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Guidance on methodology for evaluation of the effectiveness of options to reduce the risk of introduction and spread of organisms

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Introduction

- **Increased focus on identification and evaluation of Risk Management Options in Terms of Reference**
  - As part of a complete risk assessment
  - Evaluation of technical files by 3rd countries requesting a derogation from existing phytosanitary measures

- **Guidance document on Harmonised Framework (2010):**
  - Risk Management Options are addressed concisely:
    - Overview of categories
    - Aspects to be evaluated
    - Aspects outside of EFSA PLH remit
    - Insufficient detail to serve as guidance

Introduction

- Self task EFSA PLH (ToR):
  - To develop guidance on methodology for the evaluation of the effectiveness of options to reduce the risk of introduction and spread of harmful organisms in the EU territory.

  Including guidance on:
  - Quantitative methods
  - Information and data to be provided
  - experimental designs and statistical methods

  N.B. Only the evaluation of proposed (already identified) options is addressed in this Guidance Document.

Definitions and terms

- Risk Reduction Option (RRO):
  - option to reduce the risk of introduction and/or spread of a pest and/or the risk that a pest causes a biological impact
  - Term is equivalent to Risk Management Option
  - Comply with EFSA principles:
    - Seperation of risk assessment and risk management
    - Transparency
- Effectiveness of a RRO:
  - Capability of an option to reduce the risk caused by a harmful organism
  - Reliability and reproducibility
  - Technical feasibility

Overview of RROs

- Options for consignments
- Options preventing or reducing infestation in the crop
- Options ensuring that the area, place or site of production, remains free from the pest
- Options for other types of pathways

Overview of RROs

- Singular application or combined in systems approach
- Most RROs may serve to reduce probability of entry and probability of spread
  - Depending on area and conditions for implementation
  - Requirements for exporting countries
  - Internal measures for the EU territory

Overview of RROs

- Options for consignments (8)
  - Prohibition
  - Prohibition of parts of the host or of specific genotypes of the host
  - Pest freedom: inspection or testing
  - Pre-entry or post-entry quarantine system
  - Preparation of the consignment
  - Specified treatment of the consignment/ Reducing pest prevalence in the consignment
  - Phytosanitary certificates and other compliance measures
  - Restriction on end use, distribution and periods of entry

Overview of RROs

- Options preventing or reducing infestation in the crop (5)
  - Treatment of the crop, field, or place of production in order to reduce pest prevalence
  - Resistant or less susceptible varieties
  - Growing plants under exclusion conditions (glasshouse, screen, isolation)
  - Harvesting of plants at a certain stage of maturity or during a specified time of year
  - Certification scheme

Overview of RROs

- Options ensuring that the area, place or site of production, remains free from the pest (3)
  - Maintaining pest free area (PFA)
  - Maintaining pest free production place or site
  - Inspections and surveillance

Overview of RROs

- Options for other types of pathways (3)
  - Preventing or reducing natural spread
  - Preventing or reducing spread by human activities (people movement, transports, machineries, trade)
  - Preventing or reducing spread by vectors, incl. phoresy relations

Evaluation of a RRO

- Aspects of a RRO that need to be evaluated:
  - Description of the RRO: purpose and scope
  - Experimental evidence for the effectiveness to reduce pest infestation in plants/products/fields
    - Laboratory / controlled conditions
    - Operational conditions
  - Applicability (technical feasibility) of the RRO
  - Experimental or observational evidence for the effectiveness to reduce the probability of pest entry from an infested to a pest-free area

Evaluation of a RRO

To enable systematic evaluation of a proposed RRO, a checklist was developed:

- To check if, and which, evidence is provided on:
  - Plant material information
  - Pest material information
  - Experiments and observations: design and analysis
  - Facilities and equipment
  - Conclusions of the experiments / observations
- Formulate conclusion on the effectiveness of the RRO

Evaluation of a RRO

More detailed guidance was developed for:

- Experimental designs for assessing effectiveness of RROs
- Statistical methods for assessing effectiveness of RROs
- Surveillance in RROs
- Use of quantitative pathway analysis

Experimental designs for RROs

- RROs requiring experimental development prior to implementation:
  - Preparation of consignment
  - Specified treatment of consignment
  - Specified treatment of crop, field, place of production
  - Resistant or less susceptible varieties
  - Growing plants under exclusion conditions
  - Harvesting plants at certain period / maturity stage

Experimental designs for RROs

- Methodology is too diverse for the scope of this guidance document
- Experiments for treatment of consignments:
  - ISPM 28: criteria for treatments of consignments
  - the checklist in this guidance document includes all IPSM 28 criteria, but has larger coverage
- Experimental results are only valid for the investigated organism, extrapolate with caution
  - Temperature duration for *Bursaphelenchus xylophilus* and *Agrilus planipennis*

Statistical methods for RROs

- Assessing the uncertainty of the effectiveness of a RRO

  Recommendation:

  – Compute confidence/credibility intervals to assess uncertainty about effectiveness of RROs

- Comparing the effectiveness of RROs with a threshold

  Recommendation:

  – Not systematically use the probit 9 threshold as a reference threshold

Statistical methods for RROs

- Testing the equivalence of two RROs

  Recommendation:

  – When possible, justify the equivalence of two RROs using equivalence test

- Estimating dose- effectiveness relationships

  Recommendation:

  – Choose an appropriate statistical model taking into account the type of available data

Surveillance in RROs

- Obligatory under IPPC, specified in ISPM No.6
- General surveillance:
  - Systematic collection, verification and compilation of qualitative and quantitative information on pests from a wide range of sources
- Specific surveys:
  - procedures by which NPPOs obtain information on pests of concern through structured, representative sampling on specific sites in an area over a defined period of time

Surveillance in RROs

efsa
European Food Safety Authority

Need for surveillance for specific RROs:

- Maintenance of official pest list
  - Demonstration of pest absence in importing country
- Reduce probability of entry
  - Demonstrate pest absence in exporting country or to sustain pest free area
- Reduce probability of establishment
  - Early detection for succesful eradication in pest free area or country
- Reduce probability of spread
  - Containment of pest in infested zones
- Reduce impact of pest occurrence
  - Monitor pest prevalence for official control

Surveillance in RROs

Evaluation of the effectiveness of surveys based on:

- Formulation of survey hypothesis (pest X is absent in the identified area)
- Quantitative information on distribution of host plants and other pest niches in the area
- Mathematical background (e.g. binomial distribution)
- Sampling method (random sampling …… simulated annealing)
- Confidence level (the survey has 95% confidence to detect the pest in the area, if it is present at or above the detection threshold)
- Use of traps, lures, etc. where possible
- Quantitative results of the survey
- Explicit conclusion of the survey as related to hypothesis

Quantitative pathway analysis to evaluate RROs

- Advantages of quantitative pathway analysis:
  - Effectiveness of RROs can be assessed at relevant spatial and temporal scales
  - The model can be used to identify influential parameters and to identify the RROs that would strongly reduced the risk
  - Several RROs can be compared on a common scale using such models
  - Several RROs can be combined and evaluated together using a pathway model, allowing for evaluation of system approaches

Quantitative pathway analysis to evaluate RROs

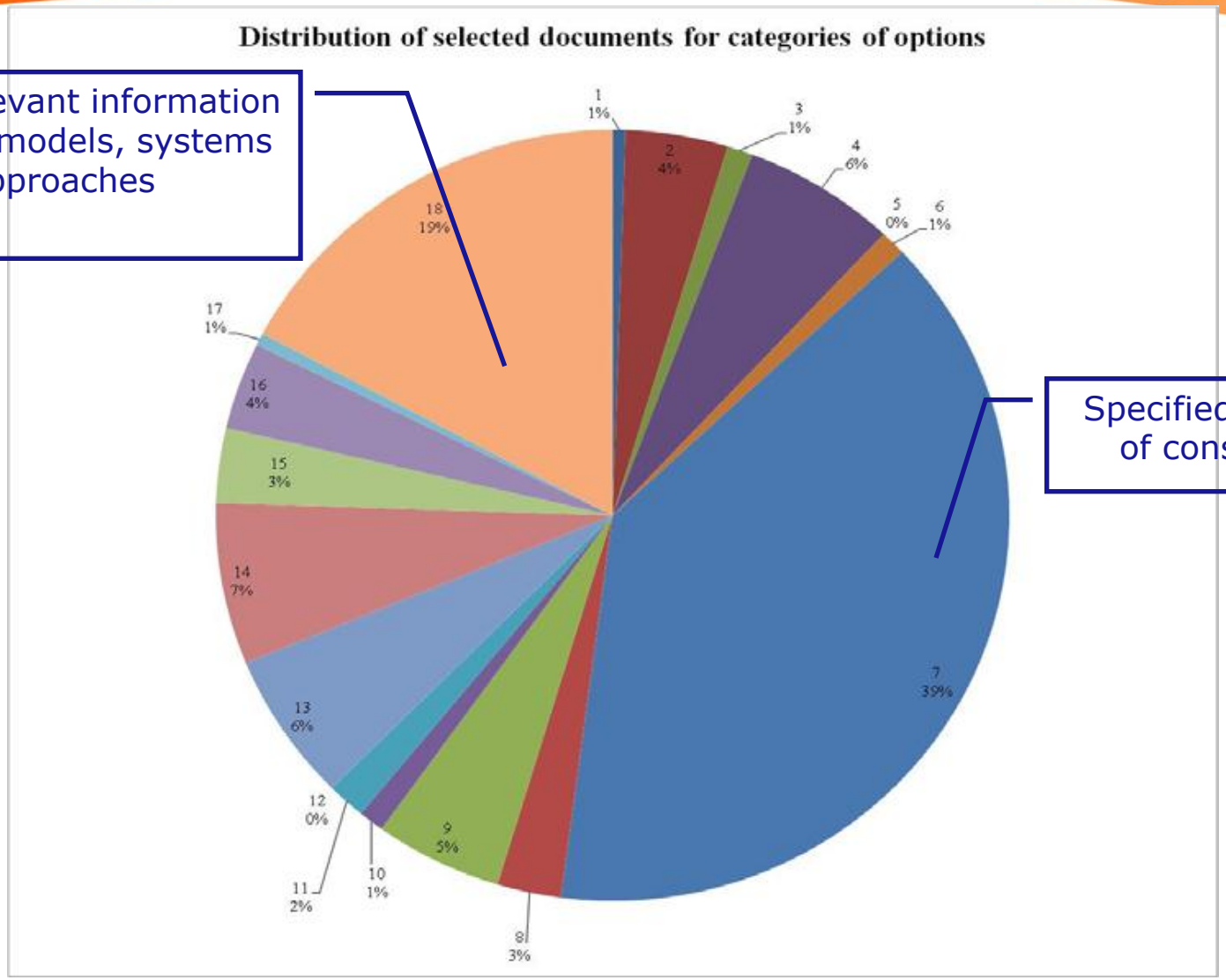
- Limitations of quantitative pathway analysis:
  - Quantitative pathway models usually include many parameters, which might be uncertain
  - Calibration and evaluation against real measurements is generally not presented, because this type of model is usually used to assess future risks
  - Quantitative models do not usually predict the complete absence of a pest. All results should therefore be compared to acceptable levels of infestation or risk of introduction / spread.

Systematic literature review

- To develop this guidance, a wide range of documents on RROs was reviewed
- Documents were collected by systematic literature search
  - According to EFSA methodology
  - 192 relevant documents out of 358 total documents
    - 58% guidance documents
    - 32% experimental studies
    - 10% miscellaneous (e.g. reviews)

→ Database of literature on RROs

Systematic literature review



Other relevant information e.g. risk models, systems approaches

Specified treatment of consignment

Conclusions

This guidance document contains:

- Checklist for evaluating a RRO
- Extensive database of literature on RRO
- Recommendations on:
  - Experimental designs for RRO
  - Surveillance in RRO
  - Use of statistical methods for evaluating RROs
  - Use of quantitative pathway analysis

Any questions?