



THE ADMINISTRATION OF THE REPUBLIC OF SLOVENIA FOR FOOD SAFETY, VETERINARY SECTOR AND PLANT PROTECTION

Plant Protection Products Unit

Experiences and challenges

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- Staff and structure
- Regulation 1107/2009 - experiences and challenges



ORGANIZATION

- **Administration is an expert body within the Ministry of Agriculture, Forestry and Food and is managed by the Director General, who is directly responsible to the Minister of MAFF**
- **Under the Director General operate at the Central level:**
 - Seven technical divisions, including Food Safety, Veterinary and Plant Health Inspection
 - Internal Audit Office
 - General Affairs Service
 - Public relations office



TASKS AND GOALS OF THE ADMINISTRATION

- **legislative framework preparation and implementation**
- **risk monitoring**
- **managing public health in the field of food, animal health and plant health risks, risks for the environment**
- **official inspection and control along the entire food and feed chain**



PLANT PROTECTION PRODUCTS UNIT

Responsible for PPPs: technical division, operating at the central level - Plant Protection Products Unit

- **the competent authority for authorization of plant protection products**
- **responsible for coordination, exchange of information and international matters in the PPP field**
- **responsible for reporting to the EU Commission**



ORGANISATION OF THE PPP UNIT

- Ministry of agriculture, forestry and food
 - ❖ **Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection,**
 - ❖ **Food Safety, Veterinary and Plant Health Inspection** (inspection control),
 - ❖ Laboratories appointed by the Administration (analytical and other scientific and technical work),
 - ❖ **Evaluation** of PPPs, active substances and other expert work:
 - 4 contracted Institutes : (16 evaluators, 9 full time, 7 part time)-coordinated by the Administration
 - Agricultural Institute of Slovenia
 - Slovenian Institute of Hop research
 - Institute of Public health of the Republic of Slovenia
 - Regional Agricultural Institute Nova Gorica



TASKS OF THE PPP UNIT (1)

Main administrative and technical tasks connected with *PPPs*:

- preparing legislation and taking care for its implementation;
- authorisation of PPPs and issuing permits;
- inter-ministerial coordination of work and cooperation in connection with the authorisation of PPPs;
- technical requirements for spraying equipment;
- monitoring conditions in the sphere of placing on the market and use of PPPs and cooperation in preparing measures,
- adopting control programmes regarding measures for the proper use of PPPs, including monitoring of pesticide residues in plants and plant products;



TASKS OF THE PPP UNIT (2)

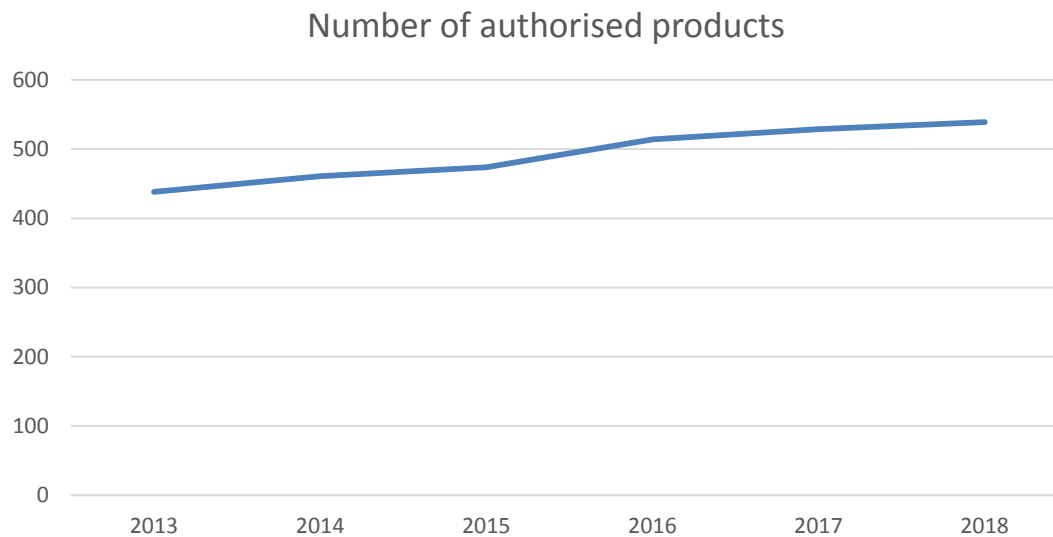
- **introducing the principles of good plant protection practice and integrated pest management**
- **managing the system for training of farmers in using PPPs,**
- **setting up and maintaining an information system in the field,**
- **keeping records, registers and lists,**
- **preparation of the reports, analyses, information and other materials**

Legal base is the Plant Protection Products Act (ZFFS-1) (UL RS 83/12) , harmonised with Directive 2009/128/EC and Regulations (EC) 1107/2009 and 396/2005

- 8 employees in the Administration (1-PPP users training and spraying equipment; 3-management, 4- authorisation and coordination of work)



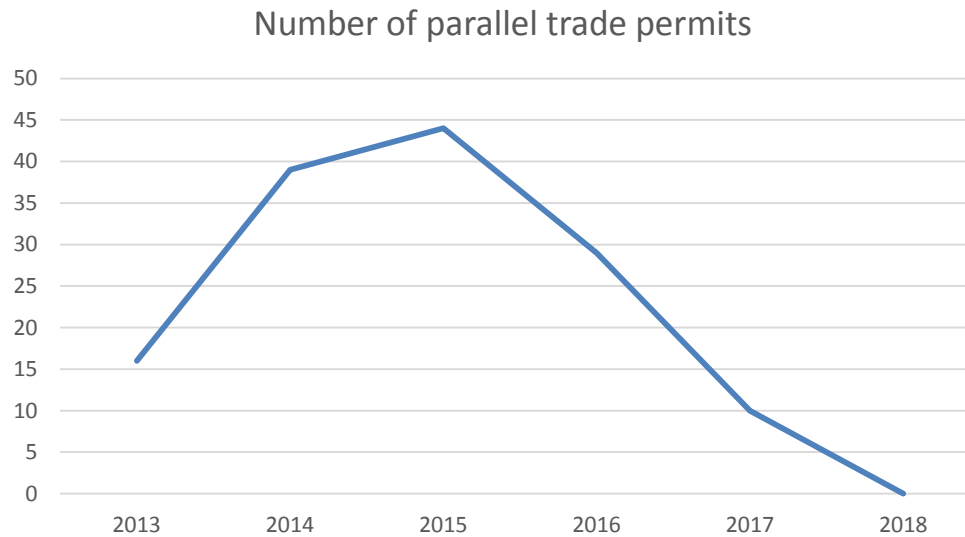
Authorised products



increasing trend - generic PPPs after data protection expiry
- authorisation without placing on the market



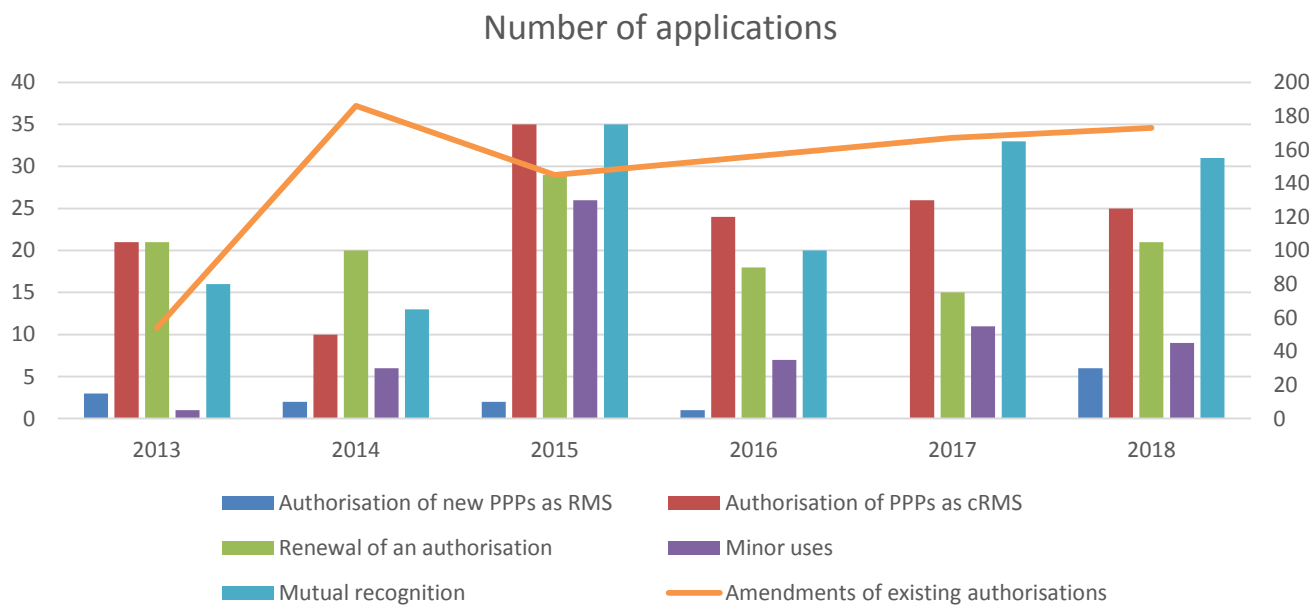
Parallel trade permits



decreasing trend



Number of applications





Issues and challenges (1)

- **PPPs:**
 - Difficult planning of Art. 43 renewals due to delays with a.s. renewals
 - PPP authorisation without subsequent placing on the market
 - Brexit
 - Increasing number of parallel trade names (placing on the market the same PPP under a different name)
 - many applications from generics after data protection expiry
 - lower quality dossiers
 - growing differences in evaluations between MS



Issues and challenges (2)

- **Active substances:**

- increasing demands (endocrine disruptors, Brexit, long process of renewal of approval, new forms...) with unchanged capacity of employees

- inevitable delays lead to poor commenting and issues with mutual recognition; priority evaluation of active substances and new and Art. 43 authorisations as RMS

- number of active substances in decline -> increased number of emergency authorisations and minor uses



Suggestions for more effective work

- Preparation of more elaborate and authentic guidance documents to avoid constantly changing them
- A.s. renewal with endpoints lowered - issues not finalised (ED,...) usually delay the evaluation for 30 mths. In terms of consumer health and safety it is better to conclude the evaluation and make a confirmatory data request
- Require the preparation of higher quality dossiers (generics)
- Growing differences in evaluations – training?



REPUBLIKA SLOVENIJA
MINISTRSTVO ZA KMETIJSTVO IN OKOLJE

UPRAVA RS ZA VARNO HRANO,
VETERINARSTVO IN VARSTVO RASTLIN

Thank you for your attention.

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