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CEUREG FORUM XVI

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SESSION II A

POST REGISTRATION CONTROL OF PLANT PROTECTION PRODUCTS IN POLAND – THE NEW IDEAS

CEUREG FORUM XVI organised by Austrian Agency for Health and Food Safety

Vienna, Austria, 15th – 16th October 2012



ORGANIZATION OF QUALITY CONTROL OF PPP'S

Multi-year national programme for 2011-2015

**CROP PROTECTION TAKING INTO ACCOUNT FOOD SAFETY AND
PREVENTION OF YIELD LOSSES AND HAZARDS TO HUMAN HEALTH,
LIFESTOCK AND THE ENVIRONMENT**

Supervision: Ministry of Agriculture and Rural Development

Contractors: National Plant Protection and Seed Inspection Service

Institute of Plant Protection National Research Institute



CONTRACTORS

1. INSPECTION:

- plans
- sampling
- analysing the reports
- approval of the reports

2. IPP:

- conduct analysis
- issue certificates
- detailed annual report
- create databases



QUALITY TESTING

Laboratory of Quality Control of PPP's (GLP) IPP-NRI SOSNICOWICE BRANCH

- active substance content and identification
- physical and chemical properties of formulations
- identification and determination of impurities
- identity testing by „chromatografic profile”
- identification and determination of inert substances in a formulation
- 5-batch analysis of technical active substances

GC (FID, ECD, HEAD SPACE); GC-MS (EI, CHEM); HPLC (UV, DAD, RR)
LC-MS/MS; TLC-SCAN; SET OF PHYS-CHEM METHODS

Methods:

- CIPAC, OECD, AOAC international standard methods
- producer's methods
- own methods
- scientific literature



NUMBER OF PPP'S SAMPLES TESTED OFFICIAL CONTROL (2006-2011)

Year	Number of samples - official control	Number of samples - interventional control
2006	310	10
2007	289	11
2008	263	69
2009	261	45
2010	271	78
2011	268	40
Total	1662	253



NUMBER OF „NEGATIVE” SAMPLES (2010-2011)

„Negative” means that a product largely deviates from quality parameters. The certificate concludes that the whole batch represented by the test sample should be remove from the market.

Year	Number of samples - official control	Number of samples - interventional control	Number of negative samples - official control	Number of negative samples - interventional control
2010	271	78	2	35
2011	268	40	8	26
2010-2011	539	118	10	61



TASKS OF OFFICIAL QUALITY CONTROL

- ❑ Effective uncovering of irregularities in pesticides quality which could affect their efficacy and safety of humans and the environment
- ❑ Monitoring, that is collecting information on the quality of pesticides being sold around the country



Directing control to areas that are most at risk



Changing the system of taking samples by inspectors from the plant inspection service



Basis for the change: *statistical analysis of control results for 2010-2011*

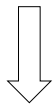


Utilizing the database



PROVISIONS OF THE NEW SAMPLING SYSTEM (for 2012)

- ❑ **General number of samples to be taken: 300 planned, 50 interventional (the number of samples similar to previous years → limits in funding)**
- ❑ **Irregularities defined by the number of negative certificates**
- ❑ **Utilizing the entire set of results included in the database for 2010-2011**
- ❑ **Dividing irregularities into groups was established based on the following three factors:**
 - **Type of authorization for sale and use (standard, parallel trade)**
 - **Product intended use (herbicide, fungicide, insecticide, other)**
 - **Type of product formulation**



Division into 14 characteristic groups



PROVISIONS OF THE NEW SAMPLING SYSTEM (cont'd)

Criteria for establishing the number of samples in each group:

- Number of irregularities in relation to the number of cases in each group**
- Product sales volume for individual groups based on sales statistics for 2010-2011**



Each criterion was given equal weight (1:1)

This resulted in tying the control directed at irregularities to monitoring



PROVISIONS OF THE NEW SAMPLING SYSTEM (cont'd)

**Criteria for defining the number of samples to be taken in each province
(PL-16):**

- Number of plant points of sale per province**
- PPP use according to use statistics for 2010-2011**
- Crop area per province**



**Allocating samples from individual groups to each province –
by random draw**



TESTED GROUPS

Group	Authorization type	Product type	Formulation
1	PT	H	SC
2	PT	H	SL
3	PT	H	WG
4	PT	H	not SC, SL, WG
5	PT	not H	EC
6	PT	not H	not EC
7	standard	F	all
8	standard	H	EC
9	standard	H	SL
10	standard	H	WG
11	standard	H	not EC, SL, WG
12	standard	I	EC, SC
13	standard	I	not EC, SC
14	standard	not F, H, I	all



OUTCOME DATA (1)

NUMBER OF IRREGULARITIES IN RELATION TO THE NUMBER OF TESTED CASES

Group	Authorization type	Product type	Formulation	Number of irregularities 2010-2011	Number of cases tested 2010-2011	Percentage of irregularities per group
1	PT	H	SC	6	17	35,3%
2	PT	H	SL	7	22	31,8%
3	PT	H	WG	7	17	41,2%
4	PT	H	not SC, SL, WG	0	8	0,0%
5	PT	not H	EC	7	26	26,9%
6	PT	not H	not EC	3	19	15,8%
7	standard	F	all	8	241	3,3%
8	standard	H	EC	5	82	6,1%
9	standard	H	SL	7	121	5,8%
10	standard	H	WG	6	57	10,5%
11	standard	H	not EC, SL, WG	3	90	3,3%
12	standard	I	EC, SC	4	96	4,2%
13	standard	I	not EC, SC	2	44	4,5%
14	standard	not F, H, I	all	2	95	2,1%

Explanation of abbreviations used above:

- PT – parallel trade products
- not H – product other than a herbicide
- other - product other than a fungicide, herbicide or insecticide
- not EC – formulation other than EC
- not EC, SL, WG – formulation other than EC, SL or WG

OUTCOME DATA (2)

SALES VOLUME PER GROUP

Group	Authorization type	Product type	Formulation	Sales in 2010+2011 [kg]	% sales
1	PT	H	SC	162 537	0,147%
2	PT	H	SL	741 117	0,672%
3	PT	H	WG	7 276	0,007%
4	PT	H	not SC, SL, WG	51 682	0,047%
5	PT	not H	EC	216 344	0,196%
6	PT	not H	not EC	616 692	0,559%
7	standard	F	all	26 449 144	23,969%
8	standard	H	EC	8 437 481	7,646%
9	standard	H	SL	37 735 331	34,196%
10	standard	H	WG	884 848	0,802%
11	standard	H	not EC, SL, WG	18 156 853	16,454%
12	standard	I	EC, SC	4 030 711	3,653%
13	standard	I	not EC, SC	1 805 691	1,636%
14	standard	not F, H, I	all	11 053 578	10,017%
Total				110 349 285	100 %



ALLOCATION OF 300 SAMPLES PER GROUP

Following statistical analyses and calculations – samples were allocated as follows:

Group	Authorization type	Product type	Formulation	Number of samples
1	PT	H	SC	28
2	PT	H	SL	26
3	PT	H	WG	32
4	PT	H	not SC, SL, WG	3
5	PT	not H	EC	21
6	PT	not H	not EC	13
7	standard	F	all	38
8	standard	H	EC	16
9	standard	H	SL	55
10	standard	H	WG	9
11	standard	H	not EC, SL, WG	27
12	standard	I	EC, SC	9
13	standard	I	not EC, SC	6
14	standard	not F, H, I	all	17
Total				300



ALLOCATION OF 300 SAMPLES PER PROVINCE

Province	Crop area	Estimated use of PPP	Number of points of sale	Average of (1),(2),(3)	No. of samples to be taken
	part in %				Sample size = 300
	(1)	(2)	(3)		
Dolnoslaskie	6,72%	8,21%	5,94%	6,96%	21
Kujawsko-pomorskie	8,37%	9,30%	7,43%	8,37%	25
Lubelskie	10,10%	9,81%	9,34%	9,75%	29
Lubuskie	2,65%	2,28%	2,43%	2,45%	7
Lodzkie	7,14%	7,45%	7,77%	7,45%	23
Malopolskie	2,95%	2,82%	7,54%	4,44%	13
Mazowieckie	12,11%	12,61%	11,79%	12,17%	37
Opolskie	4,18%	5,61%	3,01%	4,27%	13
Podkarpackie	3,08%	2,40%	5,84%	3,77%	11
Podlaskie	5,62%	1,39%	5,18%	4,06%	12
Pomorskie	5,28%	5,35%	3,76%	4,80%	15
Slaskie	2,80%	1,82%	5,47%	3,36%	10
Swietokrzyskie	3,33%	4,33%	4,06%	3,91%	12
Warminsko-mazurskie	5,62%	5,01%	3,71%	4,78%	14
Wielkopolskie	13,75%	14,15%	13,21%	13,70%	41
Zachodniopomorskie	6,31%	7,46%	3,51%	5,76%	17
Poland (total)	100,00%	100,00%	100,00%	100,00%	300

Special software was developed to perform the sample allocation



NEW SAMPLING SYSTEM RESULTS

excerpt of a table:

Sample	Province	Group
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.	.	.
.	.	.
20	Dolnoslaskie	3
21	Dolnoslaskie	14
.	.	.
.	.	.
.	.	.
.	.	.
38	Kujawsko-pomorskie	11
39	Kujawsko-pomorskie	5
40	Kujawsko-pomorskie	1
.	.	.
.	.	.
.	.	.
.	.	.
299	Zachodniopomorskie	8
300	Zachodniopomorskie	8



„OFFICIAL ” WORK RESULT

The Main Inspector of Plant Protection and Seed Inspection Service issued:

Executive order NO 9/2012 of 14.06.2012

regarding the rules of official quality control of crop protection products and introducing new rules

The Order includes:

- general information
- legal basis
- task performance guidance
- procedures to be followed in case of discovering irregularities
- allocation of 300 samples into groups
- allocation of 300 samples into provinces



SUMMARY AND CONCLUSIONS

- ❑ the task was to increase the number of discovered irregularities in PPP quality control by introducing changes in the sampling system
- ❑ input data used databases for quality control from 2010-2011 and sales and use statistics
- ❑ an irregularity was defined as a sample that ended up receiving a certificate not authorizing the product for sale and use
- ❑ a combination of three factors: type of authorization, type of product and product formulation was used to divide the irregularities into 14 groups
- ❑ two statistical criteria of equal weight were used to allocate the number of samples to individual groups, i.e. the ratio of irregularities to the total number of samples tested in each group, and the sales volume for each group
- ❑ the 300 samples were allocated to individual provinces based on the number of points of sale, total crop area and the use of plant protection products in each province
- ❑ random drawing was used to arrive at the proposal of a final table detailing the sampling system



SUMMARY AND CONCLUSIONS (cont'd)

- ❑ the new sampling system was introduced in Poland in 2012
- ❑ the system allows to tie the task of monitoring with control directed at increasing the number of discovered irregularities
- ❑ as a result of the new system more parallel trade products are subject to control
- ❑ the system is scheduled to continue to allow for trend tracking
- ❑ the new sampling system makes it necessary to introduce changes into the way products are analyzed - there is a greater need to compare compositions of test samples with the reference products

