Opinion of the Scientific Committee on Plants regarding the Inclusion of Bentazone in Annex 1 of Directive 91/414/EEC [1] Concerning the Placing of Plant Protection Products on the Market (Opinion expressed by the Scientific Committee on Plants on 2 December 1999)

Terms of Reference

In the context of the possible inclusion of bentazone in Annex 1 to Directive 91/414/EEC, the Commission consulted the Scientific Committee on Plants and submitted for response the following questions:

1. Can the Committee comment on the assessment of the Rapporteur Member State on storage stability of the residues in crop samples and confirm the acceptability of the consumer dietary risk assessment?

2. Can it be confirmed that use scenarios exist which pose no unacceptable risk to groundwater?

Background

Bentazone is an existing active substance in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market and is being one of the active substances covered by the first stage of the work programme provided for under the Directive.

In order to complete its evaluation, the Scientific Committee on Plants had access to documentation comprising a monograph prepared by Germany as Rapporteur Member State and the recommendations of the ECCO [2] Peer Review Programme.

Bentazone is a widely used contact herbicide for the control of many broad-leaved plants and sedges in agriculture and horticulture and is taken up by foliage and root tissues of plants and is translocated acropetally in the xylem. Based on the data in Volume 1 of the monograph, application rates up to 2.88 kg/ha /season are intended. However, the Committee understands that the notifier BASF has proposed reductions in the application rates for spring and summer for the single treatment to a maximum of 1.5 kg bentazone /ha and for the double application scenario a maximum of 2 x 1 kg bentazone /ha (excluding rice). Autumn and winter authorised uses of bentazone were withdrawn in 1998 in The Netherlands and United Kingdom. BASF also proposed a reduction of the application rate in rice to 1.6 kg/ha and season.

In several plant metabolism studies the residue of concern was determined as bentazone and its metabolites 6-hydroxybentazone glycoside and 8-hydroxybentazone glycoside. The residue levels found in edible crop samples from supervised field trials were close to or below the limit of determination for the applied analytical methods. The Peer Review concluded that the stability of residues in crop samples stored prior to analysis must be addressed. The lack of residue stability tests covering the time of storage of samples between harvest and analysis had given rise to uncertainty of the reported residue data.

The Rapporteur Member State had concluded, on the basis particularly of the hydrolysis stability tests on bentazone and the metabolism studies, that the data provided was sufficient to establish an absence of a risk to consumer

With respect to fate and behaviour in soil, bentazone is a readily degradable compound with no accumulation potential. Furthermore, it does also not accumulate significantly in water and air.

The Rapporteur Member State concluded with regard to the contamination of groundwater that there is no concern once applications take place only once in spring or summer with 1500 g bentazone /ha or twice in spring or summer with 1000 g bentazone/ha. However, the Peer Review meeting stressed a possible contamination of groundwater on the basis of monitoring data and missing data i.e. soil degradation studies for colder climates.

OPINION OF THE COMMITTEE

Question 1

Can the Committee comment on the assessment of the rapporteur MS on storage stability of the residues in crop samples and confirm the acceptability of the consumer dietary risk assessment ?

Assessment

Hydrolysis stability tests were only reported in the Monograph for the active substance bentazone; these tests show that bentazone is stable in the pH range 5 to 9 at 25^{o}C for 30 days.

Due to the fact that bentazone is rapidly metabolised in plants, the stability of the metabolites 6-hydroxybentazone glycoside and 8-hydroxybentazone glycoside have also to be considered. There were no hydrolysis tests for these metabolites reported by the Rapporteur Member State.

However, taking into account the severe conditions necessary to release 6-hydroxy- and 8-hydroxybentazone from its conjugates [i.e. methanolic hydrochloric acid, 90 min at 150º C], it can be assumed that the conjugates of these metabolites are also stable under the storage conditions of harvested samples at - 18 or - 20^{o}C.

The metabolism of bentazone using the radiolabelled active substance has been investigated in five different crops (monocotyledon and dicotyledon) with application rates comparable with Good Agricultural Practice (GAP). The extractable residues (including bentazone, 6-hydroxybentazone glycoside and 8-hydroxybentazone glycoside) in the plant parts relevant for consumers were very low (below 0.1mg/kg).

The calculation of the TMDI [3] as presented to the Committee were performed for the WHO [4] European diet and the German method [consumption data of a 4-6 year old girl, body weight 13.5 kg] using the proposed MRLs [5] , and for the crops for which no MRL could be proposed and also for crops without registered uses respectively, the sum of the lowest determination limits of bentazone and its metabolites were used.

The reported TMDI exhausts the ADI for 2.7% and 2.2% for the WHO European diet and the consumption data of a 4-6 year old girl respectively.

Conclusion

On the basis of the available information about the stability of bentazone and its metabolites and the result of the metabolism studies, the Committee concludes that the results from the supervised residue trials can be considered as plausible. The dietary intake calculations for adults and young children give similar results of 2 to 3% of the ADI [6]. The Committee confirms that the data provided show sufficient evidence that no risk for the consumer is to be expected.

Question 2

Can it be confirmed that use scenarios exist which pose no unacceptable risk to groundwater?

Assessment

The Committee considers that bentazone is a mobile substance under field conditions. This is confirmed by, for example, field leaching studies carried out in The Netherlands and in Sweden, although it must be emphasised that these studies were performed under autumn conditions using bare soil and in the case of the NetherlandsÂ' study a high groundwater table. The low Kom-values

(n=13) ranged from 1.7 to 102 l/kg with a median of 14.6 also indicate a high mobility. There is a large amount of monitoring data for bentazone from different European countries which show bentazone residues in groundwater > 0.1 µg/l. Examples include, monitoring data for shallow groundwater in The Netherlands and in the United Kingdom and data from Sweden and Germany. For northern European countries specific data e.g. soil degradation studies conducted under colder climates are missing. A particular problem for groundwater contamination is the applications in rice paddy fields. After flooding, the fields can come in direct contact with the groundwater resulting in high bentazone concentrations in wells of a depth up to 20 m.

Model calculations conducted by the notifier show that use scenarios exist which demonstrate that groundwater concentrations do not exceed 0.1µg/l. These are based on data from the PELMO and PESTLA leaching models, for example, assuming a $DT50_{lab}$ [7] value of 18 days and a K_{om} value of 16, and it was shown that neither the annual average concentrations nor the maximum concentrations reached the 0.1 µg/l value. A PESTLA calculation with a $DT50_{field}$ value of 13 days and a K_{om} value of 7.7 also showed no exceedence of 0.1 µg/l for the maximum concentration.

This assessment is supported by the results of lysimeter studies and field leaching studies. In seven lysimeter studies conducted in Germany with application rates of 1 x 0.5, 1.0 or 1.5 kg/ha or 2 x 1.0 kg/ha it was shown that concentrations in the leachates never reached or exceeded 0.1 µg/l (averaged over one year).

Regarding the situation in Northern Europe, it must be taken into consideration that bentazone is applied in spring (May) and that the optimum conditions for degradation in soil are from

May to July. The average temperatures for this time in Northern Europe are comparable to those of Northern Germany. The lysimeter studies carried out in the 'Sauerland' region in Germany show bentazone concentrations in leachates < 0.1 µg/l. The monthly average temperatures in this region in the May to July period is almost the same as in Jokioinen, Finland (Schmallenberg, Sauerland: 7.9, 11 and 17.9 °C respectively; Jokioinen: 7.1, 12.3 and 16.2 °C respectively). Therefore the lysimeter studies conducted in Schmallenberg may be considered in the context of other Northern European Countries. However the field degradation rate of bentazone is an important factor in determining leaching potential and groundwater contamination and the variability of degradation in different soil types should be taken into account.

Monitoring data in Germany showed the presence of bentazone in groundwater but it is possible to establish that such incidences were linked to misuse or accidents in product handling. Groundwater monitoring of 3547 wells carried out in 1996 showed 19 cases with concentrations >0.1 µg/l and in 1997 revealed 13 wells >0.1 µg/l out of 2365 sampled. Monitoring data of shallow groundwater and field leaching studies from The Netherlands, United Kingdom and Sweden show possible leaching of bentazone. The interpretation of these data is difficult. Reasons for the contamination could have been: autumn applications, applications on bare soil, high application rates, sandy soils, groundwater table about 1 m and macropore flow.

Conclusion

On the basis of the scenarios presented by the notifier it can be confirmed that use scenarios could exist which would pose no unacceptable risks to ground water.

The modelling scenarios and lysimeter/field studies presented by the notifier do not represent the full range of soil, climate and physico-chemical properties of the active substance. This is particularly relevant for the existing use on rice.

It is recommended that risk assessments should be conducted at Member State level, in particular regarding use in rice cultivation. Member States should assess leaching potential in vulnerable locations to determine whether the revised GAP i.e. reduced application rates and timing of application can achieve the desired result.

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[1] OJ No L 230, 19.8.91, p. 1.

[2] European Community Co-ordination

[3] Theoretical Maximum Daily Intake

[4] World Health Organisation

[5] Maximum Residue Limit

[6] Acceptable Daily Intake

[7] Disappearance time for first 50/90% of compound