

Introduction of the webinar and training activities

The concept of test validation in Plant Health

Webinar 1	What is test validation and why it matters for reliable diagnostics?	Monday 11 th January, 2 pm
Webinar 2	How to adopt a new test in your laboratory?	Friday 15 th January, 2pm
Webinar 3	The use and validation of on-site tests	Wednesday 20 th January, 2pm
Practical training session 1	Analysis of performance characteristics	Tuesday 26 th of January, 2pm to 4:30 pm
Webinar 4	How do companies handle quality control and validation of products and how will the EPDIA charter help in improving this task?	Monday 1 st of February, 2pm
Webinar 5	Why is communication on test selection between risk managers and diagnostic laboratories important ?	Monday 15th of February, 2pm
Practical training session 2	The use of kits: training and demonstration	Thursday 22 nd of April, 2pm

Why is communication on test selection between risk managers and diagnostic laboratories important ?

2021-02-15

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(Femke Van Den Berg (Fera))
Françoise Petter (EPPO)



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 773139

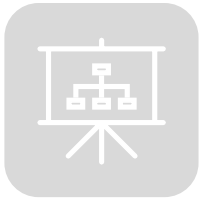


Poll 1

Are you a risk manager or a diagnostician?

select one answer

- Risk manager
- Diagnostician
- Other



Outline of the presentation

- **Recommendations from the European and Mediterranean Plant Protection Organization regarding communication between laboratories and risk managers**
- **Formalisation of testing programmes and communication needs**
- **Case study of current communication between laboratories and risk managers**

EPPO recommendations regarding communication between laboratories and risk managers

Françoise Petter



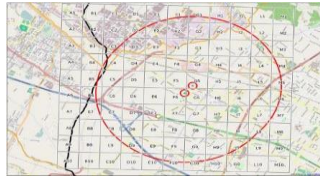
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Risk managers organize

Import inspection

Surveillance



Permanent rootstock mother plants



Permanent scion mother plants



Rootstock Scion



Grafted plants in nursery (spring until autumn)



Finished grafted plants ready for marketing



Certification of plant propagating material

EUROPEAN COMMISSION	
NOTIFICATION OF INTRODUCTION OF A COMMODITY FROM A THIRD COUNTRY	
1. COMMODITY Name: The fruit of scientific name: <i>Sesquid</i> Country: IL - Israel	4. IDENTIFICATION Identification number: 000-000
2. ORIGIN Country of origin: IL - Israel Country of production: IL - Israel	5. REGULATORY SERVICE OF THE IMPORTING COUNTRY Name: <i>plantprotection@agriculture.gov.il</i>
3. DESCRIPTION OF THE COMMODITY Botanical name: <i>Sesquid</i> Scientific name: <i>Sesquid</i> Common name: <i>Sesquid</i> Country: IL - Israel	6. IDENTIFICATION OF THE COMMODITY Name: <i>Sesquid</i> Scientific name: <i>Sesquid</i> Common name: <i>Sesquid</i> Country: IL - Israel
7. INTRODUCTION Date of introduction: 01/01/2000 Date of arrival: 01/01/2000	8. IDENTIFICATION OF THE COMMODITY Name: <i>Sesquid</i> Scientific name: <i>Sesquid</i> Common name: <i>Sesquid</i> Country: IL - Israel
9. IDENTIFICATION OF THE COMMODITY Name: <i>Sesquid</i> Scientific name: <i>Sesquid</i> Common name: <i>Sesquid</i> Country: IL - Israel	10. IDENTIFICATION OF THE COMMODITY Name: <i>Sesquid</i> Scientific name: <i>Sesquid</i> Common name: <i>Sesquid</i> Country: IL - Israel



STATE OF ISRAEL MINISTRY OF AGRICULTURE PLANT PROTECTION AND INSPECTION SERVICES	
1. Name and address of applicant Name: <i>Plant Protection Services</i> Address: <i>Plant Protection Services</i> Tel.: <i>052-5000000</i>	
2. Description of commodity Name: <i>Plant Protection Services</i> Address: <i>Plant Protection Services</i> Tel.: <i>052-5000000</i>	
3. Declaration of origin Country of origin: <i>IL - Israel</i>	
4. Declaration of destination Country of destination: <i>USA</i>	
5. Description of commodity Name: <i>Plant Protection Services</i> Address: <i>Plant Protection Services</i> Tel.: <i>052-5000000</i>	
6. Declaration of origin Country of origin: <i>IL - Israel</i>	
7. Declaration of destination Country of destination: <i>USA</i>	
8. Declaration of origin Country of origin: <i>IL - Israel</i>	
9. Declaration of destination Country of destination: <i>USA</i>	
10. Declaration of origin Country of origin: <i>IL - Israel</i>	
11. Declaration of destination Country of destination: <i>USA</i>	
12. Declaration of origin Country of origin: <i>IL - Israel</i>	
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14. Declaration of origin Country of origin: <i>IL - Israel</i>	
15. Declaration of destination Country of destination: <i>USA</i>	



Export inspection

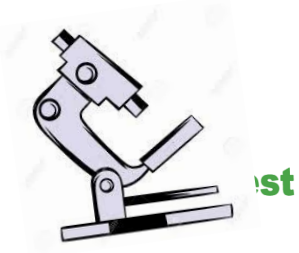
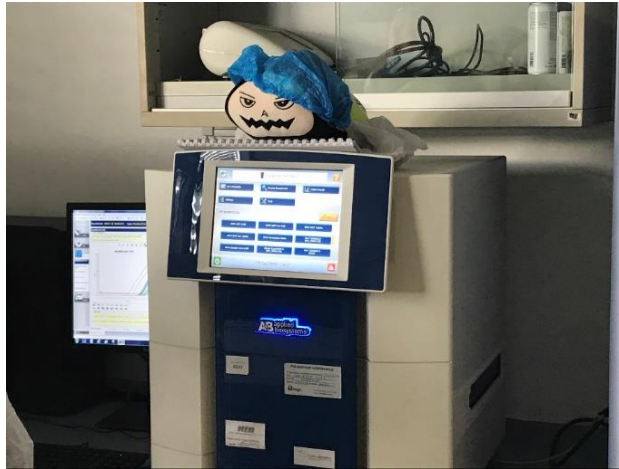
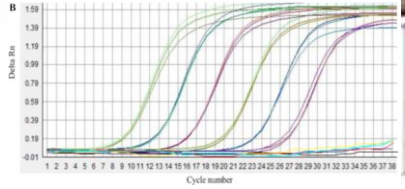
All these activities involve testing



Rapid detection and accurate diagnosis is essential



A	1	2	3	4	5	6	7	8	9
DAS-ELISA	+	+	+	-	-	-	-	-	-
RT-PCR	[Microarray image]								



Test(s) results may trigger phytosanitary action (with significant financial, social and environmental consequences)



Xylella fastidiosa (XYLE)

Eradication of *Xylella fastidiosa* in an almond
orchard of the Alicante province (Spain, 2018)
Courtesy: Camille PICARD (EPPO)

Eradication programmes



Huanglongbing in citrus groves in Florida.
<https://californiacitrusthreat.org/pest-disease/>

Consignments being rejected/destroyed at import or export



Diagnostic tests are used in different circumstances

- Routine survey(s) for the diagnosis of a pest widely established in a country
- General surveillance for pest status (e.g. demonstrate freedom)
- Surveillance for latent infestations by pests
- Surveillance as part of an official control or eradication programme
- Pest diagnostic associated with phytosanitary certification or certification of propagation material
- Routine diagnosis for pests in imported consignments
- Detection of a pest in an area where it is not known to occur
- Detection of a pest in a consignment originating in a country where the pest is declared to be absent.

Depending on the circumstances, different **test characteristics** are needed





Poll 2

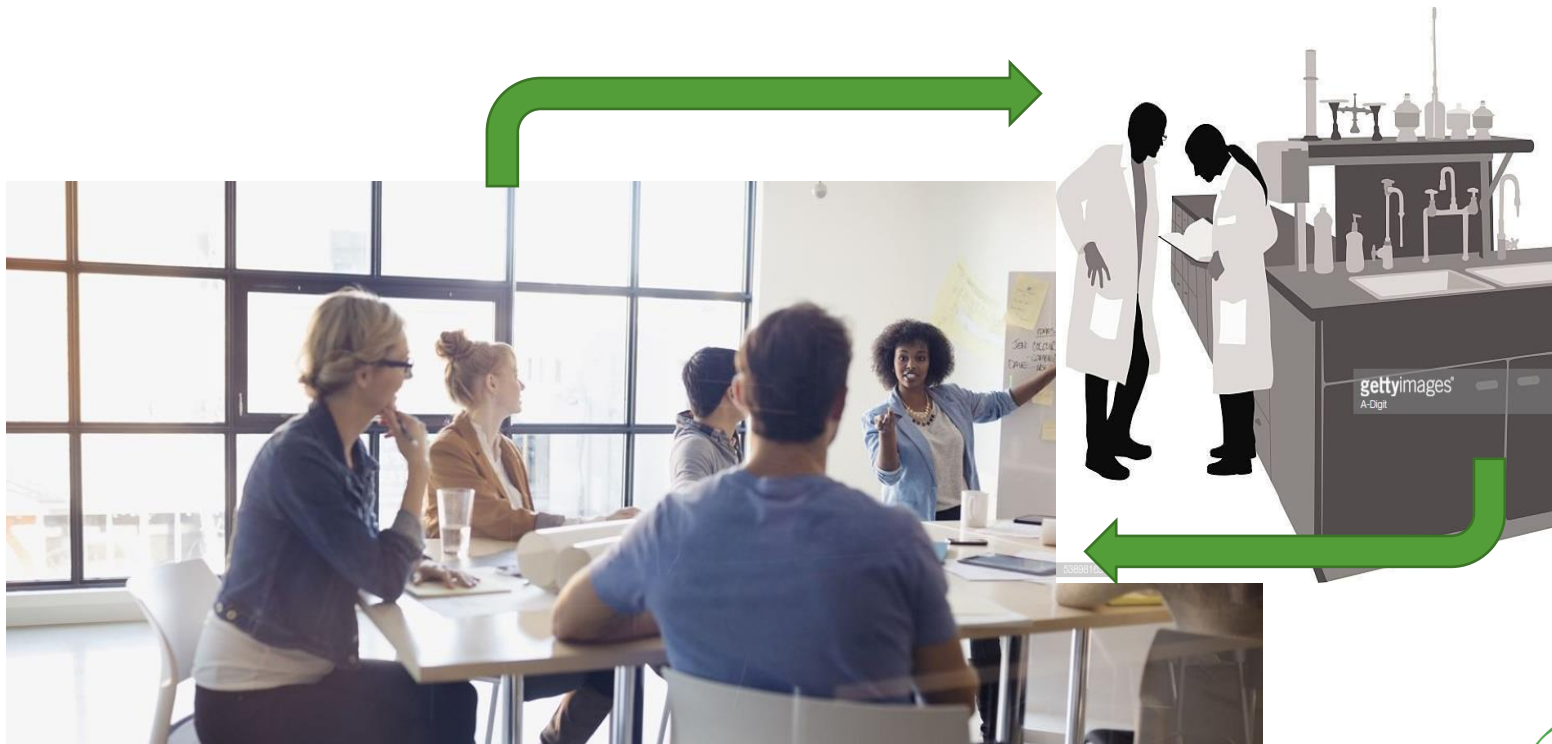
Do you discuss the choice of test(s) to be performed with the laboratory/NPPO?

select one answer

- Yes
- No
- Not concerned by this question

A specific section in the EPPO Standard PM 7/76 Use of EPPO Diagnostic Standards

**Need for communication between
diagnosticians and risk managers on
test selection**



General communication

Sample

Confidence in the outcome of a diagnosis depends on the size of the sample (and quality)



Information sharing for the selection of tests

As much relevant information as possible should be provided to the risk managers of the NPPO to help them make an informed decision.

Communication between laboratory experts and risk managers is needed to determine in advance the test(s) that are appropriate for the different circumstances.

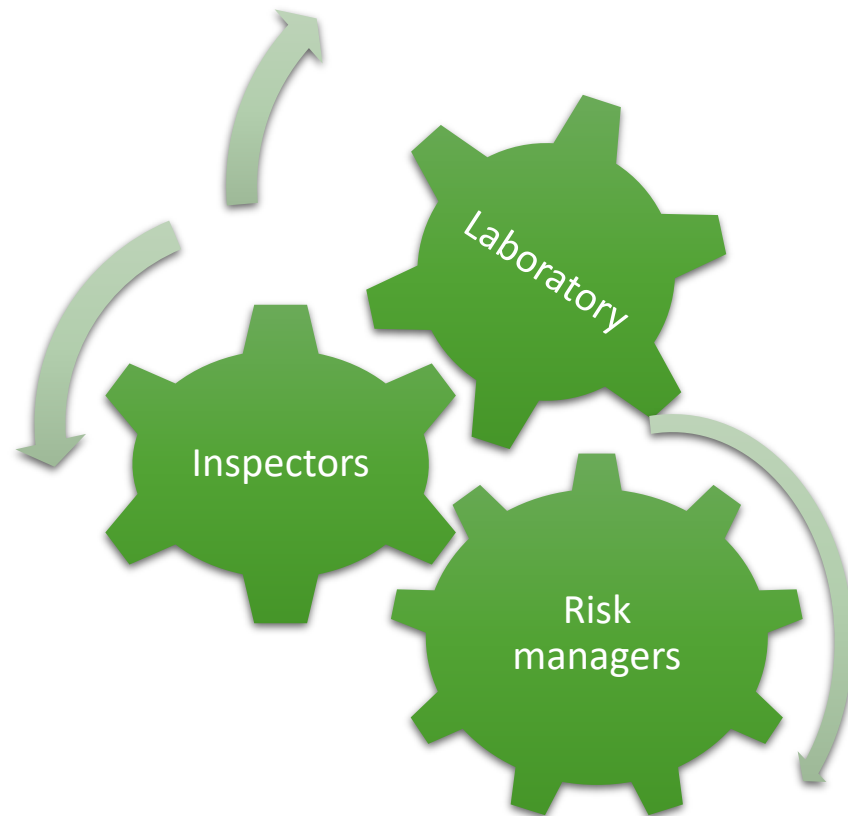
Communication with the risk managers on the level of uncertainty of a test result (risks of false positives or false negatives) taking into account the performance characteristics of the selected test.

Some examples

- For routine diagnosis or surveillance, speed and cost may be more critical than the level of analytical sensitivity or analytical specificity.
- Detection of a pest in an area where it is not known to occur, (e.g. detection of a pest for the first time in a laboratory), tests with a high level of analytical sensitivity, analytical specificity, repeatability and reproducibility may be required.
- Import of a suspected consignment of plants for planting into a pest-free area. **Phytosanitary action** may be decided **without a final confirmation of the identity of the pest** by the laboratory because of risk to an area. In such situations, the consequences of having a false-positive result of the preliminary test or a false negative result of the confirmatory test have to be evaluated.

How to achieve this?

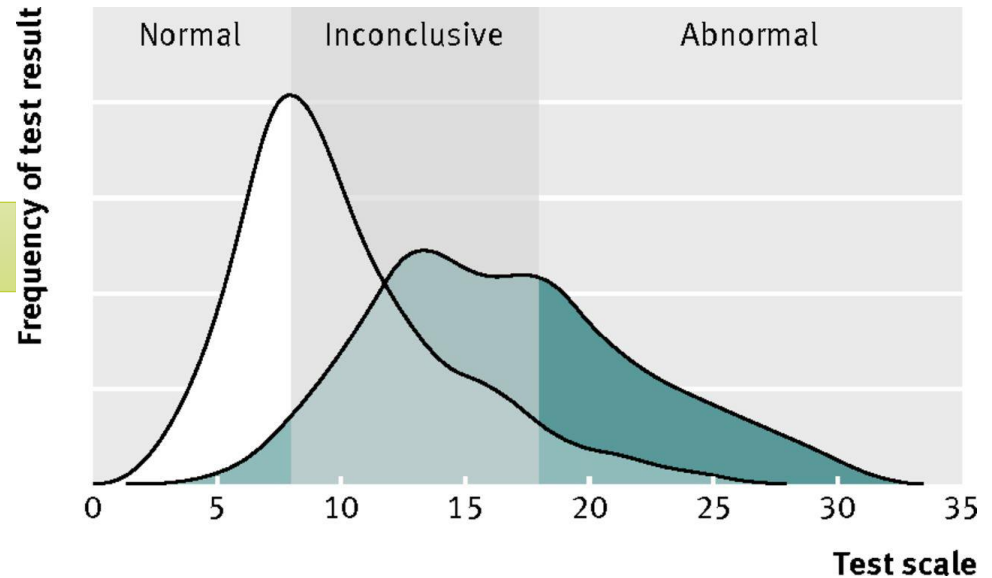
Some NPPOs establish multidisciplinary technical advice teams, emergency committees or contingency planning teams facilitating exchanges between risk managers, inspectors and laboratories, and this is recognized as important means of improving communication.





Communication on test results

Inconclusive test results



Viability of the pest: discussion between the laboratory and the NPPO needed to allow the NPPO to evaluate the risk and consequences of accepting a consignment infested with viable pests or refusing a consignment with only non-viable pests.

Formalisation of testing programmes and communication needs

Barbara Agstner



Original thinking... applied



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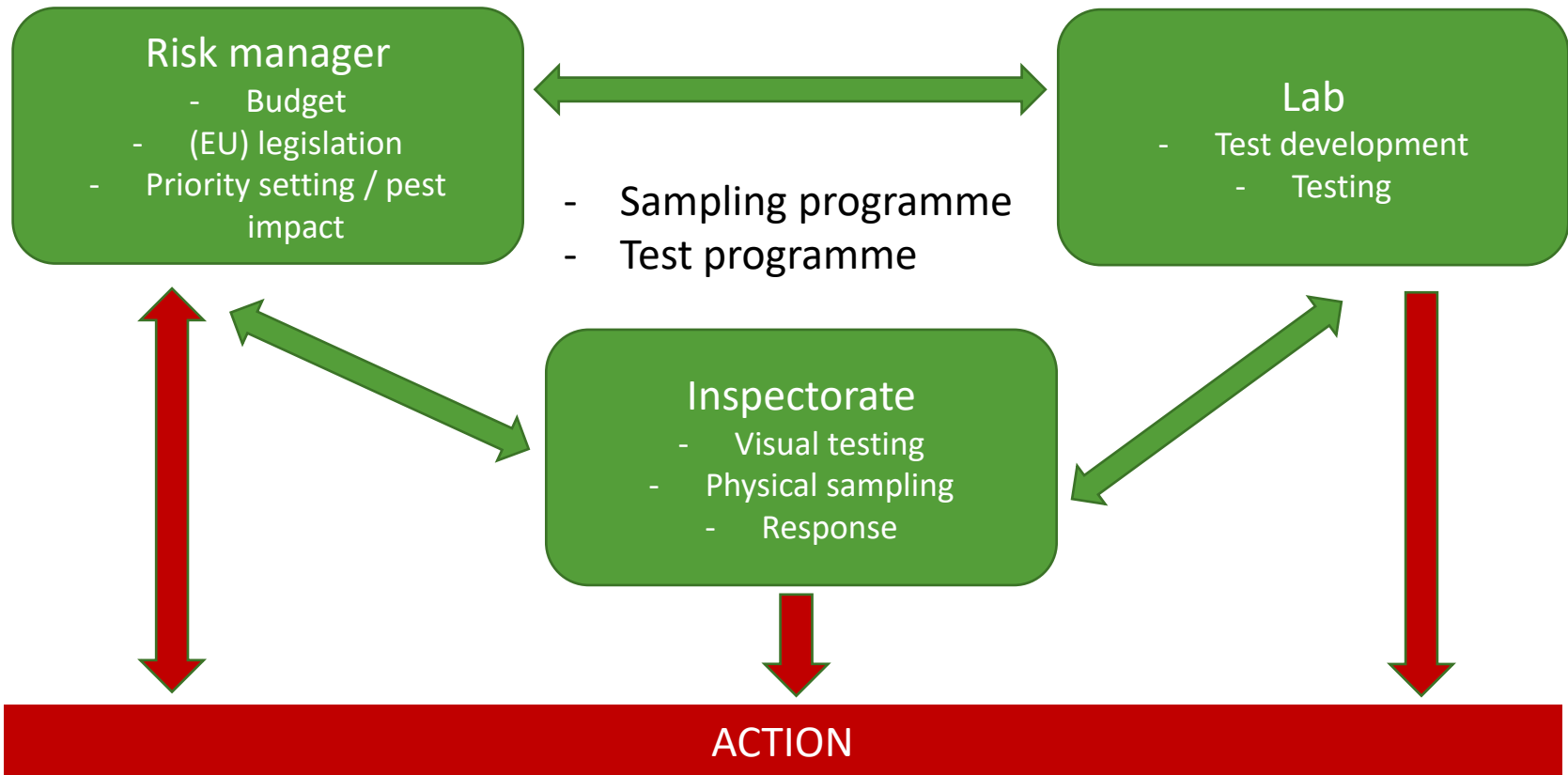


To what extent does communication take place?





Idealised communication and responsibilities





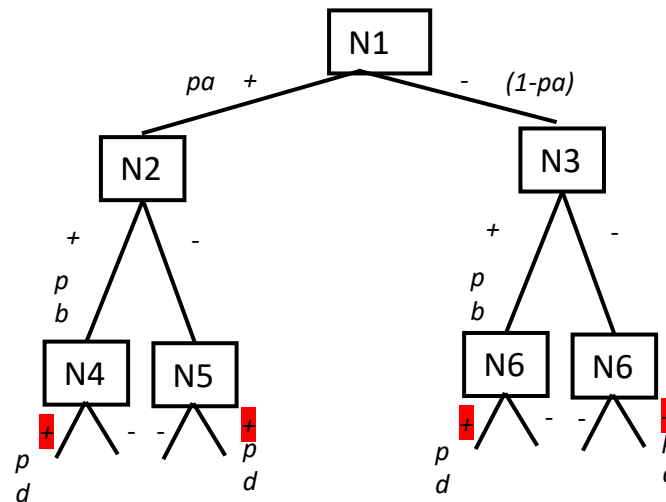
Programme performance and cost

No test performed; no disease detected

Visual assessment

Diagnostic test

Lab test



No test performed

False negatives = prevalence

False positives = 0

Test costs = £0

Impact costs: $FN * cost_FN$



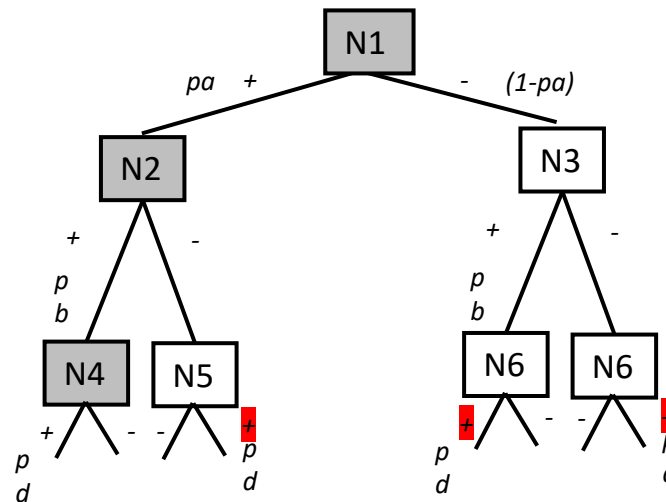
Programme performance and cost

Test symptomatic plants with LFD; when positive test confirm result with lab test

Visual assessment

Diagnostic test (LFD)

Lab test



No test performed

False negatives = $N1 * pa * (1 - pb) * pd + (1 - pa) * pd$

False positives = 0

Test costs = $N1 * cost_vis + N2 * cost_diag + N4 * cost_lab$

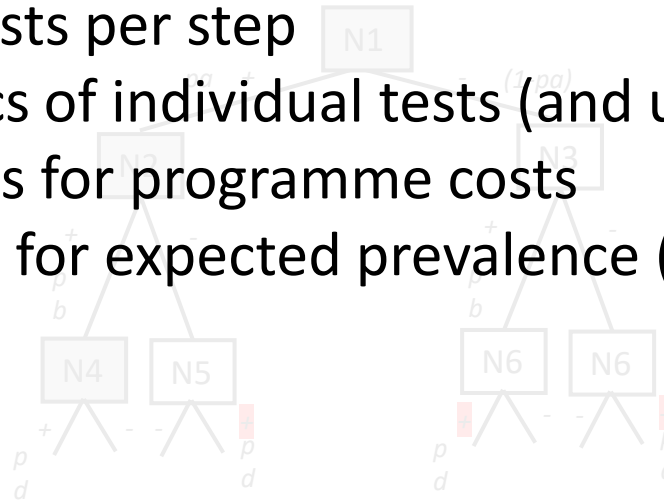
Impact costs: $FN * cost_FN + FP * cost_FP$



Programme performance and cost

Questions to explore:

- Number of steps in the programme
- Number of tests per step
- Characteristics of individual tests (and uncertainty)
- Consequences for programme costs
- Consequence for expected prevalence (damage)
- ... Lab test



No test performed

$$\text{False negatives} = N1 * pa * (1 - pb)$$

$$pa + (1 - pa) * pd$$

False positives = 0

$$\text{Test costs} = N1 * \text{cost_vis} + N2 * \text{cost_lab}$$

$$+ N4 * \text{cost_lab}$$

$$\text{Impact costs: FN} * \text{cost_FN} + \text{FP} * \text{cost_FP}$$

$$* \text{cost_FP}$$



Poll 3

For early detection of a high risk pathogen what test would you consider using for the initial survey (not the confirmatory testing)?

select one answer

- A high cost test with a diagnostic sensitivity (DSE) >95%
- A test with a diagnostic sensitivity (DSE) <85%, but which costs half of the more sensitive test
- None of the above
- Both of the above



Poll 4

For mapping current distribution what test would you consider using?

select one answer

- A high cost test with a diagnostic sensitivity (DSE) >95%
- A test with a diagnostic sensitivity (DSE) <85%, but which costs half of the more sensitive test
- None of the above
- Both of the above



Poll 5

For eradication or freedom from testing what test would you consider using?

select one answer

- A high cost test with a diagnostic sensitivity (DSE) >95%
- A test with a diagnostic sensitivity (DSE) <85%, but which costs half of the more sensitive test
- None of the above
- Both of the above

Case study of current communication between laboratories and risk managers

Barbara Agstner



Original thinking... applied

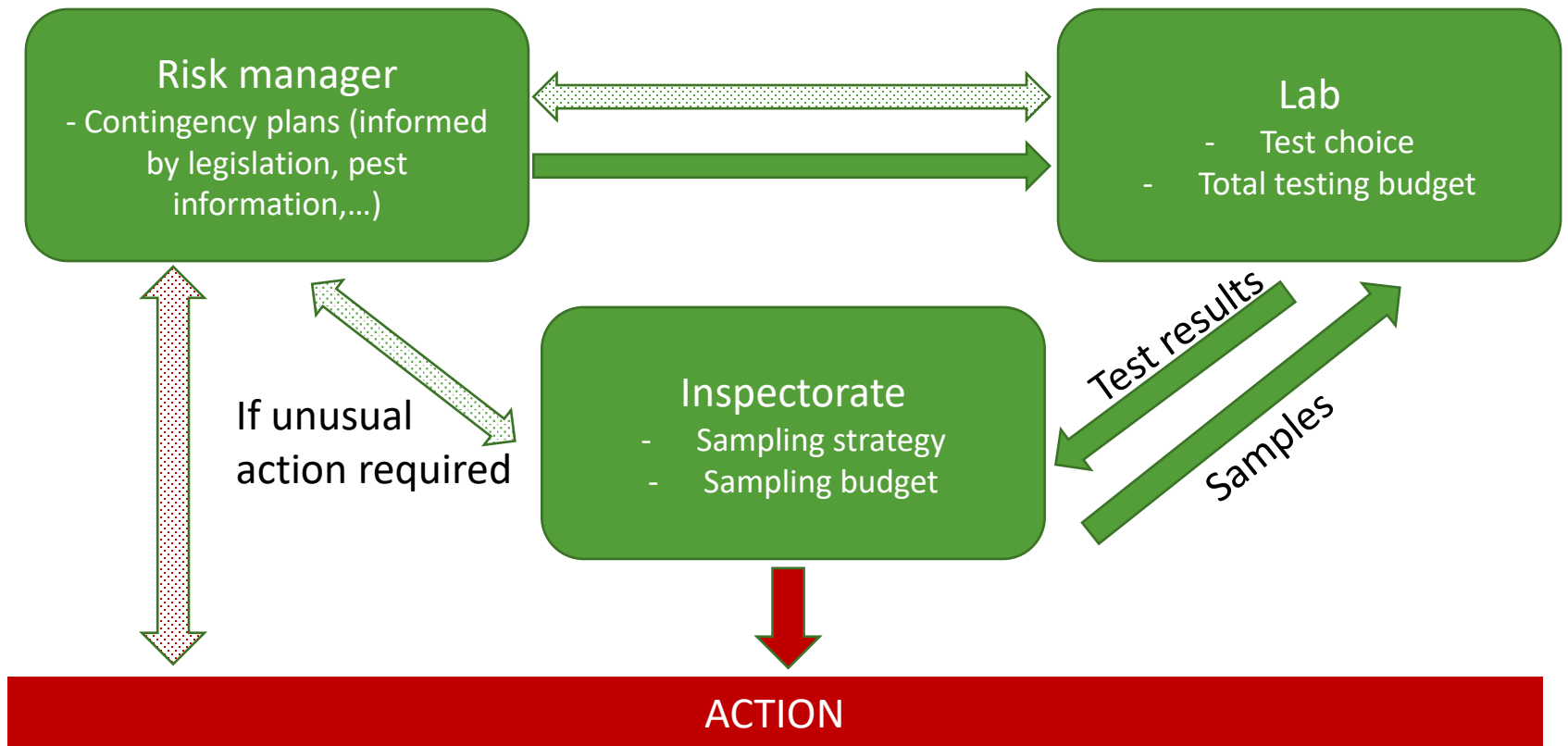


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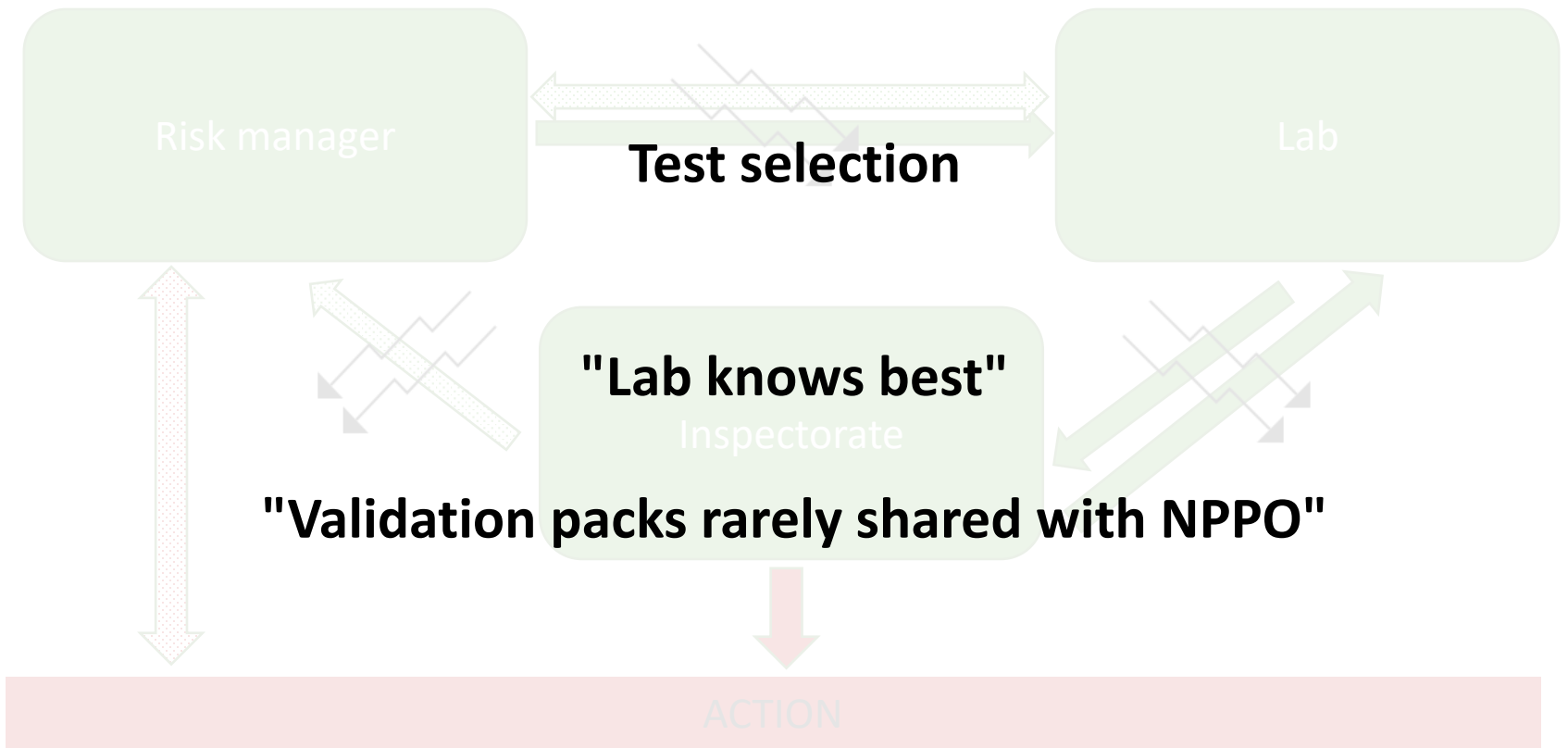


Actual situation (case study)





Actual situation (case study)





Poll 6

Which sensitivity / specificity metrics do you consider during test selection?

select one answer

- Analytical sensitivity and specificity
- Diagnostic sensitivity and specificity
- All of the above



Actual situation (case study)

When is sensitivity important?

Risk manager: ***for early detection***

- Scenario based
- Consequences of false negatives / false positives
- Can include details of the sampling strategy / prevalence "if I take 1000 potatoes from a shipment, how certain can I be..."

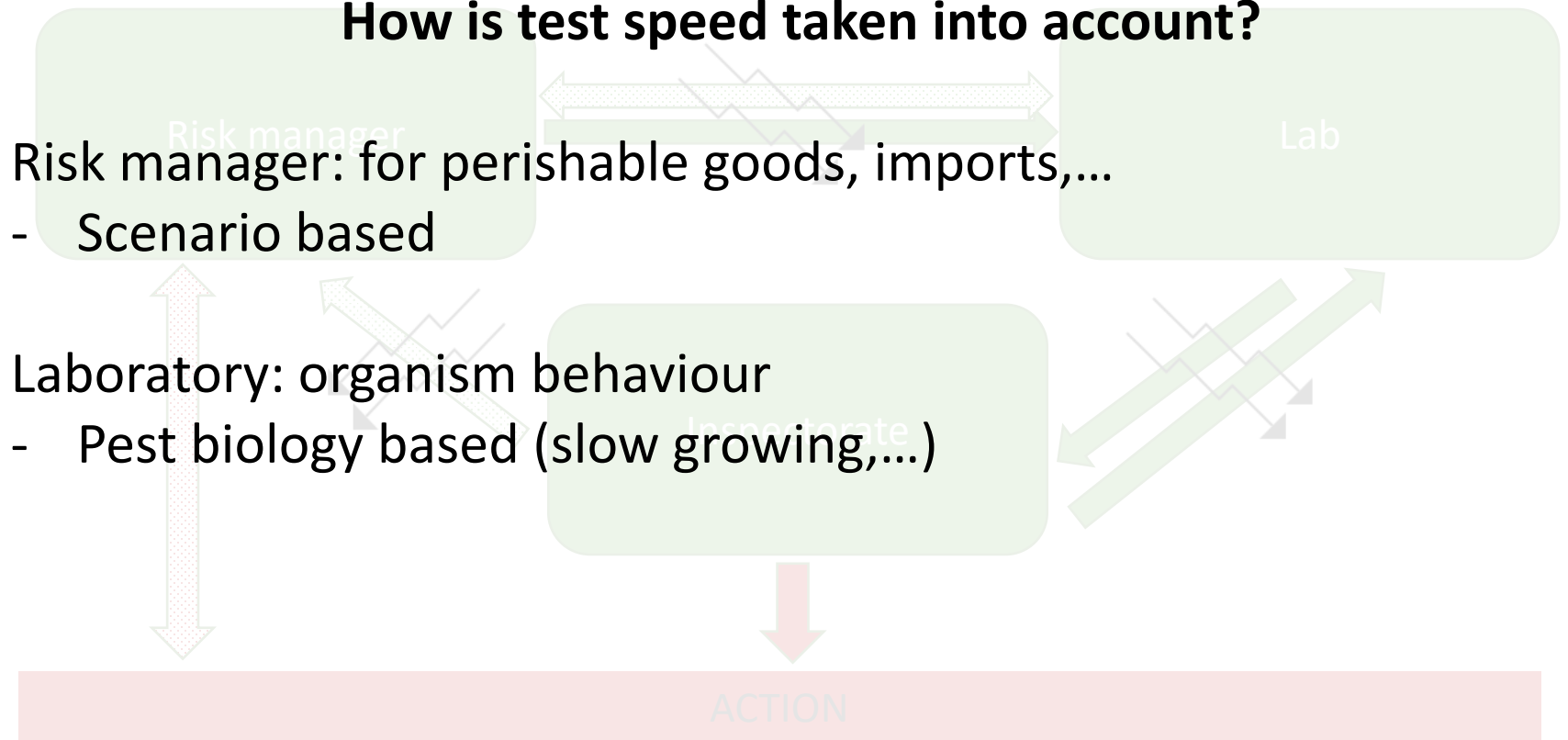
Laboratory: ***if there is not much DNA in the sample (screening)***

- Focus on analytical sensitivity (limit of detection)
- (Pest) biology based
- Implicit - visual inspection as "first test"



Actual situation (case study)

How is test speed taken into account?





Communication barriers

- Time
 - Complexity
 - Individual backgrounds
 - Language / definitions (analytical vs diagnostic)
 - Interpretation (validated for a specific purpose)
-
- Risk manager
- Lab
- Inspectorate
- ACTION



Poll 7

What is a validated test?

select one answer

- A test for which the analytical sensitivity (ASE) and analytical specificity (ASP) are known and defined by a large number of replicates
- A test for which the analytical sensitivity (ASE), analytical specificity (ASP), diagnostic sensitivity (DSE) and diagnostic specificity (DSP) are known and defined by a large number of replicates
- A test which has been shown to perform well for its intended use

Help us understand current test selection processes

- Your role involves test selection (risk manager or lab)
- Three scenarios – importance of test characteristics
- No right or wrong!
- Let us know in the satisfaction survey

Thank you 😊

Thank you for your attention!



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