Official Controls Regulation:
A new framework for better and integrated controls for animals, food and feed in the EU

Meeting with stakeholders on delegated and implemented acts related to entry into the Union

10/10/2018

DG SANTE - Unit G3
Official Controls and eradication of diseases in animals
Key principles of the new regulation

- risk-based approach
- broader scope
- transparency
- alignment (simplification)
- efficiency
## Structure of Regulation 2017/625 (OCR)

<table>
<thead>
<tr>
<th>General Principles</th>
<th>Articles 1 – 15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject matter, scope &amp; definitions, Competent Authorities general requirements</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sector Specific Requirements</th>
<th>Articles 16 – 27</th>
</tr>
</thead>
<tbody>
<tr>
<td>e.g. Products of animal origin, residues, animal welfare, plant health, GMOs, plant protection products, organic production, new risks</td>
<td></td>
</tr>
</tbody>
</table>

### Articles

<table>
<thead>
<tr>
<th>Article</th>
<th>Provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>28–33</td>
<td>Delegation of tasks</td>
</tr>
<tr>
<td>34–42</td>
<td>Sampling, analyses, tests + Diagnoses</td>
</tr>
<tr>
<td>43–76</td>
<td>IMPORT CONTROLS</td>
</tr>
<tr>
<td>77-91</td>
<td>Financing OC + official certification</td>
</tr>
<tr>
<td>92-101</td>
<td>EURs EURCs</td>
</tr>
<tr>
<td>102–108</td>
<td>Administrative Assistance + Cooperation</td>
</tr>
<tr>
<td>109-115</td>
<td>Planning + Reporting</td>
</tr>
<tr>
<td>116–124</td>
<td>Commission Controls</td>
</tr>
<tr>
<td>125–129</td>
<td>Conditions for entry into the EU</td>
</tr>
<tr>
<td>130</td>
<td>Training (BTSF)</td>
</tr>
<tr>
<td>131–136</td>
<td>IMSOC</td>
</tr>
<tr>
<td>137–141</td>
<td>Enforcement</td>
</tr>
</tbody>
</table>

### Common Provisions

- Articles 142 – 167
<table>
<thead>
<tr>
<th>Unit in charge</th>
<th>Topics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certification for ship suppliers</td>
<td>List of animals and goods, with CN codes</td>
</tr>
<tr>
<td>G.3</td>
<td>Frequency of identity and physical checks at BCPs</td>
</tr>
<tr>
<td>Unit in charge</td>
<td>Topics</td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
</tr>
<tr>
<td><strong>D.2</strong></td>
<td>Temporary measures on entry into the Union of certain goods</td>
</tr>
<tr>
<td><strong>E.2</strong></td>
<td>Control programmes and reports on VMP</td>
</tr>
<tr>
<td><strong>E.4</strong></td>
<td>National control programs on pesticide residues</td>
</tr>
<tr>
<td><strong>F.6</strong></td>
<td>Establishing standard model forms for the submission of the annual report on the operation of their multi-annual national control plan by MS</td>
</tr>
<tr>
<td><strong>G.1</strong></td>
<td>Minimum frequencies for plant health controls</td>
</tr>
<tr>
<td><strong>G.2</strong></td>
<td>Specific animal health controls</td>
</tr>
<tr>
<td><strong>G.4</strong></td>
<td>Meat inspection</td>
</tr>
<tr>
<td><strong>G.5</strong></td>
<td>Administrative Assistance and Cooperation</td>
</tr>
</tbody>
</table>

*coordination G3*
Standard decision making process

Implementing Act (IA)

- Roadmap
- Impact assessment
- Concept paper
- Draft 1
- Draft 2

Delegated Act (DA)

- Roadmap
- Impact assessment
- Concept paper
- Draft 1
- Draft 2
- Adoption

Feedback mechanism (four weeks), see Better Regulation Guidelines: SWD(2015) 111 final
Empowerments

(Main target date: 14/12/2019)
ENTRY INTO THE EU:
A modernised system for border controls

A common, risk based framework for border controls on all animals and goods entering the EU

Border Control Posts (BCPs) replace
- Border Inspection Posts (BIPs)
- Designated Points of Entry (DPEs)

Common Health Entry Document (CHED) single standard document for the prior notification of consignments

Minimum requirements for facilities - equipment - staff

Data transmitted through IMSOC = integration of existing computerised systems (including TRACES, RASFF, Europhyt)
Entry into the Union – Main rules

"High risk"

Animals, products of animal origin, germinal products, animal by-products, plant, plant products and certain feed and food of non-animal origin* =

Designated BCP of first arrival

Always documentary checks; risk based identity and physical checks

"Low risk"

Animals and goods whose inherent risks do not require systematic border controls =

An appropriate place within the customs territory of the Union

Regular, risk based controls with appropriate frequency (established by MS)

New IT system. Same set of measures in cases of non-compliance, including enforcement measures

* A list with CN codes to be established
Article 47(2)a
List of animals and goods, with CN codes
Art 47(2)(a): List of CN codes

• Identifies animals and goods subject to systematic border controls

• Plants and plant products on separate list (PHL)

• Builds on existing list (Decision 2007/275, as amended), with very few exceptions
Article 47(3)
Composite products, hay and straw
Art 47(3): Composite products, hay and straw

- Subjects composite products, hay and straw to systematic border controls
- No definitions (see recital 54, building on Reg. 853/2004)
- Linked to other acts (e.g. new import conditions)
- Current list of exemptions applies until 21/04/2021
Article 48
Derogations from BCP controls
Article 48 – Exemptions from controls at BCP

- **Par. (a)** – Goods sent as trade samples or as display items for exhibitions and not intended to be put on the market

  *Current legislation:* no control at BCP, Member state authorization in advance, goods destroyed after exhibition: Dir. 97/78, Art. 16(1) (e) and (f); for animal by-products/ABP Regulation (EU) No 142/2011, Art. 28

  *Policy choice:* no exemption for goods of animal origin, nor for ABP, nor for plants + Simplification: BCP control exemption for feed and food of non-animal origin under temporary increase of controls (and goods destroyed/redispatched after exhibition)

- **Par. (b)** – Animals and goods intended for scientific purposes

  *Current legislation:* no control at BCP, Member state authorization in advance, goods destroyed after use? Goods Dir. 97/78, Art. 16(1) (f) - ABP Regulation (EU) No 142/2011

  *Policy choice:* retain current rules + Simplification: BCP control exemption for feed and food of non-animal origin under temporary increase of controls (and goods destroyed/redispatched after being used)
Article 48 – Exemptions from controls at BCP

• Par. (c) – Goods intended for consumption by crew and passengers

Current legislation: no control at BCP, destruction of goods not consumed (or for vessel: goods transferred directly to another vessel at the same port): Dir. 97/78, Art. 16(1) (c).

Policy choice: retain current rules

• Par. (g) – Goods which have undergone specific treatment:

Current legislation: no control at BCP, Member state authorization by advance, small quantities, heat treatment in an hermetically sealed containing, sent to natural persons: Dir. 97/78, Art. 16(1) (d)

Policy choice: no exemption from BCP controls: no need to use the OCR empowerment
Article 48 – Exemptions from controls at BCP

• Par. (d) – Passengers' personal luggage:

Current legislation: Currently rules on products of animal origin in passengers' personal luggage (including certain pet feed too) are laid down in Dir. 97/78 and legislation based thereupon (Regulation (EC) No 206/2009).

Policy choice: retain current rules

• Par. (e) – Small consignments:

Current legislation: Current rules on small consignments sent to a private person are laid down in Dir. 97/78 and legislation based thereupon (Regulation 206/2009, Art. 1). Furthermore, Commission Dir. 2008/61/EC establishes the conditions under which certain harmful organisms, plants, plants products and other objects listed in Annex I to V to Council Dir. 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections.

Policy choice: retain current rules
Article 48 – Exemptions from controls at BCP

• Par. (f) – Pet animals: *Exempt pets covered by Reg. (EU) No 576/2013*

Current legislation: Rules on the controls of pets are currently laid down in Regulation (EU) No 576/2013 on non-commercial movements. That Regulation has been repealed by the AHL as from 21 April 2021, but as a transitional measure it continues to apply until 21 April 2026.

*Policy choice: Exempt pets covered by Regulation (EU) No 576/2013, subject to the control rules laid down in that Regulation.*

• Par. (h) – Low risk animals and goods: *(1) Remote territories & (2) Transfer of EU-fish in non-EU countries*

1) Current legislation: Based on Decision 94/641 (rules applicable to veterinary checks to be carried out on products imported into certain Greek islands from third countries) and Decision 2012/44 (rules applicable to veterinary checks to be carried out on live animals and products of animal origin entering certain French overseas departments from third countries).

*Policy choice: retain current rules*

2) Current legislation: Regulation 2017/1973 on fishery products caught by EU vessels and transferred in non-EU countries before entering the EU regulation establishes a simplified model health certificate.

*Policy choice: Exempt from BCP controls, subject to specific border controls (Art. 77(1) (k))*
Article 49(5)
Training of BCP staff
Official Controls at border control post
Art 49.5 of Regulation (EU) 2017/625
Training for staff performing physical checks

• Obligation for CA to develop and arrange training courses for the staff performing physical checks.

• Sets out the relevant training subjects.

• Possibility for CA to designate staff who did not attend the training specified in the act, where they received training on the same subjects elsewhere.
Some requirements concerning the subject matter of the training courses

- Clinical examination of the animals
- Examination of the fitness to travel of the animals
- Examination of the means of transport and the transport conditions, including the management of temperature-sensitive goods (cold chain) and the transport of animals
- Methods for the interpretation of laboratory test results and related decisions in accordance with the requirements of applicable Union legislation
- Principles on preventing cross-contamination and compliance with relevant biosecurity standards
Article 51(1)
Transit, transhipment and onward transportation
Transhipment of animals and goods
Time limits and arrangements for controls at BCPs

**Live animals referred in 47.1(a):**
No time limits established (documentary/identity/physical checks at time of arrival)

**Goods referred in 47.1(b) (products of animal origin, animal by-products, germinal products, composite products, hay and straw):**
Documentary checks after transhipment period of 3 days in airports, 30 days in ports (90 days if goods are not subject to AH import requirements)

**Goods referred in 47.1(c) (plants, plant products and other objects):**
Documentary checks after transhipment period of 3 days in airports, 30 days in ports (checks performed on a risk basis)

**Goods referred in 47.1 (d),(e) and (f):**
Documentary checks after transhipment period of 90 days in airports, ports (checks performed on a risk basis)
Transit of animals and goods (TC-MS-TC)

Live animals referred in 47.1(a):
If documentary, identity, physical checks at BCP are favourable

Goods referred in 47.1(b):
If consignments comply with AH import requirements, documentary and identity checks favourable, containers sealed, transported under customs supervision within 30 days, without being unloaded or split (under certain conditions possible to temporary store in customs warehouses and free zones).

Goods referred in 47.1(c):
If consignments comply with PH requirements for transit, documentary, identity and physical checks favourable, transported under customs supervision.

Goods referred in 47.1 (d),(e) and (f) (only when goods are subject to acts and specific measures or conditions):
If documentary, identity and physical checks favourable, transported under customs supervision.
Transit of animals and goods (MS-TC-MS)

Animals and goods referred in 47.1(a) and (b):

- Consignments are moved under customs supervision
- Re-enter the Union at designated BCP
- Checks at BCP of re-entry: documentary check and where required by specific rules verify the seal on containers
Onward transportation of goods

CA of BCP may authorise onward transportation to the place of final destination pending the availability of the results of laboratory tests.

Authorisation is possible for consignments of goods referred to in points (c),(d) and food and feed of non-animal origin of point (e) of Article 47(1) and is subject to certain conditions:

• Favourable results of checks at BCP (with exception of laboratory results),
• Onward transportation facility at destination is designated by the CA,
• During transport to, and storage at, the onward transportation facility, the goods remain under customs supervision and under the control of CA,
• Consignment transported directly from BCP to the onward transportation facility, without the goods being unloaded, split, within 30 days,
• Notification is carried out by BCP to the CA at final destination
Article 52
Details of BCP checks
Article 52 of Regulation (EU) 2017/625

• IA to lay down detailed rules on the operations to be carried out during and after the documentary checks, identity checks and physical checks for the performance of specific official controls for animals and goods.

• Documentary checks – examination of documents which are required to accompany consignments.

• Identity check – by visual inspection to verify content of the consignment correspond to the information in documents.

• Physical checks - to verify compliance with the rules referred to in Article 1(2) of OCR.

• Based on requirements in current legislation.
Article 53(1)a

Controls elsewhere than in BCPs
Art 53.1(a): Identity and Physical checks at control points other than BCPs

Rules will be established for:
• plants, plant products and other objects; and
• for goods subject to a temporary increase of controls at EU entry and for FNAO subject to emergency measures

Conditions for identity & physical at control points:
Similar rules for plants and goods subject to increased controls and FNAO subject to emergency measures. Conditions include:
• agreement between CAs at BCP and CAs at control points (PH);
• operator's obligation to pre-notify arrival of consignments at BCPs;
• CHED to accompany consignments to the control point;
Article 54(3)

Frequencies of physical and identity checks at BCPs
Art 54(3): Frequencies of BCP controls (id. and physical checks), part I

- Establish risk based frequency for identity and physical checks, on animals and goods referred to in point a), b) and c) of Article 47(1) of the OCR

- Necessary to take into account elements such as the outcome of Commission controls in third countries and data collected in IMSOC (Traces, annual reports etc.).

- IMSOC to recommend a frequency and to run random selection of consignments for checks
Art 54(3): Frequencies of BCP controls (id. and physical checks), part II

• It is proposed to set the recommended frequency for animals, plants and plant products at 100%, as today - Possibility for reduced frequency as provided in current legislation

• For POAO similar approach to what provided in current legislation (frequency of physical checks associated to certain categories of products and adjusted to take account of third country profile and IMSOC data)
Article 58b

Minimum time requirements for prior notification
Art 58b: Prior notification

• Basic act: "before the physical arrival"

• General minimum time requirement: "one working day"

• Flexibility: 4 hours in case of "logistical constraints"
Article 62(3), 64(2) and 64(5)

BCP designation - certain derogations
Re-designation of the BCP

**Derogation:**
- re-designation of the BCP after partial withdrawal of designation not dependent on favourable outcome of Commission controls

**Conditions:**
- Member State must notify the Commission of the measures it has taken to remedy the non-compliance with the minimum requirements;
- Within a period of one month from the date of receipt of the notification, the Commission must assess whether or not the measures taken are sufficient;
- Member State can proceed with the re-designation only where the Commission considers the measures sufficient;
- The derogation can be invoked only where the re-designation of the BCP takes place within a period of two years from the date of the partial withdrawal of the designation.
Geographical Constraints - BCP at a distance from the point of entry into the Union

Derogation:
• Member States may designate a BCP not situated in the immediate vicinity of the point of entry

Conditions:
• Specific cases of geographical constraints (e.g. points of entry with a geographical configuration that imposes major constraints on the transportation system; points of entry subject to recurrent floods in certain periods of the year; maritime wharves surrounded by cliffs; etc.)
• BCP distance from the point of entry into the Union commensurate with the need to overcome the constraints of geography and it does not go beyond that need;
• BCP at an appropriate distance from establishments or places where animals, plants, plant products or other objects likely to be infected with transmissible diseases or pests are kept or grown;
• BCP and the point of entry are under the remit of the same custom authority.
Geographical Constraints – BCP for unprocessed logs and sawn and chipped wood

Exemptions:
• Member States may designate the BCP exempted from certain minimum requirements (i.e. sufficient and suitably qualified staff, equipment/facilities, technology for the operation of IMSOC)

Conditions:
• arrangements in place to prevent at all times any undetected entry;
• BCP has access to a sufficient number of suitably qualified staff in the form of a competent authorities' mobile official control team able to reach the BCP before the arrival of the consignments;
• the competent authorities' mobile official control team provides or has immediate access to the equipment, premises and other facilities necessary for the performance of official controls;
• the competent authorities' mobile official control team provides or has immediate access to the technology and IT equipment necessary for the operation of IMSOC.
Article 64(4) and 60(2)
BCP facilities and listing requirements
Detailed rules on minimum facilities

• **Common detailed minimum requirements for BCP infrastructure**
  Example: areas or rooms where animals and goods are to be unloaded must be covered by a roof except non-containerised consignments of fishery products for human consumption, for ABP such as wool, loose manure, etc.

• **Common detailed minimum requirements for BCP equipment and documentation**
  Example: equipment to unload, open and examine consignments

• **Specific minimum requirements for BCP designated for animals**
  Example: area for the unloading of animals with adequate space and ventilation

• **Specific minimum requirements for BCP designated for POAO, ABP, etc.**
  Example: inspection rooms with facilities to maintain temperature controlled environment where necessary
BCP Listing Requirements and Inspection Centres Requirements

Listing requirements for BCP and control points
• Template to provide the required information to list BCP and control points

Requirements for inspection centres
• Inspection centres – separate facility set up within a BCP and established for the purpose of carrying out official controls and other official activities on animals and goods within the scope of the BCP designation

• Must comply with the BCP minimum requirements
Article 77(1)
Specific border controls
Art. 77.1 – Specific border controls, part I

• Par. (a) – Fresh fishery products from a vessel flying a third country flag: retain current requirements

Current legislation: checks directly at the port + frozen tuna checks at a close processing industry: Dir. 97/78, Art. 19(2).

Policy choice: retain current requirements

• Par. (b) – Unskinned, furred wild game

Current legislation: physical checks and residue search at the establishment of destination: Dir. 97/78, Art. 8(2) and Art. 8(4).

Policy choice: retain current requirements

• Par. (c) – Ship supply

Current legislation: Detailed rules for the introduction of products of animal origin for the supply of the crew and passengers of international means of transport, based on Dir. 97/78

Policy choice: retain current requirements

• Par. (d) – Wood Packaging Materials: discussed at a separate stakeholders' meeting
Art. 77.1 – Specific controls, part II

- **Par. (e) – Feed accompanying animals**

  Current legislation: Apart from the rules on pet food, hay and straw laid down in Dir. 97/78 and legislation based thereupon (Regulation 206/2009 and Regulation 136/2004), there are no harmonized rules on border controls on feed accompanying animals. Furthermore, feed of animal origin fall under the rules of animal by-products.

  **Policy choice**: no need to use the OCR empowerment

- **Par. (f) – Distance sales from third country**

  Current legislation: Currently there is no specific harmonized rule governing this case.

  **Policy choice**: no need to use the OCR empowerment

- **Par. (g) – Plant products that may spread animal disease**

  Current legislation: Currently, rules are laid down in Art. 9 and the annexes of Regulation 136/2004. As of 14 December 2019, hay and straw will be added to Art. 47(1) (b) of the OCR and hence be subject to systematic border controls (Art. 47(3) of the OCR), including the rules on details of checks to be established under Art. 52 of the OCR.

  **Policy choice**: no need to use the OCR empowerment
Art. 77.1 – Specific controls, part III

• Par. (i) – Goods entering the Union in bulk

*Current legislation: Regulation 142/2011 establishes certain requirements for the import of processed animal protein, in particular on sampling. Rules on sampling will be established in the act on details of checks laid down under Art. 52 of the OCR. Furthermore, specific requirements as regards BCP facilities will be established for goods arriving in bulk under Art. 64(4) of the OCR.*

*Policy choice: no need to use the OCR empowerment*

• Par. (j) – Neum Corridor

*Current legislation: Article 1(2) of Directive 97/78/EC (+ the Act of accession of Croatia)*

*Policy choice: retain current requirements*

• Par. (k) – Animals and goods exempted through Art. 48

*Current legislation: (1) Regulation 2017/1973 on fishery products caught by EU vessels and transferred in non-EU countries; (2) Decision 94/641 and Decision 2012/44 (French territories + Greek islands)*

*Policy choice:*

(1) for the transfer of EU-fish in third countries, rules to be laid down on documentary checks

(2) for the French territories + Greek islands, retain current control requirements

(3) for the control of passengers' personal luggage, goods ordered by sales through distance contracts and pets, retain current control requirements
Re-entry into the Union (Article 77.1(h))

- Specific official controls for animals and goods following a refusal of entry by third country.
- The competent authority shall carry out documentary and identity checks and in case of suspicion physical checks.
- The CA at the BCP shall checks if requirements for re-entry are fulfilled
  - Regarding Animal Health (animals, goods, germinal, by-products) and Plant Health (plants and plant products) requirements established in relevant sectoral legislation
  - Regarding Public Health requirements for PoAO using empowerment of Article 126 of OCR in this regulation. Similar to existing.
- Not obligatory to go back to the place of origin
- Monitoring of arrival of the consignments to the destination based on empowerment of Article 77.2 of the OCR
Article 134
IMSOC
Legal bases of IMSOC

- **General Food Law (Reg. 178/2002)**
  - Article 51 (RASFF)

- **Animal Health Law (Reg. 2016/429)**
  - Article 23 (ADNS/ADIS)

- **Plant Health Law (Reg. 2016/2031)**
  - Article 104 (EUROPHYT)

- **Official Controls Regulation (Reg. 2017/625)**
  - Article 58a (format of the CHED)
  - Article 75(2) (Cooperation with Customs)
  - Article 90(1)(f) (electronic certificates)
  - Article 102(6) and 103(6) (Administrative Assistance and Cooperation)
  - Article 134 (IMSOC)
What is IMSOC?

Name: Information Management System for Official Controls

Is it a new IT application? NO! It’s a concept to allow our EU systems to exchange information and share features (and with MS systems)

Will it add further burden to our activities? NO! It will be designed to make your life easier

Will it replace the current systems? (traces/bovex/europhyt/irasff/aac) NO/YES It will connect them and extend functionalities (some systems will be absorbed)

What is its purpose? Toward a better collective controls efficiency

Keywords CONSOLIDATION-EFFICIENCY
IMSOC and its system components (overview)

1. Administrative Assistance and Cooperation (AAC): Public health, Non compliances and Fraud suspicion
2. Certification (Animal, Animal products, Organic, Plants, Timber, Fish Catches ...)
3. Alerts (Humans, Plants, Animals)
4. Identification (e.g. bovine)
IMSOC:
Exchanges in relation to risks
AAC novelties from the OCR

1. Administrative Assistance and Coordination (AAC) defined by 7 Articles

2. New procedure for administrative assistance (clearer obligations and stricter timeline)

3. Liaison bodies have to communicate through the systems

4. Special provisions of risk or serious infringement (EC can be involved for coordination)

5. Communication to Third Countries
RASFF/AAC CURRENT FLOW

3 Networks
- RASFF Network
- Member State AAC Liaison Bodies
- Food Fraud Network

2 Platforms
- iRASFF
- AAC (AA)
  - AAC (FF)

Context
- Health risk
- Non-Compliances
  - Food Fraud suspicion (intention)
iRASFF notifications (summary)

AAC

Article 106(1) OCR risks to human, animal or plant health, animal welfare or, as regards GMOs and PPPs, the environment.

RASFF

Article 50 of GFL: direct or indirect risks to human health from food or feed

Reg. 183/2005: serious risks to animal health or environment from feed for animals not kept for food production

FF

All the above when: intentional, to gain undue advantage, while deceiving customers

• Plant health risk
• Animal welfare risk
• Non-serious risk animal health
IMSOC
Certification and integration
IMSOC TODAY – an example

IMSOC will make automatic what you are currently doing manually

The original information from the BIPs is every time manually copied from one system to another, and enriched with further data.

IMSOC will be able to aggregate data on official controls from every system, and display it according to the “need to know” principle.
CHED from TRACES to TRACES-NT
Opportunities

1. Streamline control process in the EU Single Market
2. Paperless flow opportunity for far more efficiency
3. Align control performances in EU
4. Better implement EU access restrictions in case of issue
5. Feeding a common knowledge base
6. Predictive analysis to better target controls and align performances
Principles

1. Evolution and no revolution
2. Worldwide applicable standards for interoperability
3. Integration at EU level (effort on Commission side)
4. eIDAS EU regulation principles as basis for paperless
5. Personal data protection
CERTIFICATION

Paper VS Electronic

- Signature can be falsified
- Stamp can be falsified
- Problem of "original certificate" and copies
- Deterioration
- Storage
- Difficult to read
- You can make paper planes

- Very difficult to falsify signature, stamp or dates
- Bring with you as many as you want
- Accessible everywhere
- No problem of obtaining "officially certified copies"
- No Deterioration
- Unlimited storage
- You cannot make paper planes
Applicable international standards

1. Data structure based on:
   1. IPPC, OIE & WCO standards defining the semantic used in exchange
   2. UN/CEFACT eCERT electronic message standard

2. Electronic signature: ISO 14533 & 14888

Document Management standards
# Electronic document following European eIDAS Regulation (2014/910)

<table>
<thead>
<tr>
<th>Paper Certificate</th>
<th>Electronic Certificate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Text</td>
<td>electronic data</td>
</tr>
<tr>
<td>Format</td>
<td>Qualified Timestamp</td>
</tr>
<tr>
<td>Layout</td>
<td>Advanced Electronic Signature</td>
</tr>
<tr>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Signature of Authorising Officer</td>
<td>Advanced Electronic Seal</td>
</tr>
<tr>
<td>Stamp of the Organisation</td>
<td>Electronic fingerprint of document</td>
</tr>
<tr>
<td>Paper Security features</td>
<td></td>
</tr>
</tbody>
</table>
Actors and Elements

- Competent Authority Officer from non-EU country (CAO-nonEU)
- Competent Authority Officer from EU country at BCP (CAO-EU)
- Trusted Third Party provider (TTP)
- Economic Operator
- Electronic Stamp (also called eSeal)
- Electronic signature of an individual
- Electronic Fingerprint of content of document
Paperless SPS certification flow within IMSOC-TRACES

EO
creates

CA origin
validates & eSigns

Paper copy
(Optional)

Trust Third Party

CA EU borders
Checks, clones & eSign EU entry doc

Health and Food Safety
Paperless SPS certification with non-EU system

NonEU System

EO creates
CA origin validates & eSigns

Trusted Third Party

IMSOC-TRACES

Paper copy (optional)

Checks, clones & eSigns EU entry doc

CA EU borders

Health and Food Safety
Advantages of the solution

• Each step of the transaction can be checked against its "fingerprint" at any time during document lifecycle (even years later)
• Is recognised by law (in all 28 EU MS) as an original electronic document replacing paper
• Solution supported worldwide by electronic signature standards and Trusted Third party providers
Acceptable implementation of eSignature with non-EU countries

• Option 1: use TRACES interactively and eSign (for free)
• Option 2: Use non-EU system using our EU eSignature Trust Provider (for free)
• Option 3: non-EU system using non-EU eSignature Trust Provider accepted after a conformity check with the 'EU Advanced eSignature' level
• Option 4: Apply eSign with Trust Provider on Hub (as discussed with IPPC ePHYTO)
• Option 5: Paper still accepted...
Implementation of eSignature in the EU Certification system (IMSOC-TRACES)

- Phytosanitary certificates from **Feb 2018**
- EU entry documents by **Nov 2018**
- Veterinary certificates by **July 2019**
- eSigned XML by **Q1-Q2/2019**
Common Health Entry Document (CHED)

Option 1: TRACES flow (CHED fully in TRACES)

Option 2: MS national system (withIMSOC seal)

CHED (not valid)

IMSOC seal (CHED is valid)

PRINCIPLES:

1. Operators: "simple" electronic signature (eIDAS art. 3 pt. 10)
2. Competent Authorities: qualified electronic signature for inspectors + qualified electronic seal for stamps
3. Full non-repudiation is granted, also for bank guarantees
4. 100% eIDAS compliant and compatible
Thank you for your attention
See SANTE website for more information:

http://ec.europa.eu/food/safety/official_controls_en
Have your say: Give feedback on draft acts

Contribute to EU policy and law-making by giving your feedback on Commission draft delegated and implementing acts.

https://ec.europa.eu/info/law/better-regulation/have-your-say
Stakeholders' feedback procedures

- Stakeholders are invited to provide feedback along the policy cycle.

- Structured feedback can be received for draft DA and IA, during a period of 4 weeks, usually:
  - once informal discussions with MS of a DA are concluded, or
  - after the vote of an IA in the standing committee (PAFF).

- Comments received will be analyzed by the Commission services before the act is finally adopted.
THANK YOU!