

Committed *since 2002*
to ensuring that Europe's food is safe



Guidance document on a harmonised framework
for pest risk assessment and the evaluation of pest
risk management options by the EFSA

Jan Schans
PLH Panel

EVIRA Joint event on plant health, Helsinki, 1st October 2012

Type of requests to the PLH Panel:

- Evaluation of PRA documents
 - Risk assessment
 - Risk management options
- Evaluation of a national PRA document and extension of its scope to the territory of the EU
 - Risk assessment
 - Risk management options
- **Since 2009: Preparation of pest risk assessments for the EU territory ‘from scratch’**
 - **Risk assessment**
 - **Risk management options**

- To develop a harmonised framework for EFSA to assess the risks of organisms harmful to plants and plant products in the EU to advise the EU risk manager
- Guiding principles on assessment practices
- To implement EFSA key values
 - **Separation of risk assessment and management**
 - **Independence**
 - **Transparency**
 - High scientific excellence

- EFSA framework:
 - 178/2002
- EU framework:
 - 2000/29/EC
- IPPC framework:
 - ISPM 2 – framework for pest risk analysis
 - ISPM 11 – pest risk analysis for quarantine pests
 - ISPM 5 – terminology
- Friction:
 - Processes in ISPMs engage both risk assessors and risk managers without differentiation of their roles and responsibilities
 - → adaptation to EFSA needs was necessary

To provide a transparent, science-based framework for:

- pest risk assessment
- evaluation of pest risk management options

Satisfying these constraints:

- i. Based on IPPC and its standards
- ii. Addressing the needs of EU risk managers as laid down in 2000/29/EC
- iii. Fitting the EFSA key values as specified in 178/2002:
 - i. Separation of risk assessment and management
 - ii. Independence
 - iii. Transparency
 - iv. High scientific excellence

The harmonised framework shall include:

- i. Assessment of introduction and spread of harmful organisms
- ii. Assessment of potential consequences associated with the introduction and spread of harmful organisms
- iii. overall characterisation of the risk of a harmful organism
- iv. Assessment of the effect of risk management options on the level of risk
- v. Harmonised methodologies to allow for consistent characterisation of risk and evaluation of pest risks
- vi. Definition of data requirements allowing for transparent assessment of pest risks
- vii. Principal requirements for documentation of pest risk assessment process

(i) Assessment of introduction and spread of harmful organisms (1)

- Both qualitative and quantitative approaches are used
- Qualitative approach may include quantitative elements
- Qualitative approach:
 - EPPO scheme in line with IPPC and standards, but not with EFSA principles
 - EPPO scheme modified to harmonise with EFSA principles
→ EFSA scheme

(i) Assessment of introduction and spread of harmful organisms (2)

- Scoring in qualitative approach:
 - Transparency: number of ratings and the description of ratings needs to be described prior to assessment
 - For each Opinion, ratings and descriptions are formulated
 - provided as appendix to the Opinion
- Models in quantitative approach:
 - Explanatory description of model and parameter estimation must be provided with the published opinion

(ii) Assessment of potential consequences (1)

- Potential direct and indirect consequences on all affected plant species
 - Crop yield and/or quality
 - Undesired (environmental) effects of control measures
- Environmental consequences
 - Direct effects on biodiversity (reduction of keystone species)
 - Effects on ecosystems services

(ii) Assessment of potential consequences (2)

- Quantification of economic losses in monetary values or other related economic quantifications do not belong to the Panel's remit. Thus, no effects assessment on:
 - economic impacts in monetary terms,
 - export markets,
 - Social impacts (employment, tourism, etc)
 - tourism, etc

(iii) overall characterisation of the risk of a harmful organism

- Quantitative approaches
 - compute an overall risk level
- Qualitative approaches
 - risk matrices for combining scores
 - Caution: still active area of research
 - No robust implementation yet
 - Overall risk is formulated as summarizing conclusion on entry, establishment, spread and potential consequences

(iv) Assessment of the effect of risk management options on the level of risk (1)

- Upon request by the risk manager
- RM options are formulated in line with ISPM 11:
 - Options to ensure pest freedom for area, place, or site of production
 - Options to prevent or reduce infestation in the crop
 - Options for preparing and treatment of consignments
 - Additional options for specified pathways
 - Options within the importing country

(iv) Assessment of the effect of risk management options on the level of risk (2)

- RM options are evaluated with respect to:
 - Effectiveness
 - Technical feasibility
- Aspects of RM options outside of EFSA remit, not evaluated:
 - Cost-effectiveness
 - Minimal impact
 - Non-discrimination
 - Acceptability of risk
 - Selection of RM options for implementation

(iv) Assessment of the effect of risk management options on the level of risk (3)

- **Quantitative risk assessment**
 - effectiveness of RM option is expressed as the expected change of each risk element, should the management option be applied
- **Qualitative risk assessment**
 - effectiveness of RM option is expressed as the expected new score for each risk element, should the management option be applied

(v) Harmonised methodologies for consistent characterisation and evaluation of pest risks

- Explicit identification and characterization of uncertainty for each process stage
 - Imperfect information and data
 - Natural variability and randomness
- Uncertainty and sensitivity analysis on the overall risk assessment
 - Explicit rule for combining scores is required
 - Not yet implemented in EFSA scheme

(vi) Data requirements

- Transparency:
 - all data considered in the risk assessment, and the conditions for their generation, need to be described in the Opinion
- Data categories are as described in ISPM 11, e.g.:
 - taxonomy, biology and distribution of the pest,
 - Environmental data affecting potential establishment and spread
 - Farming practices and crop characteristics
 - Transport and other pathway characteristics
- Process of data collection and documenting the results of data searches are recorded in the assessment

(vii) documentation of pest risk assessment process and submission of dossiers

- Summary
- background and terms of reference
- The strategy of data searching
- The assessment (entry, establishment, spread, impact, uncertainties)
- Identification and evaluation of risk management options
- Final conclusions and recommendations
- Confidential data and information if any
- List of references and documentation

Developments:

- Experience of PLH Panel with this framework in risk assessment of pests from wide-ranging taxonomic groups
- PLH Guidance Document on Risk Reduction Options
- PLH Guidance document on Environmental Risk Assessment
- ‘Art 36 grants’, e.g. Prima Phacie
- horizontal harmonisation activities within EFSA
- PRATIQUE project
- Preparation of new EU phytosanitary regulation

?? Building up towards “harmonised framework 2.0” ???

Any questions?

