

BfR recommends maintaining exposure-based risk assessment for pesticide approval

BfR Information 037/2008, 1 August 2008

Directive 91/414/EEC concerning the “placing of plant protection products on the market” entered into force on 15 July 1991. This Directive stipulates that active substances contained in plant protection products must be assessed regarding the possible risks for humans, animals and the environment. Only when this assessment confirms that their use does not constitute a risk for users, consumers, animals and the environment, are the active substances entered in an EU positive list which means that preparations with these active substances may be approved in the individual Member States of the European Union. Since 15 July 2006 a proposal has been on the table for the carrying over of this Directive into an EU Regulation which has since been discussed on various levels.

On 23 June 2008 the Council of the European Union agreed on the text of the new Regulation. In the autumn of 2008 the European Parliament will look at this proposal.

The Federal Institute for Risk Assessment (BfR) has voiced its opinion below on the new Regulation concerning the points of relevance for BfR's assessment work. As this is initially a Council proposal to revise Directive 91/414/EEC, changes may still be made particularly as a consequence of the proposals of the European Parliament.

To ensure consumer health protection, BfR recommends the following with reference to the current Council proposal: the approval of a pesticide should not depend primarily on the substance's genotoxic, carcinogenic, reprotoxic and hormonal properties when, instead, threshold values can be established above which a health risk is to be expected. When assessing the risk, exposure - i.e. the active substance concentration ingested by consumers - should also be taken into account.

The full version of this BfR Information is available in German on http://www.bfr.bund.de/cm/218/bfr_empfiehl_die_beibehaltung_der_expositionsbasierten_risikobewertung_fuer_die_zulassung_von_pflanzenschutzmitteln.pdf