Technological advantages

- Ozonation is most likely more efficient than the use of traditional fumigants.
- If the ozonation is performed with the right timing and the right concentration profile, studies have showed that harmful biological organisms will be completely killed.
- And controlled.
- Ozone seems to be a more “broadband” fumigant than other chemicals since it seems to attack cell walls in the organisms in a fundamental way (some refer to this as cell lysing).
- Some consider it most certain that most organisms will not be able to develop immunity towards ozone due to less or none mutations.

Ozone is not recognized for use on stored crops in the eu!

Regulatory status in USA

- FDA and EPA define it as “pure air” – GRAS (Generally Regarded As Safe). This has encouraged practical use.
- It is currently used in many organic applications.
- Major industries are currently implementing applications for:Pathogen reduction in storage of grapes, potatoes and onions.
- The author expects to supply 4 machines capable of treating up to 2000 tons of cereals within 12 months in USA.

19 - The Crop Protection Industry´s View on the Regulatory Situation for SPP Chemical

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Abstract

The regulatory situation regarding products for the protection of stored products in the EU has become increasingly complex in recent years. Since 1991, products for the control of the major storage pests – insects and rodents – were regulated by the Plant Protection Directive 91/414/EEC, one of the world´s most stringent legislations for pesticides. In the course of the EU review program for existing active substances, the number of available plant protection active substances was reduced from around 1000 in 1993 to about 250 to date. Many SPP pesticides were lost in this process already.

A second challenge for industry came with the Biocidal Products Directive 98/8/EC (BPD) in March 1998. Due to insufficient clarification of borderlines and lack of harmonisation, many products are now under the scope of both directives. Additional bureaucratic hurdles are now raised by the new European chemicals legislation REACH, requiring registration for all chemicals, including coformulants.

For many companies, especially SMEs, the costs of several million € for studies, dossier compilation and authorisation fees are not viable for the relatively small storage protection product segment.

For the remaining products, use restrictions due to the high importance of human and environmental safety are increasing, resulting in less availability of products for amateur use. At the same time, the political climate tends against the use of chemicals in general.

Awareness must urgently be raised, both on the political public level, as to the necessity and benefits of chemical storage protection.

Introduction

The Regulatory Environment: Farmers in Europe as producers of food or feed commodities are subject to a whole network of stringent regulations. The “Basic Regulation” on food and feed safety requires zero tolerances to contamination by insect pests, rodents or microorganisms. Therefore, chemical pest control is often inevitable to ensure the requ ired quality of the produce.

The use of chemical pest control agents, in turn, is subject to one of the world´s most stringent legislations. Products must be authorised according to their intended uses. Depending on the area and site of application, one product may, under European law, be subject to several overlapping bodies of legislation at a time. For example, rodent baits or insecticides when used in post-harvest treatment or storage of crops or in processing factories are

subject to the Plant Protection Directive 91/414/EEC. When used against the same target organisms in stables, barns or household areas, the same products must be authorised according to the Biocidal Products Directive 98/8/EC. Furthermore, if residues are likely to occur following application, maximum residue levels (MRLs) must be set for each crop/active substance combination.

Consequences of the Regulatory Burden: In order to comply with legal requirements, industry is facing extremely high investments in terms of time and costs. On average, the development of a new active substance takes about eleven years until EU approval. The costs of data generation for regulatory purposes alone amount to about 135 Mio Euro. As a consequence, even the leading agrochemical companies can afford to develop only one or two active substances per year as a maximum.

Due to the lengthy and costly evaluation process, the products need to be highly profitable in order to recover the costs within a relatively short timeframe before patent protection runs out. Therefore, the most profitable markets are preferred for the development of new products, with smaller segments, like storage protection, being explored at a later time or not at all.

The EU review process for existing active substances, started in 1993 and officially terminated in March 2009, has already now led to decreasing availability of plant protection products for minor uses, including storage protection. Of about 940 active substances on the market in at least one Member State before 1993, 26 % (about 250 substances) have been included in the EU positive list. Only 7% of the active substances actually failed because the evaluation showed unacceptable safety concerns for human health or the environment. The vast majority of substances (67%) have been phased out not for lack of safety but because dossiers were either not submitted, incomplete or withdrawn by industry(1). Many of those active substances were used in niche markets not generating enough value to justify the high regulatory costs.

Moreover, for those products falling under the scope of both Plant Protection Directive 91/414/EEC and Biocidal Products Directive 98/8/EC, the regulatory requirements are similar but not identical under both legislations. Dossiers must be generated in different formats and fees paid to different authorities. Especially smaller companies often lack manpower and financial resources to face this double challenge.

Future prospects: A further cut-down in availability of products for storage protection is anticipated as a consequence of the future regulation on the placing on the market of plant protection products (2). It stipulates the assessment of active substances according to their potential hazardous properties, meaning that critical effects caused by the pure active substance at high concentrations may lead to non-inclusion or substitution, even if the products can be applied safely.

According to the new provisions, active substances fulfilling the criteria to be classified as carcinogenic, mutagenic, toxic to reproduction (CMR, categories 1 or 2 according to Dangerous Substances Directive 67/548/EEC) or deemed to be endocrine disruptors, or which fulfil the criteria laid down in the REACH Regulation 1907/2006 for certain long-term environmental effects(POP, PBT, vPvB) shall not be included in the positive list in the future. Active substances deemed to possess neurotoxic or immunotoxic properties will be identified as candidates for substitution and authorised only as long as no “safer” alternative exists.

The new provisions are likely to come into effect by mid 2011. Active substances authorised under the present legislation by that date can be placed on the market until the end of their respective inclusion date. However, re-evaluation after that period will be performed applying the new criteria, and this is likely to affect a number of products presently in use in storage protection, due to their modes of action against the target organisms.

For instance, insecticides acting by their influence on growth and development of the target species are suspected to act as endocrine disruptors. Active substances of this type may not be authorised any more in the future. Other insecticides targeting the nervous system will have to be listed as candidates for substitution due to their neurotoxicity, and phased out as soon as a less critical alternative becomes available. Research activities will have to focus on active substances with new modes of action not interfering with any of these critical endpoints. Today, only one out of 100.000 chemicals screened will be authorised as an active substance. Most probably, this proportion will shift to a much higher number of unsuccessful candidates.

With rodenticides, the situation looks critical already. For plant protection products, only six active substances are presently listed on Annex I of Directive 91/414/EEC: three phosphides, two anticoagulants and carbon dioxide. For biocidal products, 15 rodenticides were notified, most of them belonging to the class of anticoagulants. Discussions are ongoing on EU expert level on the reproductive toxicity of this substance group. Furthermore, persistence is also an issue with some anticoagulants.

Under the new plant protection legislation, both endpoints are cut-off criteria which may lead to non-inclusion of the active substances concerned, even though the end-use products are formulated and applied in a way so as to avoid exposure of humans and the environment. The Biocidal Products Directive (BPD) also stipulates that substances with CMR properties shall not be authorised, however the criteria are not clearly specified. Presently,

two anticoagulant rodenticides are on the positive list of for a reduced time period of seven years instead of the usual ten.

Development of new rodenticides is particularly difficult, since it is unlikely that a selective mode of action for the control of rodents exists that would not affect other vertebrates. Due to the limited prospects of success, there is practically no research in this field. As a consequence, the availability of chemical control agents against rodents will decrease even more in the future.

Conclusions

The discussion on chemical products for the control of harmful organisms has been shifting from a factual to an emotional debate in the past years. Consumers are concerned about chemicals in the environment and what they perceive to be the potential dangers from these omnipresent but invisible substances. A wide variety of fresh foods year-round and clean drinking water are taken as a matter of course, while the necessity and benefits of plant protection and biocidal products are ignored by the general public.

Similarly, regulatory decisions are becoming more and more political instead of science-based. Both the revision of the Plant Protection as well as that of the Biocidal Products Directive are targeted to eliminating substances perceived to be of concern and promoting non-chemical alternatives, by applying the precautionary principle. The fact that there are no “zero risk” situations in life and that the benefits of chemical pesticides (comprising plant protection products and biocides) outweigh their risks if they are applied correctly must therefore be made clear to decision-makers as well as to the public.

As the bi-annual reports of the German government on the progress of implementation of the BPD and on the substitution of high-risk products (3) clearly point out, non-chemical alternatives are scarce and have so far proven insufficient in terms of efficacy and costs. On the other hand, an increasing bureaucracy blocks the development of innovative chemical products without adding to consumer or environmental safety.

The report on the impacts of the Biocidal Products Directive (4) points out that small and mid-sized companies are most affected by the requirements of the legislation. Similar conclusions had been drawn for the Plant Protection Directive in 2001 (5). Many of the niche products supplied by those smaller companies have already disappeared from the market, resulting in gaps especially for minor uses. The research-based industry will not be able to deliver new solutions for all calamities in the future. How this situation will be dealt with in case of emergencies remains open.

Literature

Review Programme of existing pesticides, http://ec.europa.eu/food/plant/protection/evaluation/rev_prog_exist_pest_en.htm

Position of the European Parliament adopted at second reading on 13 January 2009 with a view to the adoption of Regulation (EC) No .../2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (P6_TC2-COD(2006)0136). http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2009-0011+0+DOC+XML+V0//EN&language=EN#BKMD-17

Zweiter Bericht über die Substitution risikoreicher durch risikoärmere Biozid-Wirkstoffe und Biozid-Produkte, über den aktuellen Sachstand zur Umsetzung der Biozid-Richtlinie und des Überprüfungs-Programmes der Altwirkstoffe sowie der aktuellen Entwicklungen auf EU-Ebene (Bundestags-Drucksache 16/2909)

Study on Impact of the implementation of Directive 98/8/EC concerning the placing on the market of biocidal products, http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/study_implementation/report_101007pdf/_EN_1.0_&a=d

Report from the Commission to the European Parliament and the Council: Evaluation of the active substances of plant protection products (doc. COM (2001) 444), 25 July 2001

20- Actual registrations for post harvest disinfestations and perspectives in France

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Abstract

During the last few years, many pesticides were banned. For SPP, in France, this situation is particularly critical since they were key compounds. For grain, DDVP was used to meet the requirement of zero insect when the grain was sold, for mills, methyl bromide and DDVP were the base of the disinfestation.