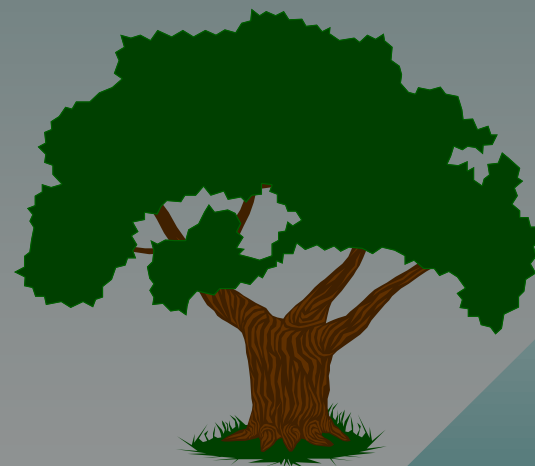


Regulation (EU) 2017/625 on official controls-current status, and related issues

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1) Regulation (EU) 2017/625 (Official Controls Regulation) - state of play

REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (Official Controls Regulation)

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 and plant protection products,

amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC

(Official Controls Regulation)

Official Journal of the European Union L 95, 7.4.2017

Unless some exceptions it shall apply from 14 Dec 2019

Official Controls Regulation (1)

Article 1 *Subject matter and scope*

1. This Regulation lays down rules for:

a) the performance of official controls and other official activities by the competent authorities of the MSs;...

2. *This Regulation shall apply to the official controls performed for the verification of compliance with the rules, whether established at Union level or by the Member States, to apply Union legislation in the areas of: ...*

h) requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticides application equipment;

Official Controls Regulation (2)

Article 24 *Specific rules on official controls and for action taken by the competent authorities in relation to plant protection products*

- 1. **Official controls to verify compliance with the rules referred to in point (h) of Article 1(2) of this Regulation shall include official controls on active substances and safeners, synergists, co-formulants and adjuvants as referred to in Article 2 (2) and (3) of Regulation (EC) No 1107/2009.***

Official Controls Regulation (3)

Article 24 *ctnd.*

3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls referred to in paragraph 1 of this Article.

(i.e. to verify compliance with the rules referred to in point (h) of Article 1(2) of this Regulation)

Official Controls Regulation (4)

Article 24, paragraph 4. ctnd.

4. The Commission may, by means of implementing acts, lay down detailed rules on uniform practical arrangements for the performance of official controls on the products referred to in paragraph 1

(products, i.e. active substances and safeners, synergists, co-formulants and adjuvants)

Official Controls Regulation (5)

Very important Articles

Article 25 Delegation by the competent authorities of certain official control tasks

Article 34 **Second expert opinion**

Article 35 Sampling of animals and goods offered for sale by means of distance communication

Article 42 Official controls on animals and goods other than those subject to official controls at border control posts under Section II

Article 48 Certificates and documents accompanying consignments and split consignments

Official Controls Regulation (6)

Very important Articles (ctnd.)

Article 50 Details of documentary, identity and physical checks

Article 64 Measures to be taken in cases of non-compliant consignments entering the Union

Article 73 Cooperation amongst authorities in relation to consignments entering the Union from third countries

Title IV **Administrative assistance and cooperation**
(Articles 100-106)

Article 130 **Information management system for official controls (IMSOC)**

Title VII Enforcement action (Articles 134-137)

Commission Regulations on the Official Controls of PPPs Placed on the Market (1)

Possibility to be issued according to paragraphs 3. and/or 4. of Article 24 of Regulation (EU) 2017/625:

3. The Commission is empowered to adopt **delegated acts** in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls
4. The Commission may, by means of **implementing acts**, lay down detailed rules on uniform practical arrangements for the performance of official controls

Commission Regulations on the Official Controls of PPPs Placed on the Market (4)

Is there any planned intent of the European Commission to issue any of above Commission Regulation in question, which shall apply by EU MSs from 14 Dec 2019 at the latest?

NO!!!

At the moment, DG SANTE has none plans to issue any Commission Regulation on Official Controls of PPPs placed on the market.

2) Activities of the Working Group on PPPs Enforcement of Article 68 of the Regulation (EC) No 1107/2009

WG on PPPs Enforcement of Art.68 (1)

Established by the Standing Committee
on Plants, Animals, Food and Feed
(SCPAFF) - Plant Protection Products
Legislation

Chaired by a DG SANTE Directorate F staff
member

First meeting in Brussels - 13th & 14th
April 2016 (+ up to now 6 other meetings)

WG Terms of Reference - final version
approved in December 2017

WG on PPPs Enforcement of Art.68 (2)

- **Purpose:** To promote best practices in controls on the marketing and use of PPPs in EU MS. To be a source of expert knowledge for Commission services in this technical subject.
- **Scope:** Controls on the marketing and use of PPPs as defined under Regulation (EC) No 1107/2009 and the Official Controls Regulation (EU) 2017/625.

WG on PPPs Enforcement of Art.68 (3)

- **Authority:** Decision making by consensus with the aim of promoting good practices through guidance documents, reference documents to provide guidance, recommendations, exchange of technical information, and other tools as required.
- **Membership:** Nominated MS experts responsible for official controls on the marketing and use of PPPs in EU MS. Relevant technical experts, including industry representatives, may be invited to participate in meetings, on an ad-hoc basis.

WG on PPPs Enforcement of Art.68 (4)

- **Meeting arrangements:** Meetings are held bi-annually, with additional meetings held if required. Meetings will be held in the Directorate F building in Grange, Ireland. Alternatively, meetings may take a workshop format dedicated to a particular theme, and be hosted by a MS. A DG SANTE Directorate F staff member will provide an agenda, chair, and take minutes of all meetings. Agendas will be drafted and minutes agreed only after having taken MS comments into account. All documentation associated with WG meetings will be circulated to WG members, using the most up to date list of participants available, and will be added to the PPP Enforcement WG folder on CircaBC. Sub-groups of the WG may be established as required in order to concentrate on specific projects.

WG on PPPs Enforcement of Art.68 (5)

- **Reporting:** A DG SANTE Directorate F staff member will provide a report on the work of the WG, and any significant work outputs at least annually, to the Standing Committee on Plants, Animals, Food and Feed - Plant Protection Products Legislation.
- **Resources and budget:** Directorate F of DG SANTE will provide administrative support to the WG and reimburse MS representatives for travel costs associated with attending WG meetings in line with Commission procedures.

WG on PPPs Enforcement of Art.68 (6)

- **Deliverables 2017-2019:**

- Provision of technical guidance and sharing of best practices among MS relating to controls on the marketing and use of PPPs.
- Improving technical competence of MS staff involved in official controls.
- Developing a harmonised approach to controls on the marketing and use of PPPs among MS.
- It will also be involved in the development of tertiary legislation on the delegated and implementing acts according to the Article 24 of the Regulation (EU) 2017/625, i.e. Commission Regulations on the control of PPPs placed on the market.

WG on PPPs Enforcement of Art.68 (7)

- **The first priority** of DG SANTE Directorate F was to develop the Templates for reporting official controls („Use“ and „Marketing“, i.e. Placing on the Market, so that the templates used by MSs to report 2016 controls (in 2017), could with some modifications, be used by MS to report the outcome of controls in future years as required by Regulation (EU) 2017/625.
- **In addition**, to work with MS to strengthen what DG SANTE Directorate F believes (based on MSs audits) are weaknesses in current controls, e.g. workshop focusing on controls on manufacturers of PPPs

WG on PPPs Enforcement of Art.68 (8)

Developed Templates for reporting official controls:

- „Use“ - 4 Excel tables
- „Marketing“ - 8 Excel tables

Intended as Annexes to the developer Regulation on Multi Annual National Control Plan (MANCP)

Development started April 2016 - finalized May 2018
(i.e. 28 EU MSs experts spent 2 years on it - *sic!!!!...*)

Submitted to the Working Group on MANCP, dealing with draft templates for all types of official controls under the scope of Regulation (EU) 2017/625

WG on PPPs Enforcement of Art.68 (9)

- In the June 2018 meeting of the **Working Group on Multi Annual National Control Plan**, it was highlighted that **templates for reporting official controls („Use“ and „Marketing“)** were too detailed and did not match with the work they have been doing for other areas contained in the Multi Annual National Control Plan...
- Directorate F of DG SANTE developed **minimalized summary template** „Requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticides application equipment“, accepted as Annex to the Regulation on MANCP.

WG on PPPs Enforcement of Art.68 (10)

- **Other activities** (except Reporting templates)
 - Developing „Guidance Document“ or now „Reference Document to provide guidance“ on enforcement, e.g. on EU-wide formulation analysis programme, taking samples, etc.
 - MS supported the proposal to move from a meeting format to a workshop type format, realized e.g.:
 - February 2017 in the Netherlands to focus on controls on logistics/storage operators and re-packers
 - February 2018 in Germany dealing with controls on PPPs manufacturers
 - Co-operation of EU MSs on control in certain cases, e.g. pendimethalin, potassium phosphonates, etc.

WG on PPPs Enforcement of Art.68 (11)

Last meeting 16 - 17 May 2019
Health and Food Audits and Analysis,
Grange, Ireland

One of three back-to-back meetings:

- Working Group on SUD (Sustainable Use Directive)
- Workshop on IPM (Integrated Pest Management)
- **Working Group on Enforcement of Article 68 of the Regulation (EC) No 1107/2009**

3) EUROPOL „Silver Axe“ Project

EUROPOL Operations „Silver Axe”



Operation	Year	No of States Participating	Seized illegal or counterfeit PPPs
Silver Axe I	Nov 2015	7 EU MSs	190 tones
Silver Axe II	Jul 2017	16 EU MSs	122 tones
Silver Axe III	Jul 2018	26 (20 EU MSs + Australia, Moldova, Serbia, Switzerland, Ukraine)	360 tones
Silver Axe IV	Jun 2019	29 (26 EU MSs + Switzerland, Ukraine)	550 tones

4) OECD ONIP Project

OECD Network on Illegal Pesticides (ONIP)

As I informed the *CEUREQ* Forum community by an e-mail, the OECD Council has on 20th February 2019 adopted:

- Recommendation of the OECD Council on Countering the Illegal Trade of Pesticides

and

- Best Practice Guidance to Identify Illegal Trade of Pesticides

(both drafted by ONIP).

<https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0446>

Near future challenges in the field of PPPs Control:

- Brexit - after 31 October 2019?
missing **United Kingdom capacities for EU PPPs regulation** (is possibility to continue in the active substances evaluation via OECD work sharing ?)
- Regulation (EU) 2017/625 on Official Controls - after 14 Dec 2019
missing **implementing European Commission Regulation on the Control of PPPs Placed on the Market**
- OECD, Working Group on Pesticides - WGP
missing **worldwide unified Good Manufacturing Practice (GMP) standards for PPPs production** - „Scoping Paper on GMP“ will be prepared by New Zealand for 35th WGP (Jun 2020)
- World Customs Organization
missing **worldwide unified standard custom declaration** as to the clear identification of the consignment during the shipment incl. transit
- Needed
 - „**PPP birth certificate**“, or „**PPP passport**“, accompanying PPPs in the whole lifecycle

Thank you for your attention!

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ÚKZÚZ

Section of Agricultural Inputs

Division of Plant Protection Products

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