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Agrochemical Regulation in The EU—Changes to Legislation and Potential Impacts

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Key Developments

- Candidates for substitution and comparative assessment
- Endocrine disruptors
- Risk assessment guidance documents
- Impact on residues/MRLs

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(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 October 2009

concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37(2), Article 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Parliament by its Resolution of 30 May 2002 ([5]) and the Council in its Conclusions of 12 December 2001 asked the Commission to review Directive 91/414/EEC and identified a number of issues for the Commission to address.

(3) In the light of the experience gained from the application of Directive 91/414/EEC and of recent scientific and technical developments, that Directive should be replaced.

Candidates for Substitution

ALL TOPICS

List of Candidates for Substitution

"The European Commission is required by Regulation (EC) No 1107/2009 to establish a list of substances identified as "candidates for substitution". The list identifies **active substances with certain properties**.

For plant protection products (PPPs) containing these active substances, Member States will be required to evaluate if they can be replaced (substituted) by other adequate solutions (chemical and non-chemical). To prepare such a list, the Commission requested a consultant to prepare a report on the implementation of the criteria set by the Regulation. The report **does not contain any official listing**, but presents **different options** drawn from possible interpretations of the criteria.

Member States and stakeholders were consulted on the approach taken and on the input values taken to determine if an active substance qualifies to be a candidates for substitution. The analysis has been conducted by comparing the agreed and peer reviewed endpoints, against the relevant seven conditions specified in Annex II, point 4 of the Regulation. The information is grouped in a **comprehensive database** that will be updated on a regular basis. The current draft list contains **77 candidates for substitution**. More information can be found in the Q&A document below.

- Press release
- Final report: "Ad-hoc study to support the initial establishment of the list of candidates for substitution as required in Article 80(7) of Regulation (EC) No 1107/2009" (09.07.2013) (2 MB).
- Questions and Answers on Candidates for Substitution (356 kB)
- Draft list of candidates for substitution (10 kB)
- Database (7 MB)

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Candidates for Substitution

- List published January 2015
- 77 substances
- Press release and question and answers
- Comparative assessment from 1 August 2015
- Approval periods will only be limited to 7 years if still a CfS after renewal

Candidates for Substitution

European Commission - Fact Sheet

Pesticides: Experts endorse new EU list of candidates for substitution

Brussels, 27 January 2015

A Commission proposal to establish an EU list of 77 candidates for substitution was today endorsed by EU Member State experts. Candidates for substitution (CfS) are pesticides for which national authorities need to carry out an assessment to establish whether more favourable alternatives to using the plant protection product exist, including non-chemical methods. The aim is to encourage more sustainable crop protection.

This new list is the result of a comprehensive review of the active substances which are currently on the market and extensive consultation with stakeholders. It is based on an independent study tasked by the Commission. The study contains a comprehensive analysis of all active substance on the market on 31 January 2013. The findings of the study provided a solid evidential basis for the listing of an active substance as a CfS in a comprehensive database that will be updated on a regular basis.

The list is neither to be misconstrued as a list of banned substances, nor as a ranking of CfS. All active substances featuring on the list will still be available on the market and are deemed safe, but could be substituted in time when a viable alternative is made available. Approval periods for CfS are limited to a maximum of 7 years. However, current approval periods will not be affected.

Background

Pesticides are mainly used in agricultural production to keep crops healthy and prevent them from being destroyed by pests and diseases. The placing on the market of pesticides is governed by Regulation (EC) No 1107/2009. Under this Regulation, to qualify as a CfS, an active substance must meet specific criteria based on the properties it contains (both toxicological and environmental).

For more information:

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/index_en.htm

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Candidates for Substitution

1-Methylcyclopropene, Aclonifen, Amitrole (aminotriazole), Bifenthrin, Bromadiolone, Bromuconazole, Carbendazim, Chlorotoluron (unstated stereochemistry), Copper compounds, Copper hydroxide, Copper oxide, Copper oxychloride, Bordeaux mixture, Cyproconazole, Cyprodinil, Diclofop, Difenacoum, Difenoconazole, Diflufenican, Dimethoate, Dimoxystrobin, Diquat, Epoxiconazole, Esfenvalerate, Ethoprophos, Etofenprox, Etoxazole, Famoxadone, Fenamiphos, Fenbutatin oxide, Fipronil, Fludioxonil, Flufenacet, Flumioxazine, Fluometuron, Fluopicolide, Fluquinconazole, Flusilazole, Glufosinate, Haloxyfop-P, Imazamox, Imazosulfuron, Isoproturon, Isopyrazam, Lambda-cyhalothrin, Lenacil, Linuron, Lufenuron, Mecoprop, Metalaxyl, Metam, Metconazole, Methomyl, Metribuzin, Metsulfuron-methyl, Molinate, Myclobutanil, Nicosulfuron, Oxadiargyl, Oxadiazon, Oxamyl, Oxyfluorfen, Paclobutrazol, Pendimethalin, Pirimicarb, Prochloraz, Profoxydim, Propiconazole, Propoxycarbazone, Prosulfuron, Quinoxyfen, Quizalofop-P-tefuryl, Sulcotrione, Tebuconazole, Tebufenpyrad, Tepraloxydim, Thiacloprid, Tri-allate, Triasulfuron, Triazoxide, Warfarin, Ziram

Comparative Assessment

- **Comparative assessment required for all products containing a CfS from 1 August 2015**
- **Shall not authorise if another product or non-chemical method presents a significantly lower risk and does not present significant economic or practical disadvantages.**
- **Take into account:**
  - Effectiveness
  - Resistance risk
  - Consequences for minor uses
  - Acquisition of experience for new products
- **EPPO guidance document on efficacy aspects**
- **Commission guidance document on risk**

Comparative Assessment

- Member State issue – not zonal – less international impact
- Only for product and uses in the application
- Stepwise approach—start with efficacy

Comparative Assessment

- **Most CA is expected to stop after efficacy assessment**
  - very hard to apply to niche products
- **Expectation—few substitutions in practice**
  - very difficult to restrict 77 chemicals *cf.* 10
- **Supermarket 'restricted' lists?**
- **A lot of discussion**
  - acquisition of experience

Endocrine Disruptors

European Commission

ROADMAP			
TITLE OF THE INITIATIVE	Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation		
LEAD DG – RESPONSIBLE UNIT	DG ENV.A.3, DG SANCO.E.3	**DATE OF ROADMAP**	06/2014
This indicative roadmap is provided for information purposes only and is subject to change. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.			

A. Context and problem definition
(1) What is the political context of the initiative? (2) How does it relate to past and possible future initiatives, and to other EU policies? (3) What ex-post analysis of existing policy has been carried out? What results are relevant for this initiative?
(1) Chemicals with endocrine-disrupting properties ("endocrine disruptors" – **ED**) impact on the hormone system of animals and humans. Endocrine disruption is a relatively recent way of looking at the toxicity of chemicals. There

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Endocrine Disruptors

- **Roadmap document**
  - indicates that this is something difficult to deal with
- **Substances classified as EDs cannot be approved unless negligible exposure**
- **Guidance should have been published December 2013**
- **Significant disagreement within the European Commission**
  - DG environment dislike of pesticides, DG SANTE passed to EFSA
  - EFSA proposed scientific, risk assessment approach
- **Impact assessment required**
- **Interim criteria continue to apply**

Endocrine Disruptors

Interim criteria:

- **Shall be considered an ED**
  - Carcinogen Cat 2 and toxic to reproduction Cat 2
  - Toxic to reproduction Cat 2 and which have toxic effects on the endocrine organs
- **Hazard based**

Endocrine Disruptors

- **Public consultation – closed January 2015—27,000 responses of which 24,000 identical**
  - clicktovists!
- **Impact assessment:**
  - Screening methodology—March 2015
  - Substance screening
  - Socio-economic impact *cf.* biocides/REACh
  - Finalise Q 3/4 2016
- **Stakeholder Conference—1 June 2015**
- **Proposal end 2016**
- **Agreement on criteria 2017??**

Endocrine Disruptors

- **Impact assessment:**
  - Screening methodology—March 2015
  - Substance screening
- **Four options in the road map:**
  - Keep interim criteria
  - WHO/IPCS definition
  - WHO/IPCS definition plus categories on strength of evidence
    1. Endocrine disruptor
    2. Suspected endocrine disruptor
    3. Endocrine active
  - WHO/IPCS definition plus potency
- **Final proposal may be none of these!**

Endocrine Disruptors

- **WHO/IPCS**
  - Known or presumed to have cause endocrine mediated effects
  - Evidence that the substance has the capacity to cause endocrine mediated adverse effects
  - Evidence of endocrine mediated in the absence of other toxic effects or not a secondary consequence
  - Mechanistic data can demonstrate non-relevance

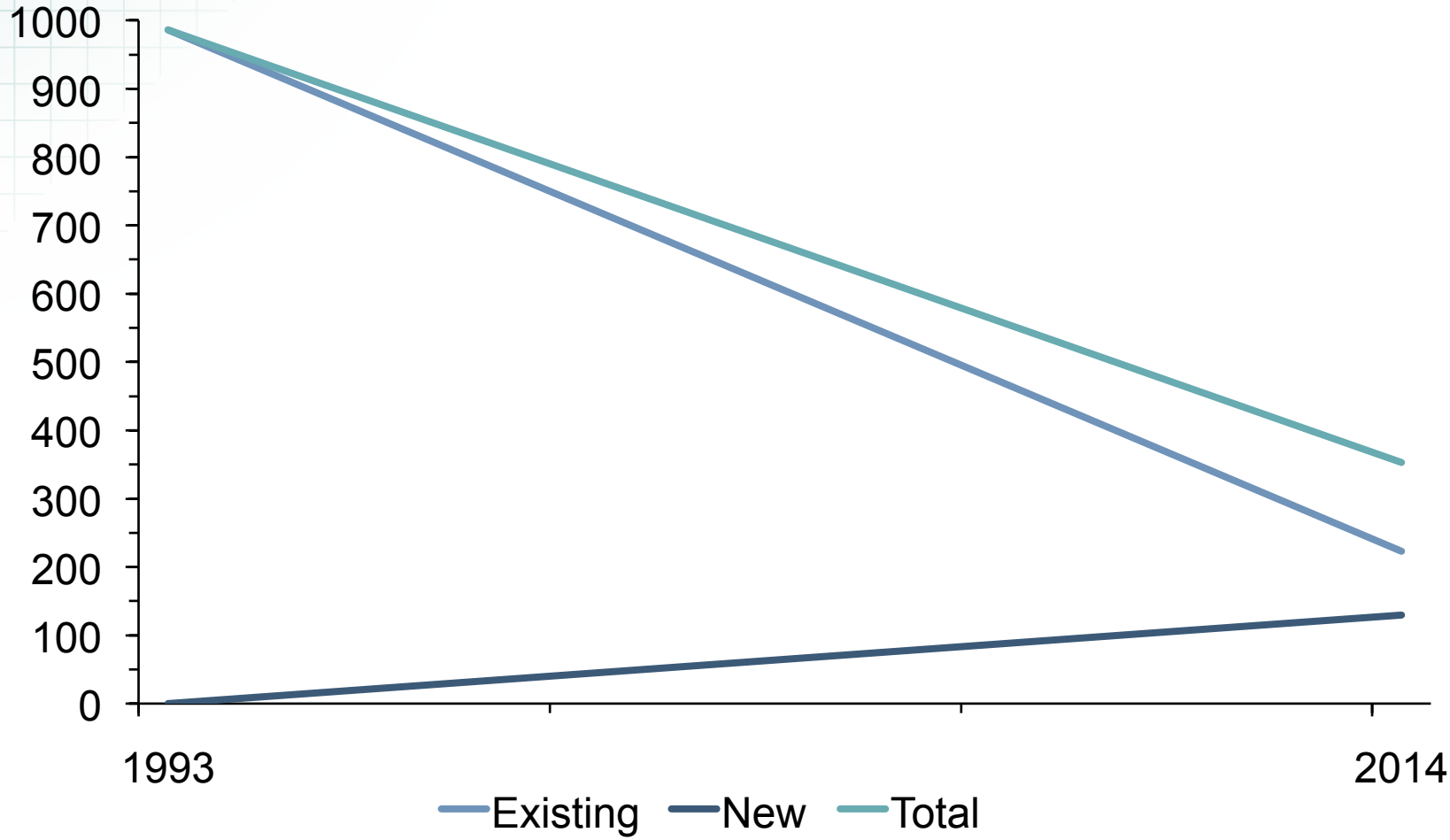
Key Guidance Documents

- **Bees**
  - EFSA GD not agreed
  - Commission roadmap
  - Sequential implementation
  - Formal Commission document awaited
- **Operators**
  - May 2015 adoption—apply from 1 January 2016?
- **New draft Registration Report guidance (product)**
  - Just published (May 2015)
- **Negligible exposure**
  - Important for hazard criteria
  - No agreement

How will this impact on trade?

- EU decision making diverging from global
- Key criteria still not defined
- Reducing numbers of active substances in EU
- Human health or environmental criteria?
- How will hazard based decisions be reflected in MRLs?

Numbers of Active Substances



MRLs, Residues and Trade

- **EU review program of MRLs continues**
  - Do not always take note of import tolerances
  - Need evidence of authorisation and national MRL
  - Need to track the review program and also SPS notifications
- **Codex MRLs**
  - Global harmonisation?
  - Increased number of reservations from European Community
    - Risk assessment
      - Workshop in September on acute exposure
      - Likely to result in a more restrictive IESTI equation
    - Residues definitions
      - More complicated in the EU
      - More rigorous assessment of metabolites
      - Do not accept TTC approach at present
    - Reluctance to agree to group tolerances
      - Extending beyond crops on the label

Conclusions

- **Agrochemical regulation continues to increase in Europe**
- **Regulation ahead of guidelines**
  - Confusion for all
- **Reluctance to accept global standards such as Codex MRLs**
  - Previously seemed to be embracing Codex system
- **The need for plant protection products has been lost in the debate**
- **When will the impact be seen on food production and imports?**

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