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Evaluating occupational health risks in the approval process of plant protection products

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Abstract

Plant protection products (PPP) have become an important production factor in many agricultural cultivation systems without which the high quality and output of agricultural products cannot be guaranteed. On the other hand however, PPP often have dangerous properties, and can therefore only be brought into circulation in Switzerland once they have been approved by the Swiss Federal Office for Agriculture (FOAG). Approval is given provided that it can be guaranteed that people, animals and the environment will be protected when such products are used. Various Federal departments are involved in the process of assessing the specific properties of a PPP, with one of them being the Chemicals and Occupational Health section of the State Secretariat for Economic Affairs (SECO), which is an assessment office responsible for the evaluation of the protective measures which are necessary to ensure the health of professional users of PPPs. The protective measures which are necessary for the application of PPPs are derived from two factors: (1) the properties of the chemicals which are hazardous to health and (2) the systemic exposure of users to PPPs. With the help of recognised calculation models, the exposure for users of PPPs and for operating staff for follow-up work in treated surfaces can be estimated. The SECO regulatory body uses this to produce a report, formulating the

necessary protective measures to ensure the protection of the health of professional users when using PPPs according to the regulations.

Keywords

Operator exposure, worker exposure, risk assessment, plant protection products, chemicals, occupational health

Introduction

Plant protection products (PPPs) contain active substances which protect plants from harmful organisms, preserve plant products and destroy unwanted plants or plant parts (ChemG SR 813.1). In today's agriculture, plant protection products are used in a number of cultivation systems to meet the high quality requirements of agricultural products and to enable increased output. For example, to guarantee the high quality levels of apples, the fruit is treated around 15 times with PPPs until point of sale. It is estimated that if PPPs were not used, the global yield losses in the principal agricultural crops in our temperate climate due to parasites, weeds and diseases would be between 50% – 80% of sugar beet, potato, barley, maize or wheat (Oerke & Dehne 2004). Despite the use of PPPs, the effective yield losses for these crops are still generally over 30%. Very few types of agricultural production can do without the use of PPPs. On the one hand, PPPs help to minimise yield losses in agricultural crops, yet on the other hand, they can also have damaging side effects. To keep these side effects to a minimum, clear and strict regulations are laid down in the Swiss chemicals law (ChemG SR 813.1) and in the Swiss plant protection products ordinance (PPPV SR 916.161) regarding the protection of people, animals and the environment. As a general rule, PPPs can only be brought into circulation in Switzerland insofar as they have been approved by the Federal Office for Agriculture (FOAG) (see illustration 1). Each request for approval is generally assessed by four federal offices. The Federal Office for the Environment (FOEN) assesses specific issues relating to the environment, the Federal Office of Public Health (FOPH) looks into general health aspects, consumer protection and the toxicological properties of the products. An assessment of the chemical properties of the PPP, their behaviour in soil, their effectiveness and the ecotoxicological risks is delegated by the FOAG to the Agroscope's agricultural research institutes, and finally the responsibility for the

evaluation of the safety of professional users of PPPs lies with the Chemicals and Occupational Health section of the State Secretariat for Economic Affairs (SECO).

The SECO's risk evaluation takes in the exposure of the actual user to the PPP, i.e. the people who mix and spray the PPP (the operators) and the exposure of the operating personnel which has to come into contact with the crop for follow-up work such as maintenance or harvesting once PPPs have been used (the workers). Manual maintenance or harvesting with possible exposure via leaf material to the previously applied PPPs often occurs for example in viniculture, fruit-growing and the cultivation of ornamental plants.

The risk for the health of professional users and the establishing of the necessary protective measures when using PPPs are derived from two factors: (1) the properties of the substances or of the product which are hazardous to health and (2) the exposure of the user to the PPP, as calculated with the aid of models which have been recognised by European authorities. The SECO's assessment unit evaluates the protection of the user in all areas of agricultural cultivation and usage and produces a report which is given to the FOAG with the enacting obligations to ensure the health of those using PPPs.

First part of risk assessment: classification and labelling of chemicals

The classification and labelling of chemicals illustrates the properties of the product which are hazardous to health by means of hazard symbols and risk statements (ChemV SR 813.11). Since December 2010, the labelling system that was in vigour in Switzerland and the European Union for chemicals is steadily being replaced by the new GHS (or Globally Harmonised System) from the UN (Rüegg 2010). Manufacturers and importers of chemicals have until mid-2015 to take on the new system. It is possible from December 2012 and compulsory from June 2018 for plant protection products to be labelled using the new system (as set out in the Agrarpaket Frühling 2012). In the new GHS system, additional hazard symbols have been introduced and the R and S statements which were previously used have been replaced by new hazard warnings (or H statements) and precautionary warnings (or P statements). With the help of classification and labelling systems, the dangers

inherent in chemicals can be codified. For example the "skull and crossbones" symbol represents the "acute toxicity" level of danger, while the "exclamation mark" represents the "warning: danger" level (see illustration 2). In addition to the hazard symbols, the H statements set out the dangers which are inherent in the products. The P statements provide instructions on how these hazards can be avoided or reduced. The SECO regulatory body defines the protective measures to be followed depending on the hazardous properties of the PPP. For example, products which carry the H statement H318 (causes serious eye damage) require closed protective goggles or facial protection to be worn during usage.

Second part of risk assessment: calculation of systemic exposure

To calculate the systemic exposure of the user, two important toxicological parameters are required which are set out by the FOPH. Systemic exposure in this case represents the actual quantity of a substance recorded on a daily basis which has been taken on throughout the body via the airways and the skin.

(1) The AOEL (**A**cceptable **O**perator **E**xposure **L**evel in mg of a substance per day and per kilogramme of body weight) denotes the maximum dose of a substance which a user is allowed to take on per day via the airways and the skin without any demonstrable effects. The AOEL is based on the NOAEL (No Observed Adverse Effect Level) which can be calculated by means of animal experiments.

(2) The **D**ermal **A**bsorption (DA in per cent) is a measure of the amount of a substance or other content which can penetrate via the skin into the blood stream. As a rule, this is calculated by means of experiments. Should the corresponding tests not have been carried out, then 25% for the concentrated product and 75% for the diluted product should be the values used.

The SECO regulatory body uses a mathematical model to calculate exposure which was developed by the former German Federal Biological institute for agriculture and forestry (the BBA which is now known as the Julius-Kühn Institute). This model is an aid when it comes to estimating the systemic exposure for users handling

concentrated PPPs (i.e. when preparing the spray liquid) and when spraying diluted PPPs (Lundehn et al. 1992) (see illustration 3). The following parameters are required for the modelling of systemic exposure:

- Application method (tractor-drawn boom sprayer, tractor-drawn air-assisted sprayer or knapsack sprayers)
- Formulation type of the product (liquid, granulate or powder)
- Concentration of the substance (in grammes of substance per litre or kilogramme of product)
- Dermal absorption of the concentrate and of the spray liquid (in per cent)
- Applied dose (in litres or kilogrammes of product per hectare)

As a first step, the systemic exposure is calculated using the model and without taking specific personal protective equipment (PPE) into account. This includes the potential absorption of PPPs via the skin (dermal) and the airways (via inhalation) as well as during the mixing and spraying of the spray liquid. Should the exposure predicted by the model exceed the maximum accepted daily dose (acceptable operator exposure level, or AOEL), the systemic exposure is then recalculated in such a way that it is primarily reduced as much as possible by the adjustment of various protective equipment parameters, so that the exposure levels are below the AOEL and the PPP can be used safely provided that the protective equipment is used (see illustrations 3 + 4). When preparing the spray liquid (concentrate), the possible protective measures include gloves and breathing masks. When spraying the spray liquid (diluted product), gloves, protective clothing, solid shoes and breathing masks may be necessary. Each and every protective measure reduces the systemic exposure by a specific amount. Protective gloves for example reduce dermal exposure on the hands by 99%. Protective clothing reduces dermal exposure on the body by 95% and a breathing mask protects 95% – 98% of the airways. In most cases, it is possible to define each element of personal protective clothing which can be used to reduce exposure as much as possible so that the absorbed amount of PPPs is less than maximum daily dose allowed. The SECO regulatory body specifies which protective clothing is to be worn when preparing and spraying the spray liquid, based on the calculations using the model.

The SECO regulatory body also calculates the exposure of operating personnel during re-entry and follow-up work on crops that have been treated with PPPs as well as calculating the systemic exposure for users of PPPs. The model, based on calculations devised by Hoernicke et al. (1998), takes the following parameters into account:

- Application rate (in kilogrammes of substance per hectare)
- Number of applications per season
- Average work-time per day (in hours) during which a worker is exposed to the PPP due to contact with leaf material
- Leaf surfaces (in cm^2) treated with PPP with which a worker can come into contact in the space of an hour carrying out a specified activity
- The amount of PPP which comes off the leaves through contact by the worker (dislodgeable foliar residue, or DFR) (usually 1 μg/ cm^2/kg of substance)
- Penetration rate of the PPP through the protective clothing (percentage of the maximum amount which can penetrate the protective clothing – usually 5%)
- Dermal absorption value (in per cent)

The exposure during re-entry and follow-up work which is calculated by the model is compared once again with the AOEL of the substance and then there is a check to see whether the maximum daily dose has been exceeded or not. Should the calculation of the exposure for operating personnel show that the maximum tolerated daily dose (AOEL) has been exceeded without recourse to protective equipment, then the SECO regulatory body, basing its judgment on the model, will require protective gloves and clothing to be worn during follow-up work on crops that have been treated during a specific period of time (e.g. 48 hours) after spraying with the PPP.

Conclusions

The judgment of the SECO assessment office within the plant protection products approval process helps ensure the protection of the safety of professional users and minimise risks, provided that PPPs are used correctly. To this end, it is calculated whether the systemic exposure to the PPP for professional users is below the acceptable operator exposure level (AOEL) with the aid of suitable protective measures. In addition, protective measures are also required in the case of hazards whose effects do not primarily stem from systemic exposure, such as skin burns for example.

As a study (though which is not representative due to the small sample size) from the Chemicals and Occupational Health section of SECO has shown, the prescribed protective measures are not sufficiently implemented in agriculture (Kindler & Winteler 2009), despite the fact that there are clear legal requirements governing the handling of chemicals. Furthermore, product-specific regulations regarding personal protective equipment which are printed on the product label are often largely ignored by users. The research carried out showed that in around half the cases, users did not wear the prescribed protective gloves and/or the prescribed protective clothing. The SECO regulatory body is therefore planning to launch a campaign to help create awareness among users of PPPs in agriculture about the importance of using optimum protective equipment.

Further reading

Agrarpaket Frühling 2012, modifications to the plant protection products ordinance http://www.blw.admin.ch/themen/00005/01464/index.html?lang=de

Federal law of 15 December 2000 regarding protection from dangerous substances and preparations (Swiss Chemicals Act, ChemG) SR 813.1

Hoernicke E., Nolting HG and Westphal D. (1998) Indications in the instructions for use for the protection of people during follow-up work with cultures treated with plant protection products (worker re-entry). News bulletin, German plant protection department. 50: 267-269

Kindler P. and Winteler R. (2009) Applicability of exposure models for chemicals in Swiss conditions sub-project 2: Verification of the "UK POEM" model and the "German Model", State Secretariat for Economic Affairs, www.seco.admin.ch/themen/00385/02071/02248

Lundehn JR., Westphal D., Kiezca H., Krebs B. Löcher-Bolz S., Maasfeld W. and Pick ED (1992) Uniform principles to ensure health protection for users of plant protection products, statements from the Berlin-Dahlem Federal Biological institute for agriculture and forestry, Book 277, Paul Parey committee publishers, 112 S.

Oerke E.C. & Dehne H.W. (2004) Safeguarding protection – losses in major crops and the role of crop protection. Crop Protection 23: 275-285

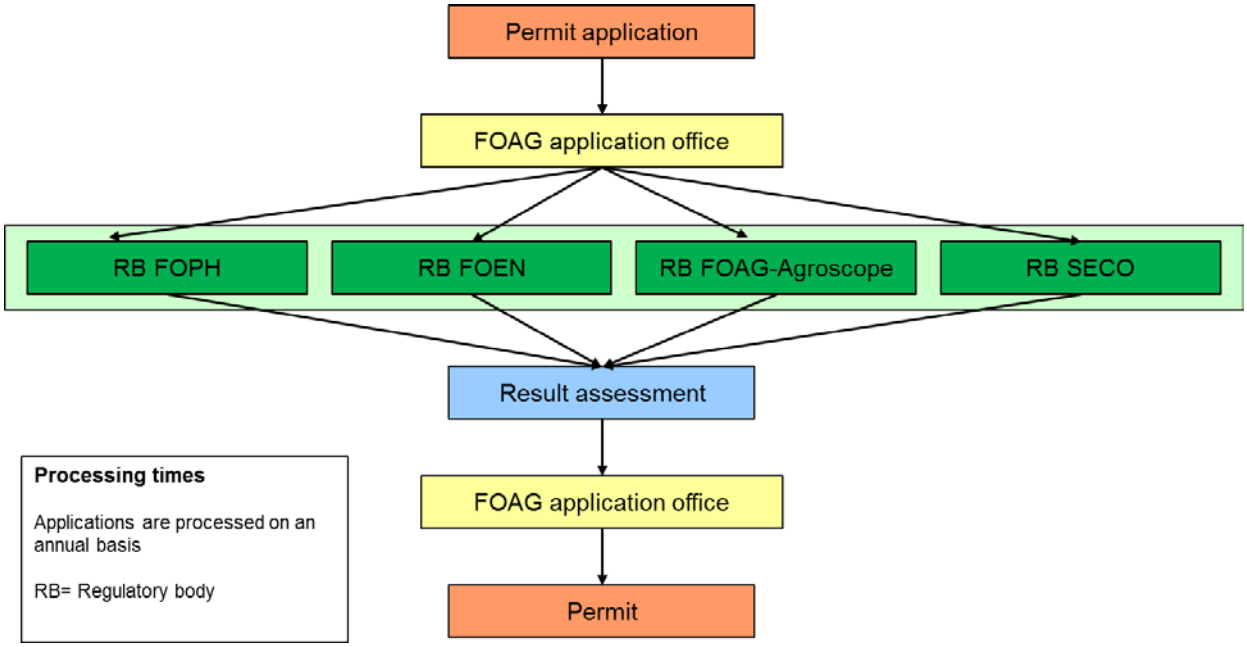
Rüegg C. (2010) GHS – the new labelling system for chemicals. EKAS bulletin 69: 26-30

Ordinance of 18 May 2005 regarding the protection against dangerous substances and preparations (Swiss Ordinance on Chemical Substances, ChemV) SR 813.11

Ordinance of 12 May 2010 regarding bringing into circulation of plant protection products (Swiss Ordinance on Plant Protection Products, PPPV) SR 916.161

Illustration 1

Overview of the approval process for plant protection products in Switzerland



Office	**Requirements and inspection within the approval process**
Swiss Federal Office for Agriculture	• Coordination, approval • Contact companies and assessment authorities
Swiss Federal Office of Public Health	• General health aspects • Consumer protection • Toxicology (hazard assessment)
Swiss Federal Office for the Environment	• Specific questions regarding the environment
Agroscope	• Chemical properties of the PPPs • Behaviour in soil • Effectiveness • Ecotoxicology
SECO	• Protection for professional users • Exposure during use • Risk assessment based on toxicology (→ FOPH) and exposure

Illustration 2a

Classification and labelling of chemicals based on the previous danger symbols

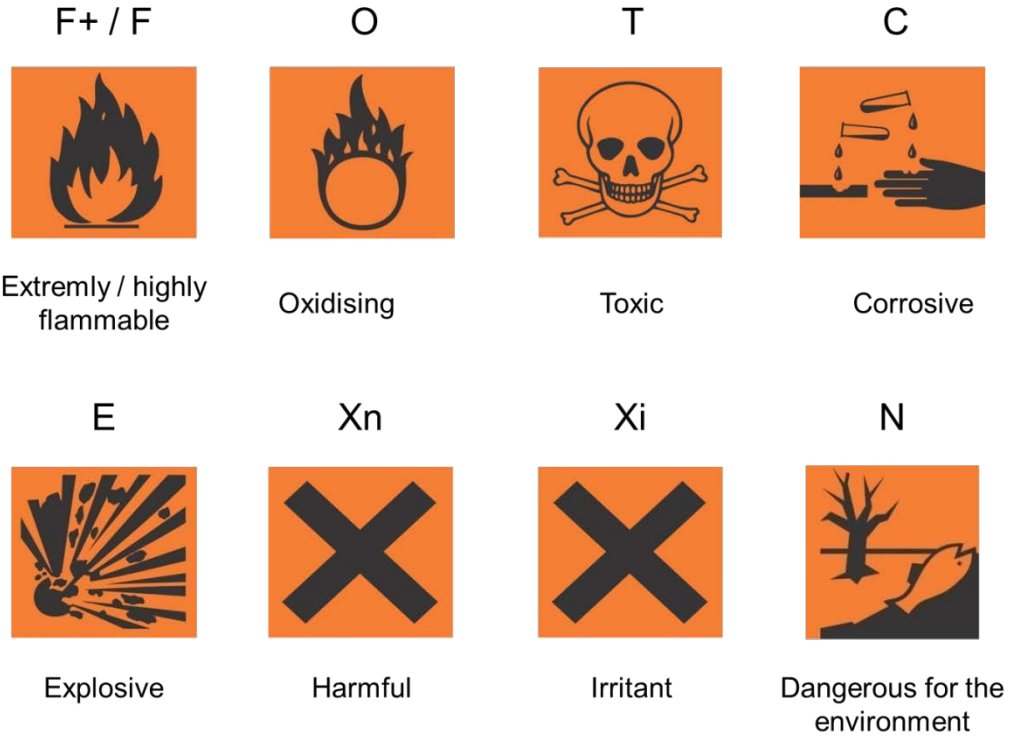


Illustration 2b

Classification and labelling of chemicals based on the new GHS system (applicable to plant protection products from December 2012)

Illustration 3

Example of how to calculate exposure of users based on the German BBA model for the application method for tractor-drawn booms sprayer (Lundehn et al. 1992)

a) Systemic exposure of the user goes beyond the AOEL of the active substance, meaning that personal protective measures are necessary to reduce exposure

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	Gugus 40 WG		Active substance	Ibidum Persulfat	
Formulation type	WG		a.s. concentration	250	g/kg
Dermal absorption from product	22	%	Dermal absorption from spray	57	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	None				
PPE during application: Head	None	Hands	None	Body	None
Dose	0.8	kg product/ha	Work rate/day	20	ha

PREDICTED EXPOSURE			
Total systemic exposure	6.4472	mg/day	
Operator body weight	70	kg	
Operator exposure	0.0921	mg/kg bw/day	
			% of AOEL
AOEL (BAG)	0.049	mg/kg bw/day	187.97

b) Systemic exposure is below the AOEL thanks to the implementation of protective measures (use of gloves when preparing the spray liquid and use of protective clothing when applying the spray liquid)

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	Gugus 40 WG		Active substance	Ibidum Persulfat	
Formulation type	WG		a.s. concentration	250	g/kg
Dermal absorption from product	22	%	Dermal absorption from spray	57	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	Gloves				
PPE during application: Head	None	Hands	Gloves	Body	Coverall and sturdy footwear
Dose	0.8	kg product/ha	Work rate/day	20	ha

PREDICTED EXPOSURE			
Total systemic exposure	0.381464	mg/day	
Operator body weight	70	kg	
Operator exposure	0.0054	mg/kg bw/day	
			% of AOEL
AOEL (BAG)	0.049	mg/kg bw/day	11.12

Illustration 4

With the help of the corresponding protective equipment (gloves, protective clothing, solid shoes and respiratory protection), it is possible to reduce exposure to plant protection products. Full protection when applying PPPs is only necessary in the rarest of cases. The guiding principle according to the SECO regulatory body when it comes to determining personal protective measures is "*as little as possible, as much as necessary*".