A quantitative risk assessment methodology for pest risk analysis

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OUTLINE

- Why a new methodology? What advances do we expect?
- What is new and how is it done?
  - Pillar 1: Plan and adapt the assessment
  - Pillar 2: Base the assessment on abundance, flow of events and integrated RROs
  - Pillar 3: Go quantitative, multiplication factors, quantile distributions, aggregation of probabilities
- Example for Entry
- Application of the new methodology
- Conclusions

WHY QUANTITATIVE RISK ASSESSMENT?

Assessors should always aim to **express** impact and uncertainty in **quantitative terms to the extent that is scientifically achievable** (EFSA Guidance on Transparency; Codex Alimentarius: Working Principles for Risk Analysis; EFSA Guidance on Uncertainty)

Principal reasons

- The ambiguity of qualitative expressions
- Their tendency to imply value judgements outside the remit of assessors
- The fact that many decisions inherently imply quantitative comparisons (e.g. between exposure and hazard) and therefore require quantitative information on uncertainty.

Quantitative methods **score better** on

- Criteria related to technical rigour
- Meaning of the output

WHY QUANTITATIVE RISK ASSESSMENT?

The EFSA Scientific Committee Opinion on risk terminology (2012) recommends that

- **EFSA should work towards more quantitative** expression of both risk and uncertainty whenever possible, i.e.
  - Quantitative expression of the probability of the adverse effect
  - Quantitative descriptors of that effect
  - Use of verbal terms with quantitative definitions
  - Associated uncertainties should always be made clear, to reduce the risk of over-precise interpretation.

- Further guidance should be developed on approaches for both qualitative and quantitative expression of risk and uncertainty.

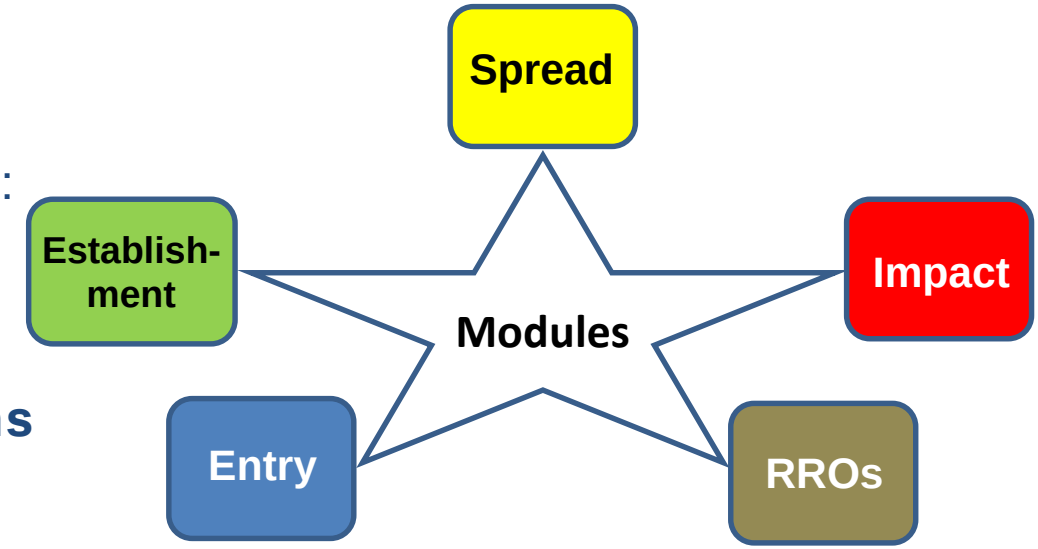
- Consideration should be given to intensify **communication between EFSA and risk managers** to
  - Enhance mutual understanding of the risk expressions and
  - Raise awareness of the potential for interpretational bias

WHAT ADVANTAGES DO WE EXPECT?

- New approach fully in line with **ISPM No. 11**
- More **transparent** procedure of risk assessment
- **Clearly defined scenarios** can be addressed following a systematic and harmonised approach
- Risk assessment **is based on knowledge affected by uncertainties** which are more specifically expressed
- **Quantification based on measurements and estimates in the real world**: helps to justify measures
- Expressing risk in quantitative terms allows **consistency in assessment outputs** and quantitative **comparison of management options**
- More **targeted documents**

WHAT IS NEW AND HOW IS IT DONE?

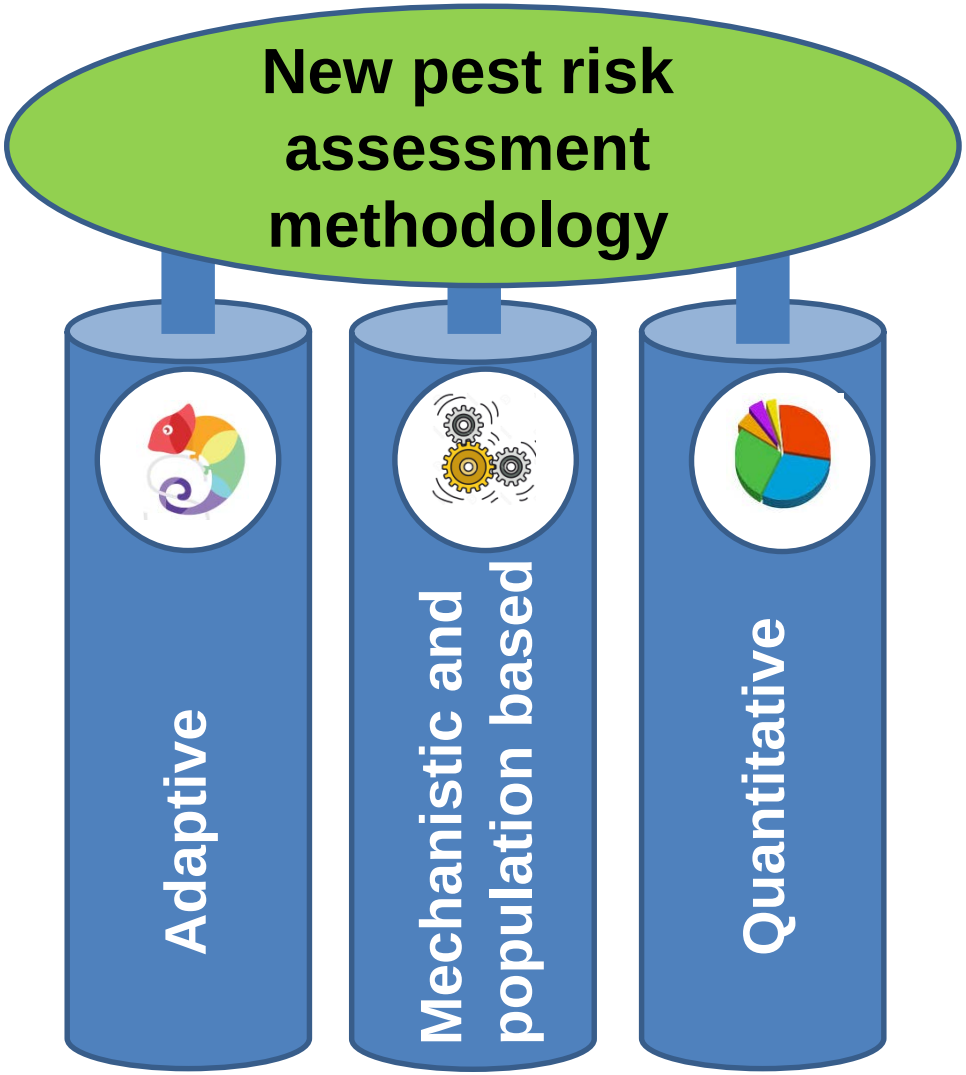
- **Conditional assessment**: modules
- **Scenarios:** Assessors and Managers **interactions (ToR)**



- Transparent and quantitative methods for **process analysis and rating**
- Methods for systematic **identification and evaluation of RROs**
- **Integration of RROs and Risk Assessment** → How much and where risk is reduced

WHAT IS NEW AND HOW IS IT DONE?

More fit for purpose approach based on three pillars



PILLAR 1 – PLAN AND ADAPT THE ASSESSMENT

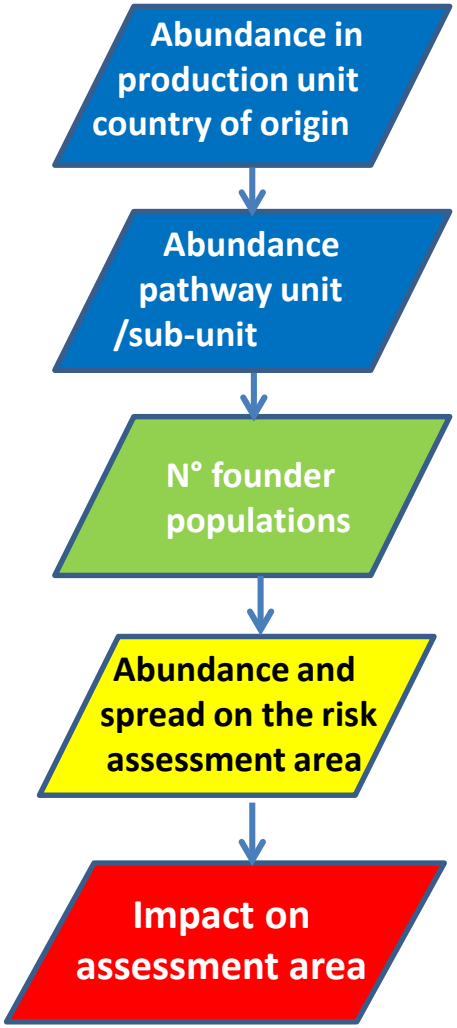
- **Adaptation is required in relation to**
  - Pest, objective, resources (data)
- **Definitions specific for the assessments to be conducted**
  - Pathways
  - Units for the estimation of the abundance: Pathway unit and sub-units, transfer unit, spatial unit to
  - Definition relevant to the impact: production unit, SPU, Endangered area
- **Scenarios for the assessments to be conducted**
  - Pathways
  - RROs
  - Ecological factors and conditions
  - Scales: extent and resolution
- **Tools to be used**

Interaction with risk managers and clear ToR

PILLAR 2 – MECHANISTIC AND POPULATION-BASED

Based on the assessment of population abundance

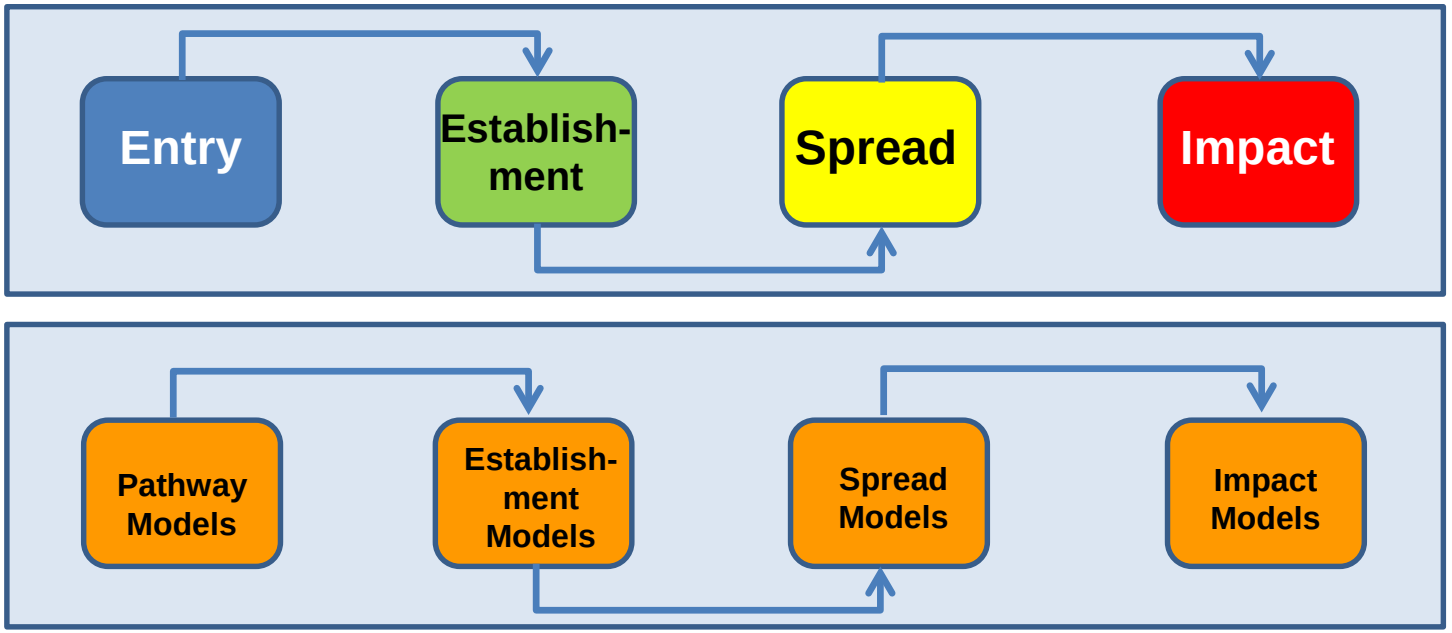
- Invasion process is seen as flow of events and processes
- Represented (measured) in terms of change in pest population abundance
- All steps and sub-steps are connected
- Reasoning is based on biological relevance
- Integration of RRO into the framework as factor changing pest abundance



PILLAR 2: MECHANISTIC AND POPULATION-BASED

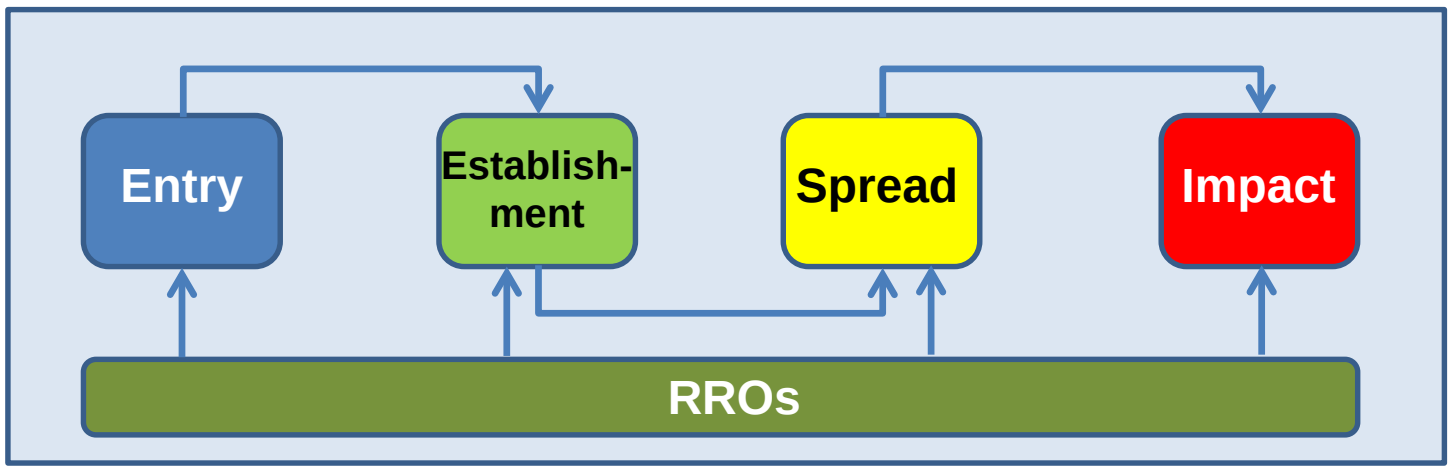
Based on the assessment of population abundance

- **Real world measurements** and estimates of population dynamics (time, space and impact)
- **Mechanistically-based** integration of steps in the assessment by the use of step-specific models (possibly process-based models)
- Information and results **propagated** throughout the scheme



Integration of RROs into the Risk Assessment

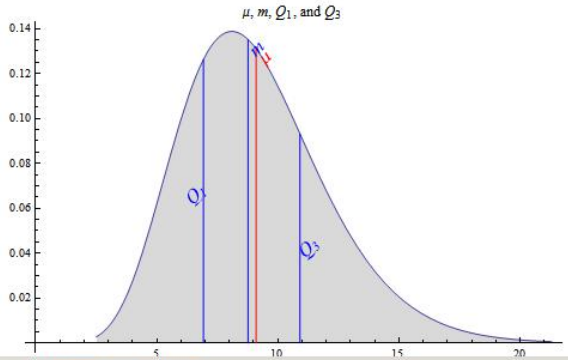
- **Inventory** of RROs
- **Full integration** in the RA
- **Connection** with the relevant steps of the RA
- **Quantification** of the effects (in terms of change in the abundance of the pest)



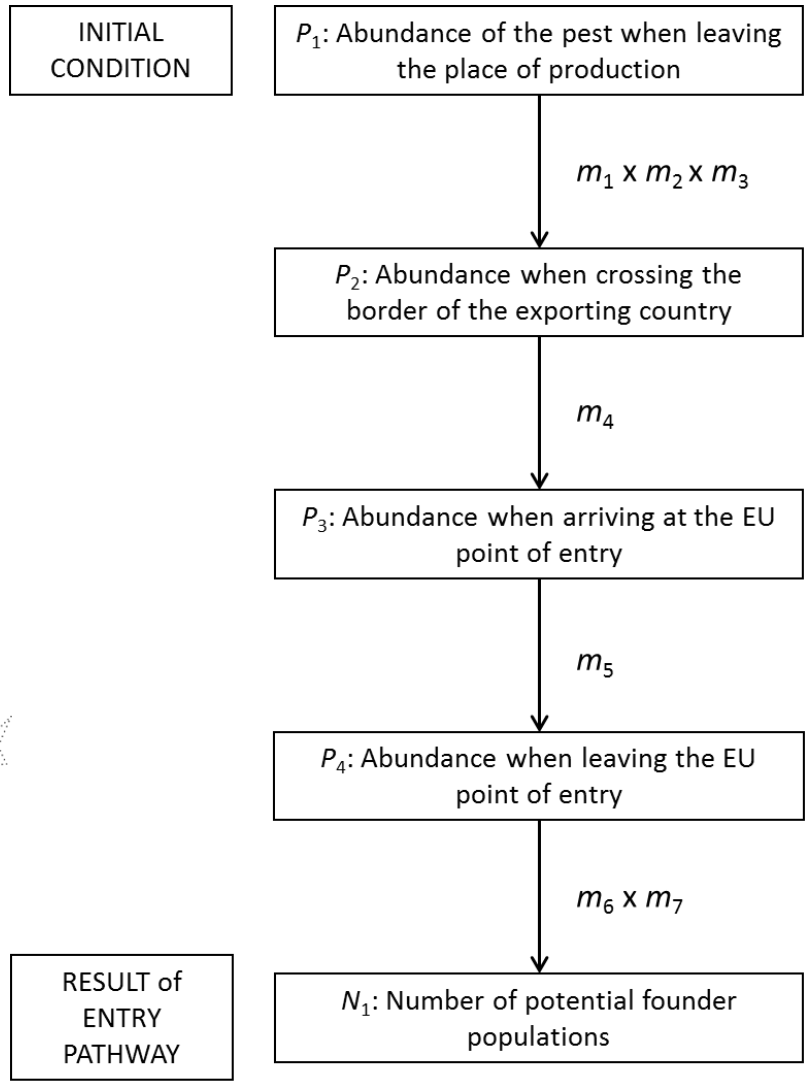
PILLAR 3: GO QUANTITATIVE

- **Measurable variables:** More consistency by using quantities measurable in the real world, e.g.:
  - Number of infected lots entering the EU
  - Number of new established populations
  - Area of newly infected plants
  - Amount of yield with specified lower quality due to the pest
- **New approach to combine knowledge and uncertainty**
- **Probability judgement**
  - Quantiles distribution

Quantiles distribution of pest abundance in the field



PILLAR 3: MULTIPLICATION FACTORS



$$N_1 = P_1 N_0 m_1 m_2 m_3 m_4 m_5 m_6 m_7$$

The aim is to estimate the number of affected units entering the risk assessment area having contact with the suitable host plants resulting in a transfer of the pest in the selected temporal and spatial scale and for the defined scenario.

Sub-steps: when and where abundance of the population is assessed. Transition processes modify the abundance in the pathway unit/sub-units.

Processes are expressed in **multiplication factors** changing the abundance of the population from one sub-step to the next.

Uncertainties in the estimation of the multiplication factor's quantiles distributions of their expected values are requested.

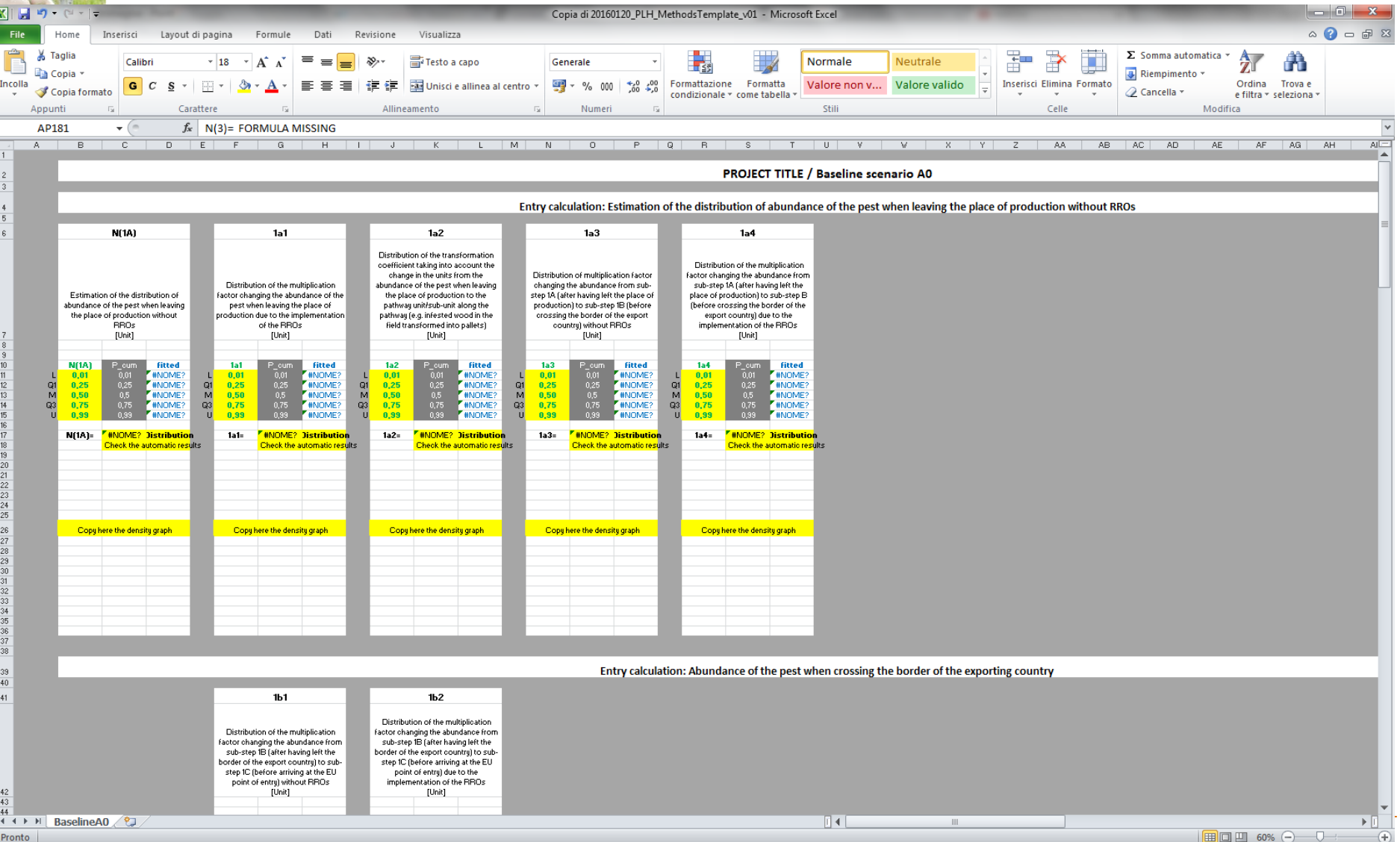
PILLAR 3: QUANTILE DISTRIBUTIONS

[m_1] Multiplication factor changing the abundance of the pest before leaving the place of production in the different scenarios (A_1…A_n)					
Quantile	**Value**				
	A_0	**m_1 for A_1**	**m_1 for A_2**	**m_1 for A_3**	**m_1 for A_n**
Lower	Not applicable				
Q1					
M					
Q3					
Upper					

Note: In a scenario, where additional measures are applied, this factor could be ≤ 1. In a scenario where measures are removed, this factor could be ≥ 1.

PILLAR 3: AGGREGATION OF PROBABILITIES

Tool for mathematical aggregation of probabilities (in @risk)



PROJECT TITLE / Baseline scenario A0

Entry calculation: Estimation of the distribution of abundance of the pest when leaving the place of production without RROs

N(1A)

Estimation of the distribution of abundance of the pest when leaving the place of production without RROs [Unit]

	N(1A)	P_cum	fitted
L	0,01	0,01	#NOME?
Q1	0,25	0,25	#NOME?
M	0,50	0,5	#NOME?
Q3	0,75	0,75	#NOME?
U	0,99	0,99	#NOME?

N(1A)= #NOME? Distribution
Check the automatic results

Copy here the density graph

1a1

Distribution of the multiplication factor changing the abundance of the pest when leaving the place of production due to the implementation of the RROs [Unit]

	1a1	P_cum	fitted
L	0,01	0,01	#NOME?
Q1	0,25	0,25	#NOME?
M	0,50	0,5	#NOME?
Q3	0,75	0,75	#NOME?
U	0,99	0,99	#NOME?

1a1= #NOME? Distribution
Check the automatic results

Copy here the density graph

1a2

Distribution of the transformation coefficient taking into account the change in the units from the abundance of the pest when leaving the place of production to the pathway unit/sub-unit along the pathway (e.g. infested wood in the field transformed into pallets) [Unit]

	1a2	P_cum	fitted
L	0,01	0,01	#NOME?
Q1	0,25	0,25	#NOME?
M	0,50	0,5	#NOME?
Q3	0,75	0,75	#NOME?
U	0,99	0,99	#NOME?

1a2= #NOME? Distribution
Check the automatic results

Copy here the density graph

1a3

Distribution of multiplication factor changing the abundance from sub-step 1A (after having left the place of production) to sub-step 1B (before crossing the border of the export country) without RROs [Unit]

	1a3	P_cum	fitted
L	0,01	0,01	#NOME?
Q1	0,25	0,25	#NOME?
M	0,50	0,5	#NOME?
Q3	0,75	0,75	#NOME?
U	0,99	0,99	#NOME?

1a3= #NOME? Distribution
Check the automatic results

Copy here the density graph

1a4

Distribution of the multiplication factor changing the abundance from sub-step 1A (after having left the place of production) to sub-step B (before crossing the border of the export country) due to the implementation of the RROs [Unit]

	1a4	P_cum	fitted
L	0,01	0,01	#NOME?
Q1	0,25	0,25	#NOME?
M	0,50	0,5	#NOME?
Q3	0,75	0,75	#NOME?
U	0,99	0,99	#NOME?

1a4= #NOME? Distribution
Check the automatic results

Copy here the density graph

Entry calculation: Abundance of the pest when crossing the border of the exporting country

1b1

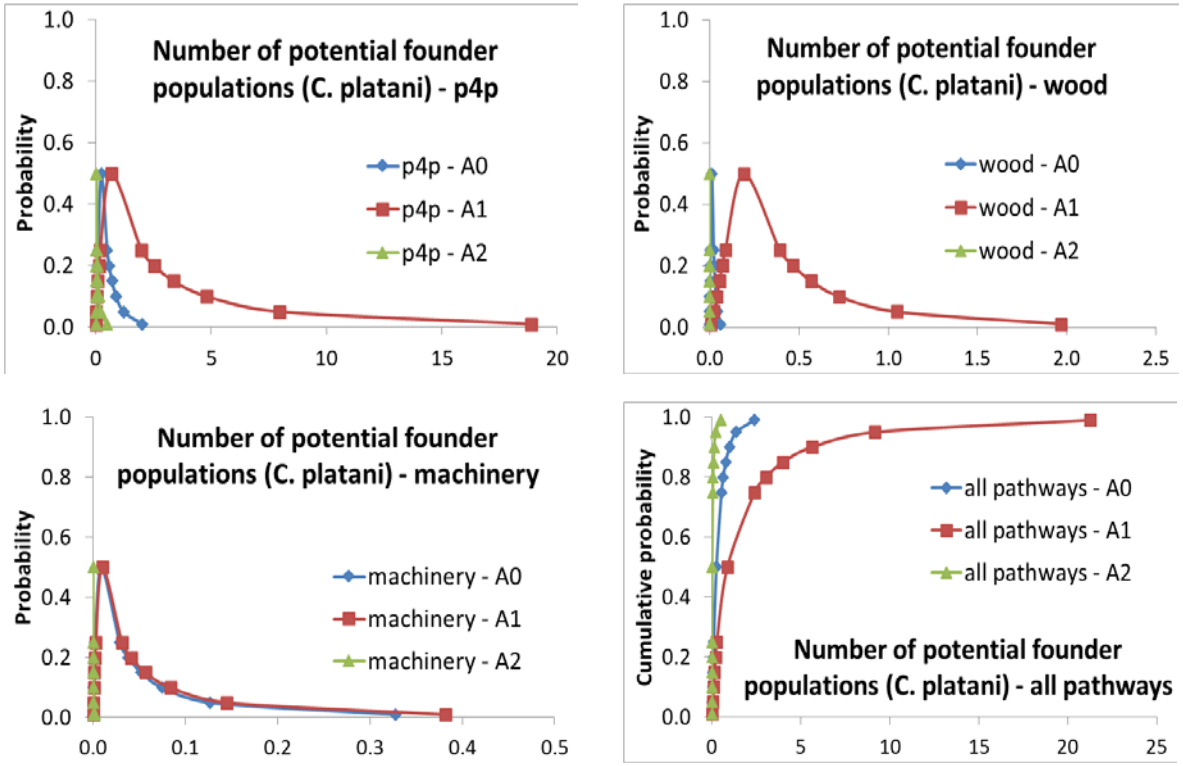
Distribution of the multiplication factor changing the abundance from sub-step 1B (after having left the border of the export country) to sub-step 1C (before arriving at the EU point of entry) without RROs [Unit]

1b2

Distribution of the multiplication factor changing the abundance from sub-step 1B (after having left the border of the export country) to sub-step 1C (before arriving at the EU point of entry) due to the implementation of the RROs [Unit]

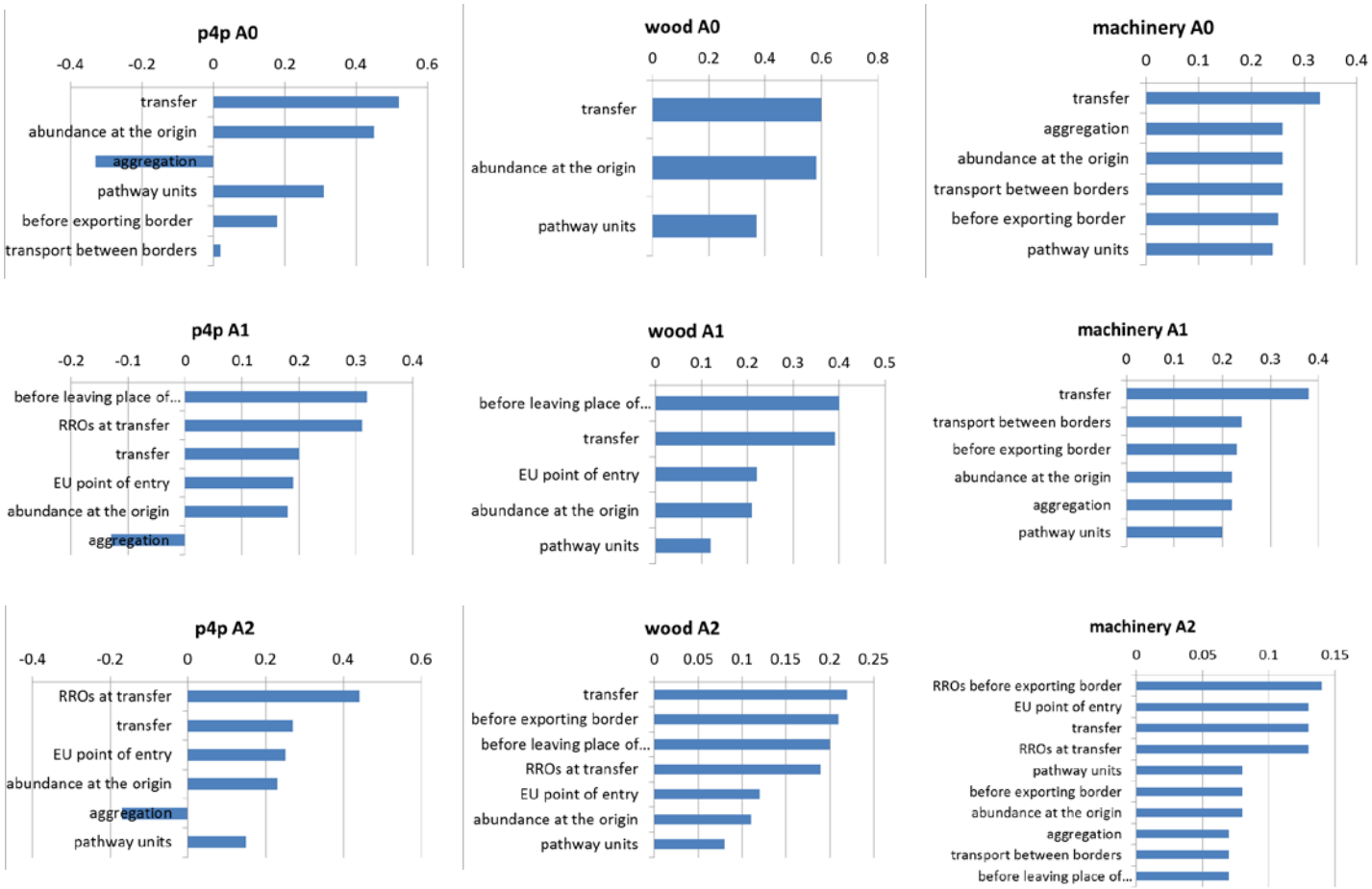
EXAMPLE: OUTPUT FOR ENTRY

Graph showing the provisional results **of the assessment of entry for *Ceratocystis platani*** expressed in terms of number of potential founder populations for the three scenarios (A0, A1 and A2), for each of the three different pathways of entry and for all the pathways combined.



EXAMPLE: OUTPUT FOR ENTRY

Graph showing the provisional **decomposition of the source of uncertainty** for the entry for *Ceratocystis platani* for the three scenarios (A0, A1 and A2), for each of the three different pathways of entry and for all the pathways combined.



APPLICATION OF THE NEW METHODOLOGY

- **Pilot studies**: «learning by doing»
  - *Ceratocystis platani*
  - *Cryphonectria parasitica*
  - Grapevine Flavescence dorée
  - *Ditylenchus destructor*

- First testing of the method by **September 2016**
  - Feedback from risk managers is important!

- **Second group of organisms** (deadline May 2017)
  - *Radopholus similis*
  - *Diaporthe vaccinii*
  - *Eotetranychus lewisi*
  - *Atropellis* spp.

STANDARDIZATION OF THE NEW METHODOLOGY

- **A set of tools**
  - Database
  - Step-specific models
  - Expert knowledge elicitation
  - Fiches for RROs
  - Calculation of RRO effects
  - Mathematical aggregation of probabilities distribution
  - Risk communication

- **A web-based platform**
  - Supporting the scenario definition for the assessment
  - Integration of tools and procedures
  - Generation of reports

CONCLUSIONS

- The PLH Panel develops a **fit for purpose quantitative risk assessment method** for plant pests providing:
  - Increased transparency of the RA process
  - Clear identification of the factors increasing the risk
  - More targeted choice of RROs, directly fitting into the RA

- **Risk managers and assessors interactions are essential:**
  - Proper description of scenarios in ToR (DG Santé; Standing committee for Plants Animals Food and Feed, (PAFF), Annexes Working Groups (AWGs))
  - Access to data from MSs (e.g. survey data)
  - Interactions during the risk assessment (DG Santé; AWGs)

THANK YOU FOR YOUR ATTENTION