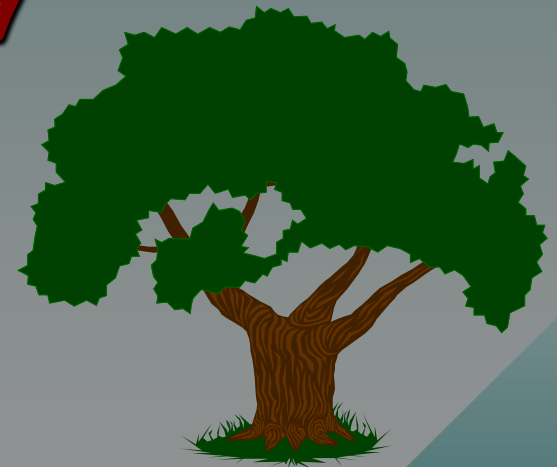


Activities of the WG on PPPs Enforcement (Art. 68) and Regulation on official controls - state of play

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- 1) Activities of the Working Group on PPPs Enforcement of Article 68 of the Regulation (EC) No 1107/2009**
- 2) Regulation (EU) 2017/625 (Official Controls Regulation) - state of play**
- 3) PPPs Regulation in the Czech Republic - Reorganization (from 1st January 2018)**

**1) 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 4 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

Submitted to the Working Group on MANCPn, dealing with the templates for all types of official controls under the 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.

2) 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)

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 (2)

Commission Official Controls Expert Group (OCEG - E00911 in the Register of Commission EGs):

https://ec.europa.eu/food/safety/official_controls/expert_working_groups_en

Mission:

Discusses and potentially agrees on issues related to the implementation and enforcement of Regulation (EC) No. 882/2004 and the Official Controls Regulation (EU) 2017/625.

It will also be involved in the development of tertiary legislation based on the empowerments provided by Regulation (EU) 2017/625.

Commission Regulations on the Official Controls of PPPs Placed on the Market (3)

Is there any intent of the European Commission to issue any Commission Regulation in question, which shall apply from 14 Dec 2019 at the latest, i.e. Regulations according to the:

- Regulation (EU) 2017/625, Art. 24, paragraph 3.
delegated acts
- Regulation (EU) 2017/625, Art. 24, paragraph 4.
implementing acts
- Regulation (EC) No 1107/2009, Art. 67, paragraph 4.
implementing measures

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

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

NO!!!

At the moment, DG SANTE have no plans for a Commission Regulation on Official Controls of PPPs placed on the market.

3) PPPs Regulation in the Czech Republic - Reorganization* (from 1st January 2018)

***changes are referring to the situation before - see please:**

[http://www.ceureg.com/20/docs/presentations/13_PPPs
Control in the CR.pdf](http://www.ceureg.com/20/docs/presentations/13_PPPs_Control_in_the_CR.pdf)



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Plant Protection Products Control in the Czech Republic

CEUREG Forum XX., BRNO, 11th October 2016





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Plant Protection Products Regulation **Changes** in the Czech Republic



Reorganization changes of the Division of Plant Protection Products, Agricultural Inputs Section, ÚKZÚZ, in the field of PPPs regulation:

Division of Plant Protection Products:

 - Department of Approvals of Plant Protection Products

~~Department of Parallel Trade Permits~~

- Department of Coordination of Expert Evaluation

- Department of Risk and Efficacy of Plant Protection Products

- Physical and Chemical Properties Department

~~Department of Inspection and Application Machinery~~

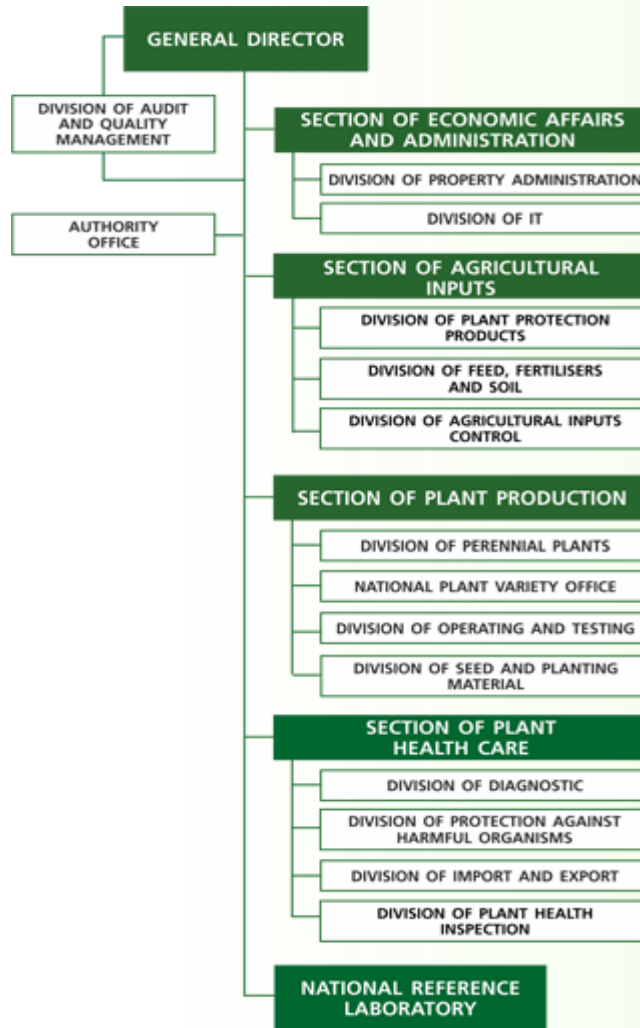
Some main activities of the Division of Plant Protection Products, Agricultural Inputs Section, ÚKZÚZ, in the field of PPPs regulation:

Continued activities:

- assessment of the compliance of criteria for PPPs, auxiliary plant protection means and bioagents, authorisation/permission and decision taking on their approval for placing on the market
- keeping an official list of authorised PPPs, auxiliary plant protection means and bioagents
- evaluation of the active substances of PPPs according to the review programme of the European Commission

Activities transferred from the 1st January 2018:

- coordination of inspection of PPPs placed on the market transferred from the Division of Plant Protection Products to the Division of Agricultural Inputs Control, both in the Agricultural Inputs Section, ÚKZÚZ, including transfer of the Department of Inspection and Application Machinery - see the next slides



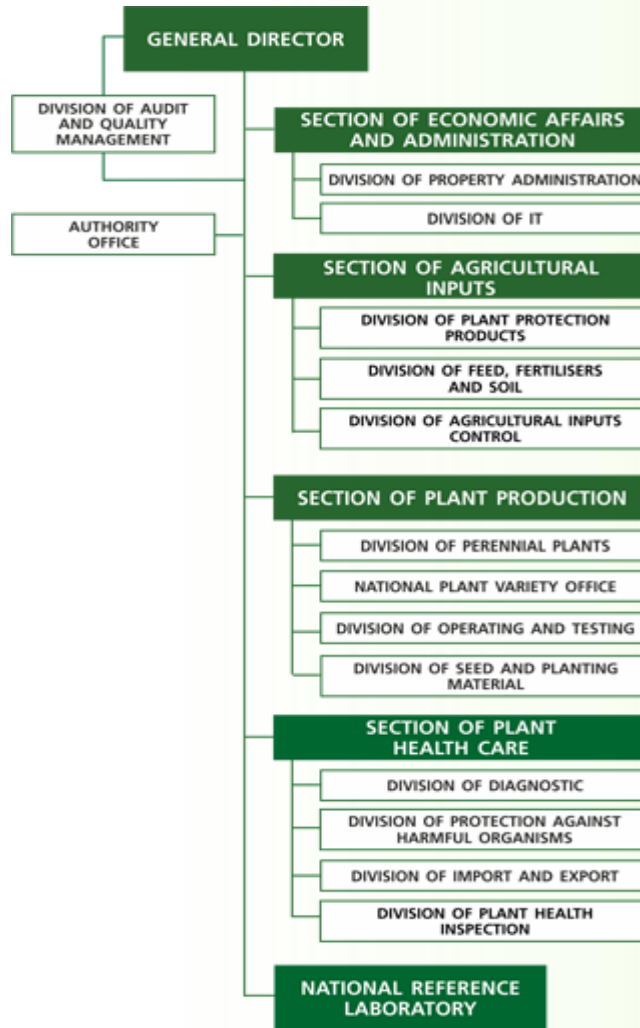
Department of Inspection and Application Machinery

7 Regional Departments of Agricultural Inputs Control

Department of Testing of Plant Protection Products



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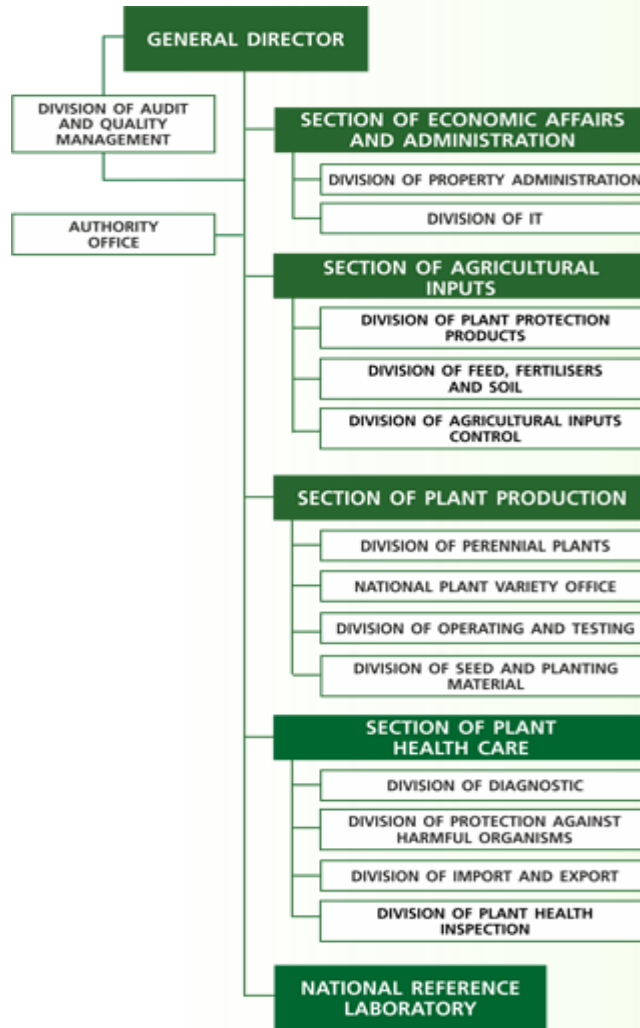
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Central Institute for Supervising and Testing in Agriculture
Section of Agricultural Inputs

~~Division of Plant Protection Products~~

Division of Agricultural Inputs Control

Department of Inspection and Application Machinery

Zemědělská 1752/1a, 61300 Brno, Czech Republic

Main activities of Department:

- As to the distribution of PPPs (marketing of PPPs)
 - creation of PPPs annual control plan
 - development of methodologies for Division of Agricultural Inputs Control
 - administration of PPP's samples
 - **coordination of inspection of PPPs placed on the market**
- Agenda of professional pesticide application equipment (Article 8 and ANNEX II of the Directive 2009/128/EC)

Near future challenges in the field of PPPs Control:

- Brexit - after 30 March 2019
missing **United Kingdom capacities for EU PPPs regulation** (possibility to continue in the active substances evaluation via the work sharing ?)
- Regulation (EU) 2017/625, on Official Controls - after 14 Dec 2019
missing **implementing EC Regulation on the Control of PPPs Placed on the Market**
- OECD
missing **worldwide unified Good Manufacturing Practice (GMP) standards for PPPs production**
- World Customs Organization
missing **worldwide unified standard custom declaration** as to the clear identification of the consignment during the 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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