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Placing biopesticides on the Polish market

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Abstract: Placing biological plant protection products on the Polish market undergo completely different rules depending on the group they do belong: if they are micro or macro organisms. The microorganisms and viruses undergo a very strict, costly and time consuming registration procedure more or less uniform for all EU countries. Placing products belonging to this group on the Polish market requires very significant financial and time investment.
The rules regarding macro organisms registration are established in EU on the member state level. In Poland at present there are no rules at all and the macro organisms used in biological control can be imported and used in Poland without any supervision. However the list of 25 biological products registered under the old regulations can be still used as a guide informing about safety and efficacy of some products.

Keywords: biopesticide, plant protection, registration

The global biopesticide sector is currently worth around USD 750 million a year, representing 2.5% of the global chemical pesticide market. According to estimations it will be worth 4.2% of the global pesticide market in 2010 [1].

The reasons for the growing uptake of biological control are linked to the decreasing number of chemical pesticides (as many of them – especially insecticides – are being removed from the market) as well as policies of many countries now actively pushing for the development and use of biopesticides. Apart from this factor, farmers of all kinds of crops are under pressure from consumers and supermarkets to reduce pesticide residues. Biopesticides are also getting better in the terms of their shelf-life. Living organisms are obviously less robust than chemical pesticides. This means that they generally cannot be stored for as long as chemicals and are prone to being destroyed or deactivated by environmental factors such as sunlight, wind, and both rain and lack of water.

Recently, however, improved formulations have helped to solve many of these issues as biopesticide producers have learnt to develop products around the hardiest species of bacteria or fungi that produce tough spores. The shelf-life of some of these products is now up to five years [1].

The biological control of harmful organisms in comparison to chemical pesticides have both advantages and disadvantages [2].

- Biopesticides tend to be slower acting and do not destroy harmful organisms immediately, but in a number of days. However, they can also persist in the environment, and are often able to reproduce and control the harmful organism much longer than chemical products.
- They tend to target a much narrower range of pests than chemicals. This specific is an advantage in terms of safety and the reduction of effects on non-target organisms, but it can be a problem if a crop is plagued by a wide range of pests.
- Biological control very often requires thorough monitoring. Crops should be checked regularly in order to determine the timing of the next release of beneficial insects or next spraying. Mistakes in timing can result in a strong reduction of efficacy, far more often than in the case of chemical pesticides.

Considering regulations regarding market placement, biological means of plant protection can be divided into two groups: microorganisms (with viruses) and macro organisms.

REGISTRATION OF MICROORGANISMS AND VIRUSES IN POLAND

This group includes products containing viruses, bacteria and fungi. The rules regarding market placement for this group of products in all EU countries are regulated by the same legal act: Directive 91/414 regarding placing plant protection products on the market. The registration procedure is similar for chemical pesticides and microorganisms.

To register a biopesticide from this group, as well as a chemical plant protection product with a new active substance, the active substance should first be assessed, approved and listed in the Annex 1 of the Directive 91/414 [3] (from the legal point of view the viruses, bacteria and fungi are considered the active substance). To this end, the producer must perform all required studies and prepare documentation. Subsequently, the producer chooses a reporting member state – one from among the EU member states, who (for a fee) assesses the data regarding the active substance. The assessment of the reporting member state is

then peer-reviewed by competent authorities from other member states. The active substance must also receive the positive opinion of EFSA (European Food Safety Authority) and SCFCAH (Standing Committee on the Food Chain and Animal Health). Finally, the active substance must be approved for use in the EU by the European Commission and included in Annex 1 of the Directive 91/414.

After listing the active substance in Annex 1, it is possible to start the registration procedure of the plant protection products containing the active substance. In contrast to the active substance, plant protection products are registered on the member states level. Placing plant protection products on the market in each member state takes place on the basis of an independent decision of the registration authority. In Poland, the responsible authority is the Ministry of Agriculture and Rural Development.

The aim of such a strict registration procedure is to ensure safety of humans and the environment. The procedure is costly and time consuming [4] and contributes to relatively low availability of biopesticides in the EU. There are over 200 biopesticide products commercially available in the USA but only around 60 in the EU [1]. On the other hand, however, the average time required to register biopesticide in the EU country is 6-8 years, while in the USA the time frame is approximately 2 years [5].

To register biopesticide containing microorganisms in Poland, the active substance must be listed in the Annex 1 of the Directive 91/414. After the listing, the producer can apply and submit all the necessary study results to the Polish Ministry of Agriculture and Rural Development. The Ministry checks the completeness of data and sends the study results to the competent authorities responsible for assessment. In the event of positive results of the assessments, the decision about placing on the market is given by the Commission for Plant Protection Products. The average cost of registration of plant protection product in Poland amounts to around 250.000 PLN [6], and according to the law the decision regarding registration should be granted within 2 years from the submission of the application [7]. This of course does not include the costs and time necessary to obtain Annex 1 listing.

Table 1 presents the list of biopesticides from the group of microorganisms currently registered in Poland. On analysing Table 1, we observe that there are 14 products registered, among them 4 containing bacteria, 2 containing viruses and 8 containing fungi. Most of these products (8 out of 14) is registered for use in forestry, the others for apple orchards, barley, ornamental plants and vegetables. This means that the possibilities of protecting agricultural and horticultural crops in Poland using microorganisms are very limited.

A matter of concern for ecological farmers is the lack of biological insecticides

registered for potato and vegetable protection in Poland. This situation is probably mainly the result of the fact that the registration costs are relatively high in comparison to the demand on the Polish market. The biopesticide for control of colorado beetle (which is an important harmful organism in Poland) in potato, vegetables and some other crops containing the active protein crystals and spores of *Bacillus thuringiensis* subsp. *tenebrionis* was registered in Poland in 1990 under the trade name Novodor 02 SC, for three years, and in 1993 the registration was renewed for further 10 years. The product was efficient and not harmful for beneficial insects, but the death of colorado beetle larvae took place only several days after treatment. Moreover, the date of treatment had to be established very precisely. Quite probably, the retarded effect was the main reason why Novodor 02 SC was not very popular among the farmers. As a consequence of the low demand, the producer has decided not to bear the costs of re-registration and in the year 2004 Novodor 02 SC was withdrawn from the Polish market.

Table 1. The list of plant protection products containing microorganisms placed on the Polish market

Product/ registration number	**Active substance**	**Application**
PPP CONTAIN VIRUSES AS ACTIVE SUBSTANCE		
Carpovirusine Super SC (insecticide) R-12/2006	*Cydia pomonella* Granulosis Virus (CpGV)	**FRUIT PLANTS** **apple tree** * *Carpocapsa pomonella* L.
Madex SC (insecticide) 3/2005	*Cydia pomonella* Granulosis Virus (CpGV)	**FRUIT PLANTS** **apple tree** * *Carpocapsa pomonella* L.
PPP CONTAIN BACTERIAS AS ACTIVE SUBSTANCE		
Cedomon EO (fungicide) R-38/2005	*Pseudomonas chororaphis* (strain MA 342)	**AGRICULTURAL CROPS** **spring barley** * *Drechslera teres*
Ekotech Pro 075 OF (insecticide) 295/98	*Bacillus thuringiensis var. Kurstaki*	**FORESTRY** **older stands** * caterpillars of: *Lymantria monacha*, *Lymantria dispar*, *Bupalus piniastris*, *Panolis flammea*, *Dendrolimus Pini*, *Tortrix viridana*, *Erannis defoliaria*, *Euproctis chrysorrhoea*, *Operophthera brumata*

Product/ registration number	**Active substance**	**Application**
Foray 04 UL (insecticide) 688/2000	*Bacillus thuringiensis var. Kurstaki*	**FORESTRY stands** * caterpillars of: *Lymantria monacha*, *Lymantria dispar*, *Bupalus piniastris*, *Panolis flammea*, *Tortrix viridana*, *Erannis defoliaria*, *Euproctis chrysorrhoea*, *Operophthera brumata*
Thuricide 02 UL (insecticide) 682/2000	*Bacillus thuringiensis var. Kurstaki*	**FORESTRY stands** * caterpillars of: *Lymantria monacha*, *Lymantria dispar*, *Bupalus piniastris*, *Panolis flammea*, *Tortrix viridana*, *Erannis defoliaria*, *Euproctis chrysorrhoea*, *Operophthera brumata*
PPP CONTAIN FUNGUS AS ACTIVE SUBSTANCE		
Constans (fungicide) 29/2000	*Coniothyrium minitans*	**ORNAMENTAL PLANTS FIELD-GROWN AND IN GLASSHOUSES** **VEGETABLES FIELD-GROWN AND IN GLASSHOUSES** *diseases caused by *Sclerotinia* spp.
PG (fungicide) 3/99	*Phlebiopsis gigantea*	**Pine** * *Heterobasidion annosum* * *Armillaria* spp.
PG – Agromaster (fungicide) 31/2001	*Phlebiopsis gigantea*	**Pine** * *Heterobasidion annosum* * *Armillaria* spp.
PG – Fungler (fungicide) 4/99	*Phlebiopsis gigantea*	**Pine** * *Heterobasidion annosum* * *Armillaria* spp.
PG – IBL (fungicide) 2/99	*Phlebiopsis gigantea*	**Pine** * *Heterobasidion annosum* * *Armillaria* spp.
PG – Poszwald (fungicide) 1/99	*Phlebiopsis gigantea*	**Pine** * *Heterobasidion annosum* * *Armillaria* spp.

Product/ registration number	**Active substance**	**Application**
Polyversum WP (fungicide) 12/2000	*Pythium oligandrum*	**ORNAMENTAL PLANTS FIELD-GROWN AND IN GLASSHOUSES** * *Pythium* spp. * *Fusarium* spp. * *Phytophthora* spp. * *Botrytis* spp. * *Sclerotinia* spp. * *Rhizoctonia* spp. * powdery mildew * downy mildew **VEGETABLES IN GLASSHOUSES tomato, cucumber, pepper, lettuce** * *Phytophthora* spp. * stem base necrosis * *Fusarium* spp. * *Botrytis* spp. * *Sclerotinia* spp.
Preferal (insecticide) 30/2001	*Paecilomyces flumosoroseus*	**VEGETABLES IN GLASSHOUSES tomato, cucumber** **ORNAMENTAL PLANTS IN GLASSHOUSES** * *Trialeurodes vaporariorum* (all growth stages)

Source. Personal elaboration of the lists of plant protection products placed on the Polish market http://www.bip.minrol.gov.pl/DesktopDefault.aspx?TabOrgId=647&LangId=0 date of access 17.02.2009

PLACING MACRO ORGANISMS ON THE POLISH MARKET

The group of macro organisms includes parasitical and predatory insects, predatory mites and predatory nematodes. Macro organisms are not considered plant protection products according to EU definition. As a result, there are no common rules regarding biological control using macro organisms and each of the EU member states establishes their own rules regarding the placement of macro organisms on the market.

Some member states (for example UK, Sweden, Denmark, Austria, Czech Republic, Slovenia and Hungary) introduced rules regarding registration of macro organisms, some other (among them Poland) do not have any registration

of macro organisms at all [5].

The situation in Poland is particularly interesting because several years ago, Poland had a law and procedure regulating the placement of macro organisms on the market. This procedure was introduced in 1995 [8]. On the basis of this procedure, 25 macro organisms were registered for use in Poland. Given that they were not formally withdrawn, we can assume that the registrations are still valid. The macro organisms registered for use in Poland on the basis of the old requirements are presented in Table 2.

Before EU accession, the implementation of EU rules to the Polish law took place and the new legal acts were issued. Among them was the new Plant Protection Act [7]. The Plant Protection Act of 2003 had cancelled the old rules regarding registration, and outlined new guidelines. The problem is that for macro organisms, no new rules were given. This means that at present, in Poland there are no rules regarding the registration of macro organisms at all, and there is a complete lack of control over macro organisms introduced into the territory of Poland to protect crops. Some of the introduced macro organisms can live and propagate in our climatic conditions and have no natural enemies. This situation could result in the uncontrolled development of their population and is potentially very dangerous. One of the reasons for such a loophole regarding macro organisms, is the fact that scientific units were almost entirely excluded from the drawing up of the Plant Protection Act of 2003.

The registration under the old requirements means that the product was assessed by a group of specialists and recognized as safe and efficient. This fact is probably important for farmers. It must be however pointed out that there is an unidentified number of unknown species of living organisms sold in Poland at present to protect crops. From the point of view of the Polish law, the sale of all these organisms is legal.

Table 2. The macro organisms registered in Poland on the basis of the old rules

Product/ Registration number	**Living organism**	**The registration valid untill**
Amblyseius System 6/99	*Amblyseius cucumeris*	26.11.2009
Aphidend 22/2000	*Aphidoletes aphidimyza*	11.05.2010
Aphidius System 18/2000	*Aphidius colemani*	15.03.2010
Aphidoletes System 13/2000	*Aphidoletes aphidimyza*	06.03.2010

Product/ Registration number	**Living organism**	**The registration valid untill**
Aphipar 23/2000	*Aphidius colemani*	11.05.2010
Californicus System 17/2000	*Amblyseius californicus*	15.03.2010
Dacnusa System 20/2000	*Dacnusa sibirica* + *Diglyphus isaea*	15.03.2010
Diglyphus System 14/2000	*Diglyphus isaea*	06.03.2010
Encarsia System 10/99	*Encarsia formosa*	26.11.2009
ENERMIX 2/2002	*Eretmocerus eremicus* + *Encarsia formosa*	23.01.2012
En-Strip 11/99	*Encarsia formosa*	26.11.2009
Entonem 24/2000	*Steinernema feltiae*	11.05.2010
ERCAL 1/2002	*Eretmocerus eremicus*	23.01.2012
Larvanem 28/2000	*Heterorhadbilis megidis*	11.05.2010
Macrolophus System 21/2000	*Macrolophus caliginosus*	15.03.2010
Migiliphus 26/2000	*Diglyphus isaea*	11.05.2010
Minex 25/2000	*Dacnusa sibirica* + *Diglyphus isaea*	11.05.2010
Mirical 27/2000	*Macrolophus caliginosus*	11.05.2010
Orius System 15/2000	*Orius insidiosus*	06.03.2010
Owinema 5/99	*Steinernema feltiae*	26.11.2009
Phytoseiulus System 7/99	*Phytoseiulus persimilis*	26.11.2009
Spidex 8/99	*Phytoseiulus persimilis*	26.11.2009
Steinernema System 19/2000	*Steinernema feltiae*	15.03.2010
Therodiplosis System 16/2000	*Therodiplosis persicae*	15.03.2010
Thripex 9/99	*Amblyseius cucumeris*	26.11.2009

Source: Data of Ministry of Agriculture and Rural Development

The placement of biological plant protection products on the Polish market is governed by completely different rules depending on the group they belong to: chiefly, whether they are micro or macro organisms. Microorganisms undergo a very strict, costly and time consuming registration procedure, more or less uniform for all EU countries. Placing products belonging to this group on the member state market requires a very significant financial and time-consuming investment.

The rules regarding macro organisms registration are established on the member state level. In Poland, at present there is a complete lack of regulation, which means that macro organisms used in biological control can be imported and used in Poland without any supervision. However, the list of biological products registered under the old regulations (Table 2) can still be used as a guide to inform on the safety and efficacy of some products.

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