SHORT COMMUNICATION

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CURRENT STATUS OF FUNGICIDE REGISTRATION IN POLAND

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Abstract

Following herbicides, fungicides are the second largest group of plant protection products registered in Poland. On 30.04.2009 – five years after Poland's accession to the European Union, there were 806 plant protection products placed on the Polish market, among them 257 fungicides (including eight biological ones). Two important factors influence the registration of fungicides: law regulations and market demand. As a result of the European Union review of active substances, the number of fungicidal active substances (AS) used in Poland decreased during the first five years of Polish membership in the EU. The total number of plant protection products registered in Poland in the analysed period has significantly decreased but the total number of registered fungicides had increased. We may therefore assume that there is a strong demand for fungicides on the Polish market.

Key words: registration, fungicides, plant protection products, agrochemicals, Polish agriculture

Introduction

Due to accession to the European Union, Poland implemented a number of EU law regulations concerning among others, agriculture and plant protection. The legal acts implementing EU rules were issued either before or after the date of accession. In respect of the Polish law, the chief deed implementing the requirements of the Council Directive 91/414/EEC of 15 July 1991 concerning placing plant protection products (PPP) on the market (Council Directive... 1991) is the Plant Protection Act voted in on the 18 December 2003 (Ustawa... 2004) and amended in

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2008 (Ustawa... 2008). The Plant Protection Act was accompanied by a number of executive regulations. The new rules introduced, among others, the new procedure of PPP registration and influenced the possibilities of crop protection in Poland (Matyjaszczyk 2007).

The aim of the paper is to present the current status of registering biological and chemical PPPs for disease control in Poland. The data are presented according to the status on 30.04.2009; that is to say, five years after the EU accession.

Registration of plant protection products in Poland

Provisions governing authorization of PPPs in all EU member states must ensure a high standard of protection, which, in particular, must prevent the authorization of products posing risks to human and animal health, groundwater and the environment. The objective of protecting human or animal health and the environment takes priority over the objective of improving plant production.

To register a PPP with a new active substance (AS) in Poland, the AS should first be assessed on the EU level, approved and listed in Annex 1 of the Directive 91/414/EEC (Council Directive... 1991). For this purpose, the producer has to 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 AS. The assessment of the reporting member state is then peer-reviewed by competent authorities from other member states. The AS must also receive a positive opinion of EFSA (European Food Safety Authority) and SCFCAH (Standing Committee on the Food Chain and Animal Health). Finally, the AS must be approved for use in the EU by the European Commission and by the legal act included in Annex 1 of the Directive 91/414/EEC.

After listing the AS in Annex 1, the registration procedure of the PPP containing the AS in Poland can start. In contrast to an AS, PPP are registered in European Union on the member states level. Placing PPP on the market in each member state takes place on the basis of an independent decision of the registration authority. The responsible authority in Poland is the Ministry of Agriculture and Rural Development.

To register a PPP in Poland, the producer should apply to the Ministry of Agriculture and Rural Development. The Ministry performs the check of completeness and sends the data to authorities for opinions regarding, among others, the efficacy and phytotoxicity of PPP, residues, influence on human health and influence on the environment. After due consideration and discussion of these opinions by the Commission for Plant Protection Products (an advisory body working for the Minister of Agriculture), if the final result is positive, the PPP can be placed on the Polish market. The Ministry of Agriculture's decision is usually valid for up to 10 years. The full list of registered PPP is available on the Ministry's website: www.minrol.gov.pl.

It is worth emphasizing that in spite of the common market there is no legal possibility of sale or use in Poland of an PPP registered in other EU countries. In effect, this means that at present a given product registered and used for example in Germany, cannot be legally used in Poland, unless it is registered in Poland as well. Even if an identical PPP is registered in Poland and in another member state, the import of this product (for example because of price difference) must be permitted by the registration authority – even if the product is imported for the private use of a farmer.

However, it should be stressed that at present new rules regarding registration are being considered at the EU level and will be probably legislated in 2009. The new rules will implement zonal registration of PPP after 2011 (European Parliament... 2009). The EU will be divided into three zones. Poland will be in the central zone together with Belgium, Czech Republic, Germany, Ireland, Luxemburg, Hungary, Netherlands, Austria, Slovenia, Slovakia and United Kingdom.

The reason behind the withdrawals of numerous active substances from use in the EU

After implementation of the Directive 91/414/EEC the European Commission started the review of all plant protection products' AS to check if they were safe for humans, animals and the environment. The review had been performed on the EU level and its results are binding for the member states, including Poland. AS were divided into four groups and were reviewed in turn. A reporting member state was assigned to each AS. The reporting member state is responsible for performing the review and reporting its results to the Commission. During the review, the notifier (usually the producer of the AS) applying for admission of the active substance for use in plant protection on the EU territory, is to prove that it induces no risk for humans and the environment. In the review, the data concerning toxicology and the influence on the food chain are also taken into account. The notifier is responsible for carrying out all required studies and for delivering their results to the reporting member state.

As a result of the review, the AS is listed on Annex 1 of the Directive 91/414/EEC, as having gained permission for use in plant protection in the European Union, or is withdrawn from use in plant protection in the EU. The withdrawal takes place when the result of the review is negative, but also when the producer has not supported his AS through the review process (e.g. for financial reasons). After withdrawal of the AS, all PPP containing this AS are also withdrawn from use in member states.

The EU review of about 1000 AS has been completed in 2009 (Review... 2009). The results of the review are presented in Figure 1: a minority of AS – only 26% had been approved, while 74% (!) had been withdrawn from the market. The withdrawal can be summarized into two points: 7% of AS had been withdrawn because they were deemed unsafe, while as much as 67% had been withdrawn because

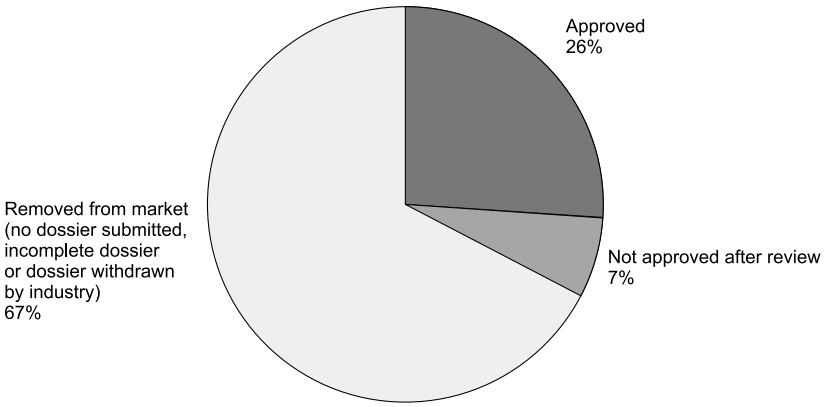

Fig. 1. Results of EU review of active substances (Review... 2009)

their producers were, for different reasons, not interested in covering the review costs.

This situation has had a substantial effect on the Polish PPP market. Since EU accession, numerous products have been withdrawn from the market. More PPP will be withdrawn in the next two years (Matyjaszczyk 2007). The reason for this delay in implementing EU decisions is the time-consuming legal procedure.

The influence of active substances' withdrawal on the Polish fungicide market

Not all AS withdrawn from use in the EU as a result of the review had been used in Polish agriculture. Therefore, the number of withdrawn PPP has been proportionally not as big as the number of withdrawn AS. Table 1 presents the list of fungicidal AS which had been used in Poland and withdrawn as a result of the review, as well as the list of AS placed on Polish market for the first time during the analysed period (1.05.2004–30.04.2009).

From Table 1 it is clear that in the analyzed period fungicides with 16 new AS had been registered, and 25 AS had been withdrawn from the use in Poland. The three AS marked with an asterisk (found in both columns) had been registered in Poland for the first time, and then withdrawn because of the review results, during the analyzed period.

The number of fungicidal AS used in Polish agriculture has in the analyzed period decreased. The decrease of PPP in the market is a problem for farmers. A matter of concern is the fact that in many cases, the products withdrawn had been present on the Polish market for many years and the farmers have known them well, given that many of them were produced in Poland. In light of the withdrawals, farmers need advice on possible substitutes. In most cases, there are effective products available which can substitute the withdrawn ones. Yet, they are often

Table 1

Active substances of fungicides withdrawn from use in Poland as a result of the EU review and those placed for the first time on the Polish market in the period 1.05.2004–30.04.2009

Substances placed for the first time on the Polish market	Substances withdrawn from use in Poland as a result of the EU review
Benalaxyl-M	Azaconazole
Benthiavalicarb	Boric acid
Boscalid	Chitosan
Cyazofamid	Cyproconazole
Dimoxystrobin	Dichlofluanid
Fenbuconazole*	Dodine
Fluopicolide	Fenbuconazole*
Fluoxastrobin	Formaldehyde
Mandipropamid	Glutaraldehyde
Metrafenone	Grapefruit seed extract
Orange oil*	Lecithin
Paclobutrazol*	Metalaxyl
Proquinazid	Myclobutanil
Prothioconazole	Ofurace
Pseudomonas chloraphis	Oksadixyl
Pyraclostrobin	Orange oil*
	Oxine-copper
	Paclobutrazol*
	Prochloraz
	Procymidone
	Quarternary ammonium compounds
	Triadimefon
	Tridemorph
	Triforine
	Vinclozolin

*Active substances marked are placed in both columns – during the analyzed period they had been registered in Poland for the first time and then withdrawn because of the review results.

much more expensive. The second factor which is probably even of greater importance, is that the withdrawal of AS has a high likelihood of increasing the probability of pathogen resistance development (Węgorek 2007). The resistance of harmful organisms against registered PPP is a matter of concern in agriculture. To prevent the phenomenon, the rotation of AS is necessary (Heimbach et al. 2002). Reducing the number of AS placed on the market obviously diminishes the possibilities of rotation.

Current status of fungicides registration

According to the data of the Polish Ministry of Agriculture and Rural Development, on April 30, 2009, there were 806 PPP registered in Poland. The fungicides, with 257 products registered, were the second group after herbicides (see Fig. 2), followed by insecticides and the "other PPP" (including pheromones, attractants, repellents, growth regulators and resistance stimulators).

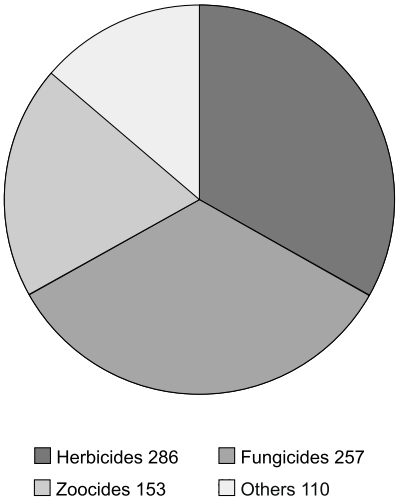

Fig. 2. Number of plant protection products placed on the Polish market on 30.04.2009 (personal elaboration based on: Official... 2009)

In the analyzed period (1.05.2004–30.04.2009), however, as well as in its last 12 months (1.05.2008–30.04.2009), the most numerous decisions concerning market placement have been given for fungicides, as well as for the registration of new formulations (82 and 30, respectively), and for re-registration of the existing ones (53 and 25, respectively). This probably reflects the demand for fungicides. We may therefore assume that the demand for fungicides is growing in comparison with the demand for other PPP groups.

The main reason for withdrawals of fungicides during the last five years was discussed above (withdrawal of AS as a result of the EU review). In the analyzed period 74 fungicides were withdrawn from the market, out of which 10 were withdrawn in the last 12 months. When comparing the data with the number of PPP registered (see Table 2), we can see that in the five years of Polish membership in the EU, the number of registered fungicides has risen in spite of numerous withdrawals of AS. From Table 2 it is clear that there were not only relatively more new registrations for fungicides (32% of fungicides registered on 30.04.2009 as compared with 26% for the total number of PPP), but also fewer withdrawals: 29% for fungicides while 38% for the total number of PPP. This resulted in an increased share of fungicides in the number of PPP registered in Poland.

Table 2

Registrations and withdrawals of fungicides and all plant protection products in Poland in the first five years of EU membership (1.05.2004–30.04.2009)

	Number of PPP placed on the Polish market on 30.04.2009	Number of PPP registered	New registrations as a percentage of currently registered products	Number of PPP withdrawn	Withdrawals as a percentage of currently registered products
Fungicides	257	82	32%	74	29%
All PPP	806	210	26%	305	38%

Registration of biological products for disease control

The placement of biological PPP on the Polish market is governed by completely different rules, depending on the group they belong to: basically on whether they are micro- or macroorganisms. The rules regarding market placement for viruses, bacteria and fungi in all EU countries are regulated by the same legal act: Directive 91/414/EEC regarding placing PPP on the market. The registration procedure is similar for chemical pesticides and PPP containing microorganisms and viruses. The current status of registration of this group of products is presented in Table 3. At present, seven biopreparations for disease control, containing fungi as the AS, are registered in Poland mostly for forest and ornamental plant protection, but two of them are also for the protection of vegetables. One fungicide containing bacteria as the AS, registered for spring barley protection, is also available in the market. There are no biological preparations containing viruses.

During the analyzed period no biological AS had been totally withdrawn from use in Poland and a new one (*Pseudomonas chloraphis*) had been registered (see Table 1).

The group of macroorganisms includes parasitical and predatory insects, predatory mites and predatory nematodes. Macroorganisms are not considered PPP according to the EU definition. As a result, there are no common rules regarding biological control with macroorganisms and each of the EU member states establishes its own rules regarding placement of macroorganisms on the market.

Some member states (for example UK, Sweden, Denmark, Austria, Czech Republic, Slovenia and Hungary) introduced rules regarding registration of macroorganisms, while other (among them Poland) do not have any registration procedure for macroorganisms at all (Tomalak 2007).

The situation in Poland is particularly interesting because several years ago Poland had a law and procedure regulating the placement of macroorganisms in the market. The procedure was introduced in 1995 (Ustawa... 1995). On the basis of the procedure 25 macroorganisms were registered for use in Poland. These rules were withdrawn during pre-accession law changes.

Table 3

The list of plant protection products for disease control containing microorganisms placed on the Polish market on 30.04.2009 (personal elaboration based on: Official... 2009)

Product/ registration number	Active organism	Application
Cedomon EO (fungicide) R-38/2005	*Pseudomonas chororaphis* (strain MA 342)	**AGRICULTURAL CROPS** **spring barley** *Drechslera teres*
Contans (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.
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.

Conclusions

At present there are 257 PPP registered in Poland for disease control, among them eight biological ones. Following herbicides, fungicides are the second largest group of PPP registered in Poland. Two important factors influence registration of fungicides: law regulations and market demand. As a result of the EU review of AS, the number of fungicidal AS used in Poland decreased by nine during the first five years of Polish membership in the EU. However, even though the total number of registered fungicides in the analyzed period had increased, the total number of plant protection products registered in Poland has significantly decreased. We may therefore assume that there is strong demand for fungicides on the Polish market.

The possibility of AS rotation which translates to ensuring suitable resistance preventing strategy and proper protection is, so far, sufficient in major crops in Poland (Matyjaszczyk 2009). In minor crops, however, sometimes there is no possibility of rotation. It can result in a serious problem for Polish agriculture, as Poland is a country with a big number of minor crops (vegetables, herbs, fruits, forest nursery trees and some minor agricultural crops). Minor crops are often grown by small farmers, so that lack of protection in this case is likely to create also some social problems.

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