

# Twinning projekt EU

"Dalje jačanje kapaciteta u fitosanitarnom sektoru iz oblasti sredstava za zaštitu bilja, zdravlja bilja, sjemena i sadnog materijala, uključujući fitosanitarne laboratorije i fitosanitarnu inspekciju"





# Criteria for preparation of work plans for PPP and presentation of EU experience

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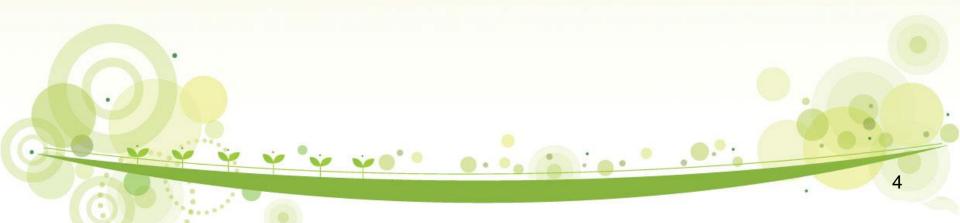
# Strategies of control



- Strategies of control are referred to the control systems in place for pesticides, in particular:
- the implementation of requirements for official controls on the marketing and use of PPPs under Regulation (EC) No 1107/2009 and Directive 2009/128/EC;
- the implementation of the requirements for official controls of PPPs at growers, as specified in Regulation (EC) No 882/2004



- A system of European Community supervision in area marketing and use of PPP is described by:
- article 4(1) of requires MSs to designate the CAs responsible for official controls and ensure that they have access to a sufficient number of suitably qualified and experienced staff, and that they have appropriate and properly maintained facilities and equipment.



- article 3 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency, taking account of
  - identified risks;
  - the past record as regards compliance;
  - the reliability of any own checks that have already been carried out; and
  - any information that might indicate non-compliance.

- article 8 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls,
- article 9 requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned,
- article 6 requires CAs to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

- article 54 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.
- article 55 states that MSs shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.



- A system of European Community supervision in area marketing and use of PPP is described by:
- article 75(3) requires MSs to ensure that CAs have a sufficient number of suitably qualified and experienced staff to carry out their obligations efficiently and effectively.
- article 68 requires MSs to transmit to the Commission a report on the scope and the results of controls to enforce compliance with this Regulation within six months of the end of the year to which the reports relate.
- article 72 states that MSs shall lay down the rules on penalties applicable to infringements and ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive.

# Marketing of PPP's



#### According to the European Community law:

- a plant protection products shall not be placed on the market unless it has been authorised in the member state - article 28 of Regulation (EC) No 1107/2009,
- certification systems of trainings should be established and all distributors of plant protection products should have access to appropriate training – article 5 of Directive 2009/128/EC,
- the sale of plant protection products to professional users should be restricted to persons holding a certificate - article 6 of Directive 2009/128/EC,
- producers, suppliers, distributors, importers and exporters of PPPs should keep records for at least 5 years - article 67(1) of Regulation (EC) No 1107/2009,

# Marketing of PPP's



- necessary measures to ensure that handling and storage of pesticides should be adopted, and handling, recovery or disposal of their packaging and remnants should not endanger human health or the environment - article 13 of Directive 2009/128/EC,
- information about authorised or withdrawn plant protection products should be electronically published article 57 of Regulation (EC) No 1107/2009,
- the advertisement of plant protection products should be supervised,
- program for formulation of analyses should be implemented.

#### PPP's use



# According to the European Community law:

- the professional users should keep, for at least 3 years, records of the plant protection products they use - article 67(1) of Regulation (EC) No 1107/2009,
- the use of PPPs shall comply with the general principles of Integrated Pest Management (IPM), as referred to in article 14 of Annex 3 to Directive 2009/128/EC,
- plant protection products shall be used, inter alia, in compliance with the authorised conditions specified on the labels - article 55 of Regulation (EC) No 1107/2009,
- all professional users should have access to appropriate training - article 5 of Directive 2009/128/EC,

#### PPP's use

- pesticide application equipment in professional use is subject to inspections at regular intervals - article 8 of Directive 2009/128/EC,
- necessary measure to ensure that handling and storage of pesticides should be adopted, and handling, recovery or disposal of their packaging and remnants shall not endanger human health or the environment - article 13 of Directive 2009/128/EC,
- professional users should conduct regular calibrations and technical checks of the pesticide application equipment article 8(5) of Directive 2009/128/EC,

# Preparation of work plans for activities in the PPP's marketing and use - expirience of Poland



# **Capacity of control - Operational criteria**



#### Requirements for control bodies:

- sufficient number of qualified and experienced staff
- accurate description of the tasks
- has the required expertise, equipment and infrastructure
- ilmpartial and free from conflict of interest
- use accredited laboratories
- communicate results and coordinate with CA

# **Capacity of control - Operational criteria**

- Control should be effective and appropriate
- Proper facilities
- Access to adequate laboratory
- Legal powers in place
- Provisions in place which oblige operators to undergo inspections and assist the inspectors
- Coordination between authorities is essential
- Internal/External audits are to be carried out
- Specific tasks can be delegated

# **Capacity of control - Operational criteria**



The controls should be carried out according to documented procedures contain information and instructions on

- tasks, responsibilities and duties of staff
- sampling procedures, control methods and techniques, interpretation of results and consequent decisions
- monitoring and surveillance programmes
- actions to be taken
- cooperation
- verification of the methods
- any other activity/information required

#### Plan of control



The control plan shall indicate in particular:

- subjects of controls, and shall specify the number of planned inspections;
- indication of controlled areas or locations of the inspection;
- dates of controls.

If necessary, regardless of the control plan, the controlling authority may decide on ad hoc controls which are regarded as intervention controls, or they might be necessary in order to urgently address emergencies.

# Planning control in Poland – marketing of PPP's



Risks associated with specifications in wholesalers and retailers should be recorded and the controls should be planned in accordance with the risk analysis with appropriate frequency

Based on the solutions accepted in Poland, during preparation of an inspection plan within the area of trade in plant protection products, the following criteria are used:

- the amount of sales and
- irregularities.

wholesalers, places of production and co-packaging of plant protection products are controlled at least <u>annually</u>,

retail outlets - once every two years, unless there are some irregularities found. In cases of law infringement, such places are controlled annually.

# Planning control in Poland – control of formulation



collecting samples of plant protection products for laboratory testing is the integral part of the inspection plan. Poland has designed a statistical model, on the basis of which, the number of samples to be tested each year is estimated. The control in this scope is prevention-oriented - on successful detection of the highest possible number of irregularities among the products sold and on monitoring activities which aim to obtain the image of the country's situation in regards of the quality of the products being in trade.



### Planning control in Poland – control of formulation



There are two types of formulation inspections: **basic and interventional**. On the basis of the inspection results from the previous years, the parameters which showed the biggest correlations with irregularities are the criterion for the division of basic samples. In 2014 those parameters were as follows:

- the type of permission for placing of PPP on the market,
- plant protection product's purpose (herbicide, fungicide, insecticide),
- product's formulation.

Pesticides are divided into several groups to which the appropriate number of samples is described. Those samples are then allocated to particular regional inspectorate offices, proportionally to the number of points of sale, estimated amount of PPPs used and the area of crops

# **Planning control in Poland - formulation**

No of group	The type of permission	PPP purpose	Formulation	No of samples		
1	parallel trade	herbicide	SC	10		
2	parallel trade	herbicide	SL	15		
3	parallel trade	herbicide	WG	15		
4	parallel trade	herbicide	no (SC, SL, WG)	3		
5	parallel trade	herbicide		7		
12	normal	herbicide	WG	16		
13	normal	herbicide	No (SC, SG, SL, WG, WP)	15		
14	normal	insecticide	EW, WG	10		
15	normal	insecticide	no (EW, WG)	7		
16	normal	other	FS, GB, SC, WG	15		
17	normal	other	no (FS, GB, SC, WG)	8		
	YYY	Sum	0.00	260		

# Planning control in Poland – use of PPP's



#### Use of PPP

In this area, inspection planning is also based on the statistical model designed on the basis of the previous years' control results. Taking into consideration the number of farms on the territory of the country, it is assumed that the number of inspections shall not be smaller than 1%. It was also assumed that the inspection of plant protection products shall be both prevention-oriented (detection of the greatest possible number of irregularities) and monitoring-oriented (shall present the image of the correctness of PPPs application).

# Selection of farmer-professional user

- The selection of professional user- farmer has to do with the questions who, when and what to be controlled. So to the annual plan we calculate the following risk factors:
  - statistic data
  - crop importance
  - infridgemens in previous year
  - illegal residues in previous year (official controls)

# **Selection of crop**



An annual plan is drifted calculating the following risk factors:

- crop importance
- tension of pesticide use
- MRL exceedances
- other illegal residues (without exceeding MRL)



# Planning control in Poland – use of PPP's



The crops inspected, due to different characteristics of protection and the amount of plant protection products used, are divided into three groups:

- arable (corns, bulb and root plants, oleaginous),
- vegetable,
- fruit.

In each group, there were three areas.

# Planning control in Poland – use of PPP's



As the risk factors, the following were assumed:

- the area of farms containing crops of a particular group and its area,
- the amount of average use of plant protection products in a given group,
- the area of cultivation,
- irregularities detected.



# **Planning control in Poland**

No.	DECIONAL	ARABLE		VEGETABLE			FRUIT			Sum	
	REGIONAL UNIT	2 - 10	11 - 50	up to 51	0,2 - 4	4 - 10	up to 11	0,2 -4	4- 10	up to 11	number of control
		(ha)									
1	1	160	92	710	14	19	52	43	45	44	1179
2	2	187	167	538	49	72	232	58	33	36	1372
3	3	615	181	325	108	175	247	575	283	387	2896
4		50	33	298	14	14	24	25	8	14	480
5		457	141	154	130	83	141	129	204	147	1586
6		306	21	63	101	72	115	170	57	6	911
7		710	215	326	127	124	93	351	591	742	3279
8		77	64	431	15	1	25	14	2	10	639
9		332	24	125	15	11	10	180	13	23	733
10		258	117	110	8	6	5	38	14	49	605
11		126	45	511	27	16	137	28	21	29	940
12		155	34	155	12	8	18	28	1	5	416
13		285	33	48	123	54	23	201	247	114	1128
14		88	82	479	6	24	42	15	23	12	771
15	V W	367	291	671	127	58	. 155	98	51	152	1970
16		64	42	662	8	3	47	27	8	234	2 <sup>1</sup> <del>9</del> 95
	Sum	4237	1582	5606	884	740	1366	1980	1601	2004	20000

# Planning control in Poland – use of PPP's



The plan of sampling for testing for the residues of plant protection products is also drawn up. As the risk factors, the following are assumed:

- the number of plantations,
- the number of residues detected,
- the amount of plant protection products used,
- the volume of export sales.

# Planning control in Poland – use of PPP's



Apart from the quantitative-oriented plans, control guidelines are issued and priority actions are established. They additionally direct controls on areas which are particularly important due to the threats diagnosed there.



# Planning control in Poland



Below is the list of the examples of such actions:

prevention of placing on the market of illegal and not genuine plant protection products. Additional recommendations concern, among others, collecting samples of those products, if there is a suspicion that they are not genuine, for interventional laboratory testing, conducting of ad-hoc controls in places, such as markets and fairs, where there may be illegal trade in plant protection products, analysing of sales offers and advertisements of plant protection products placed, for instance, on the Internet and in specialist press, informing plant protection products' users about risks of using not genuine plant protection products and about the methods of prevention of these practices,

# Planning control in Poland

- special supervision of high-productive farms on which, in the previous year, the highest acceptable level of PPPs residues was detected,
- supervision of farms which are engaged in crop production oriented on export sales to the countries of non EU countries, etc.

# Scope of control of PPP's - marketing of PPP's



#### Documentation and conditions of trading:

- formal entry into the register of entrepreneurs engaged in marketing of plant protection products and validity of the data entered in the register;
- possession of a valid certificate of completion of training in counseling for plant protection products;
- keeping and maintaining for the period of at least five years of documentation concerning imported, exported, stored and marketed plant protection products in such a way that with the exception of the sale of plant protection products to the eventual buyer it would make it possible to determine batch number and production date of the purchased and sold plant protection products.

# Scope of control – documentary check

- the fulfillment of the obligation to provide relevant information by the person making the disposal of plant protection products on demand of a buyer regarding the risks associated with the use of plant protection products purchased and their proper and safe use;
- compliance with the prohibition on disposal of plant protection products as well as on offering to sale such products to a person whose behavior indicates that they are in a state of intoxication or to a minor, in replacement packaging, by using a machine, by self-service or sales made beyond the point of a fixed location (doorstep selling and hawking on marketplaces), in rooms where food or fodder is sold, and compliance with the other prohibitions under the legislation;

# Scope of control – documentary check

- compliance with the order for sales of plant protection products intended for professional users only by persons authorized to purchase such measures – those in possession of a certificate of completion of a relevant training;
- storage of pesticides which are past the expiration date or not intended for sale for other reasons shall take place in a separate and appropriately marked place;
- storage of plant protection products according to the label recommendations;

# Scope of control – PPP's placed on the market



- Plant protection products placed on the market
- marketing authorization for plant protection products -(based on purchase invoices, and available resources);
- term of validity of the plant protection product;
- package:
  - compliance of the packaging of plant protection products placed on the market with the authorization
  - overall assessment of the state of the packaging and its closure;
  - checking whether the date of manufacture and batch number are marked clearly and indelibly;
  - checking whether the information provided on the packaging is in line with the authorization;

# Scope of control – PPP's placed on the market



- label:
  - compliance of the label with the authorization;
  - information about the person responsible for the final packaging and labeling;
  - content of the label must be written in a Polish language;
- the presence on the market of plant protection products that have received a negative certificate of analysis;
- collection of samples for laboratory tests on the composition or physical or chemical properties of plant protection products with respect to the parameters specified in the registration process.

# Scope of control – advertisiment



control of plant protection products advertised in printed or electronic media, in particular, checking whether the advertisement:

- concerns the protection product which has the appropriate approval
- contains the relevant phrases and expressions;
- does not include information in text or graphic form which could be misleading in terms of possible risks;
- does not visually present any potentially dangerous
  actions;
- is consistent with the approved label content and that all statements used in advertising are technically justifiable.

# The scope of control - PPP's use

- The use of plant protection products, taking into account the principles of integrated pest management.
- possession, by the farmers applying the pesticides, of a certificate of completion of training in the use of plant protection products;
- possession of the purchase proof or of the current certificate confirming the technical condition of the equipment intended for use in plant protection products, and marking with a validation character;
- possession and proper record keeping on the use of plant protection products;
- if possible, checking the purchase receipts or invoices of plant protection products



The use of plant protection products, taking into account the principles of integrated pest management.

- Plant protection products
  - authenticity of the packaging of the plant protection product;
  - verification whether the farmer used authorized plant protection products;
  - term of validity of the plant protection product;
  - the rules of storage of the plant protection products;
  - proceedings with the empty packages of plant protection products.



Proper crop protection activities, taking into account the principles of integrated pest management

- conducting the analysis of the records contained in the documentation of the use of plant protection products in terms of the principles of integrated pest management, in particular, the product's admission to trade, the accuracy of its use in relation to the cultivation of a pest, the date of performing the treatments and dosages.
- if appropriate, compliance with the prohibitions and restrictions on the use of plant protection products in areas of playgrounds, nurseries, kindergartens, primary schools, hospitals, and protection zones;

- taking into account the application of the provisions relating to the maintenance of appropriate distance, weather conditions, technically efficient and calibrated equipment in order to ensure the correct application of the plant protection products,
- the use of plant protection products shall be authorized in such a way as not to pose a health risk to humans, animals and the environment, including prevention of transferring of the plant protection products onto the areas and objects not targeted with the treatment which uses these agents, and planning the use of plant protection products with consideration of the period during which people will be present in the area covered by the procedure;

## Control of other activities connected with PPP'use



- Control of entrepreneurs who carry out:
- trainings for professional users of PPP's
- examination of equipment intended for pesticide application



# PROPOSAL ON CONTROL PLAN FOR 2016

# Marketing of PPP's



- All entrepreneurs engaged in the marketing of PPP's shall be registered. Actually it is not obligatory in EU, but some MS have introduced such obligations. It helps to control PPP's marketing.
- Import control each consignment of PPP's should be checked, at random active substance and hand luggage (smuggling of the illegal PPP's – memorandum with customs service)
- Production control and the places where PPPs are repacked –
  one control during a year
- Distribution control the wholesalers once a year and the retailers once a year.

# Control of marketing of PPP's

- number of entrepreneurs:
- importers xxxx(wholesalers)
- producers xxxx
- repackaging plants xxxx(producers)
- wholesalers xxxx
- retailers xxxx

Number of import consignments (2014) -

Number of control (internal control marketing and use) in 2015

– (control+re-control) xxxx

decision - xxxx

irreg: labelling, packaging (marketing) - xxxx

The number of control labelling (during each control) - xxxx

# Control of marketing of PPP's

- number of control:
- importers xxxx
- producers xxxx
- repackaging plants xxxx
- wholesalers xxxx
- retailers xxxx

Number of import consignments control – xxxx

**SUM - xxxx** 

Number of control of markets, bazaars – xxxx

Number of re-controls – about xxxx a year

Number of interventional control (information concerning pesticide less efficiency) - xxxx

## Control of formulation of PPP's



On the each stage of distribution should be possibility to take samples of PPPs in case of testified irregularities (interventional control)

(monitoring about 70 samples)

Place of control	Monitoring	Interventional control
border	30%	
producer and repackaging plants	70%	30 samples (proposal)
distibutors		

- Number of farms xxxx
- Number of control coducted in 2014, 2015 and elements under control in the farms xxxx

- Crop importance area of crops xxxx
- Tension of pesticide use (apple, grapes, tomatoes...)
- MRL exceedance in the previous year: xxxxx,
- Other illegal residues: xxxx
- Other irregularities xxxx



Control of 1% of farms – (xxxx recomendation) -

Number of re-control – xxxx

Number of intervention control (the killing of the bees by pesticide, notification testified in export and domestic market) – xxxx

Other type of control: forests, aerial spraying, railroad, green area in the city (parks, stadions, etc.) - xxxx

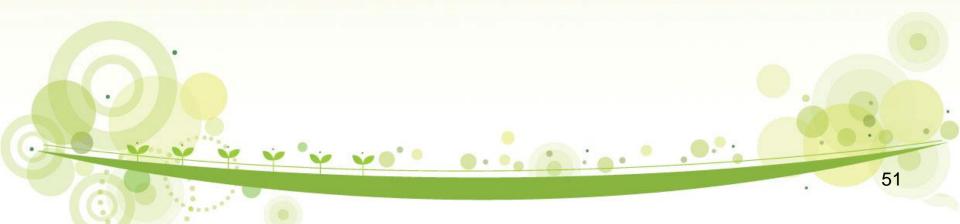
Crops	Number of control (%)
Fruits	40
Vegetables	40
Arable	20

# Control of residues of PPP's



During of the control there should be possibility to take samples for pesticides residues control

Sampling for residues control	Monitoring	Intervention control
Primary production	150 samples	20 samples (proposal)



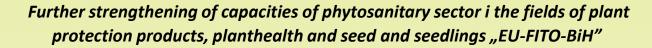
## Plan of control



The control plan shall indicate in particular:

- subjects of controls, and shall specify the number of planned inspections;
- indication of controlled areas or locations of the inspection;
- dates of controls,
- take into account the monitoring plan.







# Thank you for your attention!!!





Further strengthning of apacities of phytosanitary sector in the fields of plant protection products, plant health and seed and seedlings "EU-FITO-BiH"

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