EU legislation on the use and control of pesticides

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WE LOOK AFTER WHAT YOU DO NOT SEE...

Does this cabbage contain too much heavy metals (lead...)?

Does this bread contain high levels of acrylamide?

Too much pesticide?

Additives (e.g. colours, sweeteners and preservatives) such as acesulfame-K (E950), aspartame (E951)

Are these flavourings safe?

Does this salami contain Sudan Red, an unauthorised colour?

Plastic, wood, ceramic... risk from substances migrating into food?

What about hormones?

How about residues of veterinary medicinal products?

Do these dairy products contain aflatoxins?

Are these shrimps irradiated?

How much PCBs, dioxins?

CHEMICAL FOOD SAFETY

UNIT E3 - CHEMICALS, CONTAMINANTS AND PESTICIDES
REGULATORY FRAMEWORK

PREMARKETING APPROVAL
Directive 91/414/EEC

USE PHASE
Directive Sustainable use

RESIDUES IN FOOD/FEED
Regulation 396/2005
SUBSTANCE A

Approved at Community level

One decision applying to all the 27 Member States

Directive 91/414/EEC
Plant protection products (formulations) containing the substance A

Authorised at national level
Directive 91/414/EEC

2 Streams

Existing substances

New substances

1993

same evaluation criteria, but slightly different procedures
Directive 91/414/EEC

Approval of active substances

Applicant → Dossier

Member State → Evaluation

EFSA & all MS → Peer review

EFSA → Conclusions

European Commission → Approval/non approval

Risk management

Risk assessment
Directive 91/414/EEC

Evaluation criteria for the approval of substances

- Operator, worker, residents exposure
- Consumer exposure
- Groundwater contamination
- Impact on non target-organisms
  - Birds, mammals, bees, soil micro and macro-organisms, aquatic organisms
Is the substance safe?

- **YES**
  - APPROVAL
  - **INCLUSION in EU positive list (ANNEX I)**
  - 10 years

- **NO**
  - **NON APPROVAL**
  - Uses to expire in the **EU at the latest 18 months after non approval**

**Directive 91/414/EEC**

Human health Environment
What if a substance is not approved?

- Draft measure notified to WTO
- Adoption and publication of Decision (60 days)
- Reply to comments, if any
- NO IMMEDIATE IMPACT on MRLs!

Although the substance is not approved in the EU, existing import tolerances can be kept or new ones can be set provided that they are safe.
What if a substance is not approved?

Non approval Decision → 1 year

EFSA evaluates existing MRLs → 3 months

Commission proposal

- SPS Notification (60 days)
- Consider new data submitted via SPS
- Adoption procedure

But not final decision!

Submission of MRLs underlying data

At least 6 months

Entry into force new MRLs
What if a substance is not approved?

If existing MRLs (import tolerances) are safe and supported by data, they will be kept!
Directive 91/414/EEC

Review programme on Existing active substances

- Launched in 1993
- 983 substances, divided in 4 stages
- Finalised in March 2009
Directive 91/414/EEC

Review programme on existing active substances

- Removed from market (no dossier submitted, incomplete dossier or dossier withdrawn by industry): 67%
- Approved: 26%
- Not approved after review: 7%
Overview of Decisions on new substances 1993-2009

- Total number of new active substances: 144
- Not-approved new substances: 9
- Approved new substances: 82
- Pending new substances: 53
**Pyraclostrobin**

**Status under Directive 91/414/EEC**

- **Status:** Included
- **Directive:** 91/414/EEC
- **Date of inclusion:** 01/06/2004
- **Rapporteur Member State:** DE
- **Remarks:**

**Toxicological information**

<table>
<thead>
<tr>
<th>Substance</th>
<th>ADI:</th>
<th>Source:</th>
<th>ARFD:</th>
<th>Source:</th>
<th>AOEI:</th>
<th>Source:</th>
<th>Other:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyraclostrobin</td>
<td>0.03</td>
<td>04/30/EC</td>
<td>0.03</td>
<td>04/30/EC</td>
<td>0.015</td>
<td>04/30/EC</td>
<td>ARFD 0.05 - ADI 0.03 JMPR 2004</td>
</tr>
</tbody>
</table>

All values are expressed in mg/kg bw day

**EU - Maximum Residue Levels (Reg. (EC) No 396/2005) (MRLs)**

- **Legislation:** Pyraclostrobin
  - Reg. (EC) No 639/2008
  - Reg. (EC) No 149/2008
- **Annexes:** Pyraclostrobin
  - Annex II
  - Annex IIIIB

**Category:** FJ, PG

**No Cipac:**
FUTURE REGULATORY FRAMEWORK

PREMARKETING APPROVAL

Directive Sustainable use

USE PHASE

RESIDUES IN FOOD/FEED

WHEN? WHAT CHANGES?

Regulation ...../2009

Directive 91/414/EEC

Regulation 396/2005
New Regulation on PPPs

- Commission proposal: July 2006
- Publication: expected mid 2009
- Application: expected end 2010
New Regulation on PPPs

Will the new rules apply immediately to all substances?

- New substances
- New rules will apply at renewal of approval

- Approved substances or substances under evaluation
Main changes

New Regulation on PPPs

Directive 91/414/EEC

Regulation ...../2009
New Regulation on PPPs

Dual system maintained

- Active substances approved at EU level
- Products approved at country level

with a change:

zonal system for authorisations of Plant protection products
New Regulation on PPPs

CRITERIA FOR APPROVAL

Exclude from the market substances of high concern (health and environment)

- Carcinogens (cat 1,2)
- Mutagens (cat 1,2)
- Toxic for reproduction (cat 1,2)
- Endocrine disruptors

- POP (persistent organic pollutant)
- PBT (persistent, bioaccumulative and toxic)
- vPvB (very persistent and very bioaccumulative)
DEROGATION TO THE CRITERIA FOR APPROVAL

- Applicable to carcinogens (cat 2), endocrine disruptors, substances toxic for reproduction (cat 2)
- Max 5 years approval; minimise exposure!
- Control of a serious danger to plant health which cannot be contained by other available means
Application of CRITERIA FOR APPROVAL

- Criteria: to be applied to already approved substances only at the time of renewal
- First inclusion normally for 10 years
- Most of renewals will be after 2015
Will MRLs be affected?

- MRLs ruled under Reg. (EC) No 396/2005
- Import tolerances can be set under Reg. (EC) No 396/2005
- Risk assessment carried out by EFSA
- Risk management decision taken by the Commission
New Regulation on PPPs

SUBSTITUTION PRINCIPLE

- Substances of high risk
- Comparative assessment between authorised products
- Substitution by and search for safer alternatives

List of candidates for substitution: by 2013
LOW RISK SUBSTANCES

- Longer approval (15 years)
- Separate list
- Specific criteria for approval may be set in future
BASIC SUBSTANCES

- Not predominantly used as PPP but nevertheless useful in plant protection
- No concerns
- E.g. foodstuff

Approval for unlimited period of time
New Regulation on PPPs

SYNERGYSTS, SAFENERS

- Subject to Community approval
- Data requirements and review programme to be defined by 2014
New Regulation on PPPs

COFORMULANTS

- Negative list
- Detailed rules to be defined by 2014
New Regulation on PPPs

CLEAR DEADLINES

APPROVAL SUBSTANCES

1. Risk assessment:
   - Rapporteur Member State
   - European Food Safety Authority

2. Risk management (Commission)

AUTHORISATION of PPPs

- Member State level

Regional Symposium on Regulation of Pesticide Residues in Food
OTHER MAIN CHANGES

- Obligation to avoid repetitive testing on animals
- Report on costs/benefits of better traceability (pesticide passport)
- Information to residents:
  - before spraying
  - access to records
CONCLUSIONS

- Protection human and animal health and environment
- Dual system, with improved harmonisation
- Clear deadlines
Thank you for your attention!