

Communication for Regulatory Heads

PARAQUAT: STATUS AND ACTION REPORT COMPANY CONFIDENTIAL INTERNAL USE ONLY

Background

As a List 1 compound in review under Directive 91/414, paraquat has completed the technical stage of the review (ECCO, SCP opinion and Working Group Evaluation) which concluded in favour of Annex I inclusion with some aspects of the risk assessment to be considered by Member State at national re-authorisation.

The Commission drafted a positive proposal as a basis for discussion at the Working Group Legislation meeting on 17/18 October 2002. France and their concerns over safety to operators dominated the discussion

Due to the timing of processes at a national level the French had not raised any concerns during the technical EU stages of the review, however at the French Committee des Toxique (Technical Committee) on 16 October, the experts concluded that there were significant concerns regarding operator risk from use of paraquat in relation to knapsack/manual application under French use conditions. Their concerns were strongly influenced by a survey that suggests that the majority of farmers do not wear the recommended protective equipment when applying pesticides. On this basis the Committee proposed withdrawal of all knapsack uses in France. Further data was requested particularly in relation to the operator risk assessment for other uses in France (ie with no PPE) to be submitted for review by the Committee des Toxique. This review is scheduled to take place on the 15th or 22nd January 2003.

In the light of this information steps were taken to

- (i) prepare a submission on other uses (tractor) and knapsack to demonstrate safe use under French use conditions (with and without PPE). This draws on the extensive database for operator exposure and risk assessment database that exists for paraquat which we do not believe was fully appreciated by the Committee des Toxique
- (ii) a detailed review of the occupational health data in France (and other Member States) over the last 5 years to ascertain if there were any specific issues in France and, if so, to identify suitable mitigation measures
- (iii) to ensure a procedure with the authorities which allowed Syngenta to discuss solutions to the perceived problems of use in France.
- (iv) delay discussion of paraquat at the next EU Working Group Legislation (February 2003) to allow time to resolve the issue in France and hence their voting intentions at EU level

Current Developments in France

On Wednesday of last week we found out that the recommendations of Committee des Toxique with regard to knapsack use would be considered by the Committee de Homologation (regulatory committee) on 6 December 2002. The chairman of the Committee de Homologation was made aware of the contents of the pending submission and we were advised that it was unlikely that any precipitative action would be taken on knapsack use of paraquat until the Committee des Toxique had reviewed and commented on the submission.

Late on Friday we received initial feedback that the Regulatory Committee had supported the recommendation for withdrawing knapsack use in France (including the French West Indies). A formal communication will be sent to Syngenta in the next week.

Syngenta will be given the opportunity to discuss the risk management options but dates have yet to be established. In the meantime it should be assumed that this information will be known within the industry and regulatory authorities within a short period of time, through informal contacts, and may be released to NGOs. General stand by statements for use externally have already been provided but are attached again here for your convenience.

Focussed activity to resolve the technical and emotional issues are being initiated to resolve both the national and EU positions of France and the following actions are planned in France to resolve this development:

- Grower influencing lobby in France, and in French West Indies
- Offering risk management measures for knapsack use in France are likely to include spray dilution limits, clarity of labelling, maintenance of spray equipment, training and education of users and provision of specific PPE.
- Proactively building the stewardship support for paraquat and other products

Action Needed

The recommendation for withdrawal of knapsack use of paraquat in France will undoubtedly raise questions in the regulatory authorities of other EU member states and those outside of Europe. During the next few days and weeks we will dialogue with you and provide key messages to help manage any contact with your Authorities. It is very important that we minimise the negative impact of the current French views on the other Member States.

Points to bear in mind are

- Paraquat is an extremely important product for Syngenta in Europe, and globally. Paraquat use, including knapsack application, is extremely important to agriculture in Europe, and even more so globally.
- The minimum protective clothing recommended for the use of products containing paraquat are gloves and eye protection to be worn when mixing the concentrate. There is no need for protective equipment when applying the diluted solution – in this case normal working clothes and trousers and a long-sleeved shirt are adequate. The use of rubber boots when spraying any herbicide is considered good practice. The simplicity and reliability in use of paraquat-containing products contribute, we believe, to the overall good safety record
- The assessment of operator exposure is supported by a wide range of biological monitoring data, under a wide range of exposure conditions, and these indicate that paraquat can be used safely.
- In a first tier assessment, predicted exposure estimates from POEM modelling for both knapsack use and tractor mounted application of paraquat under conditions of use in France suggest the AOEL would be exceeded.
- However a higher tier assessment based on measured values in biomonitoring studies supports the conclusion that the AOEL would not be exceeded, from either knapsack use or tractor mounted application of paraquat, including minor predictable deviations from label recommendations.
- The opinion adopted by the EU's independent Scientific Committee on Plants (SCP) on 20 December 2001 on the question of operator risk from use of paraquat in Europe was " *While the use of predictive exposure models suggests that operator exposure to paraquat may exceed the proposed AOELs, the results of the field studies conducted in various countries indicate that the exposure models markedly overestimate the actual exposure to paraquat in real working situations. Thus modelled exposures cannot be used as the only basis for operator risk assessment. Based on the field exposure studies, corroborated by information on health surveys on operators, the SCP is of the opinion that when paraquat is used as a plant protection product as recommended under prescribed good working practices, its use does not pose any significant health risk for the operators.*"
- In France a toxicovigilance programme for agricultural chemicals is operated by the MSA. Between 1997 and 2001, 26 cases involving paraquat-containing products were reported to the MSA. 16 occupational exposures are reported that involve only paraquat. Half of these resulted in skin symptoms, the rest involved upper respiratory tract, eyes and non-specific symptoms. In the 8 cases involving effects from skin exposure including some burns, various degrees and combinations of misuse could be identified. It is important to stress that the overall number of such cases is low (8 over 5 years), that all of them fall outside normal use and good agricultural practice, and that all of them healed completely

without the appearance of any signs of systemic poisoning. A detailed assessment is attached



"Assessment of
French MSA data.doc"



"PQ MSA TOTAL
CASES.xls"

- Overall, there were no reports of systemic intoxication or long-term sequelae from these exposures. It is evident that the overall number of incidents is very low, but the incidence of skin burns associated with exposure from badly maintained spraying equipment and/or varying degrees of misuse warrants further measures to improve safe use practices in hand-held applications. Syngenta takes safety in use very seriously and will be working with the French authorities to address these concerns.
- Bipyridyl formulations are inherently irritant to skin and mucous membranes but the occurrence and severity of skin irritation is mainly determined by the concentration of bipyridyl in the solution and the time and intensity of contact with the skin. Typically, splashes with the concentrate will lead to effects more rapidly than contact with spray dilutions. Those cases where skin burns have been reported as a result of contact with dilute material show an intensive contact over several hours, usually under occluded or semi-occluded conditions, with only insufficient or completely absent decontamination. The lesions typically develop over a period of up to 24 hours, i.e. at a time when the exposure has already ceased. Therefore, the risk of significant absorption of paraquat across damaged skin is very small.
- There are no reported cases of systemic toxicity following skin irritation and burns in the MSA data. Indeed, health-monitoring studies have demonstrated that there are no health effects, from long-term and regular use of the product, with significantly less protective clothing.
- The paraquat formulations sold in France are unique and are not sold in other countries. French regulatory requirements stipulate the paraquat formulations must be thickened. We are currently investigating whether these formulations have any bearing on the French in-use situation, particularly with regard to dermal irritancy when compared with formulations sold in other countries.
- We are absolutely confident that when used according to instructions, and taking in to account minor predictable deviations from these label instructions, Syngenta's paraquat products presents no risk to humans, animals or the environment
- We will continue to work with the French Authorities to resolve these concerns