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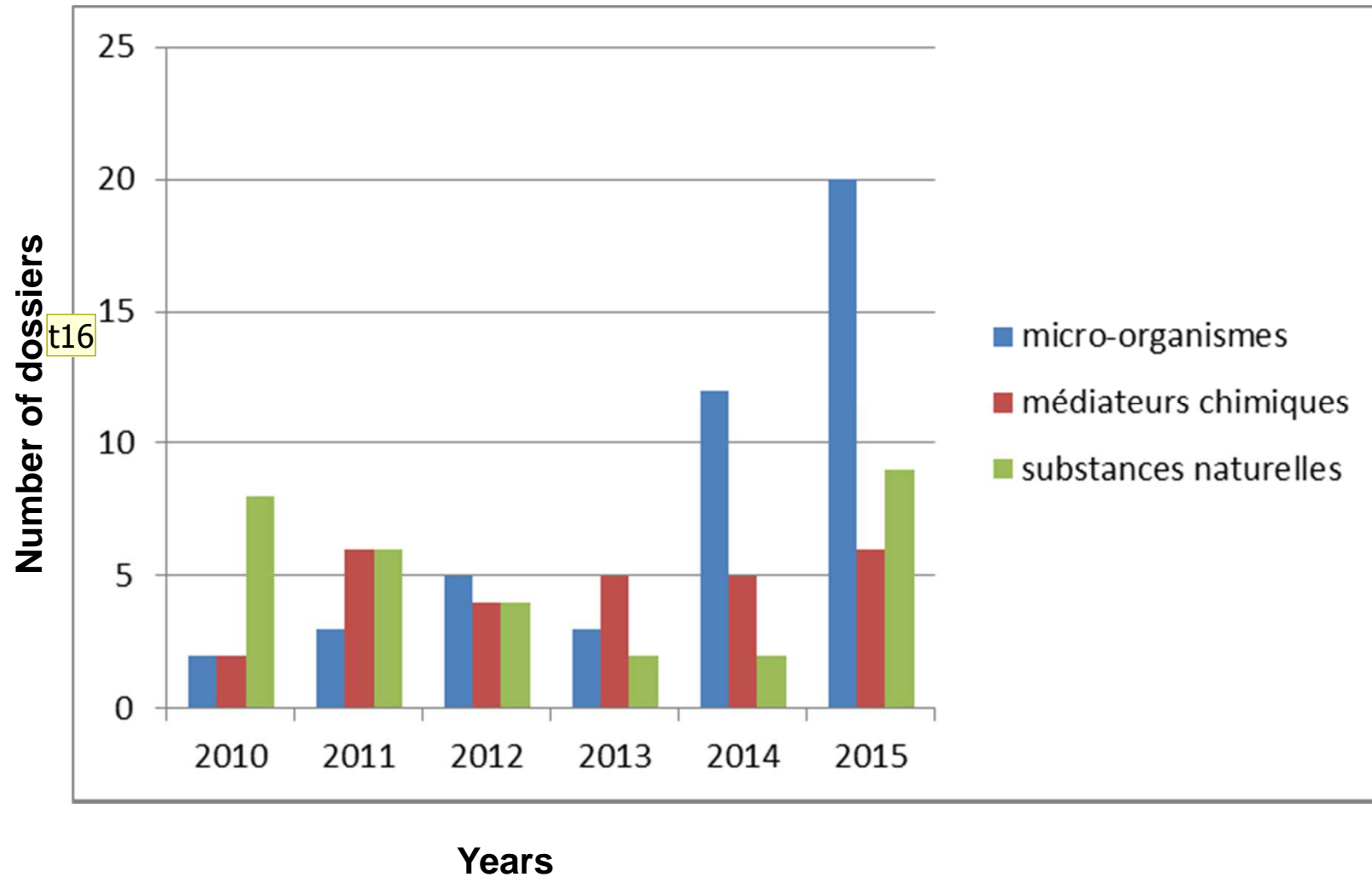
Feedback on efficacy evaluation of low-risk plant protection products ANSES point of view

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French situation

- Similar to the Netherlands
⇒ to increase the availability of Biocontrol agents – low-risk products are a priority for the French Minister of Agriculture
- Under the term low-risk products there is a lot of type of products with different issues in terms of efficacy assessment
- Low-risk products => efficacy assessment often complex to perform and dependent of the type of product
- Solution alone or tools in the global management of a pest ?

Number of conclusions ^{t17} given by the French Agency



Dia 3

t16 dossiers ou "conclusions from Anses"
t.mercier; 4-4-2016

t17 Ou conclusions issued by Anses
t.mercier; 4-4-2016

1. Low risk chemicals/botanicals/minerals

- Trials realized following the appropriate EPPO guidelines can be sufficient when a clear efficacy level can be demonstrated even if low
- In case of low and variable efficacy, trials need to be adapted with an explanation of these adaptations

- Clear determination of the mode of action to propose interesting adaptation (taking into account the importance of the climate, environment, soil...)
- Determination of an intrinsic efficacy level even if low
- Low intrinsic efficacy => practical value trials

Objective: determine the better conditions to apply the product to obtain a benefit on the management of the targeted pest

Need to pay attention to the choice of modalities to have comparable data

- Importance of the study of quality impact
 - On taste, phytotoxicity for oils
 - On visual aspect for kaolin or wax

2. Low risk micro-organisms with direct mode of action

- Virus, entomopathogenic fungus, toxin production = > most of the time, specific of one pest.
- Experimentation and evaluation close to the one realized for a classical chemical product
 - Efficacy level easier to define even if lower than a chemical standard and sometimes higher than these standards
- In that case, demonstration of efficacy on some representative crops can be sufficient for an extrapolation to other crops if the pest is the same. For the moment, extrapolation are proposed case by case at expert level.
- Importance of the determination of the minimum effective dose for this type of products ?

3. Low risk micro-organisms with indirect mode of action

- Difficult situation
- Most of the time, trials permit only to observe a low and variable efficacy level and trials have to be adapted to the product and its mode of action.
- Some specificities of experimentation and conditions of use are most of the time accepted:
 - Not GEP trial only if a complete report on the protocol, the conditions of the experiment and all raw data is available
 - Minimum effective dose ? Range of dose ?
 - Practical value trials => the objective of these trials is to determine the better conditions to apply the product to obtain a benefit on the management of the targeted pest (efficacy, reduction of the infestation, substitution of a classical chemical application of product in a program or association with a half dose...)
- Recurrent problems
 - At the end of the assessment, it is not possible to determine how to use the product to obtain an interesting effect.

4. Pheromones

- Mutual recognition is well-working for this type of product (in the southern zone)
 - Some specificities of experimentation and conditions of use are accepted:
 - Higher plot size
 - Results presented trial per trial
 - Clear information on the pest pressure
 - No “minimum effective dose”
 - In case of high pest pressure, possibility to use insecticide to control the population (pay attention to the modalities for comparison)
 - Globally clear results of efficacy (mainly measured by reduction of damages on harvested parts)
 - Variable efficacy: from a full control to a partial control, because very linked to the control of pest pressure below a too high level
- Methodology
 - EPPO guideline 1/264 “Mating disruption pheromones” (updating in progress).
 - Sanco GD on Semiochemicals_rev. 4.4.

Low risk and efficacy: **key points** and questions

At this time, for our assessment, key points are :

- A well identification of the mode of action
 - ⇒ adaptation of trials
 - ⇒ determination of possible extrapolation
- Determination of external factors (environment, climate, soil...) that can have an impact on the efficacy of the products
 - ⇒ adaptation of trials
 - ⇒ determination of the repartition of trials in the claimed zone
- Intrinsic level of efficacy if a clear response can be obtained
- And/Or Practical value trials to determine
 - ⇒ the best way to use the low-risk product
 - ⇒ the conditions in which the product is going to bring a benefit/value : efficacy, reduction of the infestation, substitution of a classical chemical application of product in a program

Low risk and efficacy: key points and questions

At this time, for our assessment technical issues which remain current are :

- How to realize relevant practical value trials ?
 - ⇒ Choice of modalities of comparison
 - ⇒ Standards choice
 - ⇒ Take into account environment, infestation ...
- How to determine possible extrapolation ?
 - ⇒ Expert judgment?
 - ⇒ EPPO tables?
 - ⇒ Importance of the mode of action (specific to the target or to the crop = possibility of extrapolation)
- Importance of the determination of the « minimum effective dose » ?
In which cases ?
- Adaptation of classical statistical analysis to low-risk products with variable results of efficacy?
- How to take into account a low and variable efficacy in a decision?

THANKS FOR YOUR ATTENTION