# EUROPEAN UNION MINOR USES COORDINATION FACILITY



# **ANNEX 5**

# of the Report of the Workshop on "Minor Uses and Speciality Crops: The way forward in Europe", 18- 20 February 2020, Paris

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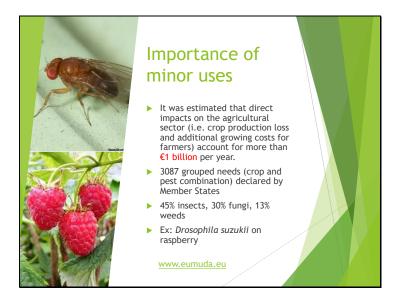
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# Objectives of the Workshop (Mr Jeroen Meeussen and Ms Flora Limache, MUCF)

# Diapositive 1





















# **Workshop Structure**

- ► The Workshop will be structured in plenary and breakout group (BOG) sessions.
- It will last 2.5 days, starting on Tuesday 18 February in the morning and finishing on Thursday 20 February by mid-day.
- 66 participants from European Commission, Member countries, growers' organisations, industry (conventional and biological), research/academia, agricultural advisers







# Perspective on the production of speciality crops in Europe (Ms Paula de Vera, Copa-Cogeca)

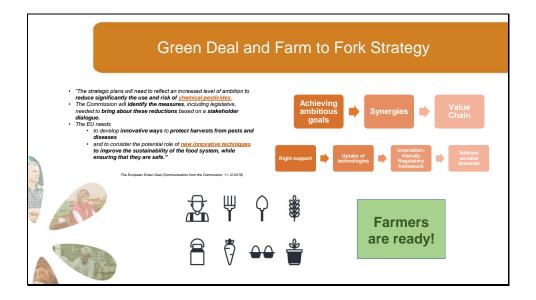
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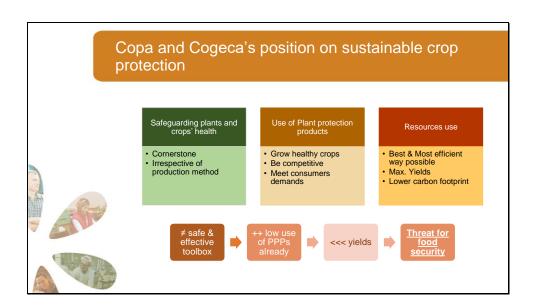


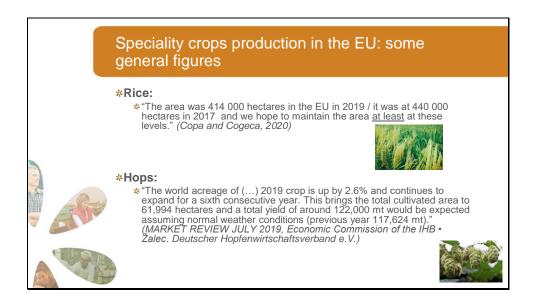


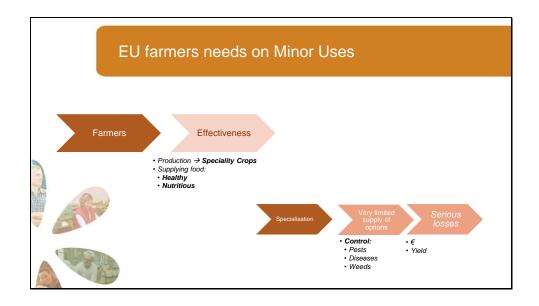


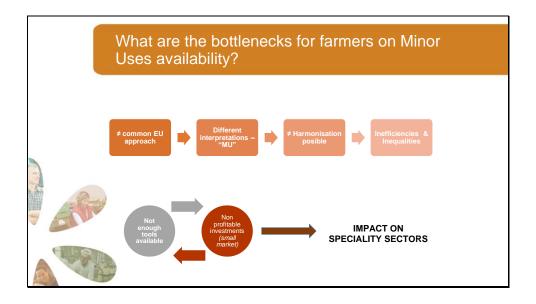


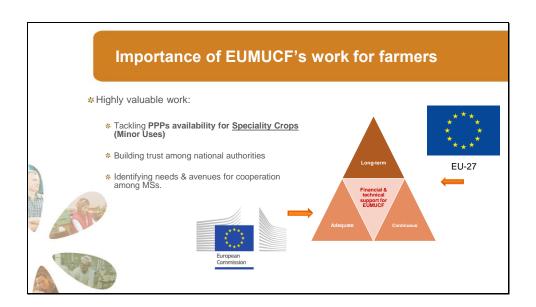














# Introduction from European Commission (Ms Desislava Ivanova, DG SANTE)

## Diapositive 1



## Diapositive 2

# Relevance of minor uses

- value of Minor crops in the EU more than € 70 billion per year (or 22% of the total EU plant production value);
- crops which are consider minor in one Member State, are major in other Member States (oranges, bananas, etc.);
- minor uses are today internationally recognised as priority topic requiring solutions.



# Impact of the lack of authorisations for minor uses

- Insufficient protection of crops against harmful organisms may endanger the production of certain high value food crops within the EU and may affect the competitiveness of EU agriculture.
- · It could lead to alternative solutions such as:
  - use of illegal plant protection
  - improper use of emergency authorisations under Article 53 of Regulation 1107/2009 ( REFIT evaluation: 54% of all emergency authorisations are for minor uses)

\*new centralised data base for emergency authorizations: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/pppeas/screen/home



## Diapositive 4

# Main challenges

- insufficient availability of PPPs for minor uses (inhomogeneous availability as economic incentives and needs vary between Member States);
- Member States are not fully using the existing provisions to facilitate authorisation for minor uses (in particular to grant extensions of use for third parties);
- lack of sufficient information for the stakeholders at Member State level;
- acceptance of residue data evaluated by other Member States and acceptance of residue trials outside the EU are insufficient.



# **Solutions**

Regulation 1107/2009:

- extension for minor uses under Article 51: simplified procedure for third
  parties, authorisation holders, official or scientific bodies, professional
  agriculture organisations or users, to ask for an extension of existing
  authorisations to minor uses not yet covered by that authorisation;
- mutual recognition procedure under Article 51(7);
- list of minor uses per Member States under Article 51(8);
- extended data protection under Article 59: by 3 months for each extension of authorisation for minor uses up to a maximum of three years.



# Diapositive 6

# **Solutions**

Minor Uses Coordination Facility:

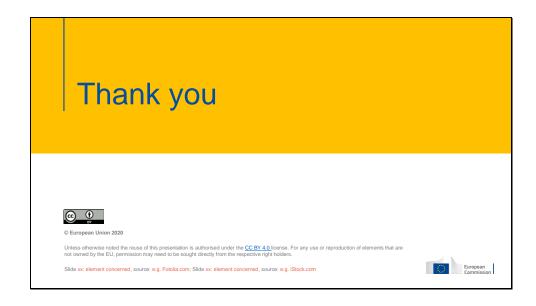
- EUMUDA database;
- Guidance document on Minor Uses Authorisations;
- The MUCF is working on solutions that fit in an IPM framework.



# Recommendations

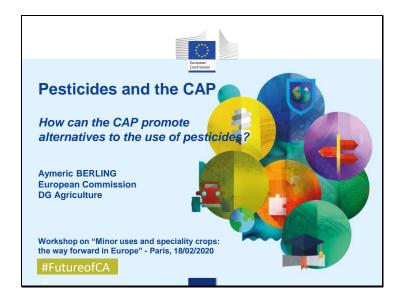
- use all the possibilities for minor uses authorisations as provided by Regulation 1107/2009 instead of emergency authorisations under Article 53 of Regulation 1107/2009;
- better communication and information to farmers, growers' organisations and scientific bodies (via the competent authorities of the Member States and Minor Uses Coordination Facility);
- regular financing of the Minor Uses Coordination Facility.



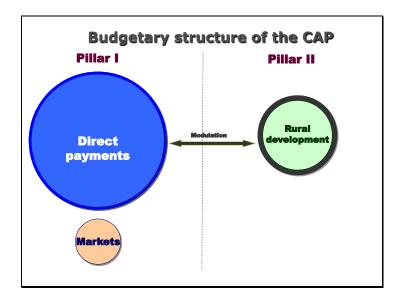


# **Introduction from European Commission (Mr Aymeric Berling, DG AGRI)**

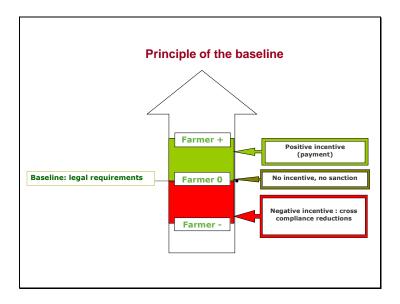
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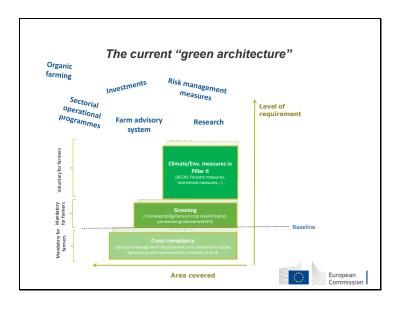












## **Cross compliance**

Cross-compliance is a link between CAP payments and a set of EU requirements. Failing to respect these rules may lead to reduction of CAP payments

Requirements are e.g.:

<u>Statutory Management requirements (SMR):</u> e.g.

• SMR 10: Regulation No 1107/2009 on PPPs

<u>Good Agricultural and Environmental Condition</u> (<u>GAEC</u>):

e.g.

• GAEC 1: Buffer strips along water courses





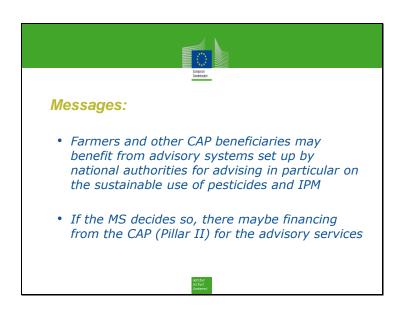
#### **Farm Advisory System**

Member States must set up a system providing advice to farmers and other CAP beneficiaries

This system must cover at least:

- Requirements under <u>cross-compliance</u>, <u>including</u> <u>the PPPs Regulation</u>
- Requirements under the <u>Directive for the sustainable use of pesticides, including Integrated Pest Management</u>
- Requirements under the Water Framework Directive
- Etc.





# **CAP** payments

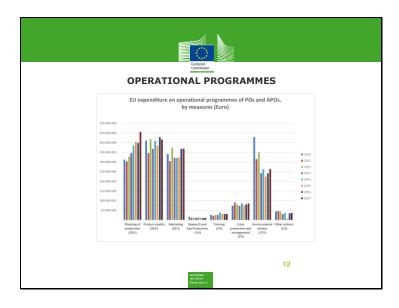
<u>Greening payments (Pillar I)</u>: in particular crop diversification and ecological focus area

Operational programmes in the fruits and vegetable sector (Pillar I): National Environmental Frameworks (17% of OP expenditure) include incentives for promoting IPM

Agri-environmental and climate measures (Pillar II): e.g. integrated farming (fruits and vegetable, vines and olive, etc.), organic farming, etc.

Investments, knowledge transfer (Pillar II)













What is proposed for the future CAP?



# Diapositive 18

## New, enhanced conditionality

New SMRs and GAEC are added

- New SMRs:
   SMR 13: Directive on Sustainable Use of Pesticides
   SMR 1: Water Framework Directive

# New GAECs (based on current greening):

- GAEC 8: Crop rotationGAEC 9: Biodiversity area



#### New, enhanced conditionality

The new framework will also allow Member States introducing into conditionality the general Integrated Pest Management (IPM) principles which are fit for this mechanism, when the principles are implemented at national level on the basis of the SUD:

# **General IPM principle 1:**

 Crop rotation (GAEC 8), cultivation techniques (GAEC 6 and 7), balanced fertilization (GAEC 5), adequate plant protection techniques (GAEC 1, 2 and 3), ecological infrastructure (GAEC 9),

#### **General IPM principles 5, 6 and 7:**

Relevant conditions for proper use (SMR 12)



# Diapositive 20

#### **Farm Advisory System**

The FAS will be integrated in the Agricultural Knowledge and Innovation System (AKIS) and its scope enlarged to all environmental legislation



# **CAP** payments

A new scheme will be implemented in place of the greening, the <u>eco-schemes</u>:

- Compulsory for MSs but voluntary for farmers
- Practices and level of support to be defined by MSs

Pillar II measures remain but are made even more flexible.









# **Relevant main objectives**

#### **General objective:**

(b) To bolster environmental care and climate action and to contribute to the environment- and climate-related objectives of the Union

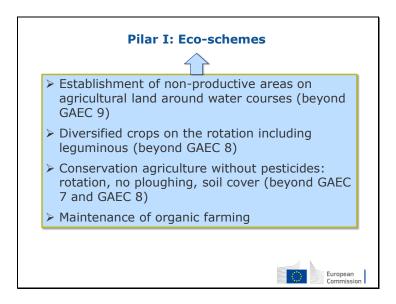
## Specific objectives:

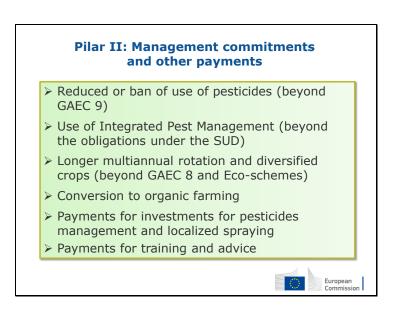
- (e) Foster sustainable development and efficient management of natural resources such as water, soil and air
- (f) Contribute to the protection of biodiversity, enhance ecosystem services and preserve habitat and landscape

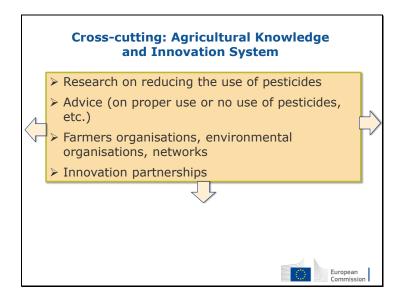


# Diapositive 26

# SMR 1: Water Framework Directive SMR 12 and 13: Pesticides legislation GAEC 4: Buffer strips GAEC 8: Crop rotation (e.g. not the same crop two consecutive years on x% of the arable area) GAEC 9: protection of landscape features and mandatory biodiversity area (%) + indirectly GAEC 7: No bare soil (e.g. residues, green cover or winter crops) GAEC 5: Farm sustainability tool for nutrients









# Experience and expectations from a Northern grower organisation (Ms Agneta Sundgren Federation of Swedish Farmers)

## Diapositive 1



# Diapositive 2

#### **Swedish Horticulture**

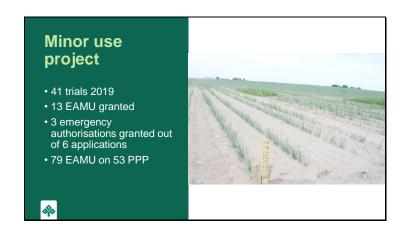
- 2000 enterprises
- 1 555 enterprises field production on 12 800 hectares
- Carrots 1700 ha, Onions 1300 ha, Lettuce 1500 ha
- Strawberries 2 400 ha, Raspberries 130 ha, Grapes 56 ha
- Apples 1500 ha, Pears 128 ha. Nursery plants 440 ha.
- 744 enterprises green house in 286 hectares
- Cucumbers, Tomatoes, Lettuce and herbs. Tulips, Viola, Pelargonium
- 14 800 persons working











# What happens next

- Trials performed during the summer
- Reports from the experimental station in the winter
- Applications sent to Chemicals Agency



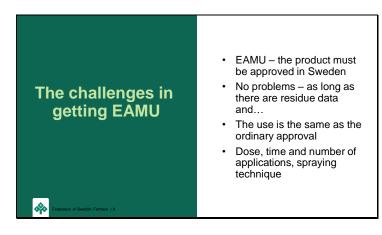


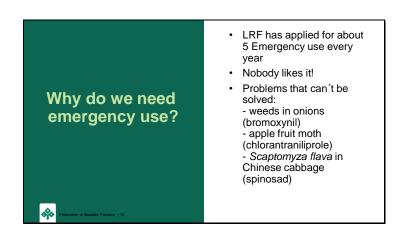
#### Diapositive 8

# How can we get access to a pesticide?

- Apply for Extension of Authorisation or Emergency Use
- · Mutual recognition?

Federation of Swedish Farmers | 8







- Possible by a Growers Association?
- Can we get access to all the data?
- How do we know that the product hasn't problems?
- Who will sell, put on labels, have response if problems?
- If we start will the companies apply for authorisation in the future?

#### Diapositive 12

## A typical problem that was solved

- Mildew in greenhouse cucumbers could only be controlled with azoxystrobin and imazalil
- · Growers: Can't we get Vivando?
- LRF: The substance, metrafenone, is authorised in cereals but in a different formulation (Flexity)
- Trials in greenhouses 2 years no phytotoxicity
- · Residue and exposure data from BASF
- · Flexity had an EAMU in greenhouse cucumber





#### Diapositive 14

# **Experiencies in a small country in Northern Europe**

- Happy to have money but rules can't be overrun
- · Small details make it all turn over
- Hard to know why some pesticides are not available in my country
- · Hard to find who is the owner of the residue data
- · Economy for the farmers and industry rules





#### Diapositive 16

# Possibilities to work together

- How the Regulation is used harmonisation?
- Find out what are the properties in a pesticide reasons for not apply
- Products not authorised because the sale is too small why not authorisation on EAMU in another country
- Must the terms for a very small use be followed?
- Mutual recognition how to do?

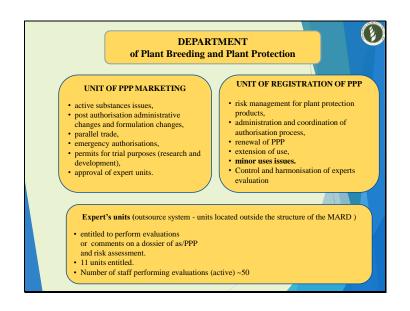




Experience and expectations from an Eastern European country from the Central Zone (Ms Malgorzata Flaszka, Ministry of Agriculture and Rural Development, Poland)

#### Diapositive 1







#### Art. 6 - ACT of 8 March 2013 on plant protection products

Minor uses of plant protection products, as referred to in Article 51(8) of Regulation No 1107/2009 include:

- 1) plants that are not commonly grown on Polish territory or plant products derived from these plants;
- 2) plants that are commonly grown on Polish territory or plant products derived from these plants and organisms harmful to them that are not commonly found on them.
- 2. The minister responsible for agriculture shall determine, by ordinance, the minor use of plant protection products referred to in Article 51(8) of Regulation No 1107/2009, by indicating plants or plant products derived from these plants and organisms harmful to them, as referred to in Paragraph 1, taking into account the acreage of individual crops or range of harmful organisms.

#### Diapositive 4

#### List of Minor Uses in PL

- ▶ The list in national regulation on minor uses is very long, only few crops are not there (for instance only apple among horticultural crops) only a few crops are classified as major crop
  - ▶ Plants that are not commonly grown on the territory of the Republic of Poland – 14 groups (over 130 crops)
  - ▶ Plants that are commonly grown in the territory of the Republic of Poland and harmful organisms which are not endemic to these plants
- ► Last up-dated October 2019

#### Minor uses - current situation in PL

- Fees are reduced the administrative fee is only 120 Euro per application
- Pre submission meeting is free of charge
- Separate queue for applications
- Facilitations for MU PL accepts mutual recognition for minor uses
- Less than 2 applications/year comes from growers
- Minor Uses vs Art. 53 (emergency authorisation)

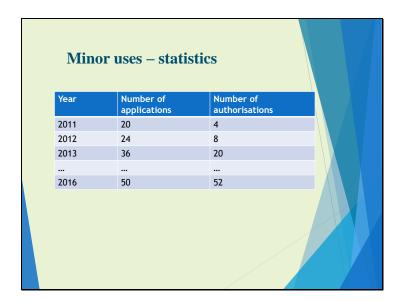
#### Diapositive 6

#### **Minor uses – requirements**

- Part B must be submitted for sections where new data or evaluations are necessary + Part A
- Each application is investigated case by case
- Decision which sections should be evaluated is made individually
- Efficacy not evaluated
- Residues always evaluated, evaluations prepared in other MS are acceptable. Administrative extrapolation is not approved.

#### Art. 51

1. The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the authorisation of a plant protection product **already** authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation.



# Minor uses – facilitations in PL (since 2016)

- Minor uses are granted at the same time when Zonal Registration or Mutual Recognition authorisation is granted.
- · The evaluation is conducted in core dossier
- Crop must be on the list in national regulation on minor
  uses
- · Additional application for Minor Uses is requirement

#### Diapositive 10

#### **Minor uses – statistics** Number of applications Number of authorisations 2011 20 4 2012 24 8 2013 36 20 2016 50 52 (2) 2017 83 66 (17) 2018 88 63 (23) 2019 97 77 (21) Currently granted 2462 authorizations for PPP (403 parallel trade) with 315 active substances in PL $\,$

# Current problems ...

- Still lack of ppp for some crops/uses classified as Minor Uses
  - Lack of products for seed treatment after withdrawal of some active substances – in particular for vegetables
- > The small number of application from growers
- Ensuring a minimum level of protection for certain crops (low economical importance)
- > Data protection period vs new applications

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#### Diapositive 12

#### **Current activites ....**

- Residues tests cooperation MARD with institutes
- Requirements for data package of MU checking the possibilities to reduce
- Encouraging authorisation holders to submit the applications for Minor Uses

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#### **Expectations....**

- Most wanted applications for Minor Uses in PL from industry:
  - > new PPP in PL
  - PPP with active substances still not authorised in PL
  - for low economical importance crops/uses
- ✓ Revision of 1107/2009
  - > Too short period of approval a.s. (for ex. low-risk, for organic farming)
  - ➤ Art. 51 not only for existing authorisations
- ✓ Residue reduce of requirements (for ex. GLP standard, number of trials) ?

# Experience and expectations from Ireland (Mr Donal Lynch, Ministry of Agriculture, Food and Fisheries, Ireland)

Diapositive 1



#### Diapositive 2

# Minor Uses and Speciality Crops – An Irish Perspective



- Introduction to IE competent authority
- · Product registration status in Ireland
- · Minor uses in Ireland
- Problems
- Solutions
- · Way forward



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# IE Competent Authority A few facts



- 2 Divisions under the Minister for Agriculture Food & the Marine
- PRD Expert Units (PPPs & biocides)
  - Chemistry evaluation unit

    Residue analysis

    Environmental chemistry
  - Toxicology unit



Environmental toxicology

- Efficacy Unit



#### Diapositive 4

# IE Competent Authority A few facts



- PCD Co-ordination and Controls
- ☐ Co-ordination of PPP and biocide evaluations
- ☐ PPP registration/risk management
- ☐ Biocide registration/policy
- ☐ Enforcement
- ☐ SUD
- ☐ Residues & sampling
- Administration



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## **PPP Approvals**



## **Current Position**

- 1231 products registered in IE
- 974 professional use products
  - 413 herbicides
  - 286 fungicides
  - 66 insecticides
- 257 amateur use products

#### Diapositive 6

#### **Minor Uses in Ireland**



- Minor uses encompasses minor crop not widely grown and also an exceptional need within a widely grown crop
- Minor crops all fruit & veg. crops, ornamentals, hardy nursery, mushrooms
- Estimated farm gate value of €435 million



e, Food and the Marine



#### **Minor Uses in Ireland**



- ≈ 1000 commercial hort. growers
- 165 field crop vegetable growers
- Majority of production is for domestic consumption
  - Mushroom exports 77%
  - Amenity exports worth €77



ure, Food and the Marine



#### Diapositive 8

#### **Minor Uses in Ireland**



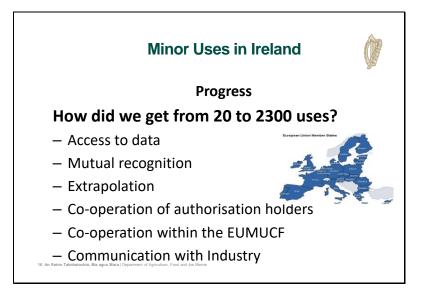
#### **Current Situation**

- $\approx 4000$  product/crop combinations approvals for minor crops
- 1700 on-label uses
- 2300 off-label uses (little or no crop safety data/efficacy data)
- >400 products have uses on minor crops
- 140 different minor crops covered



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# Minor Uses in Ireland Progress January 2005 -- 20 off-label approvals January 2007 -- 228 off-label approvals January 2007 -- 228 off-label approvals January 2007 -- 2300 off-label approvals January 2020 -- 2300 off-label uses January 2020 -- 2300 off-label uses January 2020 -- 2300 off-label uses MERCHANIST EARLY MERCHANIST EARLY MERCHANIST EARLY Al crops Al c



#### **Minor Uses in Ireland**



#### **Progress**

#### How did we get from 20 to 2300 uses?

- Data purchased from grower organisations in other MSs.
- Actively pursue authorisations to register niche products in Ireland. Dual labelling with other MS.
- Actively engage in projects with other MSs, data owners and growers

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#### Diapositive 12

#### Minor Uses in Ireland



#### **Progress**

# How did we get from 20 to 2300 uses? Residue Data

- Company owned data
- 3<sup>rd</sup> party data (e.g. grower organisations, extension services.)

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#### **Minor Uses in Ireland**



## **Extrapolation**

Residue data available for a particular crop can be used to support use in a similar crop

#### EU Guidance document

## SANCO 7525/VI/95 Rev 10.3

0220000	Bulb vegetables	onions (0220020)	<b>→</b>	garlic (0220010)	YES	YES		
				shallots (0220030)	YES	YES		
		leeks (0270060)	<b>→</b>	spring onions/green onions and Welsh onions (0220040)	YES	YES	YES	
		onions (0220020)	÷	Whole group Bulb vegetables (0220000)			YES	YES

#### Diapositive 14

#### Minor Uses in Ireland



#### **Problems**

- Access to data No residue trials conducted in Ireland, limited funding available to purchase data
- Small market reluctance of companies to register products for IF
- Smaller arsenal of PPPs available active substances disappearing, very few new A.S coming to market
- · Increasingly complex and stringent registration requirements
- · Lack of non-chemical solutions particularly in field situations

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#### **PPP Approvals**



#### **2019 Active Substance Withdrawals**

- 16 active substances removed from IE market
- E.g. Fenpropimorph, diquat, chlorothalonil, CIPC, dimethoate, methiocarb, desmedipham, thiacloprid
- 119 products removed or will be removed during 2019 and 2020.
- Glyphosate, bentazone, pendimethalin, propyzamide, azoles, etc.???????

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Diapositive 16

#### **Minor Uses in Ireland**



#### **Way Forward**

- Actively participate in the commodity expert groups and horizontal expert group of EUMUCF
- Contributing financially to support the work of the EUMUCF
- Encourage authorisation holders to apply for minor uses products through MR

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#### **Minor Uses in Ireland**



## **Way Forward**

- Contribution to funding of residue trials
- Project collaboration with other member states
- Encourage authorisation holders to apply for minor uses products through MR
- Communication with Irish hort. industry in identifying problems and solutions

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# Experience and expectations from CEG Fruits and Vegetables (Mr Jean-Claude Malet, Ministry of Agriculture and Food, France)

#### Diapositive 1



#### Diapositive 2

#### Fruits and Vegetables in Europe

- Large group of crops, with different statuses (major/minor) between countries
- Phytosanitary problems are large and varied, with emergent pests such as
  - · Tuta absoluta on tomatoes
  - · Drosophlla suzukii on red fruits and strawberries
  - · And tomorrow bactrocera dorsalis on fruits?
  - ......
- Fruits and vegetables are particulary impacted by the consequences of the renewal of active ingredients

MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

## **Fruits and Vegetables in Europe**

- The sector on fruits and vegetables is important in majority of European countries,
- The areas are limited but the value is important,
- Southern countries are the ones who have the greatest crop diversity

MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

#### Diapositive 4

#### **Actions of Member states**

- Each country develops actions for the minor crops, whether administrative, regulatory or technical
- National action plan dedicated to the minor crops in different countries
- Resources remain limited in relation to the challenges
   Minor uses is an important issue for Member states

MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

# Balance sheet of the C.E.G. Fruits and vegetables

- Many countries are present in the meetings but few participate!
- Many projects are initiated, 43 are indexed in EUMUDA
  - · Good approach, based on worksharing
  - · lack of external visibility and concrete results

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#### Diapositive 6

#### **Definition of the needs**

- The EU definition of the needs is a positive point that we need to evolve
  - with a stronger involvement of member states to improve the representation of situations
  - Inclose the emergency authorisations
  - To compare with the existing solutions and to assess their future

The expert group elaborates an action plan with timelines and disseminates to MS and stakeholders with everyone's responsibilities

🌉 JI MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

#### **Management of projects**

- The projects must respond to the selected priorities
- To develop projects which interest a maximum of Member states
- And bilateral projects which could interest other countries
- Our objective is to prioritise easier exterior legibility of the projects,in order to respond to the main concerns of the Member states

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#### Diapositive 8

#### Define and respond to other expectations

- To develop new technical items linked to expressed needs:
  - Residues extrapolations in order to use data from major crops
  - · Metabolism studies which permit us to develop projects
  - · To mobilise the EU research to empty uses
  - ...

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## **Expectations regarding the coordination facility**

- Together we need to improve our organization:
  - To insure better legibility of the needs, of projects and their deadlines
  - To increase the technical link beetween the CEG and the coordination facility particulaly for the development of the projects in cooperation with the project leader and the team
  - · To respond expressed expectations
- · The coordination facility is « spokesperson »
  - To look for financing
  - · To express difficulties to European authorities

MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

#### Diapositive 10

#### In conclusion

- · This organisation already exists
- · But it's up to us to develop it
- The current context leads us to work together on minor uses in order to share our resources, and to harmonize the solutions
- There is a significant expectation to European organization for minor uses which will permit us to give concrete responses to the Member states and growers

MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

# Experience and expectations from CEG Hops (Ms Magda Rak Cizej, Slovenian Institute of Hop Research and Brewing, Slovenia)

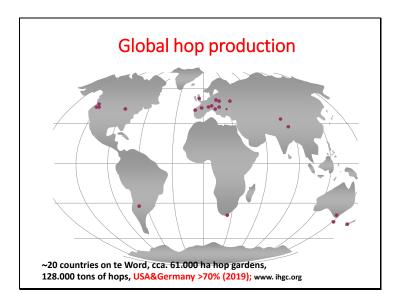
#### Diapositive 1

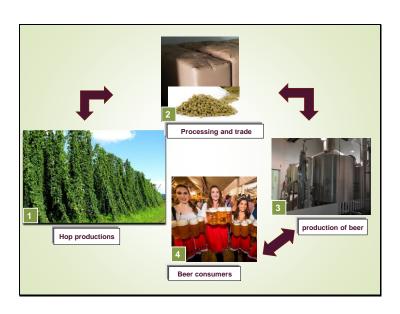


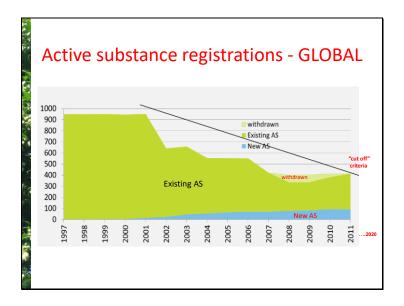
#### Diapositive 2

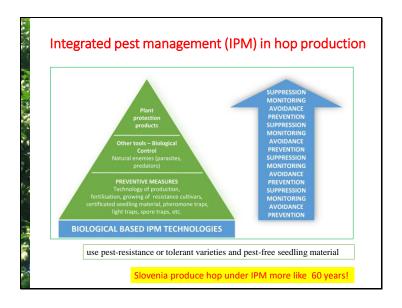
#### Introduction

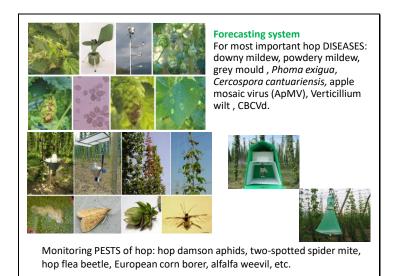
- The hop industry is an important economic/agricultural industry with a long tradition
- Most hops are exported to global markets (different MRL for different countries)
- Hop is "minor crops"/minor uses
- Limited number of active substances
- Authorisation PPP "cut off" criteria

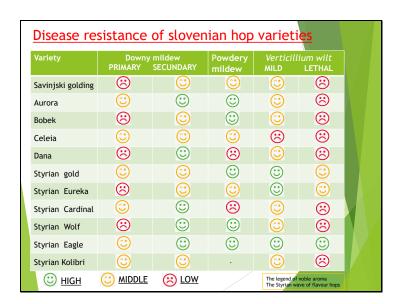


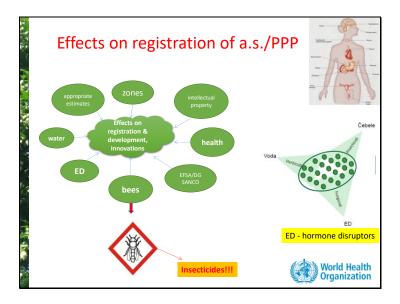


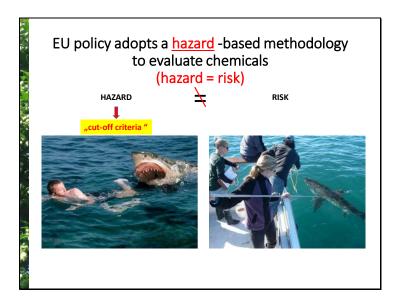


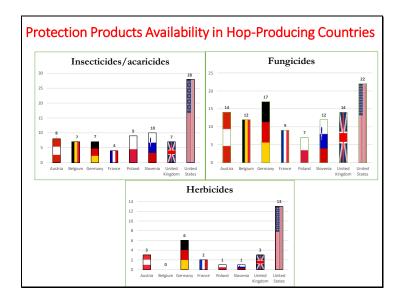


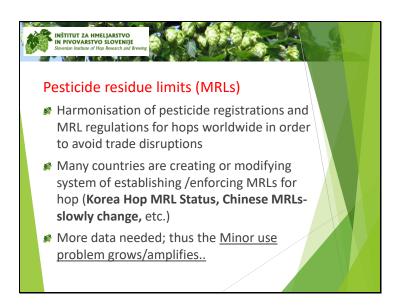


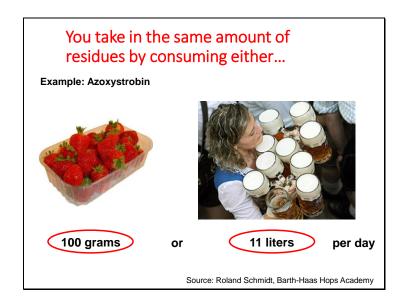




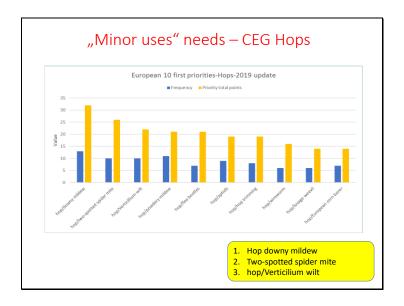
















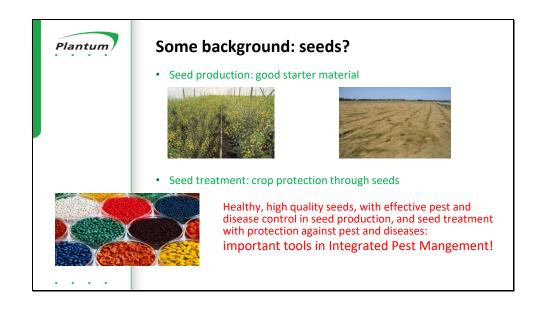


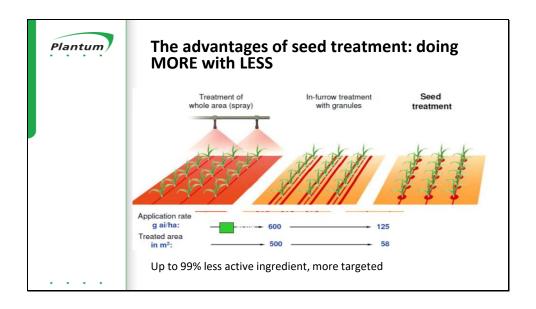


# Experience and expectations from CEG Seeds (Ms Gea Bouwman, Plantum, Netherlands)

#### Diapositive 1





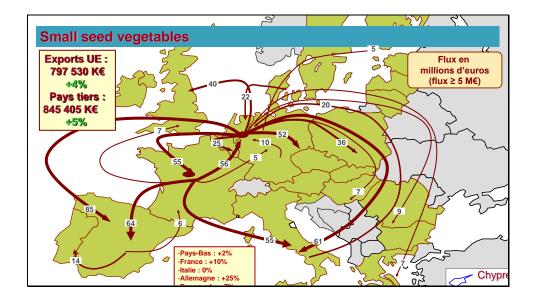






# European seeds are sold all over the world

- 62 % of the worldwide export of seeds come from the European Union
- European seeds: 60% trade inside the EU / 40 % export outside the EU
- · Export outside EU: main countries are Russia, Ukraine, USA
- Trade inside the EU:
  - specialisation in some countries (for example: France maize; Germany and France – Oil Seed Rape and cereals; the Netherlands – vegetables and flowers; Denmark, the Netherlands and Germany – forage grasses);
  - many movements inside EU!
- $\rightarrow$  European (and worldwide) market
- → need for European solutions!
- → Need for Minor Use Coordination Facility!





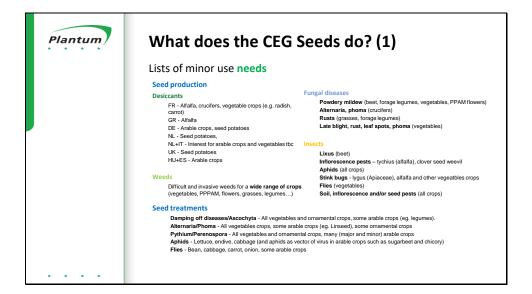
# Some background: Minor Uses?

- · Seed production: minor in acreage
- Minor in use (kilogrammes of plant protection product)
- Seed treatment: used on many minor crops
- Seed production: due to specific cultivation aspects also very specific minor crop protection needs

#### Critical issues:

- Many (very) minor uses and limited interest from crop protection industry
- High regulatory requirements for authorisation of ppp's
- Lack of EU (and worldwide) harmonisation

Euroseeds WG Minor Uses → CEG Seeds under the MUCF





# What does the CEG Seeds do? (2)

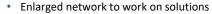
- Exchange on possible solutions (crop protection products and methods, agricultural practices)
- List of projects
- Keep an eye on (re)registration of active ingredients (both chemical and biological)
- Exchange on research
- Exchange on regulatory developments
- Exchange with CEG Fruits & Vegetables on different kind of solutions for shared minor use needs (seed – soil – foliar etcetera)

. . . .

#### Diapositive 10



# **Experiences and expectations MUCF (1)**



- More European countries; authorities and other stakeholders (eg. CEG Fruits & Vegetables); crop protection industry through IBMA and ECPA; research: etc.
- Not only chemical solutions, but also biological solutions, biostimulants, other agricultural practices, methods, etc.
- → We need to enlarge our approach and combine solutions!
- → We need EUROPEAN (and worldwide accepted) solutions!



. . . .



# **Experiences and expectations MUCF (2)**

- · Guidance and harmonisation
  - Development of Guidance Document Minor Uses;
    - harmonised approach for art. 51 (Minor Use authorisation) for seed treatment:
  - work on EU harmonised status of crops (minor/major crops)
- Spokesman, knowledge centre and coordinator for minor uses
  - At renewal inform SCoPAFF about minor use issues;
  - international contact point (for example for Global Summits)
- · Practical help and tools
  - EUMUDA;
  - search databases for solutions (eg. Homologa searches)



# Experience and expectations from conventional/ biopesticide industry (Ms Sheridawn Shoeman, ECPA)

# Diapositive 1







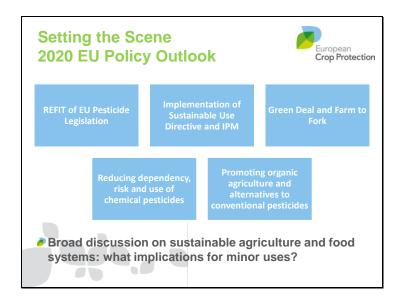


# Developing solutions for European Crop Protectio

- Industry has a shared responsibility and is expected to develop products that are:
  - Innovative based on cutting edge research and development
  - Effective working better than existing ones and/or fulfilling needs
  - Safe screened for safety, with favourable toxicological profiles
  - Sustainable compatible with Integrated Pest Management strategies and allowing for ecosystem services and biodiversity
- **▶** ECPA member companies actively developing new solutions:
  - Both conventional chemistry and products of natural origin
     (e.g., micro-organisms, semiochemicals, natural substances)
  - For both conventional and organic growers

75



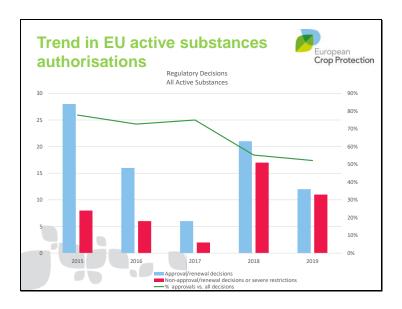


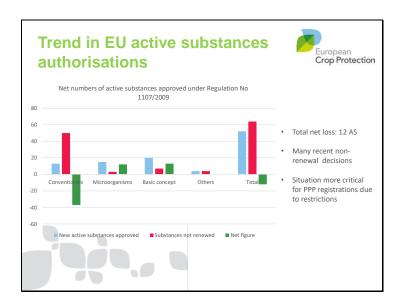
#### Diapositive 8

# REFIT Process Quotes from Ecorys Report



- Overall, the functioning of the minor uses authorisation process is assessed negatively both by the MS and by the stakeholders.
- The availability of PPPs for minor uses is negatively affected by lack of clarity on the rules for authorisation and harmonisation between the MS
- Procedures are often not clearly established, and alternative ways are used by MSs to ensure that products can be made available in their national markets (e.g. the use of emergency authorisations and dialogue with producers).
- MS tend to establish their own procedures and do not seek synergies between each other, not even within the same zonal system.
- Lack of clarity and delays in the process lead, instead, in some cases, to the use of emergency authorisations.





# Increased conservatism in risk evaluation



- Scientific Guidance Documents produced by EFSA with actual test and risk assessment schemes
- Recent guidance documents substantially increased resource needs for both industry and authorities with no evidence that previous guidance was insufficiently protective
- As a result: more tests and parameters to take into account often with no agreed methods
- High concerns over the excessive conservatism of proposed approaches and protection levels

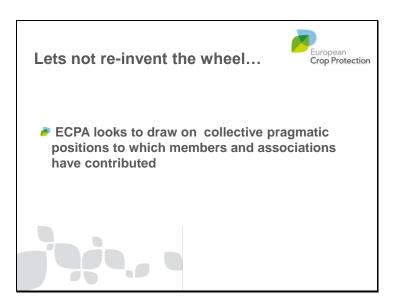
#### Diapositive 12

# **Challenges and opportunities**



- Average of 11 years and €250M for the placing on the market of a new product
- EU legislation requires simplification, greater efficiency and more transparency
  - EFSA guidance documents being fit for purpose and allowing scientific dialogue during risk assessment
  - Improving zonal delivery and efficiency with enhanced coordination
  - Improving mutual recognition and minimizing data requirements, especially for minor uses
- Faster and more efficient MRL setting





# Agri-Food Chain Round Table for Plant Protection



- Common position from all major EU agri-food chain associations including ECPA to support minor uses
- Highlighting the importance of minor uses bringing major value to EU economy (€70bn per year – 22% of ag output)
- Calling for more efforts towards an EU-wide autorisation for minor uses/specialty crops
- Encouraging MSs to make better use of zonal and mutual recognition system
- Supporting the role of the Minor Uses Coordination Facility and its sustainable funding

#### Diapositive 16

# **OECD Guidance Document on Regulatory Incentives for MU**



- Economic incentives for registrants such as data protection and expedited approvals
- ▶ Technical arrangements based on sound science: extrapolation and mutual acceptance
- Authorisation process arrangements such as third party registrations and temporary approvals
- Research

Promotion of alternatives

Liability waivers/disclaimers

# Article 51 of Reg. 1107/2009



- Registration on a major crop can be extended to a minor crop
- Data requirements
  - 4 residue trials
  - No efficacy data
  - Liability on crop damage is with the user
- Third party requests

- Collaboration with approval holder required
- EU MRLs
  - Take 2 years to establish
- Simplified procedure for faster registration \*\*ASK\*\*

#### Diapositive 18

# **Championing Minor Uses**



- Ensuring growers have access to authorised products
- Leveraging international best practices
  - Encourage the use of global data
  - Learn from IR-4 US experience and GMUP
- Continuous active collaboration among all stakeholders
  - Priority setting workshops to identify key crops and uses requiring solutions
  - Supporting the role of the Minor Use Coordination Facility (MUCF) CEGs
- Ensuring a fit-for-purpose regulatory framework at EU and national level
  - Improved interzonal cooperation

- Making use of mutual recognition provisions
- Encouraging extrapolations and mutual acceptance of data

# **Considerations on way forward**



- MUCF role is recognized as essential by the European Commission, national governments, industry and growers
- Actions taken by MUCF over the last 4 years are allowing greater collaboration and practical solutions to be found
- Lack of sustainable financing is putting its mission at
- "We all agree the minor use facility is extremely important and needs to be supported" Health Commissioner Stella Kyriakides

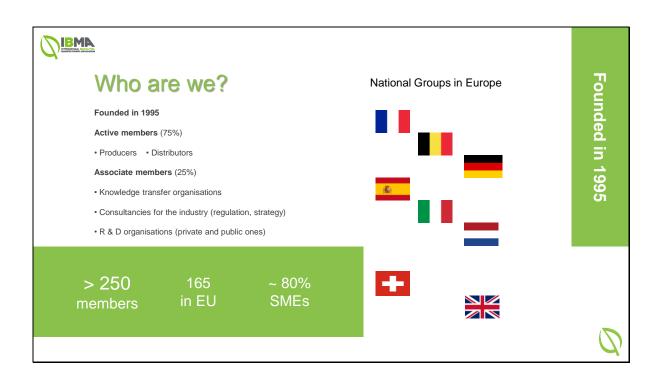
#### Diapositive 20

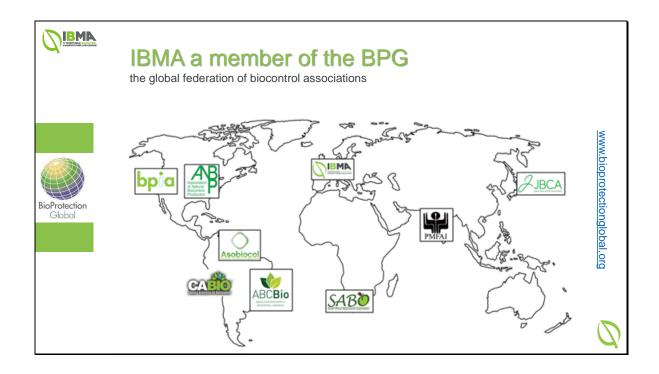


Thankyou for your attention!

# **Experience and expectations from biocontrol industry (Mr Ulf Heilig, IBMA)**Diapositive 1



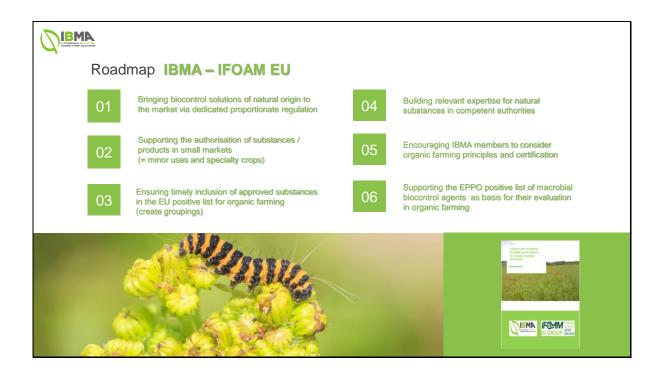


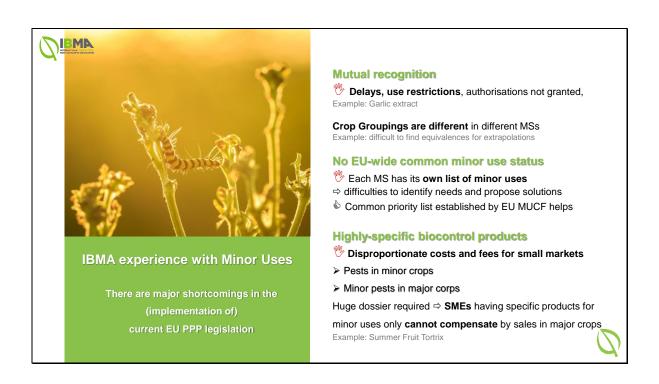






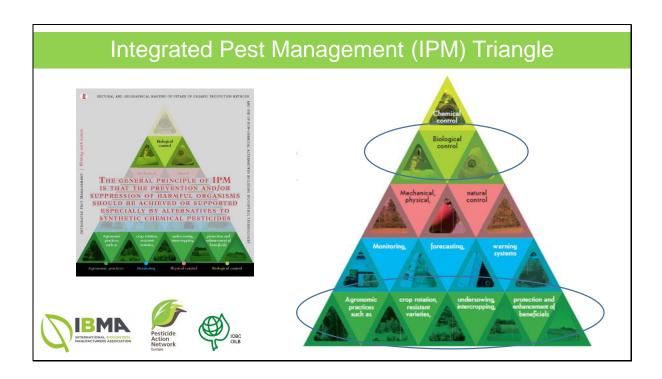


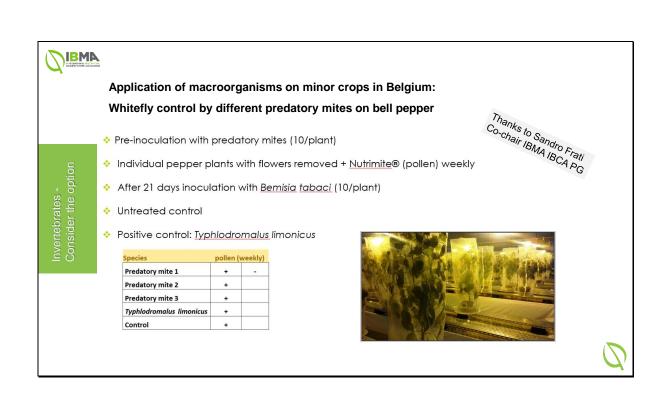


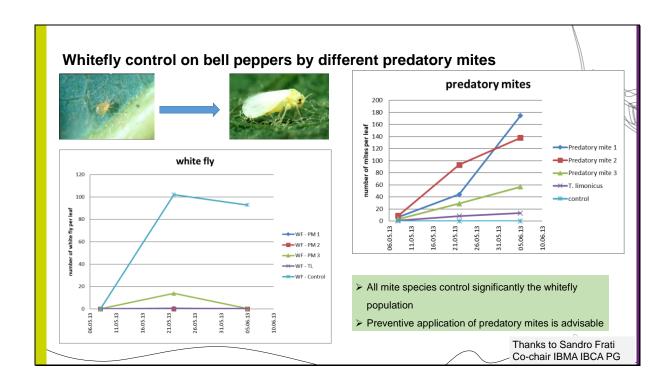










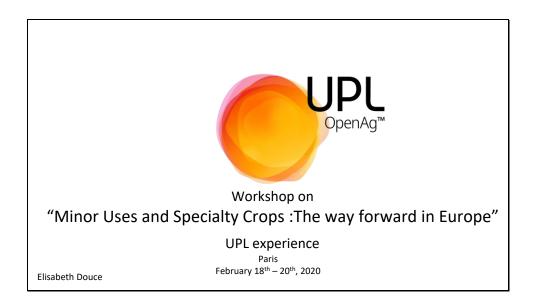


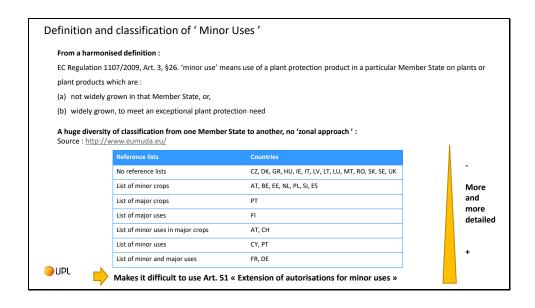




# Experience and expectations from an individual company- registration department (Ms Elisabeth Douce, UPL)

#### Diapositive 1





#### **Evaluation timing**

#### General rule applies:

- The active substances have to be EU approved,
- · MRLs or MRL exemptions have to be fixed,

Only then, product authorization can be granted in Member States

#### Evaluation process might be frozen :

During Art. 43, Renewal of autorisation, some Member States do not accept use extensions to be submitted. Some countries like
 France may accept to evaluate minor uses if possible to extrapolate from registered major uses.



Obtaining minor uses takes several years. Delays can add up.



#### Diapositive 4

#### **Procedural** issues

#### Zonal evaluation :

• Some countries do not accept dossier submitted at country level but require zonal dossier. This may not be compatible with certain uses.

#### « Third party » minor uses extrapolated from on-label uses :

- Lack of clarity around when to apply for renewal of the "third party" minor uses :
  - Should they be in the authorisation holder Art 43 dossiers, or,
  - Should the third party apply later in the Art 43 process when the likely outcome of the renewal and potential restrictions are known?
- Not possible to obtain a minor use where products with the same use on label are not marketed (e.g. UK)
- Minor use authorisations sometimes linked to a specific authorisation number so when an authorisation number changes (e.g. following
  a formulation change) a new application is needed for off label minor use even if the reference use has continued to be authorised with
  no change in authorisation conditions



Administrative burden. Complexity

UPL

#### Complex extrapolation rules & additional data requirements

EPPO rules and efficacy
Not possible to extrapolate efficacy data at crop level for Elicitors. Necessity to consider Crop / diseases. Additonnal efficacy trials are

#### Extrapolation from one formula to another

Specific efficacy trials required per formula having same active ingredients but different solvents

#### Data generated by Public Institutes (efficacy and residues)

Not always used by authorities to support extensions in minor uses.

#### Data handled by third party grower groups or farmer organisations :

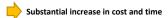
 $\label{eq:def:Difficulties} \mbox{ In preparing the appropriate risk assessments:}$ 

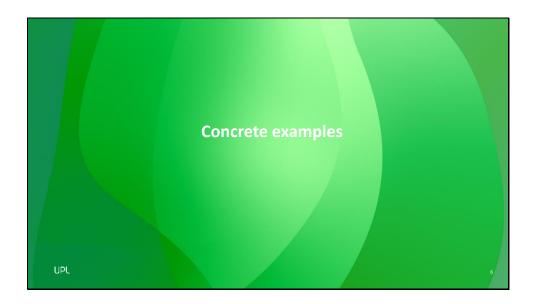
- Tools not accessible (ex. PRIMo rev. 3 required),
  Need consultants or company experts to support.

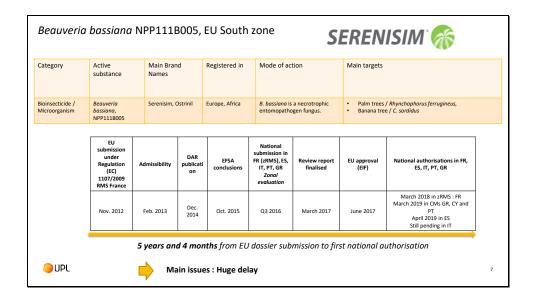
#### Risk envelop approach

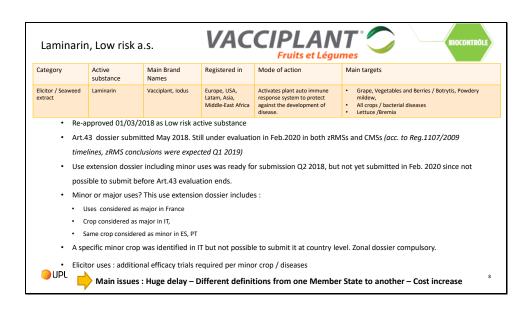
- Very difficult to determine in advance if the intended minor use falls within the risk envelop of already registered crops:
   Lack of overview on what minor crops are OK covering the risk assessment of minor crops with same gaps,
   Different focal species in ecotox risk assessment depending on the crop.
   Some authorities might be reluctant to perform additional risk assessments for minor uses











# Improvement proposals



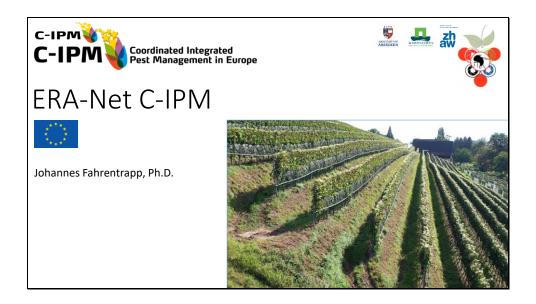
- Harmonize the classification of minor uses at EU or zonal level
- Simplify efficacy data extrapolation rules for minor uses : e.g. at crop level rather then crop/disease for Elicitors
- Clarify and ease the risk envelop approach for minor uses
- Facilitate evaluation timelines for minor uses in parallel to other processes (EU approval, Art.43 evaluation)
- Reduce administrative burden whenever possible
- Make it possible to submit minor uses at country level, and not necessarily at zonal level

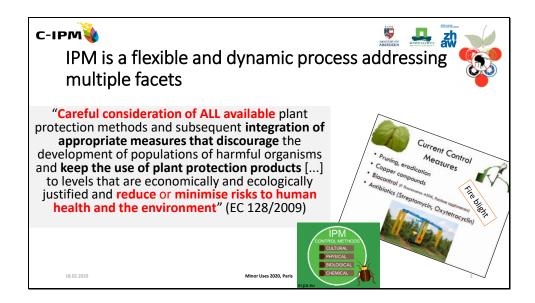


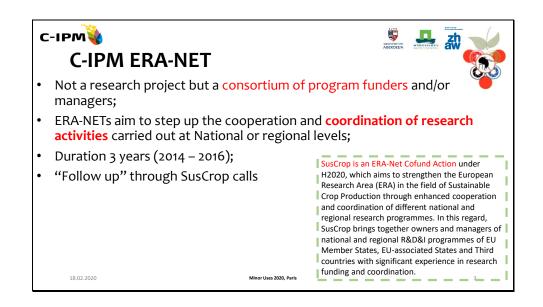


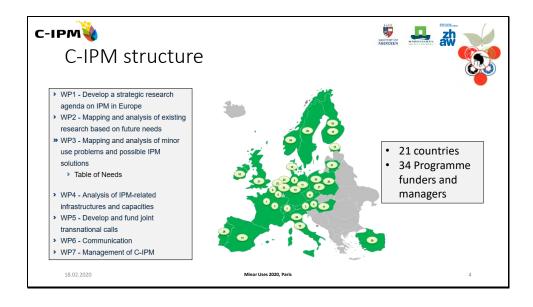
# Experience and expectations from IPM research network (Mr Johannes Fahrentrapp, C-IPM Eranet)

Diapositive 1











# **C-IPM** objectives



- Create synergies from investments in National research programmes, European initiatives, and private sector activities in the areas of IPM and minor uses;
- The specific objectives are to:
  - Identify synergies and gaps in existing national and transnational programmes;
  - Define a specific strategic research agenda for IPM in Europe;
  - Align IPM research throughout Member States
  - Organise and fund joint transnational calls;
  - Ensure better translation of National and European IPM-related programmes into applicable innovations.

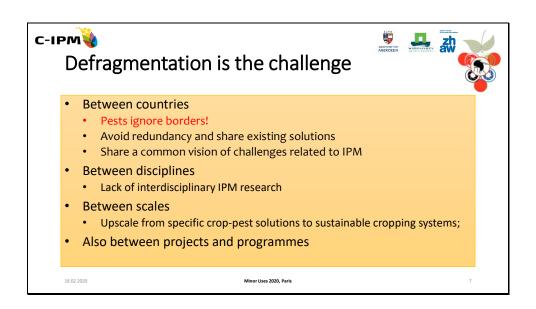
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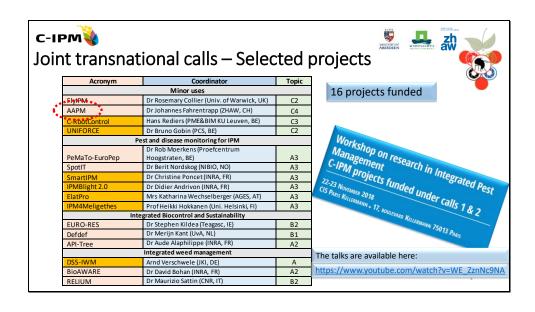
nor Uses 2020, Paris

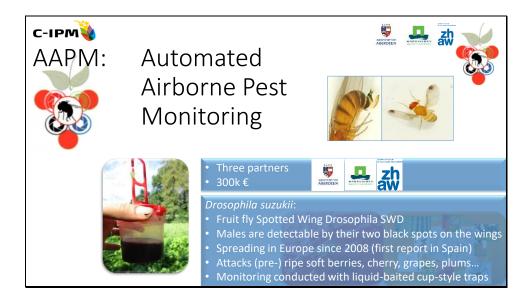
Diapositive 6

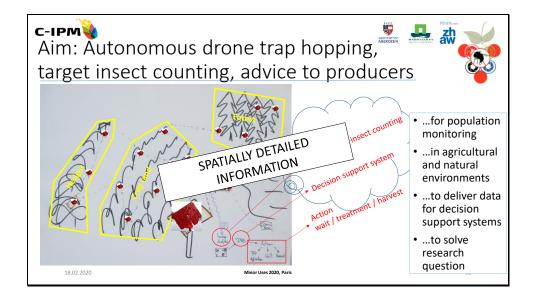


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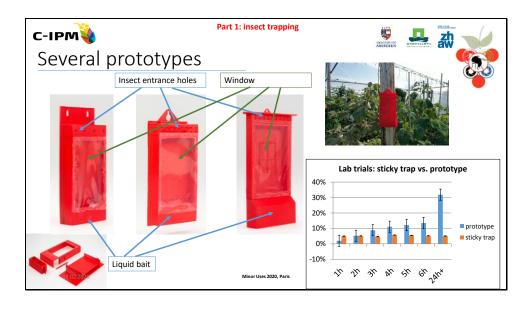


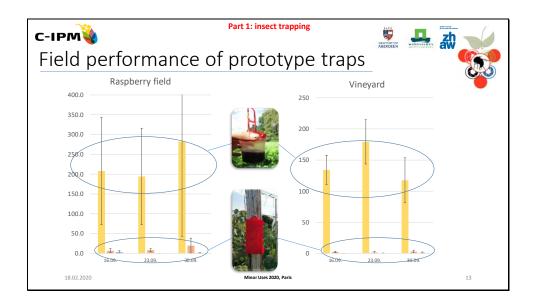


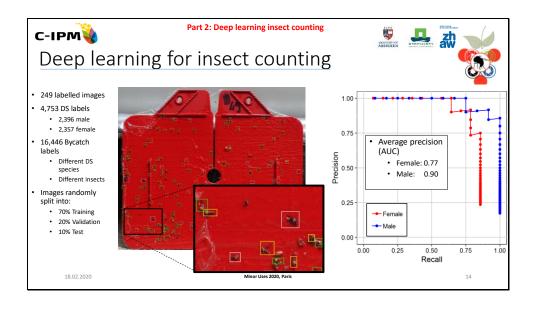


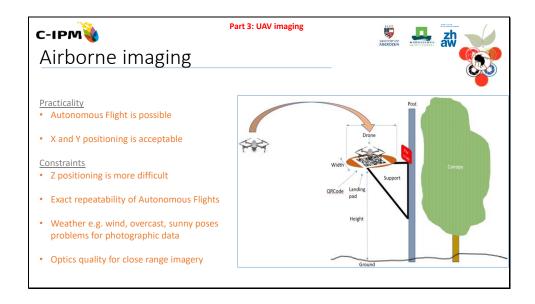


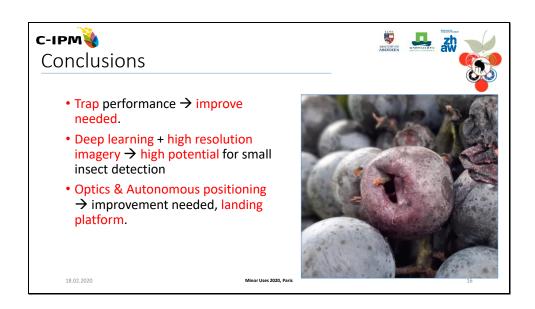














# Experience and expectations from IPM research network (Ms Rosemary Collier, EUVRIN)

### Diapositive 1





## **Aims of EUVRIN**

- Establish and improve cooperation between vegetable R&D institutes and teams within Europe
- Promote the exchange of information on vegetable research and development
- Enhance and facilitate coordinated research, development and technology transfer, focused on aiding sustainable vegetable production
- Enhance joint bids for funding of R&D in European, International, programmes
- Conduct surveys on the changing priorities in Vegetable R&D within the participant countries
- Establish and update a research agenda and communicate it to national, European and international authorities
- Several working groups...





### Diapositive 4

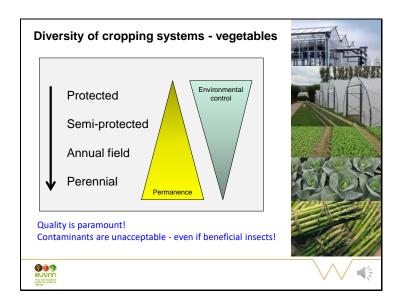
## **EUVRIN Working Groups**

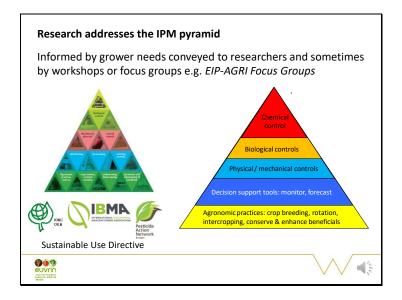
- Fertilisation and irrigation
- ► IPM for vegetable production
- ► Genetic resources, breeding and seed production
- Greenhouse crops
- Postharvest chain
- ► European Mushroom Working Group (EMushWG)

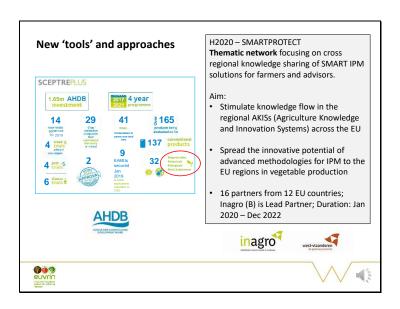




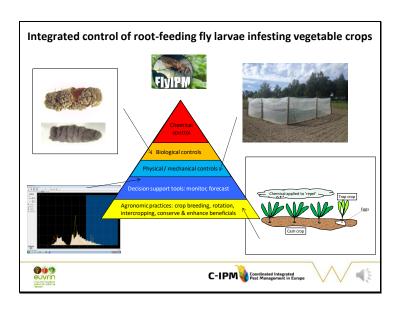














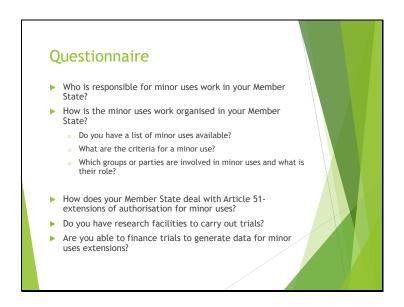


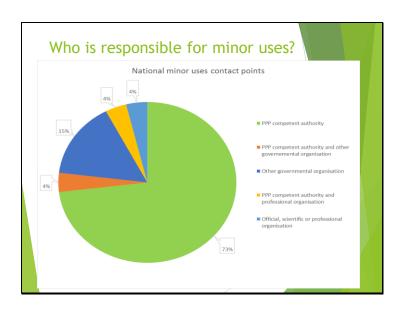
# Overview on how Member States organise minor uses work (Ms Flora Limache, MUCF)

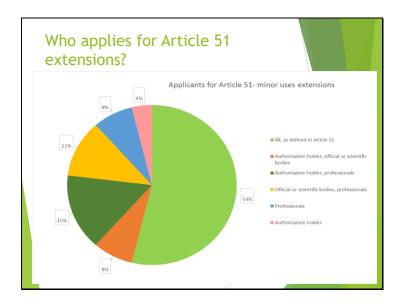
### Diapositive 1

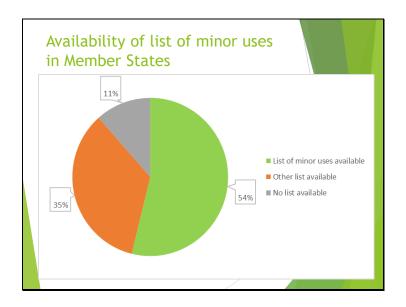


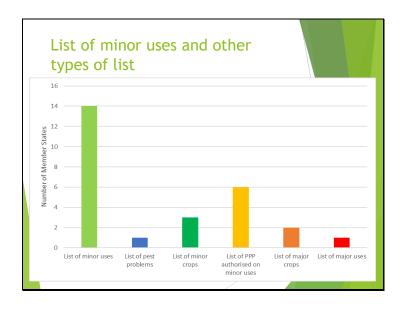


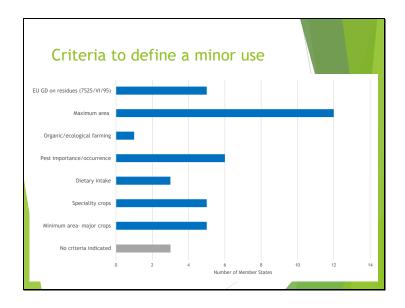


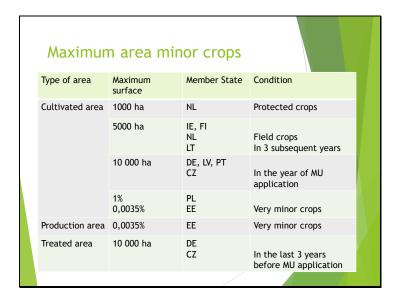


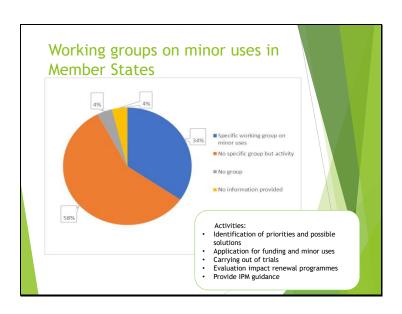


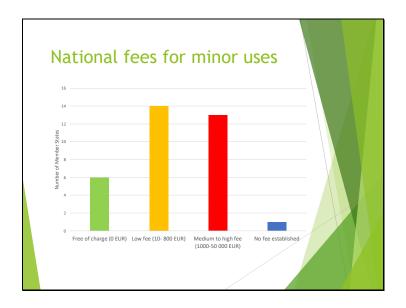


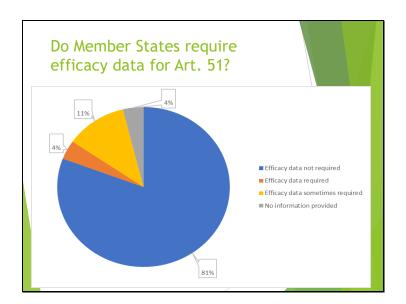


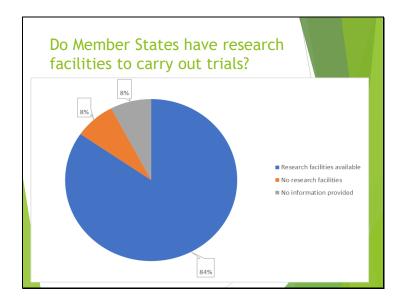


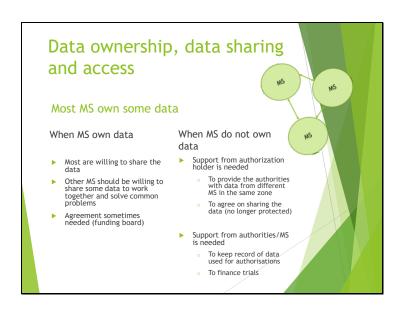


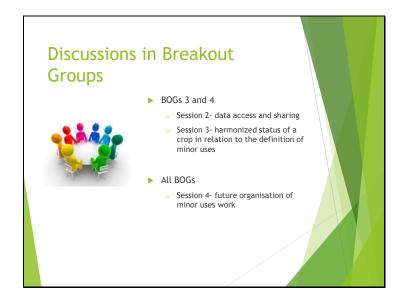














# Experience and expectations of advisory services (Mr Niels Enggaard Klausen, Hortiadvice, Denmark)

Diapositive 1



Experience and expectations of advisory services:

# The role of HortiAdvice in minor use in Denmark

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### Diapositive 2



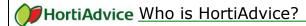
Who is HortiAdvice?

 ${\sf Background.}$ 

How do we do in Denmark?

Interaction between Gardeners, Advisory service and University.

Interreg Project.



HortiAdvice is a private horticultural advisory service.

We advice gardeners and growers of all horticultural crops in Denmark.

We also advice in Sweden, Poland, Rumania and others.

Approximately 35 employees.

We are a part of Delphy.





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# **HortiAdvice** Background

Regarding advisory services:

In Denmark we have a strong tradition for private and independent advice.

Both in agriculture and horticulture.

Denmark has produced under IPM principals for many decades, and many strategies has been developed because of the lack of sufficient chemical pesticides.

We also have a strong tradition for working together with the universities in research and development projects, mainly performed under practical conditions at the growers and the gardeners.

# **HortiAdvice** Background

Regarding the opportunities for plant protection:

It is the well known situation about the lack of plant protection products in minor crops.

- especially because we are in the North zone.

Because of few products and the risk of resistance, growers have been forced to use alternative products for some years.

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# HortiAdvice How do we do in Denmark?

The advisory service play a central role in applying for minor uses.

We have important functions that are in daily / weekly contact at the office:

Crop specific advisers (several, in all the crops). One application expert (me).

One doing the applying for minor use (Michael Nielsen).

When a urgent need occur, Michael will get data and apply.

The advisory service is a link between the practise and the universities.

# **HortiAdvice** Interaction

Interaction: Gardeners, Advisory service and the University.

The crop specific advisers have daily contact with the gardeners and growers, this gives precise knowledge of the demand of plant protection.

We conduct practical tests of alternative products at the gardeners; biostimulants, biopesticides and others. Both single products and as a part of a IPM strategy.

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# HortiAdvice Interaction

During our projects, we are often in close contact with e.g. Aarhus University, Flakkebjerg, (Peter Hartvig) that perform the trails needed for minor use in horticulture in Denmark.

At the beginning of each year we meet for planning the trails for that year in all minor crops (in horticulture). Based on input from gardeners / growers and the crop specific advisers.



# HortiAdvice \_\_\_\_\_

This close interaction between gardeners, advisory service and universities means that;

- we always know what problems the gardeners are facing,
- they tell about the problems,
- we know which products is possible to apply for,
- and what may be in the pipeline,
- we know what type of application is needed to succeed,
- we have a close dialog to the conductor of the trails,
- we can suggest suitable hosts for the trails,
- all the minor uses are disseminated direct to the gardeners and growers through newsletters and the web.

The interaction between the three segments ensures good results when applying for minor uses.

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# HortiAdvice A stronger corporation

For many years there have been a co-operation between the Scandinavian countries – we all face the same challenges.

Previously there was no formal collaboration, but in the fall 2018 we started a small Scandinavian cross-border Project.

We examined the differences in the approval procedures in Denmark, Sweden and Norway. Cataloged which issues were common.

This small project was meant as a research for a new project...

# HortiAdvice Interreg project

The newest is a close collaboration between Denmark, Sweden and Norway in the regi of a Scandinavian cross-border co-operation.

An Interreg project with the aim of improving co-operation in the work of minor use applications.

Discussing and planning trails together and sharing results, in the order to optimize our impact and our money spend on trails.





### Diapositive 12



 $1^{\text{st}}$  of January 2020 to  $31^{\text{st}}$  of September 2022.

Includes all minor crops in the three countries.

The goal is to create a binding collaboration in planning and doing trails in minor crops.

The results from trails in one country should also could be used in the other two countries.





Plans has been made for 2020, it includes both trails against caterpillars in kale and fruits, thrips in pot plants, weeds in different roots and others.

Trails for the next years will be decided based on the actual needs in these years.

Beside the economic advantage in *not* doing the same trails in similar countries, the idea is also to speak with one voice when trying to get new products in to the North zone.

Three countries make a bigger volume than one.





# Experience of the minor uses work in North America (Mr Dan Kunkel, IR-4, USA)

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### Diapositive 2



## The IR-4 Project

A US government funded research program

Facilitating the regulatory approval of sustainable pest management technology for specialty crops and specialty uses to promote public well-being



This material is based upon work that is supported by the National Institute of Food and Agriculture, U.S. Department of Agriculture, under annual awards with substantial cooperation and support from the State Agricultural Experiment Stations, USDA-ARS and USDA-FAS. In accordance with Federal Law and U.S. Department of Agriculture policy, this institution is prohibited from discriminating on the basis of race, color, national origin, sex, age or disability.



# **Objectives**

#### Food Program w/ Reduced Risk Products

- · Residue trials, some efficacy & crop safety
- Crop Grouping
- · International Harmonization, MRL's and Registrations

### **Biopesticide and Organic Support Program**

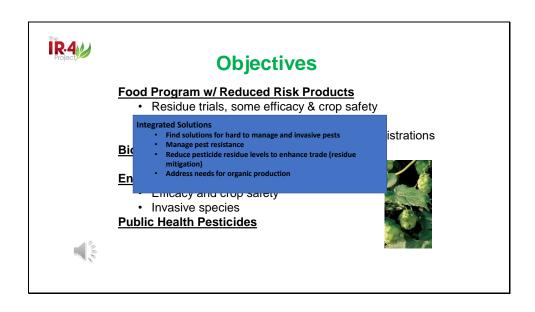
· Regulatory support and efficacy

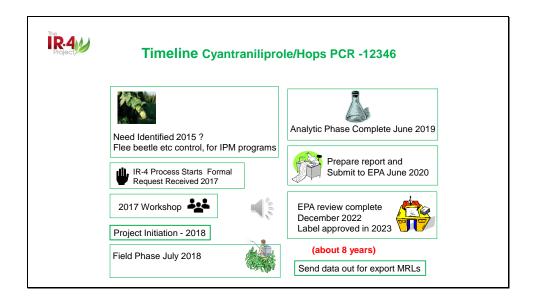
### **Environmental Horticulture Program**

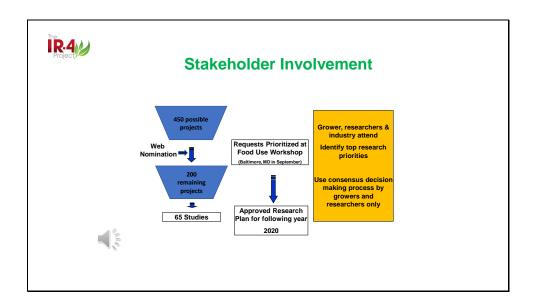
- · Efficacy and crop safety
- · Invasive species













### **Typical Year of Residue Data Generation**

- Start 65 new residue studies per year on 40 or more chemistries
- Conduct about 450 field trials to support residue work
- EPA reviews and establishes Tolerances (MRLs) on about 25 chemicals for IR-4 each year.
- IR-4 is responsible for approximately 50% of all new MRLs established by EPA each year.
- Through crop group extrapolations etc IR-4 data supports an average of more than 700 new uses each year.
- · 2019 1,545

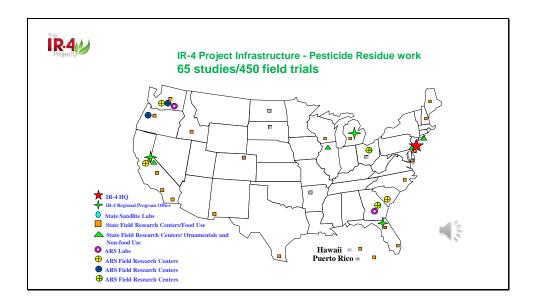
### Diapositive 8

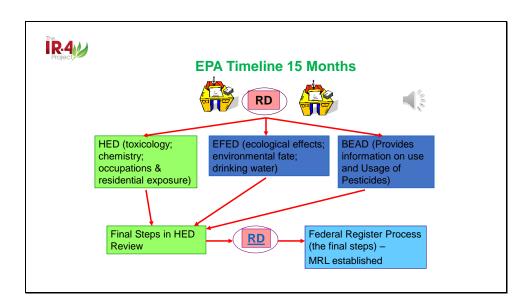


### **IR-4 Offices**

- IR-4 HQ Rutgers in NJ and NC-State
- Northeast Region U of Maryland
- Southern Region University of Florida, Gainesville, Florida
- North Central Region Michigan State University, East Lansing, Michigan
- Western Region University of California - Davis, California
- USDA ARS Companion program









### **Funding**

<u>GROUP</u>	<u>AMOUNT</u>	PROGRAM(S) SUPPORTED
USDA-NIFA	<b>\$</b> 11,916 000	Food, Ornamental, & Biopesticide
USDA-ARS	\$ 3,570,000	Food & Ornamental
USDA-FAS/STDF	\$ 350,000	Food (International) MUF
USDA-APHIS/NIFA SCRI	\$ 900,000	Ornamental (Invasive pests/Pollinators)
NRSP-4	\$ 481,156	Food, Ornamental & Biopesticide
Grants from Industry	\$ 1,100,000	All, workshops, travel etc

\*Does not include in-kind contributions that are provided by State Agricultural Experiments Stations, Canada, EPA, growers and the crop protection industry. In-kind contribution valued at over \$18 million annually



### Diapositive 12



### **Our Vision**

Global network of capable minor use programs working together to solve the MUP

- Help establish and mentor these minor use programs
- Partner with other data development groups
- Address the many unresolved needs

In the end do more studies...and harmonize as we do research - proactively



### **NAFTA Minor Use Cooperative**

#### Canada "Win-Win" Model

#### (Ag and Ag-food Canada Pest management Centre)

- Address grower pest control needs with safe effective products in a manner that does not affect trade markets
- Conduct Joint Residue Studies and provide simultaneous submissions to both regulatory agencies (EPA and PMRA)
- Submissions reviewed and registrations approved in both countries at approximately the same time with harmonized tolerances/MRLs



### Diapositive 14

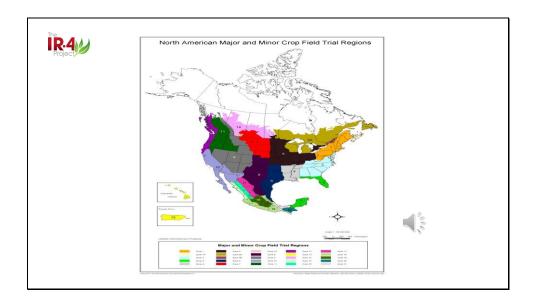


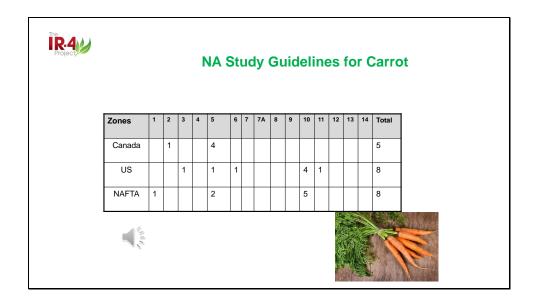
### Case study: 2017 IR-4 Residue Program

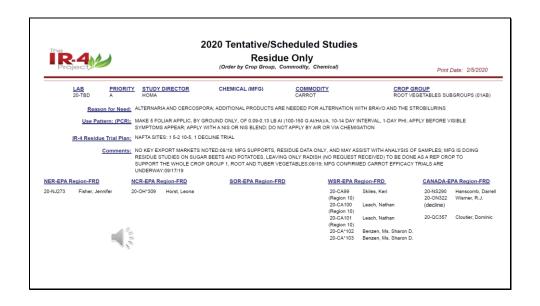
- Canadian Partnership
  - 76 Residue Studies for IR-4
    - 17 joint studies with PMC Common interest studies
    - 468 Field trials
    - 32 being conducted by Canada
    - \$192,000 direct savings to the IR-4 field program
    - PMC was SD for three studies They cover administration of the study as well an analytical cost (min of \$300,000).













### **IR-4 Global Activities**

- Codex Committee on Pesticide Residues
  - Electronic working groups
  - Crop groups
  - Submit data
- Global Minor Use Summit
  - Updates/Working groups/Cooperative projects
- OECD Expert Group on Minor Uses
  - Set Guidelines for data development
- IR-4 Global Residue Studies/Training/Capacity Development





### **Minor Use Foundation**

- 501 (C) (3)
- The organization will provide funding for research to other qualifying organizations.
- Priorities resulting from the Global Minor Use Workshops.
- Board Chair Dirk Drost, press release pending
- Seek funding to support research and future meetings
- Establish an advisory committee



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#### **HOLD THE DATE**

#### 2020 WORKSHOPS

IR-4 Food and Global Minor Use Priority Setting Workshops

- The dates will be September 14-17, 2020, Minneapolis, Minnesota, USA.
- IR-4 Food Use Priority Setting Starts  $\,$  13:00 on the  $\,$  14<sup>th</sup> until 12:00 on the  $\,$  16<sup>th</sup>.
- The Global Minor Use Priority Setting Workshop will begin at 13:00 on the 16<sup>th</sup> and conclude at 17:00 on the 17<sup>th</sup>
- Surveys have started....





#### **Biopesticide and Organic Support Program**

- 5% of the Project's efforts and resources
- Registration support and grants program for efficacy data
- Focus work with integration of biopesticides into conventional systems
- Support for organic markets
- · Plant incorporated protectants
- Successes include:
  - BT (all crops), Afla-Guard, ENTRUST



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# **Partnerships**

- EPA/IR-4 Technical Working Group
  - EPA reviews annual IR-4 residue program
  - crop group update
  - · Chemistry proposals and guidance
  - Report formats
- Crop Protection Industry
  - Protocol review, Test and reference substance
  - · Yearly visits to update cooperative projects
  - · Provide submissions documents and carry the label liability





## **IR-4 HQ Relocation**

- IR-4 Headquarters to relocate its operations from the longterm host institution (56 years), New Jersey Agricultural Experiment Station at Rutgers University, to NC State College of Agriculture and Life Sciences.
- The transition has started, and the scheduled completion is expected by September 30, 2021.
  - The long transition is to allow for IR-4 Headquarters to remain operational with minimal interruptions
  - · Allow employees to relocate etc
  - Rutgers and NC State administrators are committed to working closely to ensure a smooth transition



