

Use of pesticide monitoring data within the regulatory process.

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Legal basis



- **Act of 5 April 1963 concerning plant protection products etc.**
- **Regulations relating to plant protection products.**
- **Maximum 5 years registration period since 1963.**
- **Substitution.**

- **EEA agreement (European Economical Area), EU-EFTA (Iceland, Liechtenstein, Norway).**
- **91/414/EC is included in the agreement, but the EFTA States are free to limit access to their markets according to the requirements of their existing legislation.**

Requirements for approval



- **Satisfactory agronomical effect.**
- **The product formulation does not have unacceptable harmful effects on human health, domestic animals, animal or plant life or the environment in general, and thus is found ecological and toxicological satisfactory (to be documented).**
- **That on an overall assessment the product formulation has been found as good as or better than previously approved product formulation, or other methods for the same purpose.**
- **Vulnerable environment, cold climate.**
- **High protection for human health.**

Evaluation tools & methods

- **Assessments of high quality is necessary.**
- **Studies from the industry indicate inherent properties, but data for nordic climate is usual lacking in the documentation.**
- **International evaluations often form the basis of our hazard identifications.**
 - **OECD, EU assessments**
 - **Models used for exposure assessments**
- **Monitoring data (JOVA) indicate the potential leakage under Norwegian conditions and may be used for adjusting the exposure assessment.**
- **Risk assessment done by the Norwegian Scientific Committe for Food Safety, Group 2: Plant health, Pesticides and residues (earlier The Pesticides Board).**
- **Norwegian Food Safety Authority does the risk management after the risk assessments are completed.**

Examples

- **Pesticides detected in the JOVA-program which causes restrictions in use afterwards:**
 - Klorfenvinfos, linuron, metribuzin, propaklor, metamidon, bentazon, MCPA, mecoprop-P, diclorprop-P, metalaksyl/metalaxyl-M, ETU (mancozeb metabolite) and azinphos-methyl.
- **Pesticides which the Pesticides Board recommends monitored and assessed in the program:**
 - Kresoxim-metyl (the acid metabolite), fenamidon (the metabolites), trifloxystrobin (the metabolite trinaxapac) and fosalone.

Bentazone – detections in water

- *Monitoring data, environment 1995-2002 (JOVA):*
 - the a.i. most frequently detected, at 13 locations
 - detected in very many samples (max. conc.);
ditches (19 µg/l), streams and small rivers (6.9 µg/l), “g.w.” (1.8 µg/l), run-off (30 µg/l), drainage water, rain water (0.11 µg/l)
 - detected all season, and the following season(s).
 - detected 6 years after spraying at Kvithamar in Trøndelag
 - used on a relatively small fraction of the agricultural area in the fields
 - soil types: marine clay, sandy soils
- *Drinking water survey 1997-2000 (SNT):*
 - detected in waterworks, 0.02-0.05 µg/l (n=3)

Examples of restricted use - bentazone

- **The Pesticide Board 1997:**

- "Considering detections in groundwater, it's very serious finding bentazone in the monitoring-programme. Bentazone should thus be substituted with other methods of plant protection or pesticides".
- "Because of shortage of alternative pesticides in certain crops, bentazone can be reregistered until 1999 in certain crops. A new evaluation has to be executed until then".

- **The Pesticide Board 2000:**

- " Bentazon is a very mobile compound and does not degrade under anerobic conditions. There are many detections both in surface- and ground water. Bentazone has been very persistence under aerobic conditions in Norway. The use of the pesticide has been restricted since 1998. The period with restricted use is too short for evaluating the consequences for the environment. The sales have been reduced with 50 per cent. Since it's a shortage of alternatives and an agronomic requirement for the pesticide, bentazone can be approved for another five year period"

Bentazone - consequences of the restricted use

- **The sales was reduced from 27.6 tonn in 1997 to 6.4 tonn in 2004.**
- **Detections of the pesticide has been significantly reduced since 1996 (from 68 to ca. 10).**
- **The average concentration is low (< 0.1 µg/L).**
- **Long time-series are necessary for an evaluation.**
- **Restricted use can entail fewer detections and lower concentrations, but not always.**

Evaluation of bentazon – conclusions after the results from the monitoring-programme.

- **The results from the monitoring-programme is a correction and supplement to the industry dossier.**
 - The degradation differs from the lab-studies (DT50 = 29 d (average)) and the field studies (DT50=14 d (average)), but the degradation at 10°C is > 161 d and the mineralisation in soil is slow.
- **Monitoring data gives valuable additional information on how a.i.'s behave under Norwegian climate and soil conditions.**
- **Evaluations are difficult, how representative are the fields and the monitoring data?**
- **More knowledge needed about use and pollution.**

Evaluation: metribuzin

- **High mobility, moderate degradation.**
- **Monitoring data: frequently detected in surface and ground water, concentrations > MFI, many locations.**
- **1999: Reduced dose and new agronomic strategy, decided to follow up on monitoring data in 2001.**
- **2001: New monitoring data; still frequently detected in the environment, not reduced as required. Withdrawal.**
- **2001 (appeal): NAIS accepted industry arguments, agreed that the time-series after dose reduction were too short, approved.**

To be continued: metribuzine

- **2005:**
 - The sales has not decreased and the use in the fields is nearly the same.
 - The detections of metribuzin is still relatively frequent and there is no statistically significant decrease in the number of detections and concentrations.
- **Metribuzine has more mobile metabolites than the active ingredient.**
 - The metabolites are not included in the monitoring programme
 - The metabolites are evaluated in a Danish report and are considered as very problematic for the groundwater.
- **EU has nearly finished evaluating metribuzin and the provisionally conclusions are:**
 - metribuzin can be implemented on annex 1.
 - There is some problems with the documentation and the model simulation of the metabolites.
- **Metribuzin is evaluated in our scientific committee these days and we do not know their conclusions.**