



Registration of PPPs in the Republic of Moldova

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Phyto-Sanitary Means and Fertilizers*

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Legal frame of PPPs and fertilizers registration

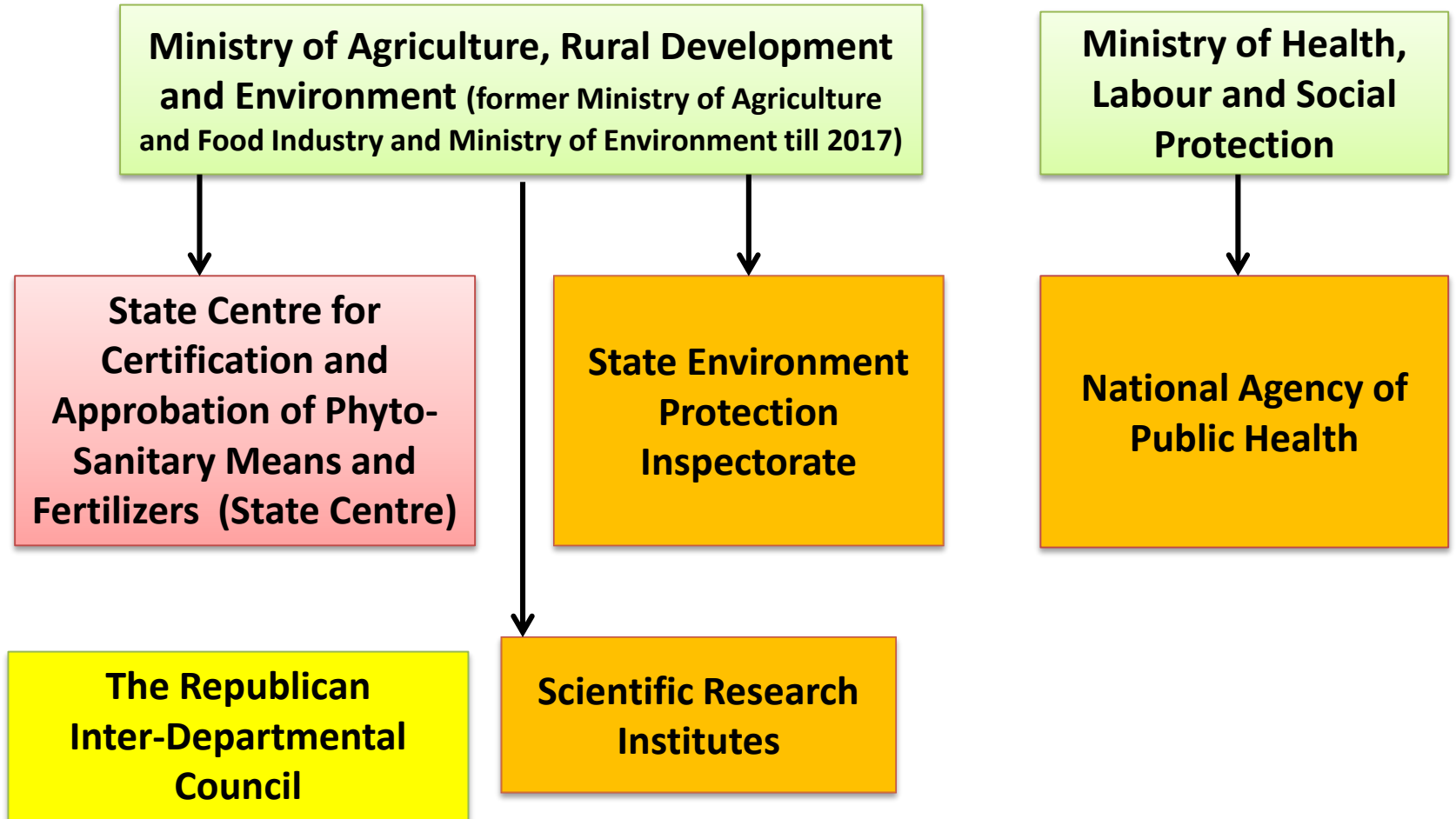
Law no. 119-XV of 22 April 2004 on phyto-sanitary (plant protection) products and fertilizers

Government Decision no. 897 (08.12.1994) on approbation and use of phyto-sanitary means and fertilizers in agriculture

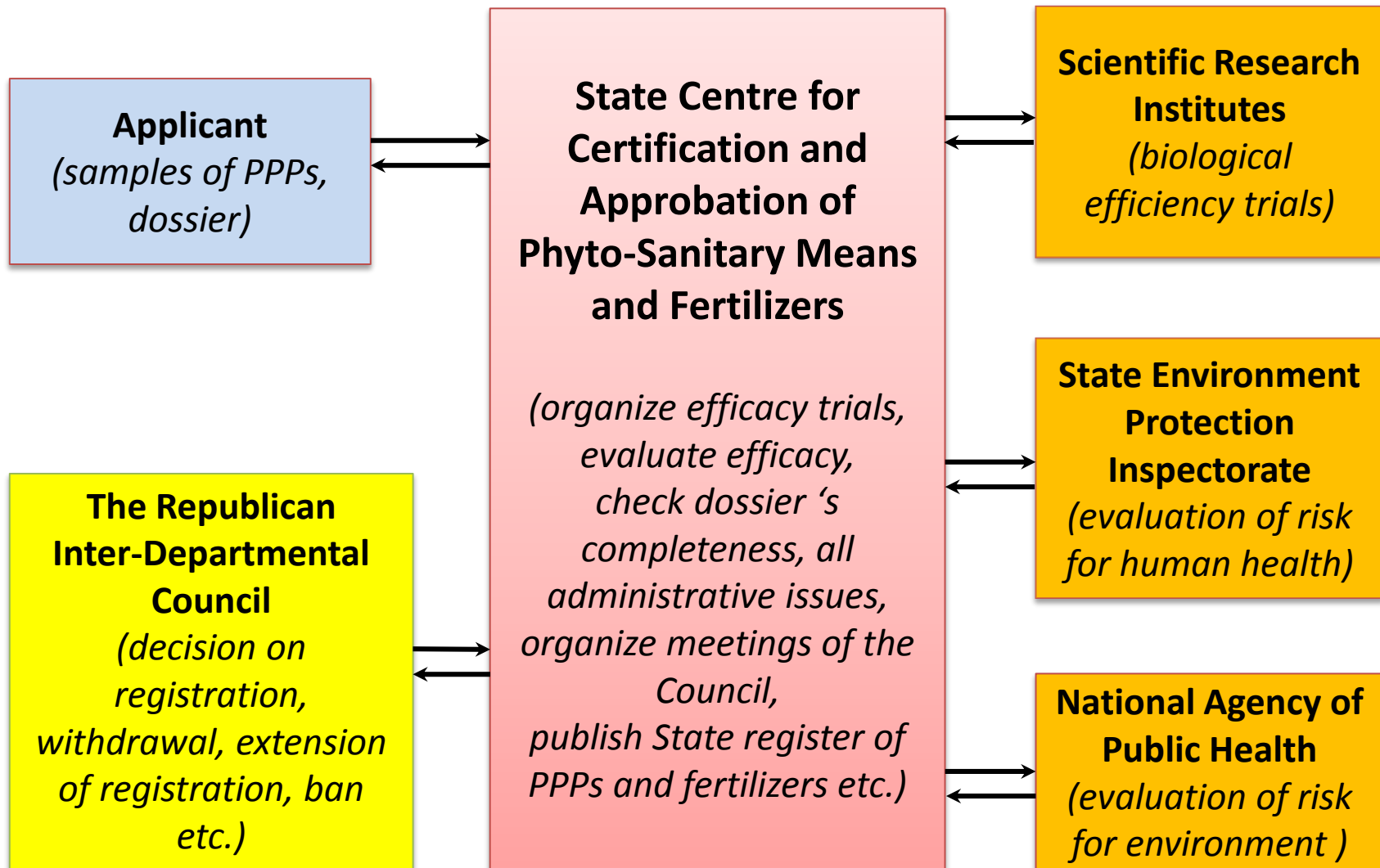
Government Decision no. 1307 (12.12.2005) on state biological efficacy trials and approval of phyto-sanitary means and fertilizers used in agriculture and forestry

Government Decision no. 200 (27.03.1995) on fees for state biological efficacy trials of phyto-sanitary means and fertilizers

Authorities involved in PPPs registration process in the Republic of Moldova



Registration process of PPPs in the Republic of Moldova



Registration procedure

Active substance has to be approved at EC level

Obligatory to conduct biological efficacy trials in Moldova

- 1 vegetation period for a.s. already registered in Moldova;**
- 2 vegetation periods for new a.s.**

Conclusions regarding impact on human health and environment

- 2 months for dossier evaluation**

Application form in Romanian, Russian

Dossier from EC and CIS is accepted (Romanian, Russian, English)

Registration decision – 1-3 years

Registration grant period is 7 years or 2 years in case of insignificant (lack of) information

Second trade name = new product (efficacy trials + registration)

Change of the trade name, registration holders – free of charge, 1-2 months

Recognition procedure

Starts from 12.10.2015, amendment of GD no. 1307 of 12.12.2005 - 1 vegetation period of efficacy trials for outdoor use

No efficacy trials, amendment of Law no.119-XV of 22. 04.2004 in 2017

PPP authorised according to Regulation EC 1109/2009

All zones are accepted

Application form in Romanian, Russian and English + dossier (1 paper copy+ 1 CD):

- copy of authorisation issued by EC MS (notary authorised) + translation in Romanian language
- copy of the label from EC MS + translation in Romanian language
- draft label for Moldova in Romanian language
- declaration of identity of the products proposed for recognition
- RR (part A+B+C) + BAD (electronical version)
- SDS in Romanian language
- EC technical equivalence report(s) for the a.s. manufacturing site(s) (if relevant)
- letters of access to a.s. data package(s) (if relevant)
- letters of access to formulation data package(s) (if relevant)

Assessment for ensuring identity of a.s. specification, formulation, label, scrutiny of the other country's data evaluation and risk/efficacy assessment

Opinion of evaluators regarding the registration -10 working days

Registration decision - 3 months

Registration grant period - 7 years

Information of registered PPPs in the Republic of Moldova

www.pesticide.md

The screenshot shows the website interface for the State Center for Attestation and Homologation of Products of Phytohygiene and Fertilizers. The main header includes the coat of arms of Moldova and the logo of the State Center. Below the header, there is a navigation menu with the following items: CONSILIUL REPUBLICAN INTERDEPARTAMENTAL (CRI), CERCETARE-TESTARE-EXPERIMENTARE DE STAT, OMOLOGARE ȘI ÎNREGISTRARE, PRODUSE OMOLOGATE, ORGANISM DE CERTIFICARE PRODUSE, and LABORATORUL DE ÎNCERCĂRI. The main content area is titled "REGISTRU CAUTARE" and contains a table with search results. The table has 11 columns: Denumirea comercială, forma preparativă, numărul și data înregistrării/expirării; Substanța activă, conținutul ei; Norma de consum a produsului (l/ha, kg/ha); Cultura; Organismul nociv (Denumirea științifică, Denumirea populară); Modul, perioada și limitele de utilizare; Intervalul de pauză înainte de recoltare (Numărul maximal de tratamente); Termenul de ieșire în câmp pentru efectuarea lucrărilor manuale (mecanizate); Categoria de pericol de toxicitate acută orală, om/albini; and Notă. The first row of data shows a product named "2,4-D 500" by "Nufarm GmbH & Co KG", Austria, with a registration number of 17-10-04-03-0169 and an expiration date of 04-10-2017/04-10-2024. The active substance is 2,4-D (sare de dimetil amină), 500 g/l. The consumption norm is 2,4 l/ha, and the culture is Romanian. The harmful organism is Buruieni dicotiledonate anuale. The application method is spraying on the leaves of the plants in the 2-4 leaf stage. The interval before harvest is -1, and the term of exit from the field is -3. The toxicity category is III/III.

Indice de produse Print

Căutarea produsului

REGISTRU CAUTARE

Denumirea comercială, forma preparativă, numărul și data înregistrării/expirării	Substanța activă, conținutul ei	Norma de consum a produsului (l/ha, kg/ha)	Cultura	Organismul nociv		Modul, perioada și limitele de utilizare	Intervalul de pauză înainte de recoltare (Numărul maximal de tratamente)	Termenul de ieșire în câmp pentru efectuarea lucrărilor manuale (mecanizate)	Categoria de pericol de toxicitate acută orală, om/albini	Notă
				Denumirea științifică	Denumirea populară					
1	2	3	4	5	6	7	8	9	10	11
2,4-D 500 "Nufarm GmbH & Co KG", Austria 17-10-04-03-0169 04-10-2017/ 04-10-2024	2,4-D (sare de dimetil amină), 500 g/l	2,4	Romaniță	-	Buruieni dicotiledonate anuale	Prin stropirea plantațiilor în faza de 2-4 frunze adevărate a culturii	-1)	-3)	III/III	-
2,4-D 500 "Nufarm GmbH & Co KG", Austria	2,4-D					Prin stropirea				

Changes in legislation

2017- Law no.119-XV as of April 22, 2004 on pesticides and fertilisers:

- no obligations to authorise EC fertilizers (Regulation 2003/2003) – just notification of import
- no efficacy trials for recognition procedure
- confidentiality and data protection provisions according to Regulation 1107/2009

2019 - Ministry of Agriculture, Rural Development and Environment has to transpose Regulation 1107/2009 into the Law no.119-XV as of April 22, 2004 on pesticides and fertilisers and present it for approval to the Parliament

2010-2018 Draft “Law on Chemical substances” (transposition of some articles from REACH, CLP, GLP, PIC, PPPs, biocides, detergents etc.).

Voted in first reading in the Parliament in 2017. Waiting for second vote.

GD no.600 of 27.06.2018 on National Agency of Food Safety functioning (establishment of Central Phyto-sanitary Laboratory by means of absorption of State Center)

Law on chemicals (draft)

The present law on chemicals **partially transposes** Article 191 of the **Treaty on the Functioning of the European Union** of 25 March 1957, published in the EU Official Journal C 326 of 26 October 2012 (the consolidated version); Article 1, 2, 4, 5, 6, 8, 35, 43, 46, 47, 49 in **Regulation (EC) No. 1272/2008** of the European Parliament and of the Council of 16 December 2008 **on classification, labeling and packaging of substances and mixtures**, amending and repealing Directives 67/548 / EEC and 1999/45 / EC, and amending Regulation (EC). 1907/2006 (Text with EEA relevance) published in the Official Journal of the European Union L 353 of 31 December 2008; Article 1-3, 5-7, 14, 31, 32, 34, 35, 56, 60-62, 68, 118, 119, 121, 123, 125, 126, Annex IV and Section 18a (Mercury) of Annex XVII of **Regulation (EC) No. 1907/2006** of the European Parliament and of the Council of 18 December 2006 looking **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency**, amending Directive 1999/45 / EC and repealing Regulation (EEC) No. 793/93 and Regulation (EC) no. 1488/94 and Directive 76/769 / EEC and Directives 91/155 / EEC, 93/67 / EEC, 93/105 / EC and 2000/21 / EC Commission(Text with EEA relevance) published in the Official Journal of the European Union L 396 of 30 December 2006; Article 1-4, 18, 28 of **Regulation (EU) no. 649/2012** of the European Parliament and of the Council of 4 July 2012 **concerning the export and import of hazardous chemicals (recast)** (Text with EEA relevance) published in the Official Journal of the European Union L 201 of 27 July 2012; Article 1, 2, 4-6, 10 of **Regulation (EC) No. 648/2004** of the European Parliament and of the Council of 31 March 2004 **on detergents** (Text with EEA relevance) published in the Official Journal of the European Union L 104 of 8 April 2004; Article 1-3, 28, 29, 31, 33, 40, 44 of **Regulation (EC) No.1107/2009** of the European Parliament and of the Council of 21 October 2009 **concerning the placing of plant protection products** and repealing Directives 79/117 / EEC and 91/414 / EEC, published in the Official Journal of the European Union L 309 of 24 November 2009; Article 1, 3, 17, 19, 20, 22, 25, 48 and Annex V of **Regulation (EU) no. 528/2012** of the European Parliament and of the Council of 22 May 2012 **on the placing on the market and use of biocidal products** (Text with EEA relevance), published in the Official Journal of the European Union L 167 of 27 June 2012; Article 1, 3, 8 of **Regulation (EC) No. 850/2004** the European Parliament and of the Council of 29 April 2004 **on persistent organic pollutants** and amending Directive 79/117 / EEC published in the Official Journal of the European Union L 158 of 30 April 2004; Article 1 of **Directive 2004/9 / EC** of the European Parliament and of the Council of 11 February 2004 **on the inspection and verification of good laboratory practice (GLP)** (codified version) (Text with EEA relevance) was published in the Official Journal of the European Union L 50 of 20 February 2004; Article 1 and the notion of "good laboratory practices" in Section 2.1 of Annex 1, Section I of **Directive 2004/10 / EC** of the European Parliament and of the Council of 11 February 2004 **on the approximation of the laws, regulations and administrative provisions relating to the application of good laboratory practice and the verification of their applications for tests on chemical substances** (codified version) (Text with EEA relevance), published in the Official Journal of the European Union L 50 of 20 February 2004; Article 1 of **Directive 2006/66 / EC** of the European Parliament and of the Council of 6 September 2006 **on batteries and accumulators and waste batteries and accumulators** and repealing Directive 91/157 / EEC (Text with EEA relevance), published in the Official Journal of the European Union L 266 of 26 September 2006; Article 1 of **Directive 2011/65 / EU** of the European Parliament and of the Council of 8 June 2011 **on the restriction of use of certain hazardous substances in electrical and electronic equipment** (Text with EEA relevance), published in the Official Journal of the European Union L 174 of 1 July 2011 and Article 11 of **Directive 94/62 / EC** of the European Parliament and of the Council of 20 December 1994 **on packaging and packaging waste**, published in the Official Journal of the European Communities L 365 of 31 decembrie 1994.

Law on chemicals (draft)

(1) In the context of Article 17 of the present Law and para. (1) letter a) of this Article, the **authorisations** mentioned in Article 24 para. (1) letters a) and b) of this Law, **can not be issued, if the plant protection product or the biocide:**

1) contains or consists of:

- a) mercury and/or its compounds;
- b) persistent organic pollutants;

2) being intended for placement on the market for use by the general public in accordance with the requirements on classification, labelling and packaging of substances and mixtures, approved by the Government, meets the criteria to be classified:

- a) **toxic or very toxic;**
- b) **carcinogenic of category 1 or 2;**
- c) **mutagenic of category 1 or 2;**
- d) **toxic for reproduction of category 1 or 2;**
- e) **in the acute oral toxicity hazard class of category 1 or 2 or 3;**
- f) **in the acute dermal toxicity hazard class of category 1 or 2 or 3;**
- g) **in the acute inhalation toxicity (gases and dust/mist) hazard class of category 1 or 2 or 3;**
- h) **in the acute inhalation toxicity (vapours) hazard class of category 1 or 2;**
- i) **in the carcinogenicity hazard class of category 1A or 1B;**
- j) **in the mutagenicity hazard class of category 1A or 1B; or**
- k) **in the reproductive toxicity hazard class of category 1A or 1B;**

Regulation (EU) no. 528/2012 of the European Parliament and of the Council of 22 May 2012 on the placing on the market and use of **biocidal products**

4. **A biocidal product shall not be authorised** for making available on the market for use by the general public where:

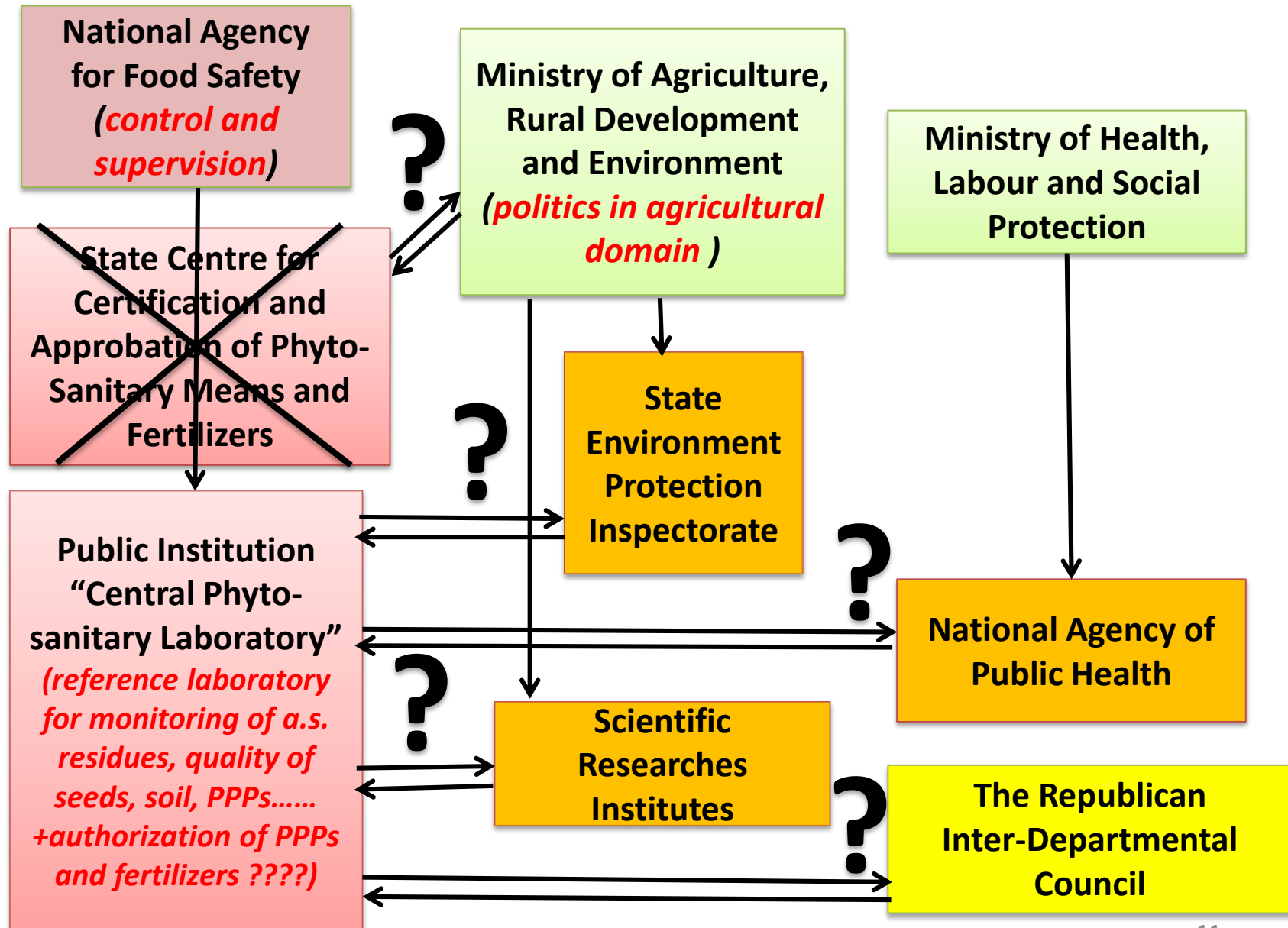
(a) it meets the criteria according to Directive 1999/45/EC for classification as:

- **toxic or very toxic,**
- **a category 1 or 2 carcinogen,**
- **a category 1 or 2 mutagen, or**
- **toxic for reproduction category 1 or 2;**

(b) it meets the criteria according to Regulation (EC) No 1272/2008 for classification as:

- **acute oral toxicity category 1 or 2 or 3,**
- **acute dermal toxicity category 1 or 2 or 3,**
- **acute inhalation toxicity (gases and dust/mist) category 1 or 2 or 3,**
- **acute inhalation toxicity (vapours) category 1 or 2,**
- **a category 1A or 1B carcinogen,**
- **a category 1A or 1B mutagen, or**
- **toxic for reproduction category 1A or 1B;**

Changes of authorities involved in PPPs registration process, start 2019





Thank you for your attention