
 **BCPC**

BCPC Food Chain Forum

The impact of new EU legislation on UK food production, availability and price

**Society of Chemical Industry,
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Proposal for a Regulation to replace Directive 91/414/EEC

A Simple Guide

Colin Ruscoe, BCPE


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Proposal for a Regulation to replace Directive 91/414/EEC – A Simple Guide

- Nature of Proposals
- Process and Timetable
- Proposed Criteria – Commission
- Proposed Amendments – Parliament
- Present Status

*Boring but important background
Further detail at PSD and BCPC websites*

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Nature of the Proposals

Commission proposal (2006):
‘Cut-Off’ Criteria for approval of existing and new active ingredients and for “Candidates for Substitution”.

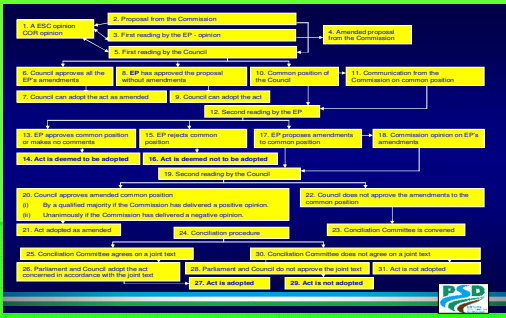
EU Parliament proposal (2007):
Range of more restrictive amendments/additions

- Tighter cut-off criteria
- 5 year approval period for “Candidates for Substitution”

- Proposed “Cut-Offs” based purely on intrinsic hazard - no reference to risk in use, food residues, etc. No evidence of improved safety

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
The Twenty-Nine Steps

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EU Process and Timetable



The proposed legislation will be implemented unless action is taken

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
Cut - Off Criteria

1) Commission Proposals

a) **Non-Approval.....**

- Category 1 or 2 CMR (carcinogenic, mutagenic or reprotoxic) - unless exposure 'negligible';
- Endocrine disruptors - unless exposure 'negligible'
- POPs, PBTs, vPvBs (= persistent, bioaccumulating, toxic organic pollutants – eg DT50 in water > 2 months)

Impact of some criteria (endocrine, repro-tox) difficult to assess without full guidance being given.



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Cut - Off Criteria – Endocrine Disruption

“An active substance shall only be approved if, on the basis of the assessment of Community or Internationally Agreed Guidelines, it is considered not to have endocrine disrupting properties that may be of toxicological significance in humans”

Commission wording

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
Cut - Off Criteria

1) Commission Proposals

b) **Candidates for Substitution:**

- Acceptable daily intake, Acute Reference Dose or Acceptable Operator Exposure Level significantly lower than those for the majority of approved substances
- Meet two criteria to be a PBT

Again, criteria difficult to assess without guidance in place (e.g. “Significantly lower”)




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Cut - Off Criteria

2) Amendments proposed by Parliament

a) **Approvals.....**

- Deregister actives with risk of developmental neurotoxic or immunotoxic properties
- Changes to the POP criteria
- Use each POP criterion separately rather than together
- Inclusion of C&M category 3 to classify substances as Toxic in the PBT criteria
- Deregister actives with Hazard Quotient for bees <50
- Deregister actives on priority list for water in Directive 2000/60/EC.



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Cut - Off Proposals

2) Amendments proposed by Parliament

b) **Candidates for Substitution.....**

- Meets one criterion to be a PBT
- Prone to leaching to groundwater
- “Potentially” endocrine disrupting, neurotoxic or immunotoxic properties.

Parliament also proposed that Candidates for Substitution be approved once only, for a five years – no re-approval

