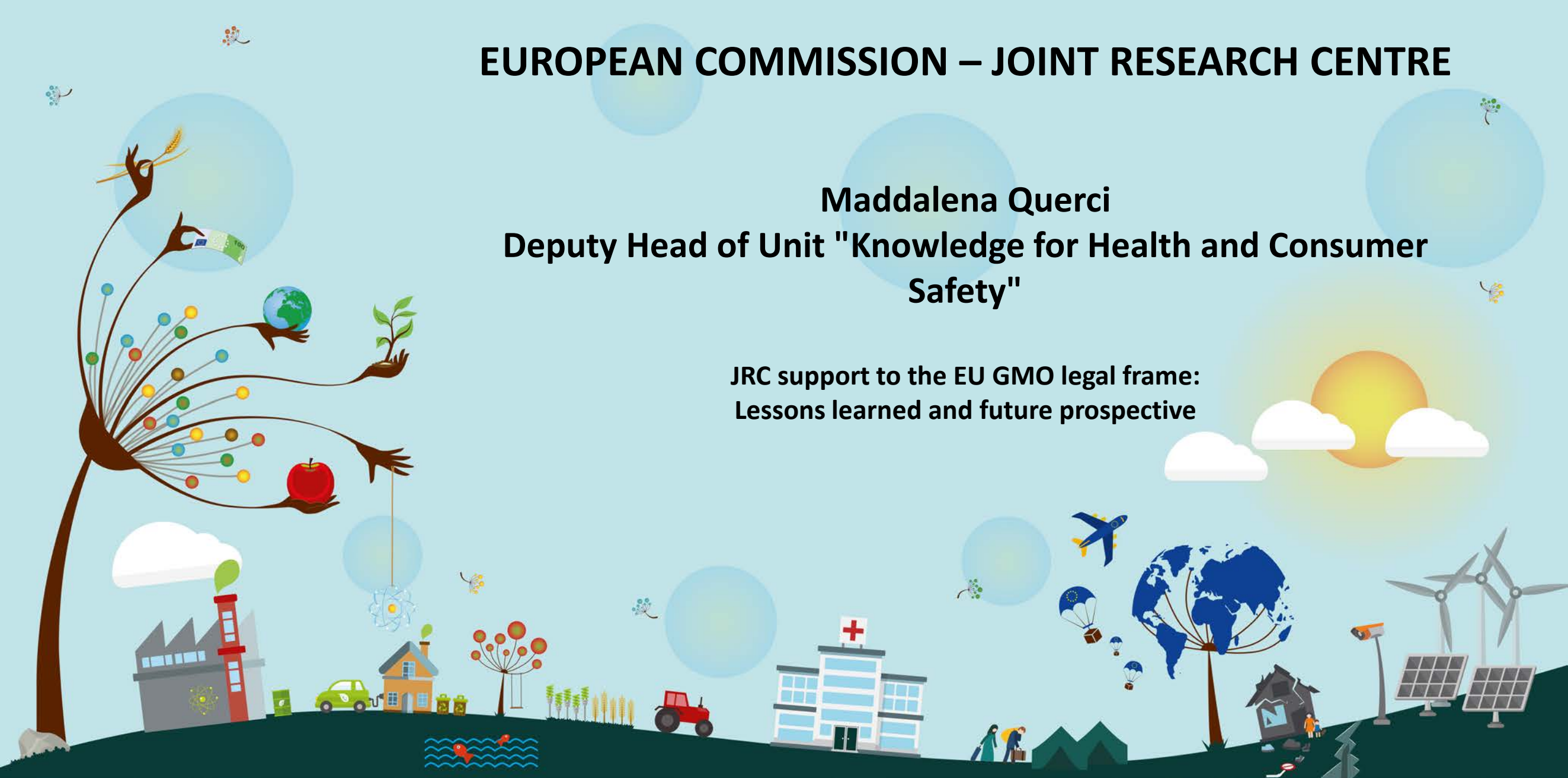


EUROPEAN COMMISSION – JOINT RESEARCH CENTRE

Maddalena Querci
Deputy Head of Unit "Knowledge for Health and Consumer Safety"

**JRC support to the EU GMO legal frame:
Lessons learned and future prospective**



Basic principles of EU GMO legal frame

1. Zero Tolerance for un-authorized GMOs
2. Authorisation for
 - a. cultivation,
 - b. and/or use in food
 - c. and/or use in feed
3. Authorisation requires
 - a. Risk assessment (**EFSA**: European Food Safety Authority)
 - b. Validated method for detection, identification and quantification of the authorised event (**EURL GMFF**: EU Reference Laboratory for GM Food and Feed)
 - c. Availability of Certified Reference Material (**CRM**)
4. Authorisation triggers labelling of GM-food or feed products
 - a. containing GMO as ingredient
 - b. with unavoidable GMO-contamination >0.9% of total ingredient

JRC role in support to EU GMO legal frame

EURL GMFF (mandate according to Reg. EC No 1829/2003)

Support to the GMO authorisation process

- Validation of methods for detection, identification and quantification of GM events as mandatory requirement for the authorisation process
- Provision of control samples
- Role in dispute settlements
- ad hoc policy advice



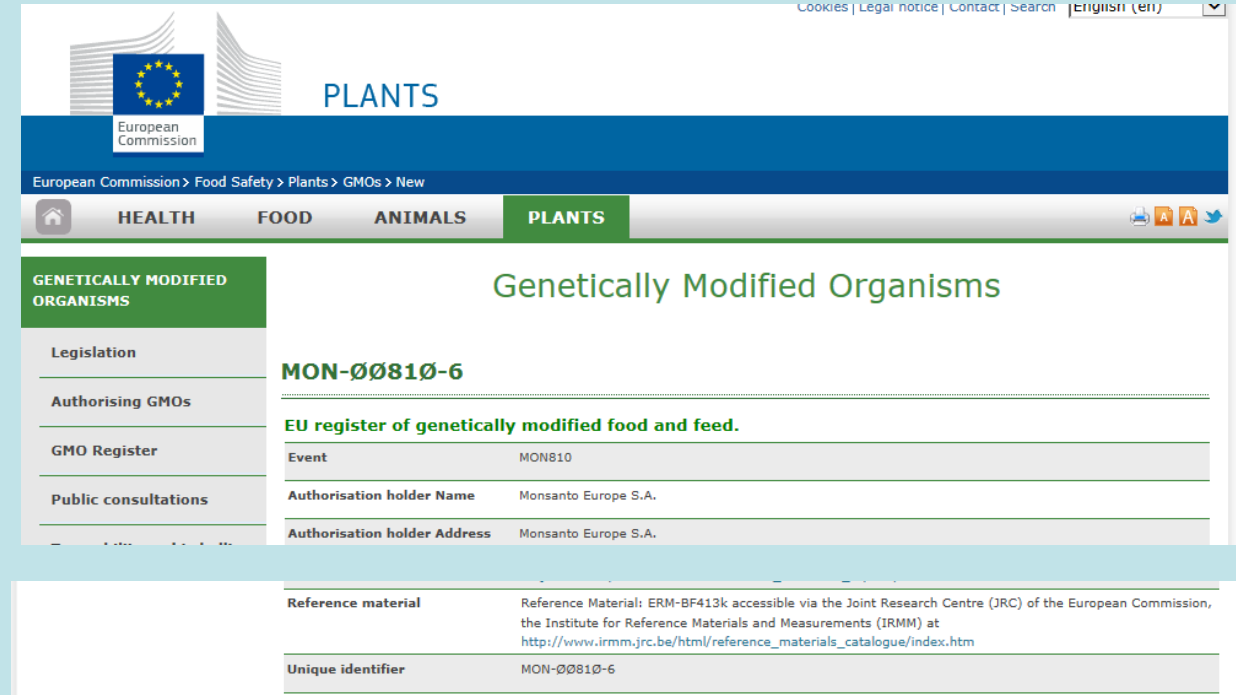
JRC role in support to EU GMO legal frame

Production of Certified Reference Materials

In Support to the implementation of
Regulation EC 1829/2003

EU Register of authorised GMOs

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm



The screenshot displays the 'EU Register of authorised GMOs' website. The header includes the European Commission logo and the word 'PLANTS'. A navigation bar shows 'HEALTH', 'FOOD', 'ANIMALS', and 'PLANTS' (selected). The main content area is titled 'Genetically Modified Organisms' and features a sidebar with links: 'Legislation', 'Authorising GMOs', 'GMO Register', and 'Public consultations'. The main content displays details for 'MON-00810-6', including the 'EU register of genetically modified food and feed', 'Event' (MON810), 'Authorisation holder Name' (Monsanto Europe S.A.), and 'Authorisation holder Address' (Monsanto Europe S.A.). A table at the bottom provides 'Reference material' and 'Unique identifier' information.

Reference material	Reference Material: ERM-BF413k accessible via the Joint Research Centre (JRC) of the European Commission, the Institute for Reference Materials and Measurements (IRMM) at http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm
Unique identifier	MON-00810-6

Status of dossiers & GMO authorisations

EURL GMFF Register of validated methods

<http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>

Validations completed 128

Validations in progress 16

EU Register of authorised GMOs

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

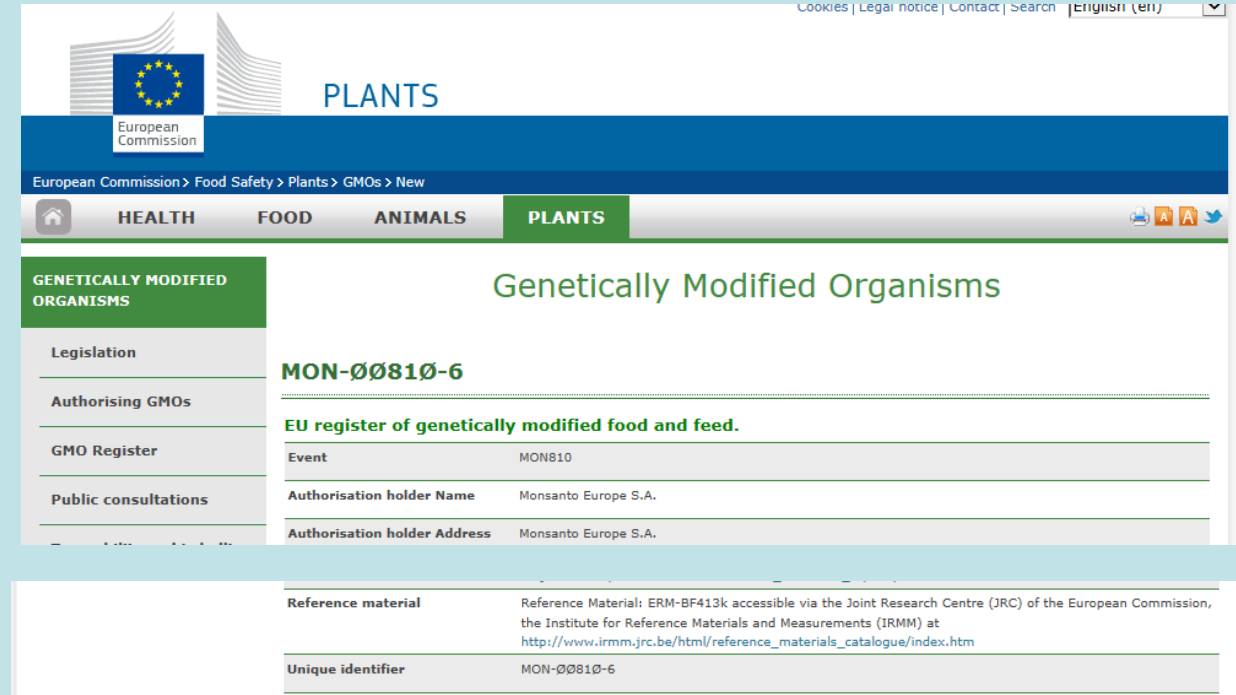
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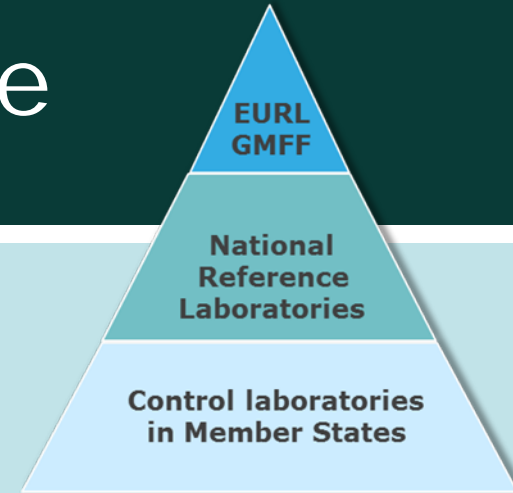
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Unique identifier	MON-00810-6

JRC role in support to EU GMO legal frame

EURL GMFF (mandate according to Reg. EC No 882/2004*)

Support to Feed and Food law & official controls

- Coordination of EU National Reference Laboratories (NRLs)
- Providing NRLs with reference analytical methods
- Coordinating the accurate application of analytical methods
- Organising **comparative testing** (CT) for NRLs and EU control laboratories
- *Ad hoc* support, e.g. for emergency situations (unauthorised GMOs on EU market)
- Provision of **training** support



* Replaced by Reg. (EU) 2017/625 of 15 March 2017

JRC training programme - *Objectives & Numbers*

2000 –

- >40 training courses on GMO analysis and EU-GMO policy (EU, global)
- Scientists from more than 300 laboratories trained worldwide
- Specific training for trainees initiatives
- External facilities as 'Training Sites'
- Didactic material



JRC role in support to EU GMO legal frame

Contribution to

The Better Training for Safer Food (BTSF) initiative



A DG SANTE training initiative for EU and non-EU country officials who undertake controls on food safety and veterinary issues

Areas covered

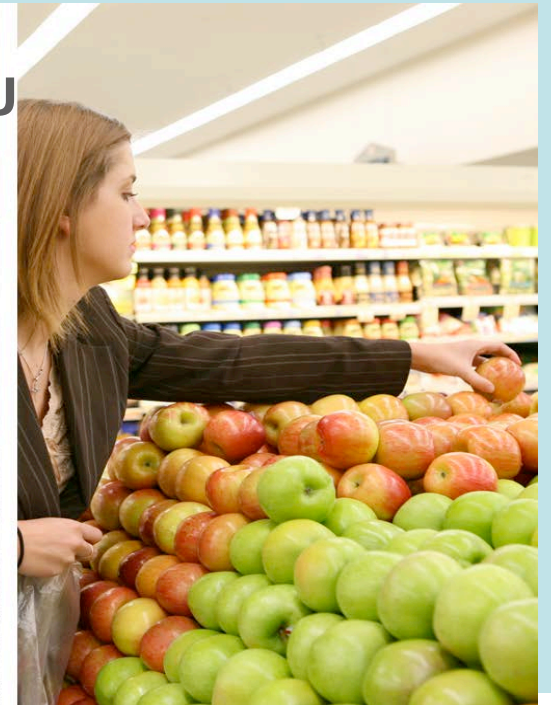
*Food law
Feed law
Animal health rules
Animal welfare rules
Plant health rules*

https://ec.europa.eu/chafea/about/index_en.htm
https://ec.europa.eu/food/safety/btsf_en

The Better Training for Safer Food Programme

BTSF General objectives

- Competence & awareness of EU rules amongst official control staff
- Uniform, objective and efficient controls throughout the EU
- High levels of consumer protection, animal health and welfare, and plant health
- Level playing field for food businesses
- Enhance trade of safe food



The Better Training for Safer Food Programme

BTSF specific objectives for non-EU countries

- Help non-EU countries to better understand and meet more easily EU rules/standards
- Reduce rejections at EU borders and facilitate access to the EU market
- Contribute to safer food for non-EU country consumers and a more diverse range of safe food products in the EU
- Enhance Sanitary and phytosanitary regulatory cooperation with non-EU countries
- Ensure fair trade with non-EU countries, particularly developing countries



The 'Global Harmonisation of GMO Analysis Support to Regional Networking' Project

- Launched in 2009 with full endorsement by DG SANTE under the Better Training for Safer Food Programme (BTSF)
- Complementary to EURL GMFF tasks under mandate of Reg. (EC) No 882/2004*

Objectives

- Share the networking experience & support the establishment of regional networks outside the EU
- Contribute to the enforcement of an harmonised approach in GMO analysis
 - Workshops
 - Training courses / knowledge sharing / didactic material



START of the
'Global Harmonisation of GMO Analysis Support to Regional Networking' Project

Focus on
Practical training courses on
The analysis of food & feed samples for
the presence of GMOs

Focus on
The regional dimension & Networking

Focus on
Thematic trainings
(+ networking)

1998 2000-2002 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018



'Networking the networks'



Eastern Europe

Timeline activities

2007 Bulgaria (ABI) in coll. with BSBA
Training Course on "The Analysis of Food and Feed Samples for the Presence of Genetically Modified Organisms"

Turkey
International workshop on harmonisation of GMO detection and analysis

Turkey
Training Course on "The Analysis of Food and Feed Samples for the Presence of Genetically Modified Organisms"

Croatia
2nd International workshop on harmonisation of GMO detection and analysis

Macedonia
International Workshop on Harmonisation of GMO Detection and Analysis

2009 2010 2011 2012 2013 2014 2015 2016 2017 2018

Training on "Practical aspects of regulatory GMO testing"

Training on "Practical aspects of regulatory GMO testing"

Training on "Implementation of quality systems/ ISO 17025 accreditation"

Italy
1st International Workshop of GMO Analysis Networking

Italy
2nd International Workshop of GMO Analysis Networking

Slovenia
Training WS on the use of digital PCR for GMO analysis

Belgium
Training WS on practical aspects for regulatory GMO control implementation



JRC training programme & Networking

Global - Country contacts



Achievements/Impacts

- Validated methods for detection – identification – quantification;
 - Reference materials
 - Agreed procedures for method uncertainty, reporting, ...
 - Global harmonization efforts
-
- No major issues of unapproved GMOs on the market – no trade disputes
 - Confidence in testing and in test systems
 - Strong capacity in DNA-based detection technologies

Policy intervention/action/decision ought to be based on solid, evidence-based scientific facts that have been obtained with adequately validated reference methodologies

Example of best practice: control of GMOs on the EU market

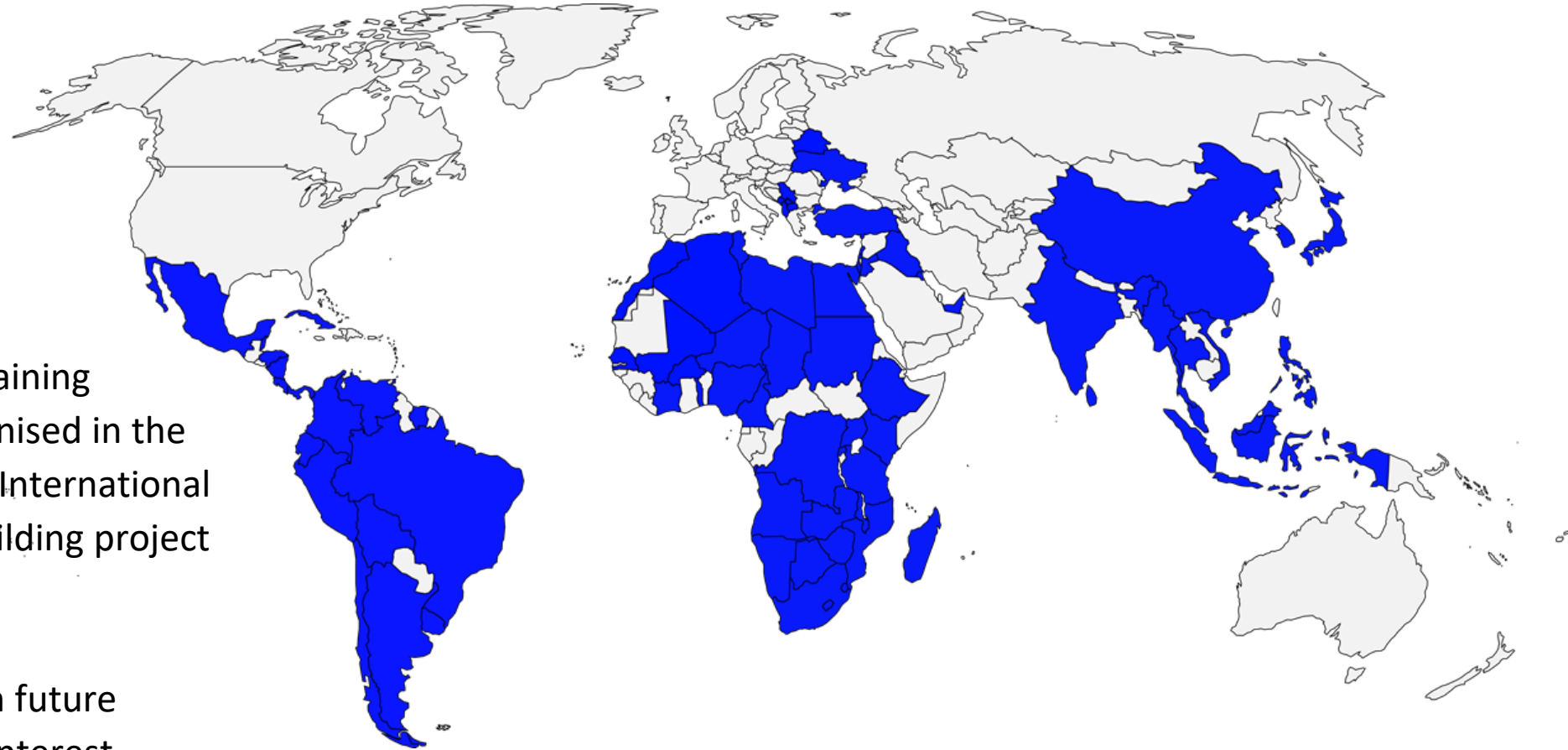
Does the same exist for more complex & urgent issues
e.g. bio-preparedness?

Not really...

Global network on GMO analysis - information update

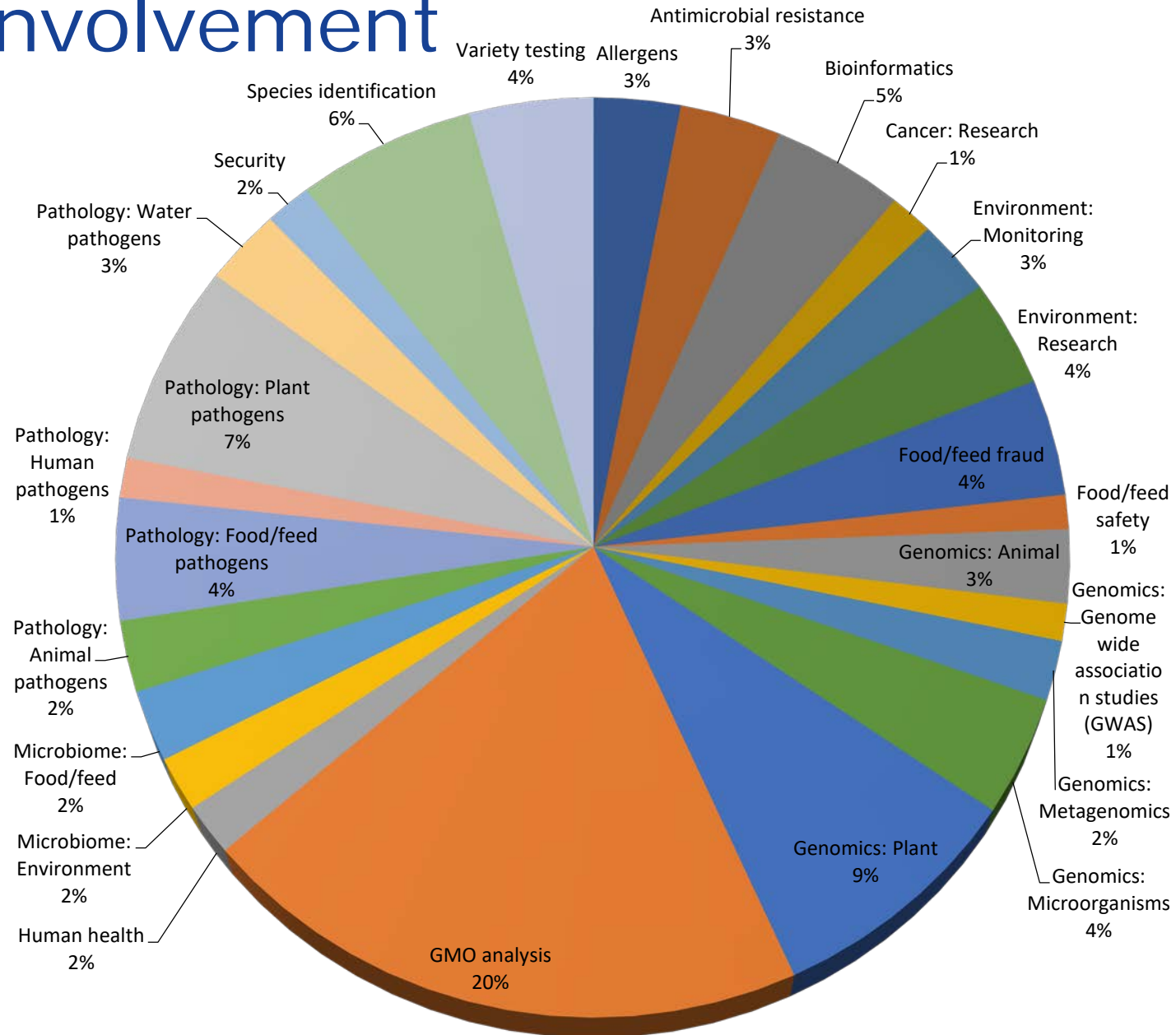


- Directed to all involved in training activities or workshops organised in the context of its Enlargement, International Collaboration & Capacity Building project
- Launched with the aim
 - To involve colleagues in future initiatives on topics of interest
 - To improve collaboration & to better focus on areas of mutual interest

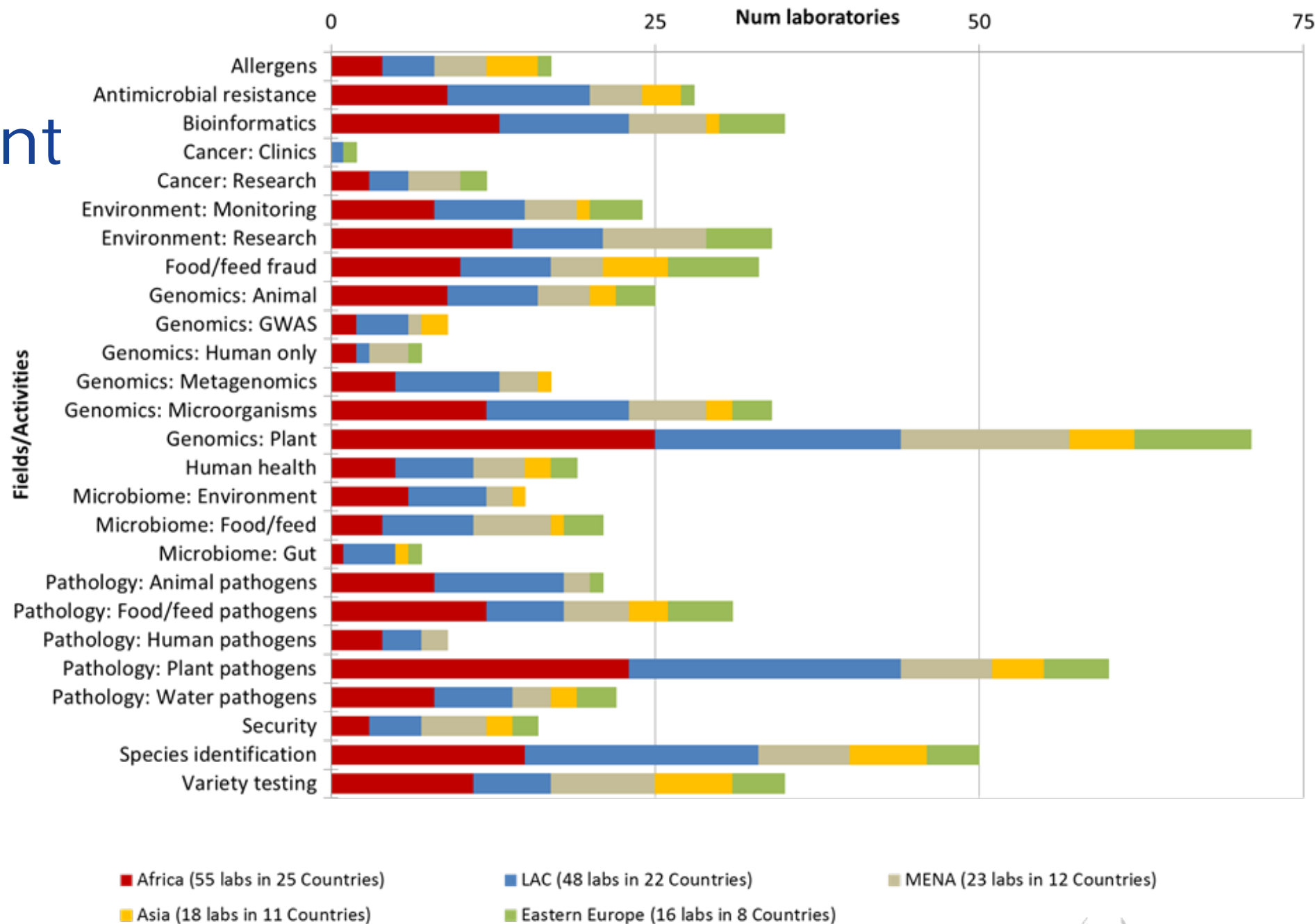


> 200 responses received

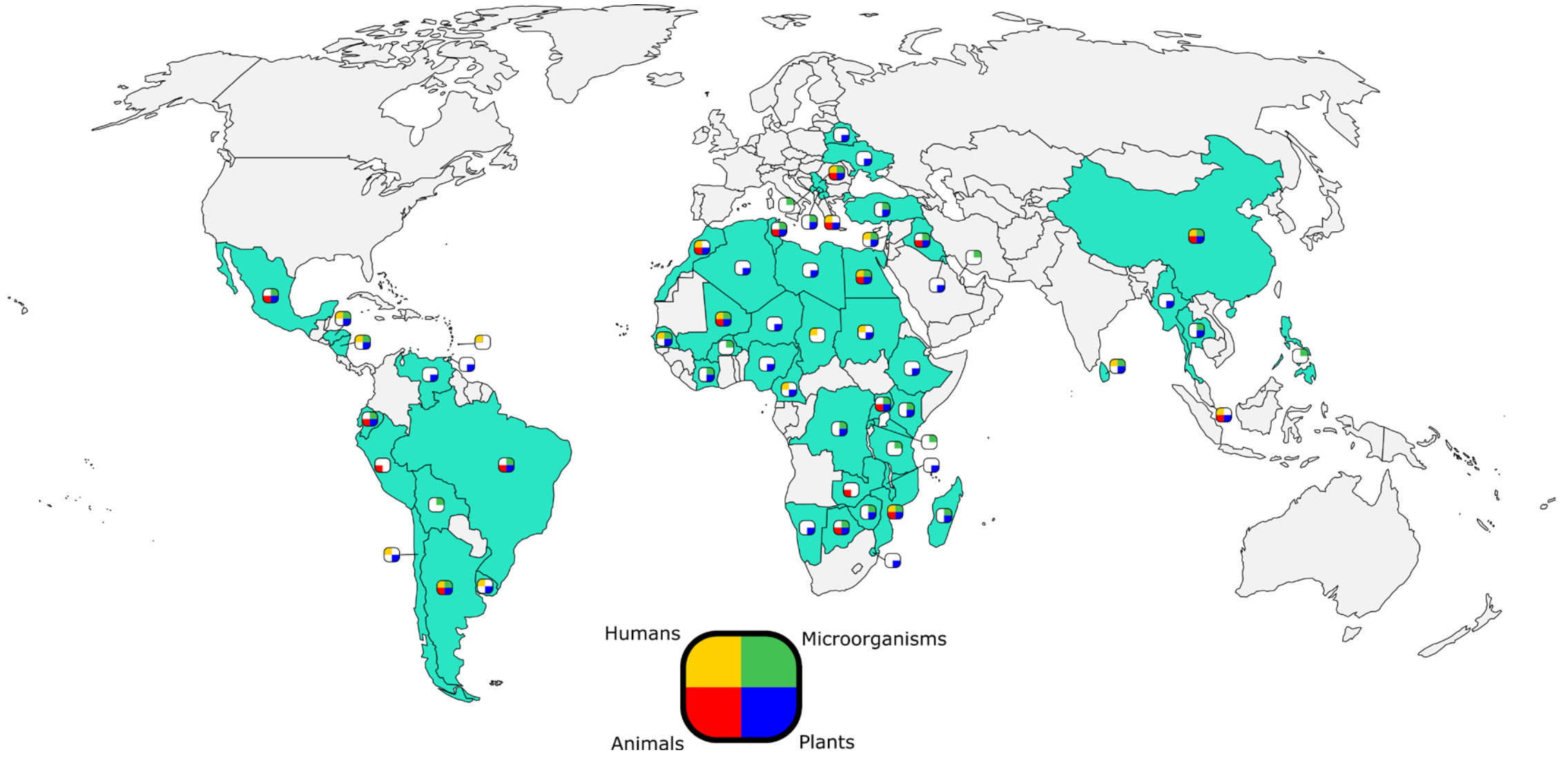
Areas of Involvement



Areas of Involvement by region

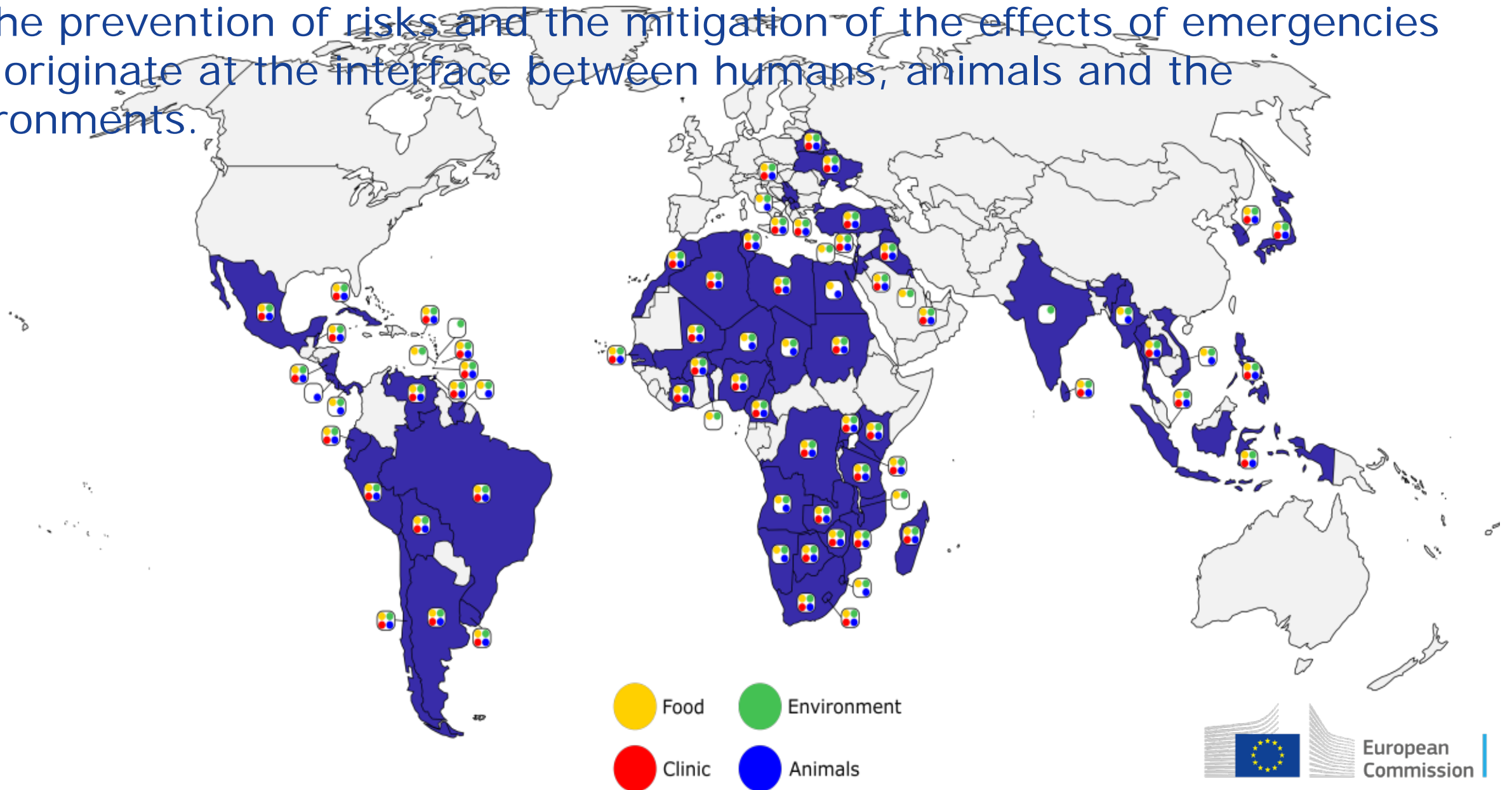


Countries involved in Genomics



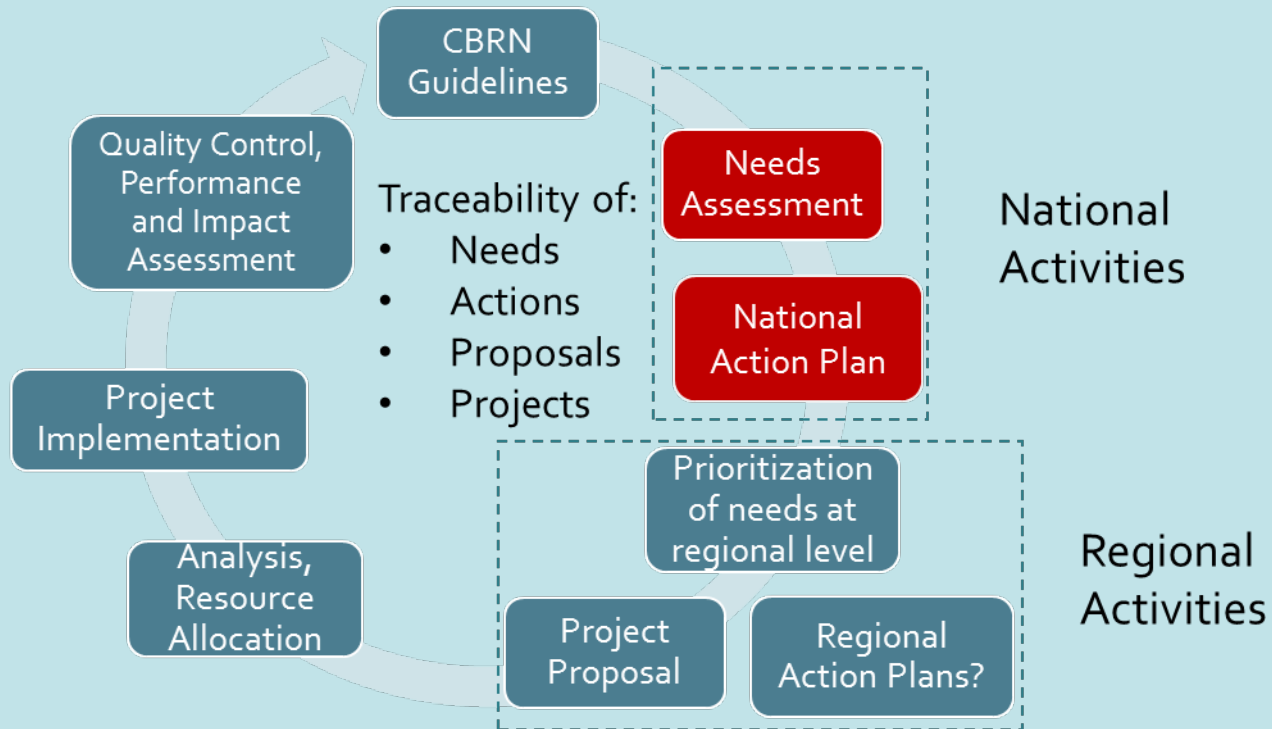
Bio-preparedness

The 'One Health' approach globally adopted as a potentially winning strategy for the prevention of risks and the mitigation of the effects of emergencies that originate at the interface between humans, animals and the environments.



The EU CBRN Risk Mitigation Centres of Excellence Initiative

CoE Cycle of Activities



The EU CBRN Risk Mitigation Centres of Excellence Initiative & INFORM

CoE - NAQ sections

1. Legislation and Regulations

2. CBRN Managing Authorities

3. Risk Mitigating Strategy

4. CBRN Prevention Measures

5. Detection of CBRN Material

6. Preparedness & Response

7. CBRN Recovery Measures

8. Sustainability

9. Strategic Trade Control



INFORM is a global, open-source risk assessment tool for humanitarian crises and disasters, *now including Epidemiological Model*;

It can support decisions about prevention, preparedness and response

<http://www.inform-index.org/>

... on Genome Editing...



Participants: experts in scientific and regulatory aspects of genome editing from

- EU and neighbouring countries
- Enlargement and Integration Action 2016
- Horizon 2020 Associated countries

Participants: experts in scientific and regulatory aspects of genome editing from

- ICGEB Member States
- JRC collaborating countries in the context of the Global Networking





Thank you
for your
attention !!