Seed Coatings using Neonicotinoids (1)

- **NT6991 - The seed treatment shall only be performed in professional seed treatment facilities, which are registered (…)**
- **NH6831 - The following label must be printed on the seed package: Treated seeds may only be sown by using a pneumatic seeding machine which operate with negative pressure, if this machine is registered (…)**
- **NH682 - On packaging containing dressed seeds, the following label is necessary: The treated seeds, including any dust they contain, or dust which is produced during the sowing process, has to be incorporated completely into the soil.**

Special Labels applied in Germany for Seed Coatings using Neonicotinoids (2)

- **NB6632 - The following label must be printed on the seed package: The farm manager is obligated to notify the area designated for the sowing of the treated seeds to beekeepers, whose bee hives are located within a radius of 60 m to the sowing area, at least 48 hours prior to sowing.**

Risk Management for wild Bees

Special Labels applied for B4-Insecticides

- **NN410 - The product is classified as harmful for populations of pollinating insects. The application of the product onto flowering crops should be avoided or performed in the evening in particular to protect wild bees.**

Post-registration Monitoring

Relevance

Monitoring studies:

- complement the risk assessment performed in accordance with Regulation 1107/2009/EC,
- address possible uncertainties that may not have been fully covered through studies for time/space, scale reasons,
- cover effects in real life when organisms are subject to additional stressors (eg. Varroa, Nosema, Viruses),
- generate feedback to risk assessment and risk management.

Post-registration Monitoring

Current Monitorings, Surveys, Reports (1)

- **FAO (Food and Agriculture Organization),**
  Through support from FAO's Global Action on Pollination Services, a group of biologists have outlined a simple and cost-effective method for enacting a monitoring system.
  http://onlinelibrary.wiley.com/doi/10.1111/j.1523-1739.2012.01962.x/abstract

- **STEP-EU (Status and Trends of European Pollinators)**
  Aim is to assess the current status and trends of pollinators in the EU, to identify drivers and impacts of change, mitigation strategies and policy instruments.
  http://www.step-project.net/

Post-registration Monitoring

Current Monitorings, Surveys, Reports (2)

- **COLOSS (Prevention of honey bee COlony LOSSes)**
  The colony loss monitoring group has been active since the start of the COLOSS COST action, now the COLOSS Association, to study reasons for colony losses.
  http://www.coloss.org/coreprojects/monitoring/startpage

- **EPILOBEE**
  The project has implemented an active epidemiological surveillance programme on honeybee colony mortality (EPILOBEE) in 17 European member states.
  http://ec.europa.eu/food/animals/live_animals/bees/docs/bee-report_en.pdf

Post-registration Monitoring

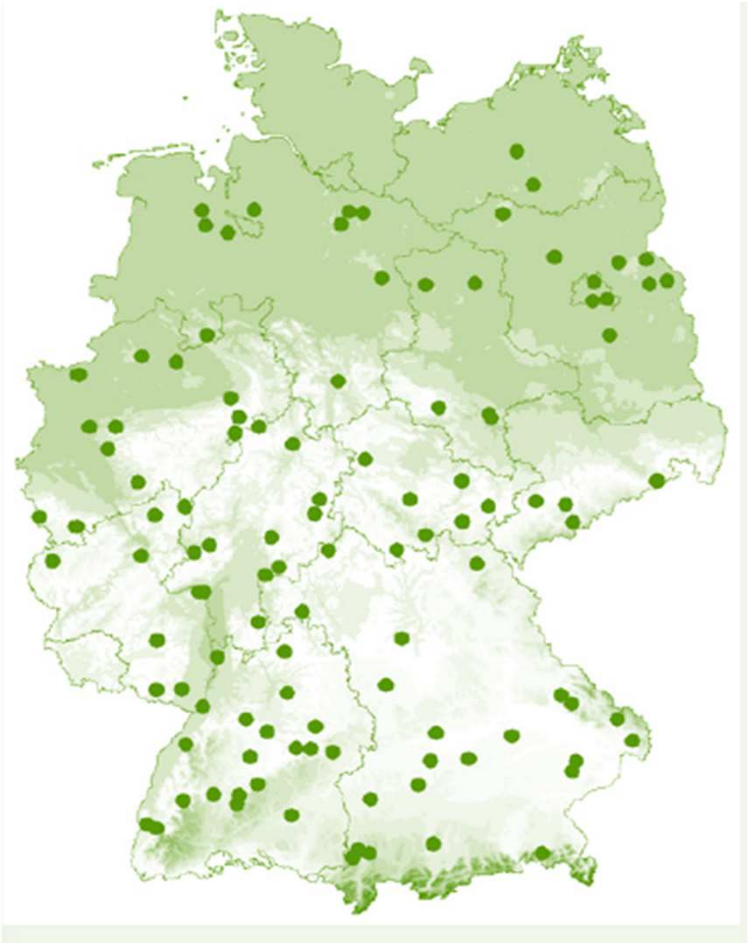
Current Monitorings, Surveys, Reports (3)

- **DEBIMO (German honeybee monitoring)**
  More than 100 beekeepers are involved in the collaborative German bee monitoring project. They provide representative, up-to-date information on colony management and overwintering dynamics/success of their bee colonies. In addition, samples of bees, honey and pollen are supplied by these beekeepers for the analysis of bee diseases and chemical residues.
  http://www.bienenmonitoring.org/88604?L=1

Status Quo of Bee Keeping in Germany

DEBIMO German Bee Monitoring Project

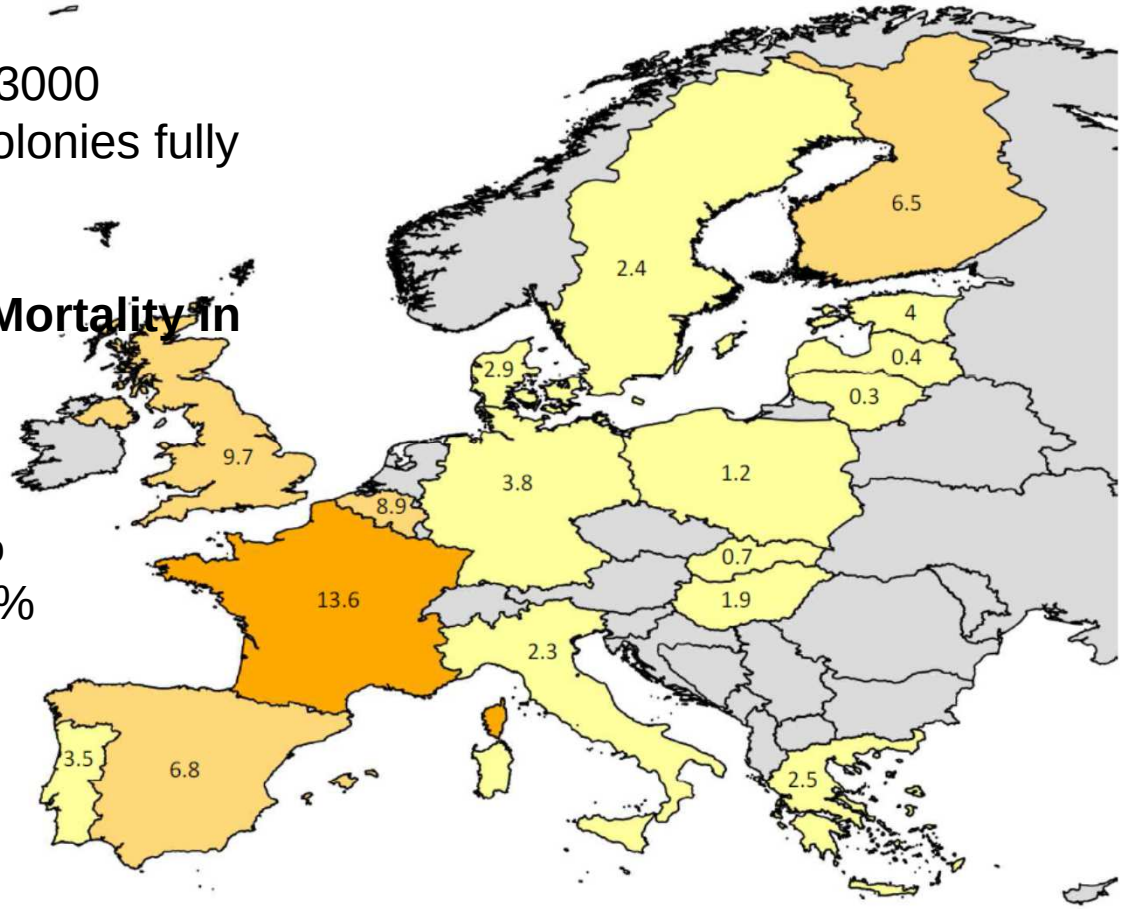
- **Start: 2004**
  - 112 to 125 beekeepers/10 colonies
- **Aim: Multifactorial data analysis of the overwintering success (diseases, parasites, pesticides)**
- **Results:**
  - residues in approx. 90% of bee bread samples/up to 20 different actives
  - bee toxic actives 8% of samples
  - Neonicotinoid findings (IMI, CLT, TMX, LOD 2 µg/kg):
    2005, 2006 (0/110)/ 2010 (1/209)/ 2011(2/216)/ 2012 (6/218)
  - *Varroa sp.* is the dominant factor for colony survival during winter



Status Quo of Bee Keeping in Europe

Seasonal Mortality Rates (EPILOBEE 2013)

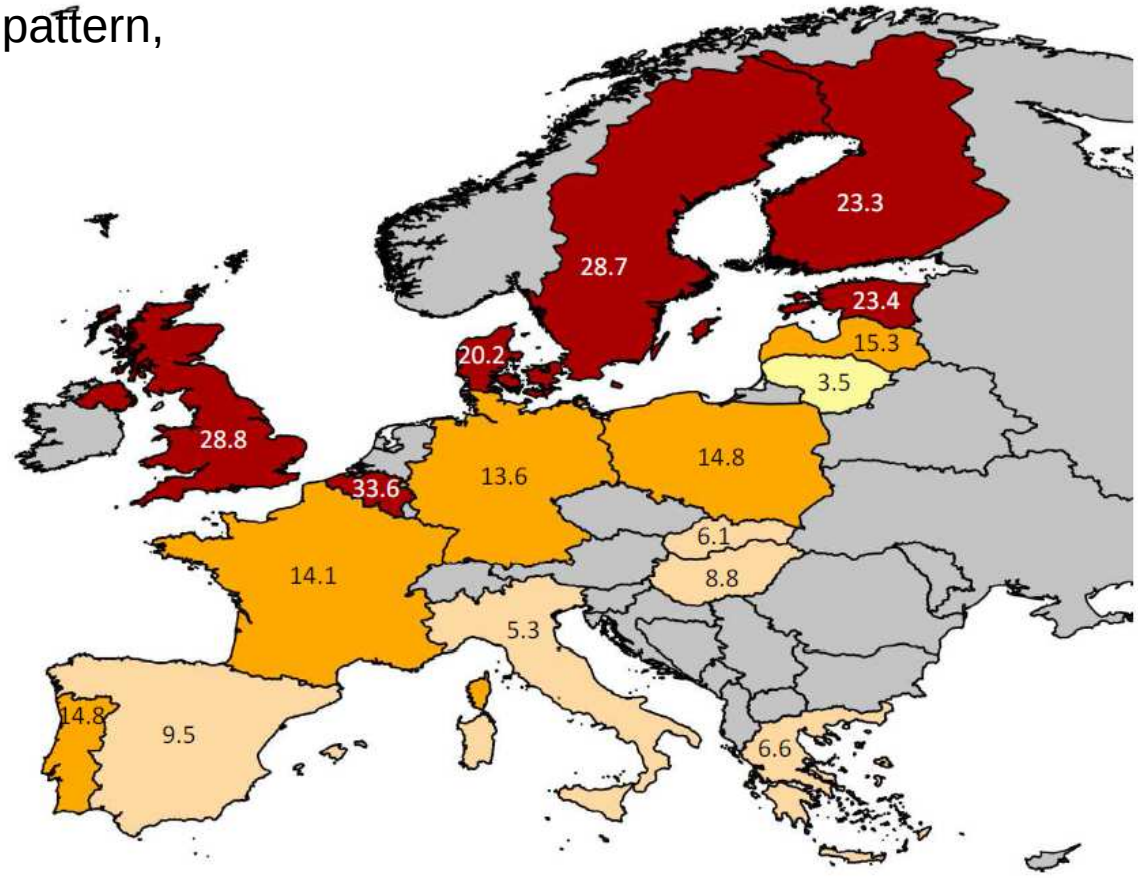
- **Start: 2012**
  - 17 EU-countries/>3000 apiaries/>30000 colonies fully visited
- **Aim: Monitor Colony Mortality in spring/summer**
- **Results:**
  - 12 of 17 MS < 5%
  - 4 MS > 5% < 10%
  - 1 MS > 10 %



Status Quo of Bee Keeping in Europe

Winter Mortality Rates (EPILOBEE 2012/13)

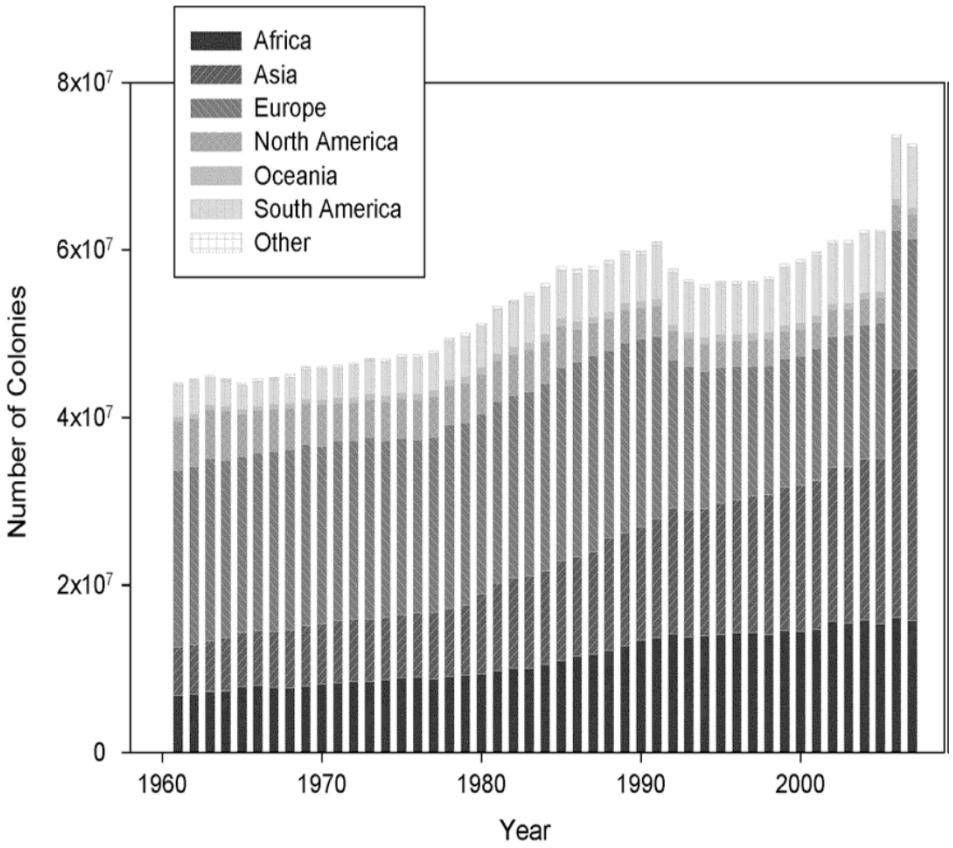
- **Results:** Geographical pattern, probably climate.
- **Open Question:** What is an acceptable winter mortality rate?



Status Quo of Bee Keeping in Europe

A Review of managed Honeybee Populations*

- Global honeybee populations have increased over the last 5 decades, this increase has not been universal: For example Europe has steep declines.
- Colony numbers in Europe decreased from over 21 Mio in1970 to about 15.5 Mio in 2007 (FAO, 2009).
- While this decrease was slow before 1990, a much steeper decline was observed lateron.
- *Varroa* together with the associated viruses are likely one of the major biological causes in the EU.



*Dennis vanEngelsdorp and Marina Doris Meixner (2010)

Risk Assessment and Management

Conclusions

- The protection of bees is of vital importance for agriculture and nature.
- A new risk assessment concept is currently discussed in Europe – while the future implementation and requirements remain uncertain.
- Risk mitigation and labelling is harmonized within the EU – however, national experiences and requirements are respected.
- Post-registration monitoring is a powerful tool to verify the appropriateness of the risk assessment and risk management under real field conditions on relevant space and time scales.
- There seems to be no general or permanent decline in honeybee colonies in the EU attributable to pesticide use – but more research on indirect and sublethal effects on bees is requested!

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Many thanks for your interest!

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Status Quo of Bee Keeping in Europe

Winter Mortality Rates (COLOSS 2014)

- **Start:** 2008
  - 20 countries
- **Aim: To understand the risk factors for colony losses**
- **Results:**
  - The risk factors identified so far include beekeeper management (e.g. treatment strategies to control *Varroa,* the age of queens) and environmental factors (e.g. local weather or forage available).