



**ÚSTŘEDNÍ KONTROLNÍ
A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ**
**Central Institute for Supervising
and Testing in Agriculture**

ISO 9001: 2008 certified

www.ukzuz.cz

Plant Protection Products Control in the Czech Republic

CEUREG Forum XX., BRNO, 11th October 2016



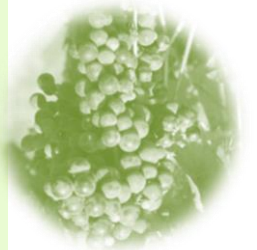
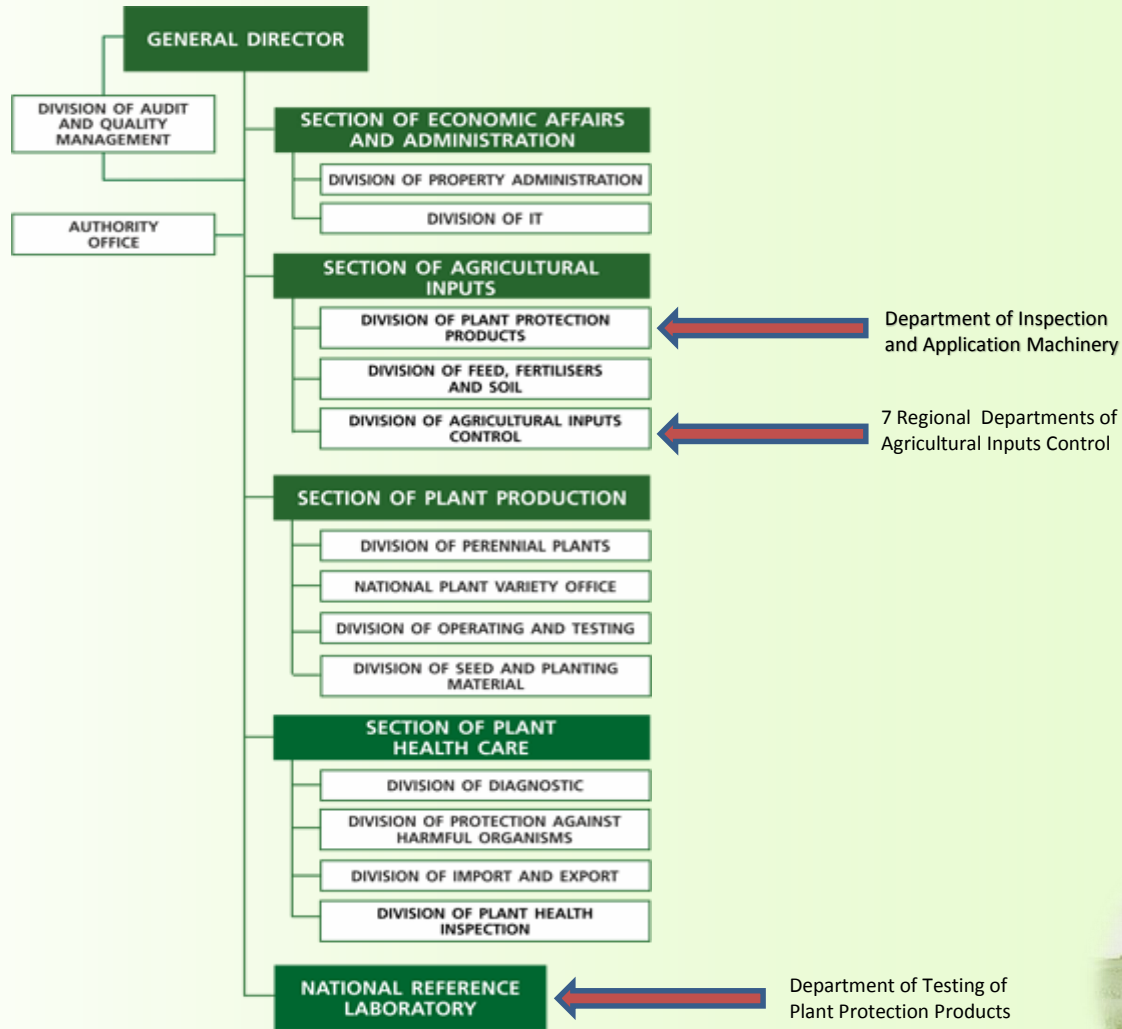
(hereinafter „CISTA“) has its' position embodied in the Act No. 147/2002 Coll.* , on Central Institute for Supervising and Testing in Agriculture and on amendments to certain related Acts (Act on the Central Institute for Supervising and Testing in Agriculture), as last amended (hereinafter "Act No. 147/2002 Coll. "). The Institute is according to Article 1 of this Act, the administrative authority subordinate to the Ministry of Agriculture.

CISTA is also the Czech Republic state plant protection organisation in accordance with the FAO International Plant Protection Convention and is the authority responsible for exercising its powers in the field of phytosanitary care and in compliance with the laws of the European Community.

Coll.* = Czech Republic Collection of Laws



Central Institute for Supervising and Testing in Agriculture



Central Institute for Supervising and Testing in Agriculture
(ÚKZÚZ)

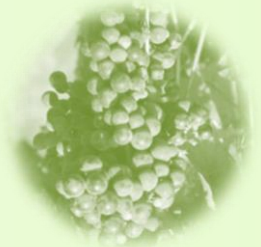
Section of Agricultural Inputs (SAI)

Division of Agricultural Inputs Control (DAIC)

Hroznová 2, 628 00 Brno, Czech Republic

Main activities of Division:

- Inspections of placing on the market, labelling, packaging and storage of fertilizers and sampling of fertilizers
- Inspections of placing on the market, checks of the production, import, storage, labelling and using of feed and sampling of feed
- Inspections of Distribution of PPPs (marketing of PPPs), storage, packaging and labelling of PPPs + sampling of PPPs
- Other Activities



Central Institute for Supervising and Testing in Agriculture
(ÚKZÚZ)

Section of Agricultural Inputs (SAI)

Division of Plant Protection Products (DPPP)

Department of Inspection and Application Machinery (DIAM)

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 (DAIC)
 - administration of PPP's samples
- Agenda of professional pesticide application equipment



Central Institute for Supervising and Testing in Agriculture
(ÚKZÚZ)

National Reference Laboratory (NRL)

Department of Testing of Plant Protection Products (DTPPP)

Zemědělská 1752/1a, 61300 Brno, Czech Republic

DTPPP was accredited by the Czech accreditation body (Czech Accreditation Institute) in May 2008 and received the Certificate of Accreditation that follows European standard ČSN EN ISO/IEC 17 025:2005 „Conformity assessment - General requirements for competence of testing and calibration laboratories“.

This laboratory is accredited for the analyses of PPPs samples taken from the market as to their compliance with their specification, either taken from the market by CISTA - results are used for the administrative offences procedures by CISTA, or on the request - for customs or police only - results are provided for the purpose of criminal prosecution.



Some main activities of CISTA in the field of PPPs:

- Agricultural Inputs Section (AIS), PPPs Division

- 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
- control of PPPs placed on the market (in the close cooperation with Division of Agricultural Inputs Control - DAIC)



Sampling of PPPs for laboratory analysis

PPPs from parallel trade constitute a part of annual plan. Of the total planned number of samples is 28% PPPs from parallel trade.

Forwarding process of sampled PPPs:

- Sampling
 - DAIC or DIAM
- Processing of request for analysis
 - DIAM in cooperation with Department of Physical and Chemical Properties (DPCP) of DPPP
- Laboratory analysis
 - Department of Testing of PPPs of National Reference Laboratory
- Evaluation of the results of laboratory analyzes
 - DIAM in cooperation with DPCP
- Report or action for the relevant company
 - DIAM
 - if is everything in compliance, sample is returned



PPPs samples

Year	Number of samples	Parallel trade	Non compliance
2013	51	34	10
2014	36	14	9
2015	55	23	6

The types of non compliance:

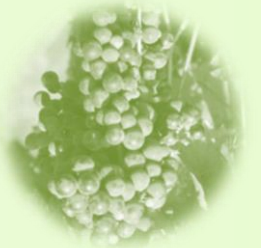
- the composition or phys.-chem. properties of PPP does not correspond to the data in the registration documents
- PPP from parallel trade is not the same, or equivalent, to the reference PPP





CISTA is the central competent authority responsible for controls of placing of PPPs to the market and usage of PPPs following the Article 68 Monitoring and control of the Regulation No 1107/2009/EC of the European Parliament and of the Council of 21 October 2009, concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

- Act No 326/2004 Coll., as last amended, Article 72, paragraph 1c) and 1e)
- Act No 350/2011 Coll., as last amended, Article 31





Current legislation in force in the Czech Republic

- Regulation No 1107/2009/EC
- Implementing Regulations to Regulation No 1107/2009/EC
- Act No 326/2004 Coll., on phytosanitary care and changes of some other related acts, as last amended
- Implementing Decrees to the Act No 326/2004 Coll.
- Act No 500/2004 Coll., administrative code, as last amended
- Act No 255/2012 Coll., on control (control code)





Other related legislation in force in the Czech Republic

- Regulation No 1907/2006/EC (REACH)
- Regulation No 1272/2008/EC (CLP)
- Act No 350/2011 Coll., on chemical substances and chemical mixtures, as last amended
- Implementing Decrees to the Act No 350/2011 Coll.





Surveillance and checks:

- Act No 326/2004, as last amended:
 - Article 43;
 - Article 74 paragraph 1 f) and 2
- Act No 350/2011, as last amended:
 - Article 31 a)

Penalties:

- Act No 326/2004, as last amended:
 - Articles 75, 76;
 - Articles 79a to 79i
- Act No 350/2011, as last amended:
 - Article 31b and 34





Strengths (advantages):

CISTA competences as to the PPPs control are on the placing on the market incl. advertising, labelling, storage, use and records keeping by all stakeholders.

Weaknesses (disadvantages):

- Missing unified standard custom declaration as to identification of the consignment during the transit (needed „PPP birth certificate“, or „PPP passport“, accompanying PPPs in the whole lifecycle).





Weaknesses (disadvantages): (ctnd.)

- Missing harmonized Commission Regulation on the PPPs control placed on the market according the third subparagraph of the Article 68 of the Regulation 1107/2009/EC (using as a part the Regulation No 2006/2004/EC - Regulation on consumer protection cooperation ?).
- Missing implementing measures to ensure the uniform application of harmonized Commission Regulation on keeping the records on the PPPs produced, imported, exported, stored or placed on the market, according to the paragraph 1 of the Article 67 of the Regulation 1107/2009/EC.



Communications between EU MSs competent authorities outside our country

Feedback is not enough functional - not in time, missing or wrong (not up-dated) contacts.

There is not legally binding Article on the possibility of such communication in the Regulation 1107/2009/EC.

Thus again also in this field there appeared that as in the case of control of PPPs placed on the market, there is missing harmonized Commission Regulation on PPPs control (third subparagraph of the Article 68 of the Regulation 1107/2009/EC).



Current Tool to Be Used !!!

Regulation No 1107/2009/EC of the European Parliament and of the Council of 21 October 2009, concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Article 3 Definitions

9. 'placing on the market' means the holding for the purpose of sale within the Community, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves, but not the return to the previous seller. Release for free circulation into the territory of the Community shall constitute placing on the market for the purposes of this Regulation;



Near Future Improvement ???

Proposal COM(2013) 265 final 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 („SUD“)

(Official Controls Regulation)





Case C-108/13 - What does it mean in fact in the relation to the PPPs parallel trade ?

- PPP authorised (after evaluation) in France
- Parallel import of this PPP to United Kingdom (UK) approved in UK
- Mac GmbH. (Germany) application for parallel import of this PPP from United Kingdom to France not approved - justification of the French Ministry of Agriculture
 - PPP not authorised (after evaluation) in UK
- Mac GmbH. (Germany) v French Ministry of Agriculture: Judgment of the Court of Justice of the European Union:

PPP paralelly imported to United Kingdom (UK) from France can be paralelly (re-)imported to France as it is an identical PPP.

Thus „*per analogiam*„ , e.g.: PPP paralelly imported to United Kingdom from France can be paralelly imported to the Czech Republic as it is find as identical PPP (based on comparison of composition in UK and CZ).



Case C-108/13 - What does it mean from the legal point of view in the relation to the PPPs parallel trade ?

Guidance document concerning the parallel trade of plant protection products, SANCO/10524/2012, vers. 5.2, dated 14th July 2015, replaced the preceding text by:

Therefore Article 52.1 concerns plant protection products authorised under Article 28 of the Regulation or under national laws transposing Directive 91/414/EEC.

For applications for parallel trade permits for products placed on the market under parallel trade permit reference is made to the jurisprudence of the Court in C-108/13.





Case C-108/13 - What does it mean (under the scope of the Regulation (EC) No 1107/2009) in the relation to the PPPs parallel trade ?

The whole title of the Guidance document concerning the parallel trade of plant protection products is:

Guidance document concerning the parallel trade of plant protection products

under Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection product on the market ...

Thus „per analogiam,, , e.g.: PPP paralelly imported to United Kingdom from France can be paralelly imported to the Czech Republic as it is find as identical PPP (based on comparison of composition in UK and CZ).





Case C-108/13 - BUT !!! What does it mean from the legal point of view as to the PPPs parallel trade ?

There was and also now is stated on the title page of the Guidance document concerning the parallel trade of plant protection products:

„COMMISSION GUIDANCE DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION

This document has been conceived as a working document of the Commission Services which was elaborated in co-operation with the Member States. **It does not intend to produce legally binding effects** and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) 1107/2009 nor any case law developed with regard to this provision.“



Other relevant involved Czech authorities

1) Customs Administration of the Czech Republic

- Intellectual Property Rights Infringement - up to now none cases as to the plant protection products.
- In 2015 CISTA signed an agreement with Customs Administration on providing the information on imports of PPPs from the third countries.

2) Police of the Czech Republic

- Only in cases of suspicions of criminal proceeding (against human or animal health, environment), not in case of violation of duties
- None criminal cases connected with plant protection products within 5 years before 2014.
- In 2014 (up to now) 4 cases being investigated on the basis of criminal announcement by authorisation holders of the reference plant protection product decisions.



Thank you for your attention!

Josef ŠVAŘÍČEK, Tomáš JEDLIČKA
ÚKZÚZ / CISTA

Section of Agricultural Inputs

Division of Plant Protection Products

Department of Inspection and Application Machinery

Zemědělská 1a, 613 00 Brno

Czech Republic

