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NOTE

from:	General Secretariat of the Council
to:	delegations
No. Cion prop.:	9464/13 + ADD 1 + ADD 2 - COM(2013) 265 final
Subject:	Proposal for a Regulation of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [….]/2013, and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation)

Delegations will find in Annex two presentations shown during the Working Party of Veterinary Experts (Public Health) and Phytosanitary Experts on 14 June 2013.

Regulation proposal on official controls

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Joint Working Party Veterinary Experts (Public Health) and Phytosanitary Experts
Council – Justus Lipsius - 13 and 14 June 2013

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Objectives of the review of Regulation 882/2004

- **Simplify and clarify** the legal framework applicable to official 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

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Main changes

- Broadened **scope** (extended to plant health, plant reproductive material, animal by products 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**

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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, eradication, containment and other disease control tasks)

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"Risk basis" confirmed – Anti-fraud controls included

- **Risk based official controls in all sectors** allowing cross-sector prioritisation according to risks
- Regular unanounced 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)

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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.

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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

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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

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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)

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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

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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 dignosis, analysis or test** of the sample

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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

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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

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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 <u>all</u> methods used** (if accreditation already for representative/significant ones)
- **Temporary derogations to mandatory accreditation** by CA (new methods, emergency situations, emerging risks)

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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)

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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)

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Modernised integrated controls at the borders (3)

- **Common Health Entry Document (CHED)**
  - 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**

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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)

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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.)

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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

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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)

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Better financing of official controls (3)

- **Exemption of micro-businesses** (no cross subsidiation)
- 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

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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)

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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.)

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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)

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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)

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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

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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

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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

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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

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Tougher penalties

- **Sufficiently dissuasive financial penalties** in case of intentional violations:

  → Fines to be set at a level which offsets the economic gain expected from the violation (**deterrent effect**)

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

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Thank you for your attention!

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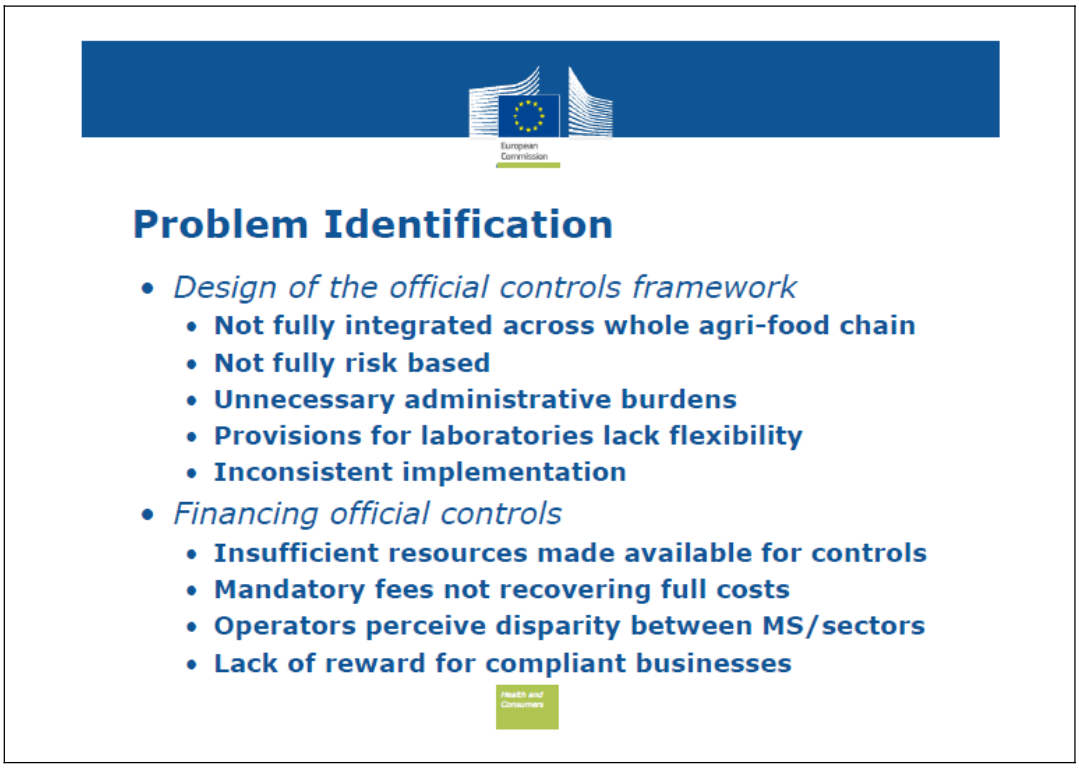
European Commission
Commission proposal on official controls – Impact Assessment
DG Sanco E5
European Commission
14 June 2013
Health and Consumers


European Commission
Problem Identification
Design of the official controls framework
Not fully integrated across whole agri-food chain
Not fully risk based
Unnecessary administrative burdens
Provisions for laboratories lack flexibility
Inconsistent implementation
Financing official controls
Insufficient resources made available for controls
Mandatory fees not recovering full costs
Operators perceive disparity between MS/sectors
Lack of reward for compliant businesses
Health and Consumers


European Commission
Commission proposal
• Integrate PH, PRM and ABP into common framework
• Streamline rules on:
- border controls for animals and goods from third countries subject to controls at borders
- residues of veterinary medicines
• Align to the risk-based approach
• Strengthen control-coordination between MS
• Simplify provisions for official laboratories
• Repeal redundant legislation
• Expand mandatory fees to most of OC/sectors
• Full cost recovery of mandatory fees
Health and Consumers


European Commission
Micro-enterprises
• Micro-enterprises exempted from mandatory fees
• In line with Commission policy *Minimizing regulatory burden for SMEs - Adapting EU regulation to the needs of micro-enterprises*
"micro-enterprises should in principle be excluded from regulatory burdens, unless the necessity and proportionality of their being covered can be demonstrated"
Health and Consumers