Regulation proposal on official controls

Objectives of the review of Regulation 882/2004

- Simplify and clarify the legal framework applicable official to control activities
- Consolidate the integrated approach across the agri-food chain in its widest meaning (food and feed, plant health, plant reproductive material, animal health, animal welfare)
- Ensure that MS appropriately resource control authorities through fees charged on operators

Main changes

- Broadened scopes (extended to plant health, plant reproductive material, animal by products, organic, plant protection products, GMOS and 'other official activities')
- Empowerments to lay down sector-specific rules.
- Common rules for all controls carried out on animals and goods entering the Union.
- Cost based mandatory fees for most official controls.
- New integrated information management system.

Extended scope

- Whole agri-food chain covered;
    - New sectors: plant health, plant reproductive material, animal by products, plant protection products.
    - Residues of veterinary medicines fully included.
- All activities;
    - Official controls (verification of compliance)
    - Other official activities (i.e. Survey, surveillance, monitoring, eradiction, containment and other disease control tasks)

‘Risk basis’ confirmed – Anti-fraud controls included

- Risk based official controls in all sectors allowing cross-sector prioritisation according to risks.

- Regular unannounced official controls directed at identifying intentional violations (fraud).

- Without prejudice to:

    - Frequency and modalities for controls in view of official certification
    - Specific control rules (e.g. Meat inspection)

Flexibility for sectorial needs: Specific rules on official controls

- Sector specific EU rules for official controls if needed (delegated acts):
  - Mandatory minimum frequencies.
  - Uniform controls modalities.
  - Mandatory measures in case of non-compliances.
  - Specific/additional tasks and responsibilities of competent authorities, etc.

Flexibility for sectorial needs: Specific rules on official controls

- Sector specific EU rules for official controls if needed (delegated acts):
- Food of animal origin
- Residues of certain substances in food and feed
- Animals, products of animal origin, germinal products, ABPs
- Animal welfare
- Plant Health
- Plant Reproductive Material (PRM)
- Genetically modified organisms (GMOs) and GM food and feed
- Plant Protection products
- Organic products, Traditional Specialities Guaranteed, Protected Geographical Indications, Protected Designations of Origin
- Newly identified risks in relation to food and feed

Competent authorities (CAs)

- Single authority responsible for coordination and contact in each of the sectors covered (already in the plant health sector)
- Delegation of official tasks (official controls and other official activities)
- Delegation to natural persons (e.g. veterinarians) (conditions adjusted)
- Special form of delegation for official laboratories: designation

Improved transparency on official controls (OCs)

CAs:

- Obliged to make available information on organisation /performance of OCs

- Obliged to publish timely and regularly:
  - type/ number/outcome of OCs
  - type/number of non-compliances
  - cases where measures taken and/or penalties imposed

- Allowed to publish outcome of OCs on individual operators (conditions apply)

- Entitled to publish rating of individual operators (scoring schemes – conditions apply)

Clarified and flexible rules on methods

Cascade of methods of sampling, analysis/ diagnosis/testing:

- Applicable to official controls and other official activities in all sectors
- 5 years transitional period for plant health and plant reproductive material
- Clarified and addition of methods validated by EURLs or NRLs
- Derogations to cascade in case of screening, targeted screening or other official activities

Clarified right for "second sampling"

- Right of operators to a supplementary expert opinion:
  - Always documentary review by another expert
  - Where relevant and technically feasible:
    - A sufficient number of samples taken for a supplementary expert opinion, or if not possible:
    - Another diagnosis, analysis or test of the sample

New rules for distance selling (on-line trade)

- Official sample even when competent authority does not identify itself.
- Operator to be informed and its rights preserved.

Clarified and adjusted rules for official laboratories (1)

- Requirements applicable to all official laboratories.

- 5 years transitional period for plant health laboratories to be accredited ISO/IEC 17025 .

- Scope of accreditation ISO/IEC 17025.

  = all the methods used by laboratory when operating as official laboratory
  = one or several methods / fixed or flexible scope – hence a flexible approach.

Clarified and adjusted rules for official laboratories (2)

- Permanent derogations to mandatory accreditation for laboratories carrying out:
  - Only detection of *Trichinella in meat*
  - Tests/analyses to verify compliance with plant reproductive material rules
  - Only diagnoses/analyses/tests within other official activities
  - Empowerment for permanent derogations to mandatory accreditation for all methods used (if accreditation already for representative/significant ones)

- Temporary derogations to mandatory accreditation by CA (new methods, emergency situations, emerging risks)

Modernised integrated controls at the borders (1)

- Common set of rules for all controls on animals and goods (subject or not to specific controls at borders) entering the Union.

- Risk based controls more broadly used.

- List of categories of animals and goods subject to controls at Border Control Posts (BCPs) + empowerments to:
  - Establish detailed lists (CN codes)
  - Exempt specific animals and goods (e.g. commercial samples, pet animals)

Modernised integrated controls at the borders (2)

- **Border control posts (BCP)**
  - BIPs, DPEs, points of entry become BCPs
  - Minimum requirements (common + sector specific by implementing acts)
  - Designation by MS (FVO visit in some cases)+ MS list
  - Withdrawal and suspension of the designation (clearer rules)

Modernised integrated controls at the borders (3)

- Common Health Entry Document (CHED)
  - Main purpose is that it will be Used:
    - By operators for mandatory prior notification of arrival
    - By CAs to record controls and decisions
    - By customs for all animals and goods subject to controls at BCPs
  - Duly completed CHED for customs procedures
  - Full electronic use.

Modernised integrated controls at the borders (4)

- Common set of rules for animals and goods subject to controls at BCPs
  - Documentary and identity checks (all consignments)
  - Risk based physical checks
  - Empowerment for establishment of reduced frequencies for identity checks
  - Checks at the BCP where the good is first presented (empowerment for establishment of exemptions)

Modernised integrated controls at the borders (5)

- Actions in case of:
  - Suspicion of non-compliance
  - Non-compliance
- Cooperation:
  - With other authorities (including customs) and operators.
  - To ensure access to relevant information and timely exchange (complete identification of consignments, decisions taken by authorities, etc.)

Better financing of official controls (1)

- General obligation for MS to resource adequately control authorities

- Cost-based mandatory fees for most official controls:
  - All controls on:
    - Registered/approved food and feed business operators
    - Operators subject to plant health controls and controls on PRM
  - Official certification controls
  - Official controls to grant/check approvals/ authorisations
  - Official controls at BCPs
  - Emergency measures (unless otherwise decided)
  - No fees for controls on organic products, PDO, PGI, TSG
  - No fees for controls on national disease control measures

Better financing of official controls (2)

- Full cost recovery .

- Possibility for MS to:
  - Establish fees at a flat-rate, or

  - Calculate them on basis of actual costs of each individual control and apply them to the operator(s) subject to this control

- *Bonus malus principles to lower fee level for compliant businesses (in case of flat-rate fee)*

Better financing of official controls (3)

- Exemption of micro-businesses (no cross subsidiary)
- Full transparency on:
  - How fees are calculated and used
  - How thrifty and efficient use of fees is ensured
- Consultation of operators on calculation methods of fees

Clear general rules for official certification

- General rules for official certification in all sectors
- Also for official certificates for exports
- Can take the form of:
  - 'Official certificates' issued by certifying officers
  - 'Official attestations' (official labels, marks, etc.) issued by operators under official supervision of CAs (or by CAs)

New reference laboratories and centres

- EU Reference Laboratories (EURLs) in new sector (plant health)
- Possibility to designate European Union reference centres for animal welfare and PRM
  - Tasks: support Commission and MS (scientific and technical expertise, training courses, dissemination of research findings and technical innovations, etc.)

Improved cooperation on cross-border enforcement

- Re-enforced and clarified rules to increase usability and effectiveness
- General principles (without undue delay, written notification)
- Assistance and cooperation channelled through liaison bodies (EU list) to enhance coordination
- Mandatory (instead of recommended) EU coordinated control plans (e.g. horse meat like cases)

Improved planning and reporting

- Planning (MANCP)
  - Single authority responsible for coordinating the preparation and ensuring coherence
- Reporting
  - Legal basis to progressively adopt standardised templates (taking into account existing requirements where appropriate)

Conditions for entry into the Union of animals and goods (1)

- Clarified and streamlined procedures for the establishment of general conditions for entry of animals and goods into the Union (delegated acts)

  - Where necessary to ensure that animals/ goods meet standards at least equivalent to EU ones

  - "Positive listing" of third countries - Rules for the approval of third countries

Conditions for entry into the Union of animals and goods (2)

- Establishment of special targeted measures (implementing acts)
  - For the entry of certain animals and goods into the Union
  - From certain TCs or regions
- Where health risk or serious widespread non-compliances with EU rules

Improved exchange of information

- Integrated information management system
  - Integrate all existing and future computerised systems (e.g. TRACES, RASFF, Europhyt, etc.)
  - Exchange among CAs and with the Commission (+ operators where appropriate)
  - Exchange of information, data, documents regarding official controls

Clarified and completed enforcement actions

- General principle: priority to health

- Actions in case of suspicion
  - Investigations to confirm or eliminate doubt
  - Increased official controls, official detentions

- Actions in case of non-compliance
  - Certain measures reformulated to adapt them to all sectors
  - List completed with further measures

Tougher penalties

- Sufficiently dissuasive financial penalties in case of intentional violations:
  - Higher than the economic gain expected from the violation (deterrent effect)

- Appropriate penalties in case of operators failing to cooperate and of official certification frauds

Main comments at the COPA- COGEGA CONFERENCE

1- General support towards the Commission's approach to clarify the official system of controls in Europe.

2- General support for risk-based system approach.

3- The fees system is the major concern of stakeholders.

4 - Important to find a common approach to fees systems in Europe in order to show benefits to MS Authorities and Stakeholders.

5 - Welcomes measures to deal specifically with food fraud .

6- Further clarification is needed on

- *transparency*
- *harmonisation of rules*
- *impact on third country trade (both import and export)*
- *administrative burden*
- *competitiveness of the private sector*
- *ensuring sufficient resources at MS authorities*

7- Important to keep in mind non food issues as well food .

8- Coordination between competent authorities both between and within Member State is crucial.

Main comments by Malta

- *Official comments sent on the accreditation of labs.*
- *Fees proposal - Goes against principle of self sustainability.*
- *Delegated and implementing acts*
- *Accreditation of labs – Comments sent in writing that Malta cannot be fully accredited.*
- *Certain areas of plant health are not covered in this official controls regulation and the Regulation needs more drafting as suggested by MS.*

Thank you for your attention!