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OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS ON AN ADDITIONAL QUESTION FROM THE COMMISSION CONCERNING THE EVALUATION OF DIQUAT IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC

(Opinion adopted by the Scientific Committee on Plants, 20 December 2001)

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A. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS ON AN ADDITIONAL QUESTION FROM THE COMMISSION CONCERNING THE EVALUATION OF DIQUAT IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC
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B. TERMS OF REFERENCE

In its opinion SCP/DIQUAT/002-Final 5 April 2000[1] adopted on 17 March 2000, the Scientific Committee on Plants found "that 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".

Now, the notifier (Syngenta Ltd) has provided additional information on certain aquatic uses of diquat, which were evaluated by the Rapporteur (United Kingdom). The rapporteur now considers that the body of evidence available supports the conclusion that acceptable use of diquat in the aquatic environment is possible.

The Committee is requested to comment on this conclusion.

C. OPINION OF THE COMMITTEE

The new data do not substantially modify the original opinion of the Committee. In the Committee's opinion it cannot be expected that diquat can be used for aquatic weed control without incurring some effects on non-target species, and for non-target plants these effects are likely to be substantial. The additional data supplied include refined exposure estimates and toxicity values for more non-target aquatic organisms. This new information to some extent allows a refined risk assessment. However, the Committee found a number of deficiencies in this new information and its interpretation.

The SCP's reanalysis of some additional effects and exposure data indicates that measurable effects on non-target fish and invertebrates are likely to occur following aquatic weed control with diquat. In addition, concerns remain regarding effects on a wide range of non-target plants, i.e., non-weed macrophytes, phytoplankton and benthic microalgae, as well as indirect effects on aquatic food chains.

Insufficient additional information was provided on indirect effects, on recovery of non-target species or on the effectiveness of risk mitigation, which were also concerns raised in the Committee's original opinion.

It is not within the mandate of the Committee to comment on the risk management question, i.e., whether a Community prohibition of aquatic uses should be maintained, or if it could be more appropriately addressed at member state level.

[1] http://europa.eu.int/comm/food/fs/sc/scp/out64_ppp_en.pdf

A. TITLE

REPORT OF THE SCIENTIFIC COMMITTEE ON PLANTS ON AN ADDITIONAL QUESTION FROM THE COMMISSION CONCERNING THE EVALUATION OF DIQUAT IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC

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C. BACKGROUND

Diquat 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 one of the active substances covered by the first stage of the work program provided for under the Directive. In 1995, the notifier Syngenta Ltd (formerly Zeneca Agrochemicals) submitted an application for inclusion of diquat dibromide on Annex I of the Directive. On 5 March 2001, inclusion was granted by the Commission under Directive 2001/21/EC[2]. A specific provision in the Annex to this Directive states that the use of diquat for aquatic weed control is not authorised.

During discussions prior to the Standing Committee on Plant Health (SCPH), it was proposed that aquatic use could not be included on the basis of the opinion given by the Scientific Committee on Plants (SCP, 2000). The notifier has requested that the aquatic use of diquat is reconsidered based on submission of two new laboratory studies, three recently published articles, and a consolidated summary (document SCP/DIQUAT-bis/004). The rapporteur member state (RMS, UK) considers that the body of evidence available, from regulatory studies and published papers, supports the conclusion that acceptable use of diquat in the aquatic environment is possible. The properties and risk assessment for the active substance indicate concerns that the rapporteur concludes can be addressed when considering applications for product authorisations but are not considered to support a restriction on use as an aquatic herbicide as a specific provision of Annex I inclusion.

The Commission seeks specific clarification from the Scientific Committee on Plants and further development of its opinion with respect to:

1) whether the consolidated summary and supporting data modifies the original opinion of the Committee;
2) whether the conclusions drawn from all the available information support a prohibition on aquatic use or whether any remaining areas of uncertainty could be appropriately

[2] Directive 2001/21/EC of 5 March 2001, OJ N° L 69/17 of 10. 3.2001.

addressed at Member State level when considering specific products and use scenarios for which appropriate data could be requested and risk reduction measures defined.

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 non-selective herbicide in amenity situations. 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. 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 (SCP, 2000).

<u>Source documents made available to the Committee:</u>

1. Diquat: Terms of reference, submitted by Health and Consumer Protection DG, 12 July 2001 (SCP/DIQUAT-bis/001).

2. Evaluation of RMS on Notifier assessment of aquatic use of Diquat, submitted by Health and Consumer Protection DG, 12 July 2001 (SCP/DIQUAT-bis/003).

3. Notifier assessment of aquatic use of Diquat, submitted by Health and Consumer Protection DG, 12 July 2001 (SCP/DIQUAT-bis/004) and the 20 references (5 to 25) on which it was based.

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19. Surprenant DC (1987). The chronic toxicity of diquat concentrate to fathead minnow (*Pimephales promelas*) embryos and larvae. Chevron Chemical Co. Report No. S-2912.

20. Tapp JF and Caunter JE (1988). Diquat: Determination of acute toxicity to rainbow trout (*Salmo gairdneri*). ICI Brixham Laboratory. Report No. BL/B/3336.

21. Tapp JF and Caunter JE (1988). Diquat: Determination of acute toxicity to mirror carp (*Cyprinus carpio*). ICI Brixham Laboratory. Report No. BL/B/3337.

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D. SCIENTIFIC BACKGROUND ON WHICH THE OPINION IS BASED

Question:

Can the Committee comment on the rapporteur's conclusion that, on the basis of new information provided by the notifier, acceptable use of diquat in the aquatic environment is possible?

Opinion of the Committee:

The new data do not substantially modify the original opinion of the Committee. In the Committee's opinion it cannot be expected that diquat can be used for aquatic weed control without incurring some effects on non-target species, and for non-target plants these effects are likely to be substantial. The additional data include refined exposure estimates and toxicity values for more non-target aquatic organisms. This new information to some extent allows a refined risk assessment. However, the Committee found a number of deficiencies in this new information and its interpretation.

The SCP's reanalysis of some additional effects and exposure data indicates that measurable effects on non-target fish and invertebrates are likely to occur following aquatic weed control with diquat. In addition, concerns remain regarding effects on a wide range of non-target plants, i.e., non-weed macrophytes, phytoplankton and benthic microalgae, as well as indirect effects on aquatic food chains.

Insufficient additional information was provided on indirect effects, on recovery of non-target species or on the effectiveness of risk mitigation, which were also concerns raised in the Committee's original opinion.

It is not within the mandate of the Committee to comment on the risk management question, i.e., whether a Community prohibition of aquatic uses should be maintained, or if it could be more appropriately addressed at member state level.

Scientific Background on Which the Opinion is Based:

1. Committee's concerns from the initial risk assessment

In its first opinion (SCP, 2000) the Committee identified three major concerns with respect to aquatic uses of diquat:

1. Acute TERs[3] for fish and Daphnia were well below the Annex VI trigger of 100 indicating the need for more refined risk assessment.

[3] Toxicity Exposure Ratio.

2. Due to both high toxicity and the non-specific mode of action of diquat, it is likely to cause harm to most if not all aquatic plants and planktonic algae in the concentrations normally applied to achieve efficacy.
3. Indirect effects of diquat would be likely to include oxygen depletion and disruption of aquatic food chains.

2. Committee's evaluation of the new studies

Ritter *et al.* (2000) employed computer simulations (EXAMSII) and a joint probability method to evaluate the variability of diquat cation environmental concentrations for various scenarios (i.e., farm ponds, lakes and canals) in the United States. On the basis of these calculations (which includes a DT_{50}[4] of < 1 hour) the authors predicted that the 90^{th} percentile exposure concentration for diquat would be 0.194 mg/L, or less, one hour after application and would typically reach 0.01 mg/L by 96 hours.

The SCP has several concerns with the use of the results of Ritter *et al.* in the risk assessment for diquat. Some of those concerns relate to the applicability to European field and usage conditions while others relate to the methodology itself including the selection and the use of parameters and values.

1. Their exposure calculations are based on a maximum usage rate that is less than half that proposed for European usage.
2. Their lake and pond scenarios used a greater depth and their canal scenario used higher flow rates than would be typical of European usage scenarios, and would therefore lead to underestimation of potential exposure in the EU (SCP/DIQUAT-bis/005).
3. In applying the joint probability method they have not used the full distributions of input variables but have assigned discrete probabilities to a few selected input values (see Ritter *et al.* 2000, Tables 3, 4, and 5). It is not clear how using such discrete probabilities (as opposed to the actual distributions of input variables) would alter the outcome of the exposure assessment. Furthermore, Ritter *et al.* provide only limited information justifying the choice of the values used. In particular, there is no indication as to how frequently values outside the range of those selected will occur in the field.
4. The authors did not consider dependencies among the input variables. This could lead to irrelevant scenarios or make the output distributions inaccurate. The authors recognise (p. 758) that some correlations will exist, but they have made no attempt to show how this would affect the outcome.
5. The Committee cannot judge the appropriateness of the sorption coefficients to suspended matter and sediment as these values were not documented. In addition there are uncertainties about the importance of partitioning onto macrophyte surfaces and concern that their estimate of dissipation of diquat due to this process is an overestimate. These are critical input parameters, and any uncertainties in them can have an important influence on the exposure assessment.
6. The field measurements referred to by the authors (p. 758, 2^{nd} paragraph) in support for their predicted concentrations in fact cast doubt on the robustness of their 90^{th} percentile concentrations. The PECs[5] in both their lake and pond scenarios are all based on a dissipation half-life in water for diquat of less than one hour whereas the data quoted from field studies include half-lives of up to 1.5 days.

[4] Time require for 50% dissipation.
[5] Predicted Environmental Concentrations.

7. This exposure assessment is not relevant for assessing risk from the gel formulation of diquat described by the notifier (see also below).

As suggested by Mackay (SCP/DIQUAT-bis/005), the Committee used the pond scenario of Ritter *et al.* (2000) and corrected their estimated exposure concentrations (i.e., time-weighted mean concentrations (TWMC) during one and 96 hours following application = 0.129 mg/L and 0.014 mg/L, respectively) by a factor of four (to account for a halving of depth and a doubling of usage rate in Europe). This gave a 90th percentile TWMC of 0.52 mg/L 1 hour after treatment and of 0.056 mg/L during 96 h following treatment. The Committee recognises that halving the depth of a system will not lead to a time-weighted mean concentration in water that is twice as high but considers in this case this simplification acceptable.

Campbell *et al.* (2000) provide additional toxicity data for a range of fish and invertebrate species that can contribute to a refined risk assessment for diquat. The SCP has a number of concerns with the approach used in this paper:

1. It is unclear whether the toxicity values presented by Campbell *et al*. (2000) represent nominal or actual exposure concentrations. The latter could potentially be substantially lower than the former.
2. The toxicity data were taken from various sources, and there was a very large degree of variability among species (e.g., the lowest invertebrate 96 h LC_{50}[6] was a factor of 2083 times lower than the highest; the lowest fish 24 h and 96 h LC_{50}s were 1234 and 1550 times, respectively, lower than the highest values). It is unclear how much of this variability is due to real differences among species (for which it would be appropriate to use an SSD[7] approach), and how much of the variability is due to differences in test design/protocol (e.g., flow-through vs. static) among studies.
3. The database contained more than one toxicity value for a given test duration for some, but not all, species. The authors appeared to use all of the values in fitting their distributions that, would bias the distribution toward species for which more test results were available. It is not clear for many of those values if they were derived from a) different sub-groups (e.g., age/size classes) in the same study, or b) from different studies using the same test guideline (using/reporting same test species and test duration but with possible variation otherwise; e.g. nominal versus measured concentrations which would be an important factor for this substance). The undifferentiated use of all those values in the distribution added considerable variability because, in several cases, the values for the same endpoint (e.g., LC_{50}'s for same species and same duration) ranged over one order of magnitude. The Committee considers that, for cases in which several life stages are tested, it would be more appropriate to choose the most sensitive life stage for input into the distribution; for cases in which several replicate results are available, the most common approach is to take the geometric mean.
4. The fact that the toxicity values represent LC_{50}s means that significant mortality of the species populations would occur below these concentrations. How far below cannot be determined without detailed knowledge of the slopes of the concentration-response curves.

Twenty-four hour LC_{50}s (the shortest test duration reported) were presented for a total of 20 species of fish and 14 species of invertebrates. The lowest 24-h LC_{50} for fish was 0.35 mg/L

[6] Lethal concentration, median
[7] Species Sensitivity Distribution.

for fry of smallmouth bass (*Micropterus dolomieu*); the lowest 24-h LC_{50} for invertebrates was 0.58 mg/L for adult *Hyalella azteca*. Ninety-six hour LC_{50}s were presented for a total of 25 fish species and 10 invertebrate species. The lowest 96-h LC_{50}s were determined for yellow perch (*Perca flavescens*; 0.1 mg/L) and *Hyalella azteca* (0.048 mg/L).

To address the issue of more than one toxicity value per species, the Committee recalculated the species sensitivity distributions using a single LC_{50} for each species. Where there was more than one value for a species it was sometimes, but not always, obvious that these represented different life stages. For consistency, the Committee chose the lowest LC_{50} value reported for each species and ranked these from lowest to highest. The Committee thus generated species sensitivity distributions for 24 h and 96 h by estimating the percent species affected as 100 x rank (n + 1) where n is the number of species tested (Klaine *et al.* 1996). This analysis suggested that:

1. Approximately 5 % of the fish species represented by this distribution would have 24 h LC_{50}s $\leq$ 0.35 mg/L and 10% would have 24 h LC_{50}s $\leq$ 0.54 mg/L;
2. Approximately 7% of the invertebrate species represented by this distribution would have 24 h LC_{50}s $\leq$ 0.58 mg/L;
3. Approximately 4% of the fish species represented by this distribution would have 96 h LC_{50}s $\leq$ 0.1 mg/L;
4. Approximately 9% of the invertebrate species represented by this distribution would have 96 h LC_{50}s $\leq$ 0.048 mg/L.

Thus, comparing the TWMCs to the effect probabilities calculated above indicates that about 10% of fish and 7% of invertebrate species' 24 h LC_{50}s could be exceeded. Although comparing a 24 h LC_{50} with a 1 h PEC may overestimate risk, no estimates of toxicity over a shorter time period are available. However, even using the 96 h estimates of both toxicity and exposure indicates that around 9% of invertebrate species' LC_{50}s could be exceeded. This reanalysis indicates that acute LC_{50}s will be exceeded for some species of invertebrates and fish (and toxicity thresholds (NOECs[8]) for more species). There remain substantial uncertainties as to how to apply this result, based on a wide range of species used in the above distributions, to affected European freshwater systems, many of which (e.g., ditches and small streams) have only very few species (especially fish), the sensitivities of which and their position on the overall SSD used is unclear. As was also noted above, the TWMCs employed by Ritter *et al.* (2000) and Campbell *et al.* (2000) imply a half-life of diquat of only 1 hour, which on the basis of other field studies may be a substantial underestimate. This means that the estimated exposure values, and hence risk, may be underestimates.

Bartell *et al.* (2000) used a modelling approach to evaluate risk of diquat to non-target organisms. A physiological energetic model was used to assess risk to individual Daphnia, a demographic modelling approach was used to assess risk to populations of bluegill sunfish, and a 'Comprehensive Aquatic Systems Model' was used to assess risk at the level of the community/ecosystem. Though an interesting tool to aide in exploring potential mechanisms of pesticide impacts at different ecological levels, in the Committee's view these approaches have not been sufficiently validated as predictive tools and therefore do not provide additional information that would alter the Committee's assessment of risk in this case. In any case the exposure estimates would need to be corrected to European usage scenarios, and it is not clear how this would affect the outcome of the modelling exercise.

[8] No Observed Effect Concentrations

Toxicity of diquat to *Chironomus riparius* (Ashwell, 1999) was tested at a nominal concentration of 100 mg diquat ion/kg dry weight sediment. There was no effect on emergence time or emergence rate, suggesting low risk to sediment-dwelling species. The exposure concentration used in this study is likely to be much greater than that expected to occur during field use. The way that the study was performed, (i.e., the sediment was spiked and allowed to settle for 3 days prior to introduction of test animals) would be appropriate for assessing the potential for recolonisation of previously treated areas but not for assessing the initial risks of diquat treatment to intact midge populations.

Toxicity of diquat to the green alga, *Selenastrum capricornutum*, was tested in the presence of sediment (Smyth *et al.*, 1998). Based on the area under the growth curve, the NOEC was estimated to be 0.320 mg/L (nominal) in a 72-h static test. This was compared to a 96-h EC_{50} in the absence of sediment of 0.012 mg/L. However, there are several deficiencies in this study that make interpretation of the results uncertain. A silty clay loam soil was added to each test vessel (3 g dry weight soil plus 100 ml test solution). It was stated that the test vessels were shaken so that ‘some’ sediment was in suspension, but no measurements of actual suspended sediment concentrations were performed, and therefore it is not clear how realistic these conditions are with respect to likely field exposures. Actual diquat concentrations were measured at the start of the test, and were reported to be 85-100% of nominal, however they were not measured at any other point during the test. Given the tendency of diquat to bind to sediment, it would be expected that toxicity to algae should decline in the presence of sediment. However in this study algal growth appeared to be stimulated by diquat relative to control; relative fluorescence values for all treatments were above that of the control (and for 5 and 10 microgram/L treatments they were significantly greater than control). Given the mode of action of diquat, it is not expected that phytoplankton growth should be stimulated.

In summary, neither the additional information provided by the above three studies (i.e., the Bartell *et al.* (2000) modelling study, the *C. riparius* study, and the *S. capricornutum* study) nor the paper by Campbell *et al.* (2000) and Ritter *et al.* (2000) significantly alter the SCP’s original conclusion.

3. SCP’s comments on the Notifier’s summary of the evidence (SCP/DIQUAT-bis/004)

- The notifier states that application rates of 5-10 kg diquat/ha to 100 cm of water are used for aquatic weed control. Yet many of the PECs as well as the measured environmental concentrations referred to in their summary are based on water depths greater than or equal to 100 cm and/or lower application rates. Application of 10 kg a.s./ha to a 100 cm water body would give an initial PEC of 1 mg/L.

- One of the formulations described by the notifier is a viscous gel which when applied to the water surface sinks rapidly in the form of dense strings and droplets, which adhere to weeds. It is likely that such a formulation would result in very uneven exposures to non-target organisms which have not been considered in the exposure data presented.

- In this document as well as in two others provided to the Committee (SCP/DIQUAT-bis/003, Hamer, 1993) it is generally acknowledged that major impacts on aquatic ecosystems can be expected from the use of diquat for aquatic weed control. All of these references discuss in broad terms the effect of diquat versus mechanical weed control.

Methods for risk mitigation in association with aquatic weed control at national level have been used in the U.K. (SCP, 2000; MAFF 1995). However, none of the new documents supplied by the notifier provide information 1) on the efficacy of risk mitigation measures, and 2) on other mitigating factors (such as conditions necessary for recovery; e.g. size/location of untreated areas as refuges for re-colonisation, duration of recovery of non-target species following different methods for aquatic weed control, etc.). No data that would allow an assessment of relative risks following mechanical weed control were made available to the Committee.

- Although not influencing the Committee's interpretation of the results, it was noted that there are a number of errors in the notifier's summary of the Chironomus test (Ashwell, 1999 in SCP/DIQUAT-BIS/004). For example, it was stated that the chemical was dosed to the sediment at a range of concentrations. In fact only one concentration and a control were used (4 replicates of each).

4. Committee's Overall Conclusions

The additional data include refined PECs and toxicity values for more non-target aquatic organisms. This new information to some extent allows a refined risk assessment, however, there remain substantial uncertainties. Although the Committee in principle recognises the potential advantages of applying probabilistic approaches to risk assessment, there were significant deficiencies in the methods used in the new studies. However, even allowing for these deficiencies there remain substantial uncertainties in the risk assessment. The SCP's reanalysis of the new effects and exposure data (Ritter *et al.* 2000, Campbell *et al.* 2000) indicates that measurable effects on non-target fish and invertebrates are likely to occur following aquatic weed control with diquat. This conclusion that diquat cannot be applied without causing effects on aquatic biota was not altered by considering additional data provided from ecological effects models (Bartell *et al.* 2000), or from tests with sediment-dwelling invertebrates and algae. In addition, concerns remain regarding effects on a wide range of non-target plants, i.e., non-weed macrophytes, phytoplankton and benthic microalgae, as well as indirect effects on aquatic food chains.

Very little data were provided on recovery of non-target species on indirect effects, or on the effectiveness of risk mitigation, which were also concerns mentioned in the Committee's original opinion. What little information is available is of limited relevance and insufficient for an objective assessment to be performed of the relative risks of diquat compared to alternative methods for weed control.

In summary, the new data do not substantially modify the original opinion of the Committee. In the Committee's opinion it cannot be expected that diquat can be used for aquatic weed control without incurring some effects on non-target species, and for non-target plants these effects are likely to be substantial.

It is not within the mandate of the Committee to comment on the risk management question, i.e., whether a Community prohibition of aquatic uses should be maintained, or if it could be more appropriately addressed at member state level.

E References

SCP, 2000: Opinion of the Scientific Committee on Plants regarding the inclusion of diquat in Annex I of Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/DIQUAT/002-Final 5 April 2000).
http://europa.eu.int/comm/food/fs/sc/scp/out64_ppp_en.pdf

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