Plant protection products: placing on the market, evaluation of the active substances (Directive 91 /414/EEC). Report

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PURPOSE: To evaluate progress on the implementation of EEC Directive on the placing of plant protection products on the market. CONTENT: Council Directive 91/414/EEC on the placing of plant protection products on the market marked a departure for the European Community in that it placed consumer protection and environmental considerations over and above agricultural priorities. Moreover it was one of the first Directives to advocate use of the precautionary principle. It provided for a 12-year programme of evaluation of 834 active substances already on the market at the time of its entry into force in July 1993. These 834 active substances were placed on a positive list for use within the European Community. Products not listed were forbidden from use with the EU. Further, bearing in mind the need for subsidiarity the Directive provided that the Commission would be responsible for evaluating the active substances on the list whilst the Member States would be responsible for authorising and evaluating products containing these substances. Article 8 (2) of the Directive stipulates that the Commission should prepare a Progress Repot on the evaluation of the programme by July 2001. In preparing this Report the Commission is fulfilling its obligations under the terms of the Directive. The Article also suggests that the Commission should decide whether the 12 year deadline for the evaluation of the substances should be extended. In light of the many difficulties and lack of resources for the implementation of this Directive the Commission is urging an extension of the deadline to 2008 as opposed to 2003 as originally envisioned. The Report notes that progress on evaluating the substances has been considerably delayed thanks, in large part, to procedural difficulties. Thus, a typical dossier could contain around 50 000 pages and take approximately four and a half years to prepare. In addition standardised risk assessment procedures needed to be established before work could progress satisfactorily. The Report does make note of the fact that the Member States made a major contribution in agreeing to work in one language on technical assessments - in spite of the difficulties this imposed at national level. Because of these initial shortcomings, on average, only two decisions of the 834 substances a year were made. This has now improved with at least 20 decisions per year being made. In spite of these improvements, the Report notes that should the revised time-table of 2008 be completed an average of 50 decisions per year on existing active substances (peaking at 85 in 2007) will be needed. This, it is argued, can only be achieved through an increase in existing resources, procedural changes for dossier evaluation, tighter time-tables and improved use of information technologies. Certainly, the Report hopes that the new "European Food Authority" will help provide a foundation upon which to extend the activities of the Directive. It is estimated that at least 25 qualified evaluators will be required at the level of the EFA if the deadline is realistically to be met. Regarding the current state of play, the Report explains that prior to beginning the gargantuan task of assessing all 834 substances these substances were divided into four lists. The first is a priority list of 90 substances considered to be the most widely used in the market as well as those of clear concern.The current situation is that Directives have been or are about to be taken on 13 existing substances in Annex I of the Directive; Decisions have been taken not to include 16 substances in Annex I and withdrawing them from the market, 39 substances have been peer-reviewed and final discussions are on-going; 21 substances are undergoing or are scheduled for peer review; and one assessment report still has to be submitted. The second list contains 149 substances. Early indications imply that by 2003 at least 89 substances should be withdrawn from the market. The third list comprises the 402 remaining chemical substances, also considered "pesticides" but not as widely used as those on the second list. Again early indications would suggest that at least 235 substances should be withdrawn from the market in July 2003. Lastly, the fourth list, comprises the 193 remaining substances identified as being of lower concern and to which other data requirements might apply. Although of lower concern the Report nevertheless estimates that some 124 substances may be expect to be withdrawn from the market in 2003. The Commission is

now awaiting comments on this Report from the European Parliament and Council prior to proposing any changes or amendments to the existing Directive.