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Classification and labelling of biocide active substance and products (PT 18,14,19)

The Rodenticides (PT 14)

- Rodent pest control worldwide relies largely on the use of anti-vitamin K anticoagulant rodenticides (ARs).
- The delayed action of these compounds, with mortality occurring several days after bait consumption, makes them particularly effective
- The intensive use of these compounds has been rapidly followed by the selection of resistant strains in Norway rats, roof rats (Rattus rattus) and house mice (Mus musculus and M. domesticus).
- ARs are usually classified as First Generation AR (FGAR) (warfarin, chlorophacinone, coumatetralyl), requiring several days of feeding to be fully active, Second Generation ARs (SGARs) (bromadiolone, difenacoum, brodifacoum, flocoumafen, difethialone), more potent and active after only one day of feeding.
- Bromadiolone and difenacoum are considered less potent than the other SGARs and resistance to them is described, while there is no evidence of 'practical' resistance on the field to the three other SGARs.Alternatives to chemical rodenticides are limited

The Rodenticides (PT 14)

Rodenticides are one of the few types of pesticides which require approval under both Plant Protection and Biocidal Products regulations, according to their use.

In addition, the Sustainable Use Directive requires Member States to introduce necessary measures to restrict the sale of professional products to those users who hold an appropriate certificate, defining also the necessity of certified training for several identified categories (users, distributors, consultants).

There are initiatives in place to ensure that pesticides for professional use are only sold to qualified users, but currently a product for professional use could be sold also to untrained people.

Risk of poisoning

Primary poisoning

Limitation of risk acting on: Composition (addition of bitter agent, addition of dying agent)
Packaging (use of packaged bait, use of safety boxes)
Location of the product (use of bait stations)
Application of the products (amateurs/professionals outdoor, only Professionals outdoor)
Instruction on labels (I.e. indications about antidotes, about careful use, etc)

Secondary poisoning

Limitation of risk acting on: Use of bait stations outdoor
Specific location of the bait station
Removal of carcasses by professionals

Elements to be taken into consideration

- Risks of poisoning
- Disinfestation program
- Bait package and size
- Formulations
- Definition of “professional”
- Sustainable use
- C&L
- Good practice
- RMM outside Europe
- Conclusion

RMMs for rodenticides

- - Restrictions of use for amateurs
- - Rat control use for PCOs only
- - Restriction to indoor use
- - Picking up dead rodents and other animals (and disposal of bodies)
- - Remove bait at the end of treatments and disposal
- - Mandatory use of tamper-resistant bait boxes
- - Erection of notices to indicate presence of rodenticides - Resistance Monitoring

General recommendations:

- Resistance evaluation and monitoring
- Resistance management
- Non-target poisoning monitoring
- Training for Trained Professionals
- Training of Professionals (farmers, gamekeepers)
- Provision of information for the general public
- Best practice guidelines

RMMs for product authorization according to

- By user category
- By bait formulation
- Quantity of bait applied and pulsed baiting
- By packaging type and/or pack size
- RMMs addressing resistance selection
- Post-authorisation monitoring of resistance
- Standardised SPC template and harmonised label information
- Authorisation holder to ensure that information is provided to users

RMMs to be set at the stage of product authorization

- Bait boxes non refillable should be mandatory for amateur products.
- Various levels of protection can be obtained with the different bait boxes and it is suggested to develop specific requirements for bait boxes qualification.
- All bait formulations should be available to all user categories, with limited amounts and tamper-resistant bait boxes for amateurs.
- A standardized Summary of Product Characteristics (SPC) template should be completed for all products and readily available to all potential users. It should be the basis for label recommendations.
- It is strongly suggested to have a common and simplified label across MSs.
- Product manufacturers should provide a list of the information media available for the various user categories. Information leaflets or labels should be provided at this stage

Training is an essential component of appropriate use of ARs.

Trained professionals should receive appropriate and certified training, resulting in certified qualification.

A European standard has being developed and appears as a very promising tool.

Adaptation of existing programs is encouraged.

Professionals should also receive appropriate training.

Farmers usually receive training in Plant Protection Product application.

Rodenticides could be included in such training programs or as separate training sessions, depending on local uses of ARs (some MSs have permitted uses of ARs as Plant Protection Products).

Provision of information for the general public

- It is strongly suggested to develop specific leaflets, boards and video loops for local points of sale.
- Information should also be provided by stakeholders, but also by CA and the EU on the internet (dedicated websites).
- A suggestion to deliver ARs only in specialized shops or in shops with specifically trained personnel is made.

CLP and Harmonized classification for active substances

- New regulation BPR and the new PPP regulation provide both the non-eligibility for use (not included in all. 1) for substances classified as CMR of category 1A and 1B, PBT, vPvB, and neurotoxic (cut-off criteria)
- The assessment of the classification must be conducted and prepared by the CLH in a joint with assessment for inclusion in all.1 and by the same experts who had made evaluation for DAR (PPP) / CAR (BP)
- All biocides (and PPP) substances already allocated to MSs for the evaluation of inclusion in all.1 will proceed for the elaboration of a CLH dossier, also requiring IUCLID 5 annex
- No fees are provided for this additional workload to MSs

RAC decision on ARs

- In March 2014, at its 28th meeting, the Risk Assessment Committee (RAC) for Harmonised Classification and Labelling concluded that all AVKs rodenticides should be classified as toxic for reproduction (R1A - “Known Human Reproductive toxicant” or R1B - “Presumed Human Reproductive toxicant”).

- As the majority of rodenticide products contain >0.003%, the RAC opinions will result in such products being classified and labelled as a reproductive toxicant. As a product classified as R1A or R1B cannot be made available to the general public in accordance with Article 19(4) of the Biocidal Products Regulation (BPR), these opinions may significantly alter the number of products, in particular FGARs but also bromadiolone and difenacoum containing products, that may be available to the general public to control rodents.

Consequences

- At the current dosage, all FGAR active ingredients would become unavailable for the general public.
- Should companies seek to reformulate their products to maintain them available for the general public, a concentration below 0.003% would be ineffective for all FGARs against fully susceptible populations of Norway rat and House mice, and the SGARs bromadiolone and difenacoum would be ineffective against resistant strains of both species where they possess certain mutations of the VKORC1 gene.

Consequences (2)

- The RAC opinions could therefore lead to a greater use by the general public of difethialone, brodifacoum and flocoumafen containing products, as these would be the only products available and efficacious below the 0.003% concentration limit
- Furthermore, although the labelling of products as R1A or R1B does not mean that products cannot be authorised for professional operators, there is a concern that products which carry specific classification and labelling (including toxic by reproduction) could not be used to protect important areas such as food factories, due to restrictions placed on professional operators by individual companies in charge of these sites.
- Indeed, many organisations that use professional pest control services follow protocols for the choice of products that prevent the use of those classified as toxic to reproduction at their sites (CEPA communication with the expert team).

Consequences (3)

- Only professional use to be sold in the appropriate shops
- Applicants trying to reduce concentrations from 0.005% to 0.0025% (SCL = 0.003%)

Actions :

- New efficacy studies in progress
- New cost
- Composition changes
- New evaluations
- New fees
- Resistance ?

Insecticides

Also Insecticides are one of the few types of pesticides which require approval under both Plant Protection and Biocidal Products regulations, according to their use.

In addition, the Sustainable Use Directive requires Member States to introduce

necessary measures to restrict the sale of professional products to those users who hold an appropriate certificate, defining also the necessity of certified training for several identified categories (users, distributors, consultants).

There are initiatives in place to ensure that pesticides for professional use are only sold to qualified users, but currently a product for professional use could be sold also to untrained people.

Insecticides

An important technical risk mitigation measure is development of packaging systems enabling correct dosing of insecticides by non-trained professionals and consumers.

Furthermore, it is needed to restrict the use of insecticides in spray cans as it entails a risk to the user due to inhalation of respirable aerosols.

Consumers should be guided through awareness campaigns on sustainable use of biocides and instructions for use on leaflets in the package or given by the retailer upon purchase

Professional use is taking care of a continue developing of formulations in order to reduce risk of exposure for professionals

The relevant solutions and tools for PT 18: Insecticides, include

Technical solutions

- Packaging systems can enable correct dosing by non-trained professionals and consumers.
- This includes design of containers with dosing systems that release only the required amount of biocides per use.
- Moreover, alternatives to spray can application of insecticides can effectively reduce the identified risk to professional and private users exposed to micro-sized aerosols.

Guidance training and communication

- Integration and communication of IPM principles in guidance to professionals as well as in instruction to the consumers would be highly relevant.
- This would include strategy for sustainable use of biocides and consideration on how to minimise formation of resistance and possible bioaccumulation in the target organisms.

Efficacy in providing sustainable solutions

- Packaging systems enabling correct dosing and restriction on use of insecticides in spray cans will effectively reduce the exposure and risk of effects during use of insecticides by professionals and consumers.
- Moreover, guidance for professional users based on IPM principles, restriction of sales and better instructions to private user are likely to lead to more careful use of insecticides.
- The mentioned technical solutions are relatively low cost measures and the responsibility of the manufacturers.
- The same applies for guidance and better instructions to consumers.
- Restriction of sales and certification of retailers will probably cause an increase of the prices of insecticide products for consumer use.

Standardisation and certification

- Certification of professional users is a possible relevant measure.
- Some authorities are considering a certification for professional use of insecticides.
- Relevant measures for consumers could be a restriction of sale to certified retailers, which are trained to provide instructions on sustainable use.
- Finally, there is a need to restrict insecticides from being applied by spray cans due to an identified risk by inhalation

Repellents (PT 19)

- Repellents are often used by general public, including sensitive population (childeren, elderly, pregnant women, etc)
- Those product are used also in high density infestations abroad out of EU(es malarian countries)
- Are often used repeately
- Contains subsances very often irritating or sensitizing
- Concentration and rate of application can vary in high rates
- Could be associated to cosmetics (sunscreens)

CLP and repellents

- Relevant impact on those products containing irritating substances, depending on the concentration
- Insect skin repellents :
- Due to the specific mode of use, products containing irritating substances for skin in concentration equal or higher 10 % could be out of the market as they should classified as irritating for the skin.

CLP and repellents

Skin repellents classified as eye irritating products, could be sold only according to specific application mode and with specific risk mitigation measures:

Insect skin repellent classified as:

H318 : Causes serious eye damage

H319 : Causes serious eye irritation

- may be authorized in several formulations classified as H319 but with appropriate sentences on the label
- may be authorized in roll-on formulation classified H318 always with appropriate sentences on the label

Liquid formulation / spray classified H318 cannot be authorized

CONSEQUENCES

Skin irritating products are obviosuly in conflict withe the mode of use (skin application) and no mitigation measures could be applied.

Applicants trying to reduce concentrations from 20% to <10%

<u>Consequences:</u>

New efficacy studies in progress

New cost

Composition changes

New evaluations

New fees

New packaging type development (more roll-on)

Preservatives (PT 6)

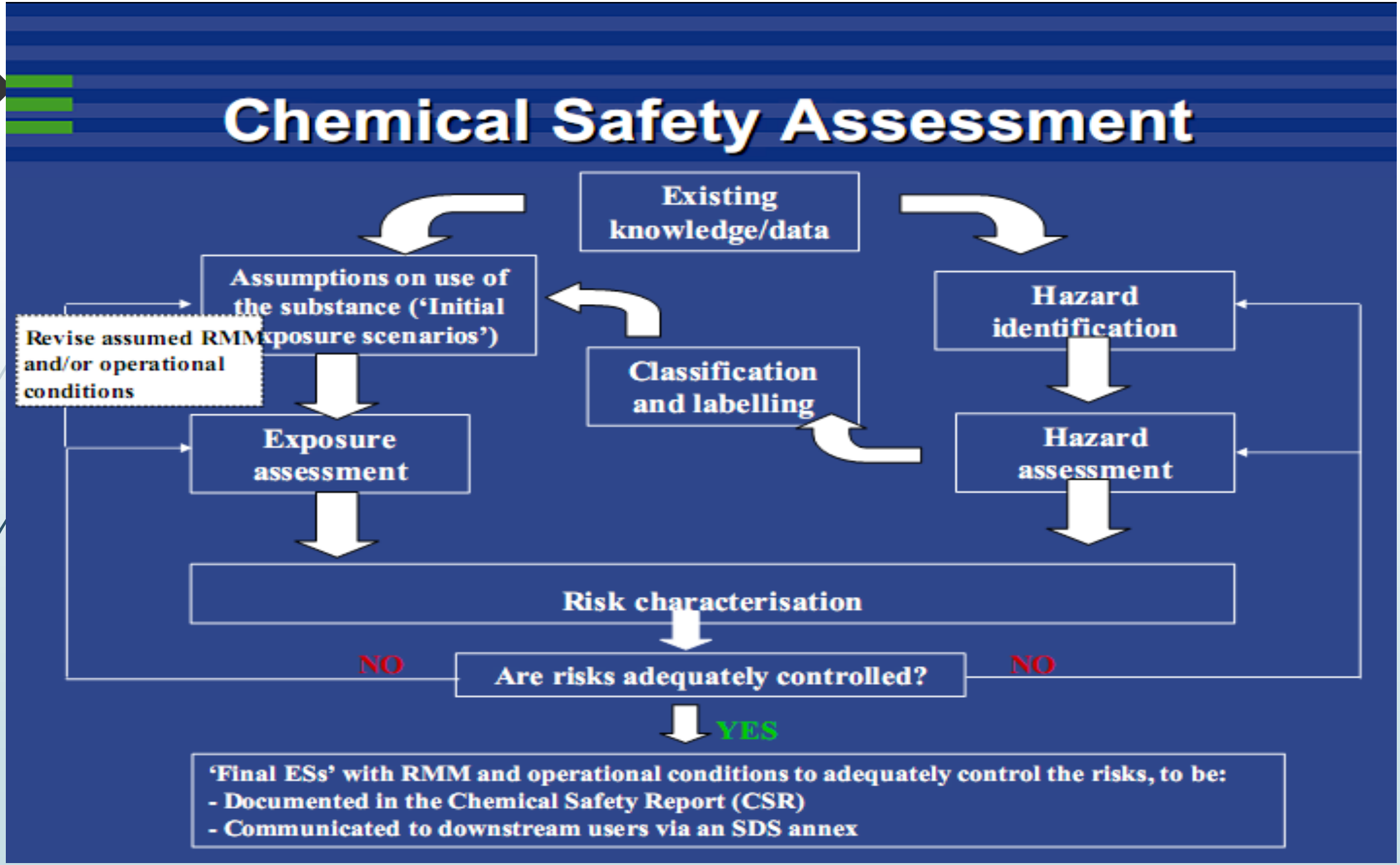
- Most common used preservatives contains sensitizing substances such as:
- Methyl iso-thiazolinon
- Benzoiso-thiazolynon
- Octabentazon
- Propiconazole (fungicide)
- Permethrin (insecticide)
- should provide the labelling phrase « Contain……(substance) . May cause an allergic reaction» (EUH 208) applicable to concentrations ranging from 0.01%- 0.001%
- Often with specific concentration limits.

Preservatives (PT 6)

- Methyl iso thiazolinon was assigned an extreme potency categorisation for skin sensitisation and a recommendation for a **S**pecific **C**oncentration **L**imit (SCL) of 15 ppm was proposed, on the basis of data provided in the original classification report and information provided during public consultation.
- As a consequencs, all products containing 15 ppm or more will be classified

Substance	Concentration limits for labeling of mixtures with  Xi, R43[1] or  H317[2]	Current concentration limits for labeling of mictures with EUH 208 *"Contains <substance>. May produce an allergic reaction"*[3] Applicable until 01.06.2015	Future concentration limits for labeling of mixtures with EUH208 *"Contains <substance>. May produce an allergic reaction"*[3] To apply from 01.06.2015
CMIT/MIT	≥ 15 ppm	not applicable	≥ 1.5 ppm
BIT	≥ 500 ppm	not applicable	≥ 50 ppm
MIT	≥ 10.000 ppm	≥ 1.000 ppm	≥ 100 ppm
NOIT	≥ 500 ppm	not applicable	≥ 50 ppm
DCOIT	≥ 300 ppm (proposal: ≥ 10 ppm)	not applicable	Regarding proposal: ≥ 1 ppm
DBDCB	≥ 10.000 ppm	≥ 1.000 ppm	≥ 1.000 ppm
IPBC	≥ 10.000 ppm	≥ 1.000 ppm	≥ 1.000 ppm
Permethrin	≥ 10.000 ppm	≥ 1.000 ppm	≥ 1.000 ppm
Propiconazol	≥ 10.000 ppm	≥ 1.000 ppm	≥ 1.000 ppm
Chlorocresol	≥ 10.000 ppm	≥ 1.000 ppm	≥ 1.000 ppm
Terbutryn	≥ 30.000 ppm	≥ 1.000 ppm	≥ 100 ppm
Glutaral	≥ 5.000 ppm	≥ 1.000 ppm	≥ 1.000 ppm

Chemical Safety Assessment



Thank you for your attention

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