



**Friends of
the Earth
Europe**

An analysis of the Commission's proposals for 'cut off criteria' and candidates for substitution

The case for clearer 'cut off criteria'

While Directive 91/414 succeeded in providing universal criteria for the inclusion of active substances onto the positive list, the generality of its approvals criteria often led to substantial delays in the regulatory decision making process caused by a diversity of interpretations by different MS. In making reference to specific hazard-based criteria the Commission's proposals define a much clearer regulatory framework capable of greatly facilitating the decisional process, at the same time granting consistency with other European legislation (i.e. REACH, Reg.850/2004).

Hazard vs. Risk

While the Commission's proposed approvals criteria greatly benefit from the clarity associated with a hazard-based approach, they make fundamental provision for estimated realistic exposure to be taken into account; thus enabling regulators to consider use pattern and rate of application. In this respect the Commission is correct to observe that its approvals criteria are not 'cut off criteria'¹ but represent a workable compromise between a hazard and risk based approach in assessing the EU's most harmful active substances.

CMR1,2 + ED = 23 active substances

PAN Europe's assessment of the 507 actives currently under Annex 1 or pending reveals 23 substances listed as CMR1,2 or Cat 1 Endocrine Disruptors². In total these actives represent 4.5% of the substances approved by the EU. PAN Europe's figures match closely with those of the Commission (1.3% CMR + ~3% ED + 'very small' POPs, PBT, vPvB) and with the lower estimates provided by ECPA in Nov 2007 (3% CMR, 3% ED, <1% POPs, PBT, vPvB)³. PAN Europe's analysis identifies no actives under the Commission's definitions of POPs, PBT, vPvB.

Existing MS restrictions on CMRs & EDs

Existing MS restrictions on CMR and ED substances are commonplace, though piecemeal. Thus by providing a consolidated approach the Commission's proposals have substantial potential to bring greater harmonisation across the Community. A PAN Europe analysis of 8 representative MS found that of the 23 actives identified as CMR1,2 or ED, 13 (57%) are currently withdrawn in Denmark, 10 (43%) in Germany, 14 (61%) in Finland, 5 (22%) in Hungary, 10 (43%) in Netherlands, 4 (17%) in Portugal, 3 (13%) in Sweden, and 4 (17%) in UK⁴. Only 4 substances are registered for use in all 8 MS. To add to this Italy has withdrawn all CMR1,2 actives⁵, while France has plans to ban CRM1,2 plus at least 3 additional EDs.

Proportional and Progressive

Since the implementation of 91/414 in 1993, some 129 new actives have been introduced to the EU market (74 under Annex 1, plus 55 pending)⁶. Thus the additional scrutiny afforded to 23 substances under the Commission's proposal represents an entirely proportional

¹ Commission Non-paper circulated by Dan Jorgensen MEP, 2007

² PAN Europe: 'List of CMR1,2&ED, plus list of CMR2', Feb 2008

³ ECPA: 'EU Proposal for Pesticide Authorisation' (November 2007)

⁴ PAN Europe: 'Existing MS Restrictions on CMR1,2,3&ED, Feb 2008

⁵ European Agriculture of the Future, Nomisma, Jan 2008

⁶ European Agriculture of the Future, Nomisma, Jan 2008

regulatory approach. Furthermore very few of the 129 new substances are classified as CMR1,2 or ED. Meaning that the Commission's proposal will do far more to add greater regulatory scrutiny to the approval of old substances, than to complicate the use of new agrochemicals.

CMR1,2 and EDs are major EU food contaminants

CMR1,2 and EDs leave a substantial toxic footprint in the EU food chain. Data for 2005 show that up to 22% of all food products tested under the EU coordinated food monitoring programme contained at least one CMR1,2 or ED substance⁷. Four actives (carbendazim, procymidone, deltamethrin, maneb) were among the EU top 10 food contaminants for fruit and vegetables or cereals. PAN Europe's analysis of food monitoring data for individual countries (2005-1996) shows that CMR1,2 and EDs are dominant food contaminants in all MS year after year⁸. PAN Europe would therefore urge the Council to amend the Commission's text such that the concept of 'negligible' expose applies explicitly to consumers as well as agricultural workers and operators.

The case for CMR3

CMR3 substances account for a further 22 actives (4.3%) above and beyond those already listed as CMR1,2 or ED. Given that many of the above observations apply equally to CMR3 actives as to CMR1,2 (widespread and persistent food contaminants/ already withdrawn in many MS/ a small number of substances/ includes few 'new' actives), PAN Europe would urge the Council to incorporate CMR3 actives into the proposed approvals criteria.

Candidates for Substitution

The proposal that MS should grant authorisation to less hazardous pesticides in preference to more hazardous alternatives where possible represents a highly effective mechanism by which human health and the environment can be afforded greater protection. Furthermore under the terms of the Commission's proposals, substitutions will have little or no impact on the availability of products for use in agriculture given that a substitution will only be made where an effective substitute is available. PAN Europe would therefore urge the Council to join with the European Parliament in broadening the list of substances to be considered as candidates for substitution to include potentially endocrine disrupting, neurotoxic or immunotoxic substances.

Fewer actives, larger corporate profits

While much is often made of the non-inclusion onto Annex 1 of 629 active substances following the implementation of 91/414, ECPA's own data show that European pesticide sales actually increased in the decade 1991-2001⁹. Indeed ECPA pinpoints the loss of 15% of arable land due to CAP reform as being the principle obstacle to even greater trade in the same period – not changes to the regulatory environment. ECPA's analysis demonstrates that a fall in active substances approved need not lead to a decrease in pesticides sales.

Misunderstanding the impact

The viability of agricultural production in the absence of the 4.5% of substances categorised as CMR1,2 or ED is more than demonstrated in the many instances in which individual MS have already withdrawn such substances from use. There is no scientific basis upon which to forecast decreases in crop yields were the Commission's proposed text to be implemented.

Future CMR categorisation

ECPA's approach to assessing the proportion of active substances potentially affected by the Commission's approvals criteria, within which its maximum figure is 25%¹⁰, anticipates the future classification of many more active substances as being CMR or ED. There is absolutely no good reason for suggesting that the current CMR and ED categorisations – which cover 4.5% of active substances – should increase so as to encompass 25%.

⁷ Annual EU-wide Pesticides Residues Monitoring Report - 2005, European Commission, Oct 2007

⁸ PAN Europe: 'EU Food chain analysis', Feb 2008

⁹ Ten Years of ECPA: 1992-2002, ECPA 2002

¹⁰ Do we have adequate disease control options in the European Union? ECPA, Feb 2008