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OPINION
OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE INCLUSION OF DIQUAT IN ANNEX 1 OF DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

(Opinion adopted by the Scientific Committee on Plants on 17 March 2000)

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1. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE INCLUSION OF DIQUAT IN ANNEX 1 OF DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

2. TERMS OF REFERENCE

In the context of the possible inclusion of diquat in Annex 1 to Directive 91/414/EEC[1], the Commission consulted the Scientific Committee on Plants (SCP) on the following questions:

1. Can the Committee comment on the effects of diquat on bird reproduction and confirm the NOEC[2] of 25 ppm?
2. Considering the slow degradation of diquat in the soil, can the committee comment on the potential long term effects of its use and the adequacy of the available data.
3. Can the Committee comment on the ecotoxicological acceptability of the aquatic uses?
4. Can the Committee comment on the acceptability of the operator exposure for amateur uses?
5. The Committee is requested to comment on the acceptability of desiccant uses from the point of view of dietary exposure.

3. BACKGROUND

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

In order to prepare its opinion, the Scientific Committee on Plants had access to documentation comprising a monograph prepared by United Kingdom as Rapporteur Member State (RMS) and the recommendations of the ECCO[3] Peer Review Programme.

Diquat is a non-selective herbicide used principally for total weed control and for pre-harvest desiccation of seed crops and potatoes. It is also used for the control of aquatic weeds and as a nonselective herbicide in amenity situations. Application rates for terrestrial uses are typically 0.8 – 1 kg a.s./ha, with one or (in some cases) 2-3 applications per season. For aquatic uses, the application rate on banks is 1.3 kg a.s./ha while rates for water bodies range from 1 to 10 kg a.s./ha, depending on water depth and movement and the plants to be controlled.

[1] OJ No 230, 19.8.1991, p. 1
[2] No Observed Effect Concentration
[3] European Community Co-ordination

4. OPINIONS OF THE COMMITTEE

4.1. Question 1

Can the Committee comment on the effects of diquat on bird reproduction and confirm the NOEC of 25 ppm?

Opinion

The SCP cannot confirm a NOEC of 25 mg/kg (= ppm), because of the high likelihood of real differences in some of the mallard reproductive parameters at this concentration and the controls. The Committee proposes a NOEC of 5 mg/kg is a more appropriate endpoint.

Bird reproduction studies on leghorn chicken, bobwhite quail and mallard duck were presented. The chicken study was discounted, as the experiment was not designed to determine the NOEC for bird reproduction. Of the two remaining studies, the mallard duck study had the lowest end point, but there has been considerable debate over how the NOEC is best measured in both of these experiments. Much of this discussion has centred on specific issues relating to the most appropriate statistical techniques to use, on which the Committee comments in the sections below.

The SCP cannot confirm a NOEC of 25 mg/kg (= ppm), because of the high likelihood of real differences in some of the mallard reproductive parameters at this concentration and controls. While not all tests indicated a statistical difference between a given response measured at 25mg/kg and the controls, other approaches, with rather different underlying assumptions indicated a treatment effect. In particular, pairwise comparisons after analysis of variance (albeit with non-significant treatment effect) and randomisation tests, gave some statistically significant indications of an effect at this concentration. Given the results of these tests, the Committee proposes that a NOEC of 5 mg/kg is a more appropriate endpoint.

The philosophy underlying the NOEC approach has been challenged on numerous occasions (e.g. Laskowski 1995). OECD[4] member countries have agreed to phase out the NOEC and replace it by a regression-based parameter (based on an ECx - design). While alternatives to the NOEC approach are under discussion, it is proposed that an estimate of the power of a statistical test to detect a difference would be an extremely useful way of expressing confidence in a derived NOEC.

4.1.1. Scientific Background on which the Opinion is Based

Background

Birds may be exposed to residues of diquat principally through consumption of (a) treated terrestrial or aquatic vegetation; (b) contaminated earthworms; (c) contaminated insects. Reproduction studies on leghorn chicken, bobwhite quail and mallard duck were therefore submitted for evaluation. The details of the chicken experiment were not described in full, it was not conducted to a recognised protocol and it was carried out before GLP[5] was a requirement. However, while it is not stated, the results of this study suggest a NOEC of 1mg/kg.

In the bobwhite quail reproduction study, groups of birds were fed on diets of 0, 5, 25 and 100 mg/kg diquat for 18 weeks with 12 replicates for each treatment. The sample mean number of eggs

[4] Organisation for Economic Co-operation and Development
[5] Good Laboratory Practice

laid and sample mean 14-day survivors/hen in production were actually higher for 5-100 mg/kg treatments than control. ANOVA[6] and subsequent multiple comparisons found no significant effects of treatment, and the Notifiers therefore concluded the NOEC from this study was 100 mg/kg. A subacute feeding study was also conducted, with 3 replicates of 6 treatment levels (0, 100, 215, 464, 1000 and 2150 mg/kg). Analysis of the egg production (both log and square root transformed) using ANOVA and multiple comparisons similarly indicated a NOEC of 100 mg/kg.

The mallard duck reproduction study followed a similar protocol to the bobwhite quail reproduction study (diets of 0, 5, 25 and 100 mg/kg diquat for 18 weeks, 12 replicates for each treatment). The presence of non-proven breeders in the test (birds that do not lay eggs even under normal conditions) may have contributed to a high within-treatment variance, making the detection of treatment effects more difficult than usual. Overall, ANOVA indicated no significant effects of treatment on mortality, bodyweight or potential clinical signs of toxicity. However there was a significant ($p < 0.05$) reduction in food consumption at all concentrations in relation to controls. In the absence of effects on bodyweight this was not considered biologically significant. The original study report compared several additional reproductive parameters between treatments on the basis of pairwise tests, and concluded that 5 mg/kg was the NOEC for reproduction. However, the effects seen at 25 mg/kg were subsequently viewed to be of questionable statistical significance (no overall significant ANOVA). At the 100 mg/kg concentration, there was a significant effect on the numbers of eggs laid, and it was also reported that the number of hatchlings and the number 14-day survivors per pen differed significantly from controls (the Notifier has since reanalysed these data, with rather different conclusions). On the basis of the overall significant effects at the 100mg/kg concentration alone, the NOEC for reproduction was therefore considered to be 25 mg/kg diet.

The Danish EPA[7] has subsequently questioned the statistical basis of the conclusions drawn from both of the studies on bobwhite quail. Similarly, the NOEC suggested by the mallard study has been subject of considerable debate. In the following section the SCP comments on the objections raised, and provides its own opinion of the appropriate NOEC for birds.

Specific Comments

<u>Bobwhite quail reproduction study</u>

The Danish EPA questioned the conclusion of 100 mg/kg NOEC from the bobwhite quail study, on the basis of a highly significant positive correlation between dose and response. One possibility is that typographical mistakes were made. From the data provided it was not obvious whether this was the case, however a re-analysis provided by the Notifier.

The positive correlation reported by the Danish Authorities is surprising, in particular since it centres on relatively high mortality observed in controls. Given the data provided, the SCP provisionally supports the Notifier's and RMS estimation of 100 mg/kg NOEC for this study and species, but suggests that this study would be more convincing if it were supported by a more detailed consideration of the sources and distribution of quail mortality within and between pens.

<u>Bobwhite quail sub-acute feeding study</u>

The Danish EPA pointed out that after fitting a non-linear dose response curve to the egg production data, the EC[8]20 = 89 mg/kg (95% confidence limits 16-163) while the EC30 = 117 mg/kg (95%

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[6] Analysis of variance
[7] Environmental Protection Agency
[8] Effective Concentration

confidence limits 34, 201). Therefore on this basis a concentration of 100mg/kg would have an effect and should not be a NOEC.

Dose-response curves offer a very useful way of estimating effects at low concentrations and certainly make better use of the data available. However, in terms of NOEC philosophy at least, what is important is whether the difference in the response between control and a given treatment concentration is statistically significant. Therefore, the SCP support the Notifier's and RMS' estimation of 100 ppm NOEC for this study and species.

Mallard duck reproduction study

The Danish EPA has analysed the data on 14-day old survivors/hen in production and using a multiple comparison test have found evidence for a difference between the controls and the 25 mg/kg treatment, which is contrary to same analysis conducted by the Notifier. The SCP agrees with the analysis of the Danish EPA. Performing individual significance tests when the overall ANOVA is not significant is not common practice, since it will tend to increase the probability of type I errors (rejecting a null hypothesis when it is true). This is particularly the case when there are a number of treatment levels. However, the Committee does not consider this approach entirely inappropriate in those cases where Type II errors (acceptance of a false null hypothesis) are even more undesirable.

Due to the uncertainty surrounding this study, the RMS consulted an independent statistician. After Monte Carlo re-sampling from the data (Manly 1991), it was found that the average size of differences in 14 day old survivorship between 25mg/kg and controls would arise on only 0.046 of occasions if there were no treatment effect ($P < 0.05$). Similar simulations were conducted for differences in the number of hatchlings between 25 mg/kg treatment and control, generating a 0.054 significance probability. As both values were borderline, and 3 separate tests were made, the independent statistician argued that 25 mg/kg should be the NOEC.

In the opinion of the SCP, the randomisation tests were well conducted and entirely appropriate. The exact methodology is unclear, but as the direction of the response could be anticipated *a priori* then one-tailed significance tests would have served to reduce significance probabilities further (if they were not already assumed). Given that 2 out of the 3 tests conducted on quasi-independent variables were of borderline significance, the Committee cannot be totally confident that spurious significance has arisen through repeated sampling. However, it is noted the 3 variables analysed were chosen *a posteriori* from a longer list on the basis of perceived effects. Overall, on the basis of the data provided, and borderline significance of effects at 25 mg/kg, the SCP proposes that a precautionary NOEC of 5mg/kg be taken for this study and cannot therefore confirm a NOEC of 25 mg/kg for birds.

The NOEC approach

The philosophy underlying the NOEC approach has been challenged on numerous occasions (e.g. see Laskowski 1995), not least because it depends directly on the specific concentrations tested. Furthermore, since ecotoxicity tests often encounter high variation, it would be unlikely that studies with low replication would detect significant differences in population means even if they existed. This is unfortunate because it means that trials conducted at a few concentration levels and/or with low replication will tend to generate higher NOEC values.

While alternatives to NOEC are under discussion, an additional summary statistic that could be introduced immediately is an indication of the power of the test to detect a difference, should one exist. Most scientific analyses are primarily concerned not to reject a null hypothesis without good justification, hence the type I error rate (rejecting a NH when it is true) is generally set at $\alpha < 0.05$ and quoted extensively. However in NOEC tests, it may be more important to avoid type II errors (accepting a NH when it is false). Despite the fact that the estimated probability of a type II error (β) is often (not always) straightforward to calculate, and readily provided by statistical software packages, this statistic is rarely quoted. The SCP urges that more emphasis be placed on evaluating the power of tests when deriving NOEC values.

4.1.2. REFERENCES

Laskowski, R. (1995) Some good reasons to ban the use of NOEC, LOEC and related concepts in ecotoxicology. *Oikos*, **73**, 140-144

Manly, B.F.J. (1991) Randomisation and Monte Carlo Methods in Biology. Chapman & Hall.

4.2. Question 2

Considering the slow degradation of diquat in the soil, can the Committee comment on the potential long term effects of its use and the adequacy of the available data.

Opinion

As diquat is extremely strongly bound to soil it is practically immobile in soil and will not contaminate groundwater. The Committee concludes that there are no indications that residues of diquat in soil will contaminate groundwater or have harmful effects on succeeding crops, non-target soil-dwelling organisms or microbial activity.

All studies show a very fast, strong and extensive adsorption of diquat by soil, in particular by the clay fraction. Dissipation in the field is very slow. The non-adsorbed amount of diquat is capable of being mineralised to $^{14}CO_2$ by soil micro-organisms. The rate at which degradation occurs is controlled by the adsorption of diquat to clay minerals, i.e. by the relative amounts of adsorbed and non-adsorbed (i.e., bio-available) diquat.

4.2.1. Scientific Background on which the Opinion is Based

Fate and Behaviour in Soil

All studies show a very fast, strong and extensive adsorption of diquat by soil, in particular by the clay fraction. In laboratory studies no measurable degradation in soil after one year could be observed. Therefore it is impossible, to create DT[9]50 or DT90 values under laboratory conditions at 10 or 20 °C . Long-term field soil dissipation studies in the UK and USA indicated a very slow dissipation after applications of either single high rates or repeated annual normal rates. The UK studies show a decline of 5-7% per year, corresponding to DT50 values of 9.5 – 13.5 years.
The maximum concentration in soil residue studies for various Western European Countries is 0.11 mg/kg, in average 0.03 mg/kg. Only a study in Denmark gave values up to 2.3 mg/kg but even this concentration represents a saturation of < 1% of the SAC-WB (Strong Adsorption Capacity of soils determined by a Wheat Bioassay) of the respective soil. Repeated applications of diquat will result in PECs[10] which are typically not more than approximately 2.4 or 3.9 mg/kg as a worst case, depending on the degree of plant interception. Studies with cultures of soil microbes (soil fungi) show that diquat is capable of being mineralised to $^{14}CO_2$ by soil micro-organisms. The rate at which degradation occurs is controlled by the adsorption of diquat to clay minerals i.e. the availability of diquat for micro-organisms. Diquat is strongest adsorbed onto the clay mineral montmorillonite followed by vermiculite, illite and kaolinite.

- Relevance to groundwater
  All studies show the very strong adsorption in all the soils tested, Koc[11] values ranged from 32,000 to 7,900,000 L/kg.
  As diquat is extremely strongly bound to soil it is practically immobile. Diquat will not occur in groundwater as a result of leaching and the predicted environmental concentration in groundwater PECgw is << 0.1 µg/l (practically zero).

- Adequacy of the available data
  Although the diquat dossier submitted by the applicant is non-standard and is not entirely performed in accordance with the requirements stated in the Directive 91/414/EEC, it is possible to assess the fate and behaviour of diquat in soil. Therefore additional data are not necessary.

Potential long term effects of the use of diquat

- Succeeding crops
  The effects which might be expected from repeated applications of diquat is a shift of the adsorption equilibrium with higher amounts of the active substance in the soil solution in particular in soils with a low clay content and thus leading to damages of crop plants. A measure of this is the SAC[12]. The SAC of soils is determined by a Wheat Bioassay (SAC-WB). Diquat is mixed into the soils in different concentrations, then wheat seedlings are planted into the treated soils and the concentration is determined where the growth of the seedling roots is reduced to 50 %. SAC values of "normal" soils lay in the range of 50 – 1000 mg/kg, for sandy soils with extremely low clay content at 10 mg/kg and for heavy clay soils in the range of 3000 mg/kg.

[9] DT50/90: disappearance time for first 50/90% of compound
[10] Predicted Environmental Concentration
[11] Organic Carbon Adsorption Coefficient
[12] Strong Adsorption Capacity

Assuming a degradation rate of 5 % per year (p. 243 and 253 of the monograph) which corresponds to DT50 value of 13.5 years, after "infinite" applications of 360 g diquat per hectare and year – this is a worst case assumption for hops which is a permanent crop where an application can take place every year – a plateau concentration of 4.8 mg/kg is calculated taking into account a soil depth of 10 cm. This concentration is well below the normal SAC values. Corresponding calculations for other crops e. g. clover and alfalfa for seed production, seed potatoes, food potatoes, winter rape, field beans and field peas – taking into account that these crops are not cultivated every year – resulted in plateau concentrations of 1.3, 3.8 (seed potatoes with an application rate of 1000 g as/ha), 1.9, 1.2 and 1.8 mg/kg respectively.

In addition, plant damages have never been observed in practice although diquat containing plant protection products have been in use for more than 30 years. Furthermore, the amount of the active substance which is not adsorbed is available to microbial degradation which could be demonstrated with ^{14}C-diquat in culture suspensions (p. 235 ff of the monograph).
Taking into account all these facts no unjustifiable long term effects may be expected from repeated use of diquat-containing plant protection products.

- Effects on terrestrial organisms
  No specific risk was identified with regard to birds and mammals. In the context of this question (slow degradation of diquat in soil), only soil-dwelling arthropods have to be considered. Both laboratory and field data are available.

  - Laboratory data: Two ground-dwelling predators, the carabid beetle *Poecilus melanarius* and the Lycosid spider *Pardosa* spp were tested at an application rate of 1.6 kg a.s./ha (twice the typical dose), with no lethal or sublethal effects. For earthworms, acute toxicity was 121 times higher than the initially expected concentration in soils treated with 0.8 kg a.s./ha, thus indicating a low risk Microbial activity was not affected by up to 50 kg a.s./ha.

  - Field data: Two long-term field studies (up to 8 years) have been conducted at excessive dose rates (up to 720 kg a.s./ha, equivalent to 400% of the SAC). Only at dose rates of 198 kg a.s./ha and above (i.e., ca. 200x of the normal application rate) could the analysis detect slight differences on some groups of a wide range of soil microarthropods. In the same studies, microbial activity and populations were unaffected, with only minor differences with fungi at 720 kg a.s./ha.

  For earthworms, two field studies were conducted at rates of up to 500 and 1308 times, respectively, of the typical application rate. While the first study showed reductions in earthworm populations after 1 year by rates of 90 ka a.s./ha (50% of the SAC) and more, there were no effects in the second study over the two year study period (2.2 and 112 kg a.s./ha).

4.3. Question 3

Can the Committee comment on the ecotoxicological acceptability of the aquatic uses?

Opinion

The Committee supports the view of the rapporteur that the supplied data indicate a very high risk to the aquatic environment. Although options for risk reduction exist, no data have been submitted to demonstrate that they would be sufficiently effective to render the aquatic uses acceptable.

In addition to its crop uses, diquat also has intended uses for the control of aquatic plants (both floating and submerged) in canals, ditches and other surface water bodies, as well as on banks along those bodies. Although diquat adsorbs strongly to suspended particles and partitions into the sediment within 1-3 days, the initial concentrations to be expected in the water phase are well in the range of toxicity of aquatic fauna, indicating a very high risk of direct effects to non-target organisms. In addition to those direct effects, indirect effects could be caused by dead plant material if not removed mechanically, decaying and depleting oxygen levels and put surviving animals at risk. The same may be expected for the planktonic algae which cannot be removed mechanically. Effects on the phytoplankton could disrupt food chains for grazers triggering further disruption of the ecological system.

4.3.1 Scientific Background on which the Opinion is Based

<u>Uses</u>: Diquat also has intended uses for control of aquatic plants (both floating and submerged) in canals, ditches and other surface water bodies, as well as on banks along these bodies. Application rates on banks are given in the monograph as 1.3 kg a.s./ha while rates for the water bodies are reported to be 1 – 10 kg a.s./ha. Control of (surface-floating) duckweed is achieved at rates in the lower range while for submerged plants the standard maximum rate is 10 kg a.s./ha for 1 m depth, resulting in a nominal initial concentration of 1 mg/L.

<u>Fate</u>: Diquat adsorbs strongly onto suspended particles and partitions rapidly into the sediment, with DT50 (water phase; field studies) values between 17 hours to 2.3 days. There seem to be no measurable degradation in sediments over 1-9 months. Likewise, there was no observable desorption of diquat from the sediment into the water phase in those studies.

Toxicity: Acute toxicity to fish and *Daphnia* is in the range of the initial PEC, while algae are more susceptible. Long-term toxicity was lower, although the fate of diquat in water suggests that the acute situation is more relevant for organisms of the water phase.

Species	**Test design**	**NOEC [mg/L]**	**EC/LC[13]50 [mg/L]**
Rainbow trout	48 h static	6.7	21
Rainbow trout	96 h flow-through	Not determined (< 1.4)	6.1
Daphnia magna	48 h static	Not determined (< 0.84)	1.2
Algae (*Raphidocellis subcapitata*)	96 h static	0.0068	0.011
Algae (*Raphidocellis subcapitata*)	72 h; in the presence of constantly suspended sediment	>0.32	
Fathead minnow	34 day ELS[14] (flow-through)	0.12	
Daphnia magna	21 day (static)	0.125	0.16
Chironomus riparius	20 days; spiked sediment with 7 days to settle prior to introduction of larvae	< 100 mg/kg dry weight	
Aquatic plants	observations from efficacy trials: wide range of aquatic plants affected or killed at 0.125 – 1 mg/L		

Assessment: Acute TER's[15] for aquatic uses are far below the triggers required by Annex VI (1-10 instead of 100 for fish and *Daphnia*; 0.01 instead of 10 for algae), indicating a very high risk for all those organisms. The study on algae toxicity in the presence of suspended sediment showed lower toxicity due to the adsorption of diquat to sediment particles. However, the test conditions (constantly suspended sediment) clearly favour adsorption, and it seems questionable if such conditions would frequently occur in natural, still or slowly flowing water bodies.
Addendum II of the monograph reports observations for aquatic plants from two efficacy trials where a wide range of emergent and floating aquatic plants were controlled by 0.125 - 1 mg/L. Those data, together with the unspecific description of aquatic uses ('aquatic weeds') and the unspecific mode of action, indicate that diquat is toxic to most if not all aquatic plants and planktonic algae in the concentrations normally applied to achieve efficacy. The same range of concentrations also puts aquatic fauna at high risk.
In addition to direct effects, indirect effects would be caused by the purpose of aquatic diquat applications: dead plant material if not removed mechanically would decay and deplete oxygen levels and put surviving animals at risk. The same can be expected for the planktonic algae which cannot be removed mechanically. Effects on the phytoplankton would also disrupt food chains for grazers, triggering further disruption of the ecological system.
The rapporteur concluded on the basis of similar considerations that mesocosm or field monitoring studies would be required before a listing of diquat into Annex I can be considered. The Committee is aware that specific guidelines for aquatic weed control exist in the rapporteur member state UK (MAFF 1995). Those guidelines also highlight the risk of direct and indirect effects on the nontarget aquatic fauna and flora.

[13] Lethal Concentration, median
[14] Early life stage
[15] Toxicity Exposure Ratio

The Committee supports the view of the rapporteur that the supplied data indicate a very high risk to the aquatic environment which is unacceptable under the criteria of Annex VI. Although the UK guidelines mention several options for risk reduction in the context of restricted authorisations at Member State level, no data have been submitted to demonstrate that they would be sufficiently effective to render the aquatic uses acceptable.

4.3.2. REFERENCE

MAFF (1995): Guidelines for the use of herbicides on weeds in or near watercourses and lakes. Ministry of Agriculture, Fisheries and Food, UK.

4.4. Question 4

Can the Committee comment on the acceptability of the operator exposure for amateur uses?

Opinion

The SCP believes that exposure estimates provided can be used for an approximate risk assessment and risk characterisation of the operator exposure for amateur uses. The use of these estimates indicates compliance with the AOEL[16] . However, the SCP recognises the limitations of such an approximate assessment and recommends that, in the absence of specific models of operator exposure prediction for amateur uses of plant protection products, Member States obtain specific field studies on amateur use for diquat-containing products. Moreover, the SCP is of the opinion that it would be useful to develop specific models of operator exposure prediction for amateur uses of plant protection products in general.

The SCP recommends to the Commission to consider the need for specific risk management measures for the amateur use of these products.

4.4.1. Background

In addition to agricultural uses, other intended uses of diquat include the following:

- total non-residual weed control, in places such as road sides, preparation of seed and flower beds, weed control in the vicinity of buildings and amongst shrubs;
- total weed control, on paths or pavements, drives, on industrial or residential building sites;
- aquatic weed control, to control totally or selectively weeds which are either surface or bottom growing that can be in still or moving water.

The home garden (retail) uses and the amenity and aquatic uses are different in terms of type of users and products applied. Amenity and aquatic users are usually professionally trained to the same standard as agricultural and horticultural workers and normally use high-strength products in the same way as farmers and growers. Retail product users are untrained and treat only small areas at one time. The retail products are sold in smaller low-strength preparations through garden centres, home improvement outlets, hardware shops and supermarkets. They are freely available with no restrictions on availability. Diquat is always sold for amateur use in mixture with paraquat

[16] Acceptable Operator Exposure Level

to optimise efficacy against broad leaved weeds as well as on grasses. The mixture is sold only as a water-dispersible granules and is packed in measured-dose sachets to make up 4.5 litres of dilute solution at one time. All the currently registered diquat products for amateur use are only approved for use through a watering can fitted with a fine rose or dribble bar and are applied at water volumes of about 2,500 litres of water per hectare.

4.4.2 Terms of Reference

During the procedure of evaluation of diquat carried out in application of the EC Regulation 3600/92 under the frame of the EC Directive 91/414[17], it was noted that exposure for amateurs is less than that for professional knapsack use, due to unit dose sachets, short exposure time and directed low level application. The RMS considered the amateur use of diquat-containing products acceptable. It was recommended to consider at Member State level the risk arising from the specific uses in relation to the proposed formulation, rate of use, method of application and packaging before granting an authorisation. Although that amateur uses were proposed to be restricted to watering can application only, with prohibition of knapsack use, still concern was expressed for such an use.

The Committee was therefore asked to comment on the acceptability of the operator exposure for amateur uses.

4.4.3. Scientific Background on which the Opinion is Based

The SCP notes that amateur uses of plant protection products are a special case in the context of Directive 91/414 which mainly focuses on professional uses of plant protection products in agriculture. Amateur uses allow only a limited applicability of the basic concepts normally assumed for the risk assessment in agriculture, in particular as concerns use of GAP[18], risk awareness and training of the users, availability of proper plant protection products application machinery and storing facilities, use of effective personal protection devices and ability to understand and follow the directions of use contained in the labelling of products.

As to the specific question concerning the acceptability of the operator exposure for amateur uses of diquat, the SCP acknowledges that amateur users are different from the professionals because they are untrained and only occasionally use any agrochemical, they generally do not have access to protective clothing, and are likely to treat only small areas at one time. Moreover the plant protection products made available for such uses are different from the formulates intended for agricultural uses, as they contain lower concentrations of diquat and paraquat, are sold only as water-dispersible granules to avoid the problems of liquid spills, and are packed in measured-dose sachets to make up 4.5 litres of dilute solution at one time.
The SCP agrees that all the diquat products intended for amateur use should only be approved for use through a watering can fitted with a fine rose or dribble bar. This reduces the potential for user exposure compared to the use of knapsacks that more easily could produce higher exposure, particularly among unskilled or untrained users.

Since specific exposure models are not available for a watering-can use, a quantitative assessment of operator exposure for amateur uses can only be derived from an adapted application of the models developed for professional uses or, alternatively, from specific field studies. The SCP believes that the exposure estimates provided, combining the U.K. model for the application and the

[17] OJ N° L366, 15.12.1992, p. 10
[18] Good Agricultural Practice

German model for the preparation of the dilute solution are technically adequate and can be used for an approximate risk assessment and risk characterisation of the operator exposure for amateur uses. The use of these estimates indicates the compliance with AOEL.
However, the SCP recognises the limitation of such approximate assessments given the particular nature of the amateur uses which pertain to the field of consumer safety and are not directly comparable to agricultural professional users and the fact that the products also contain paraquat for which a risk assessment was not concomitantly provided. In the circumstances, the SCP recommends the carrying out of specific field studies on amateur uses with these products. Such field monitoring studies should take into account the variability of application practices that may be encountered among an untrained consumer population.

Moreover, the Committee is of the opinion that it would be useful to develop specific models of operator exposure prediction for plant protection product amateur uses.

In addition, the SCP recommends that proper attention be given to the need for specific risk management measures taking into account the free availability of diquat products in shops or supermarkets and the possible inadvertent exposure of children in the treated areas.

4.5. Question 5

The Committee is requested to comment on the acceptability of desiccant uses from the point of view of dietary exposure.

Opinion

Due to insufficient data, the Committee is unable to advise on the acceptability of desiccant uses from the point of view of dietary exposure.

The Committee has interpreted the question to refer to the pre-harvest treatment of small grain cereal crops for the control of weeds and cereal re-growth that may arise from crop lodging and/or delayed harvesting. The resulting grain is normally of poor quality and unlikely to be used for human consumption. Furthermore, these treatments may result in high and variable residue levels in cereal grain.

In addition to the data referred to in the 'Background' to this opinion, the Committee was supplied with an Addendum to the Monograph (dated May 1999) as well as Evaluation tables (dated April 1999). The Addendum includes updated results of an estimation of dietary intake to assess the long term (chronic) dietary exposure for adults, schoolchildren and infants based on UK consumption data and performed according to the UK technical policy as published in the "Registration Handbook"(1). This showed that the total NEDI[19] for infants exceeds the ADI[20].

The SCP examined the assessment carried out by the RMS which was performed according to the information in the "Handbook" which estimated the dietary intake as a sum of the two highest 97.5th percentile intakes for cereals and mean population intakes from other foods. This procedure may lead to an overestimation of dietary intake. However, there are no details of the total NEDI calculation, e.g. mean population intake data used, information about exhausting the ADI by single commodities and the total quantity of food consumption per person per day presented. The

[19] National Estimated Daily Intake
[20] Acceptable Daily Intake

relationship between the residue levels of diquat used by the Rapporteur Member State for the intake calculations and the results of the supervised field trials could not be fully verified by the Committee. In addition, the residue levels used by the Rapporteur Member State for the intake calculation could not be fully verified by the Committee.

The Committee noted, that the RMS made the assumption that "all produce eaten which may have been treated, has been treated". Whilst the Committee feels that this assumption seems to be an overestimation for the desiccant uses in question, it is not possible to be more precise in the absence of Community crop area treatment data for diquat desiccation uses.

The Committee noted also that sufficient processing data for oats for a more refined intake calculation are not yet available.

In addition, estimates of long term dietary intake for young children aged about aged about 1 to 6 years and other national diets were not submitted to the Committee.

4.5.1. REFERENCES

(1) "The Registration Handbook Pesticides Biocides Plant Protection Products"
A guide to the policies, procedures and data requirements relating to their control within the United Kingdom.
Issued jointly by the Pesticides Safety Directorate, an Executive Agency of the Ministry of Agriculture, Fisheries and Food, and the Pesticides Registration Section of the Health and Safety Executive

5. ACKNOWLEDGEMENTS

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