



Bayer CropScience



BCS Development – Global Regulatory Affairs

The new EU registration procedures for Crop Protection – an Update

Birgit Krauskopf – Albert Schirring

Agenda

- EU registration process: historic view
- Revision of Directive 91/414 EEC
- Other relevant EU legislation
- Sustainable use directive (SUD)

Directive 91/414 EEC – *Background/History*

Directive 91/414 EEC from July 15, 1991

- Regulates the authorizations of plant protection products (PPPs) in the EU.
- Active Ingredients are approved at EU level (Annex I). Evaluation by Rapporteur Member States (RMS), followed by assessment through EFSA (European Food Safety Authority) and peer review by all member states.
- Principle of evaluation: Risk Assessment.
- Authorizations of Products (Formulations) at country level.
- Prerequisite is inclusion of active ingredient in Annex I (exception: preliminary national approvals).
- “Old” active ingredients (i.e. on the market before 1993) to be re-evaluated on the basis of 91/414 within 12 years (process still not finished).

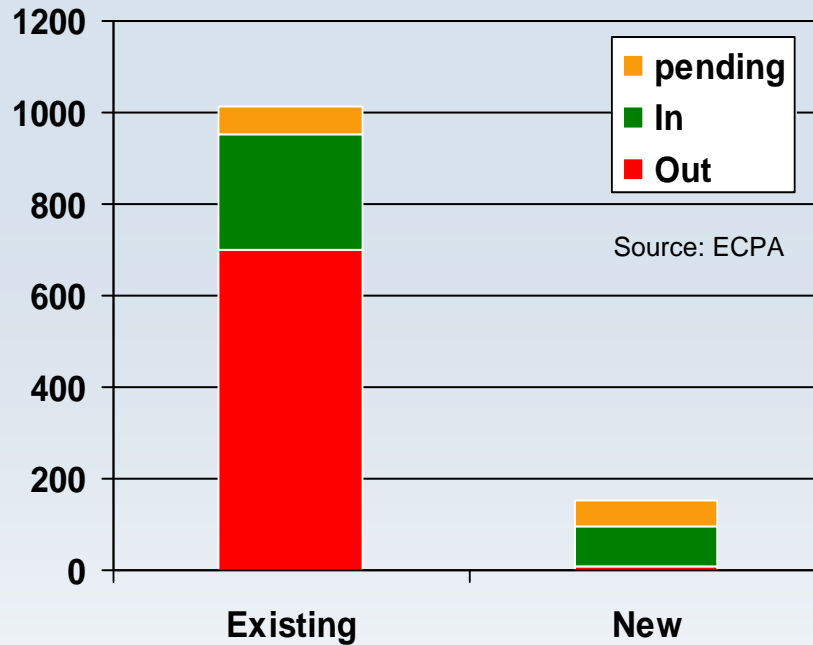


1993 / 2010 A LABORIOUS RE-REGISTRATION PROCESS ...

700 Active Substances in total
75 % of Insecticides
58 % of Herbicides
53 % of Fungicides
were lost during review process

≥ 1000 Active Substances still available for farmers outside Europe !

Review of active substances (in No.)



Existing: Compounds already on the market in 1993 and subject to review program
New: Compounds submitted since 1993

... leading to less solutions for farmers & loss of competitiveness

EU registration policy < 2009



EU Registration policy:
evaluation benefits vs risks

- registration based on risk assessment
- evaluation of all risks
- risks have to be acceptable

Hamar Euroblight Workshop – Commission Feedback

To: Mrs. Dr. Vassilliou

European Commissioner for Health
Berlaymont
Rue de la Loi 200
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About 100 European potato blight experts (= Euroblight working group) from 17 EU countries gathered on the 28 – 30 of October 2008 in Hamar in Norway to discuss new strategies for early (Alternaria) and late blight (Phytophthora) control.

At this meeting the revision of 91.414 has been discussed. This revision could lead to a serious loss of a great number of active ingredients putting in danger sustainable control strategies of early and late blight. The proposals would lead to significant yield losses, loss of quality and hinders effective Integrated Control Strategies eg active resistance management as discussed at the ENDURE conference in La Grande Motte at South France and communicated by the Fungicide Resistance Action Committee (FRAC).

The increased aggressiveness of Phytophthora infestans was discussed intensively at the workshop. New strains of the Phytophthora disease have spread over the EU. The workshop also concluded that Alternaria is an increasing problem. Effective fungicides covering different modes of action are required to control these important potato pathogens. The EU blight experts conclude that sustainable control strategies must include fungicides with different modes of action.

Impact analyses which are already available in The Netherlands, Great Britain, Germany, Sweden, indicate that the current COMMON POSITION taken by the council and the Ministries of Agriculture in which crucial fungicides will be lost, will lead to unacceptable impacts on yield, quality, food safety and rural economies.

We request the EU COMMISSION fully investigates the impact of the revision of directive EU EC 91/414 for European potato industry before any decision will be taken.

The management team on behalf of the Euroblight group


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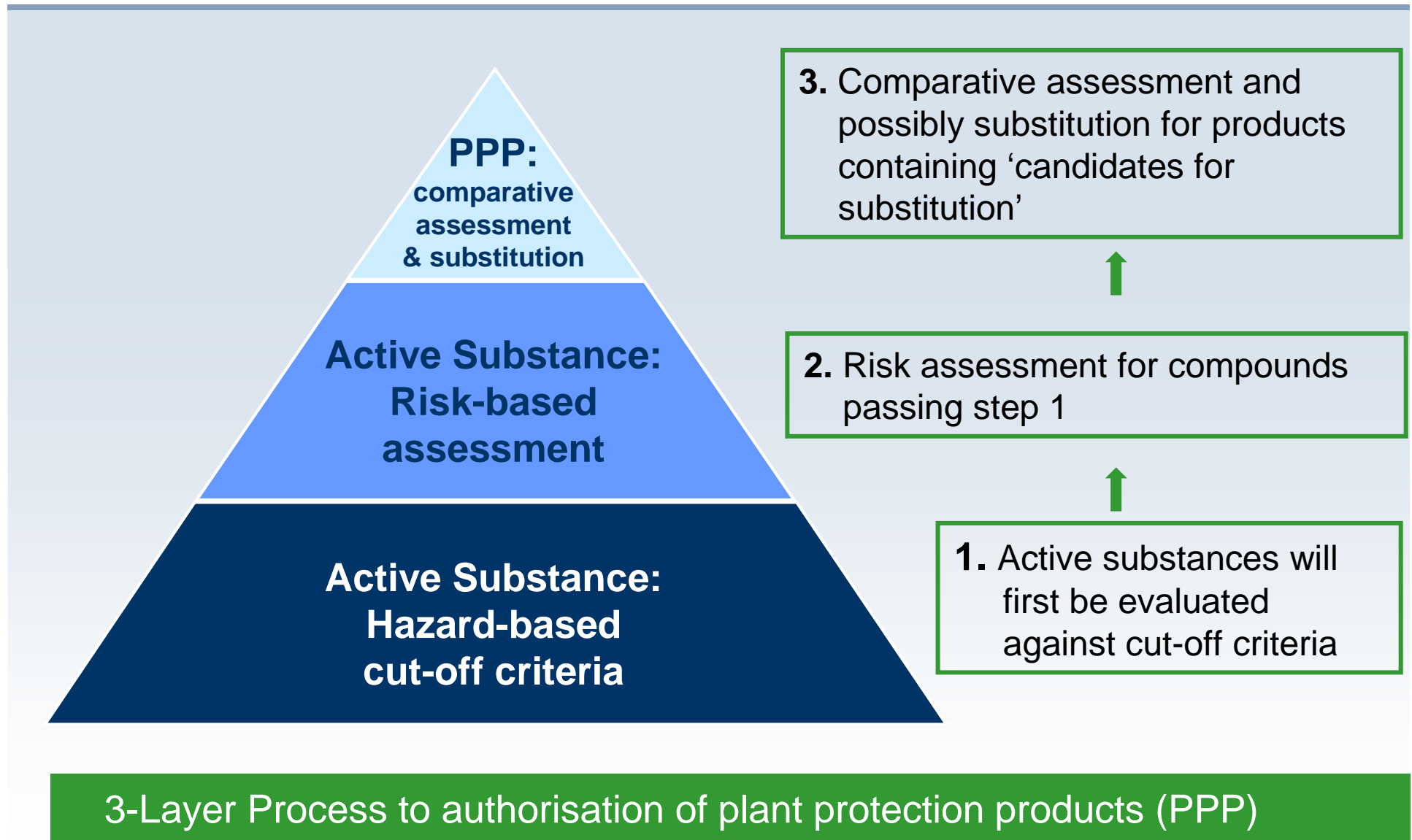

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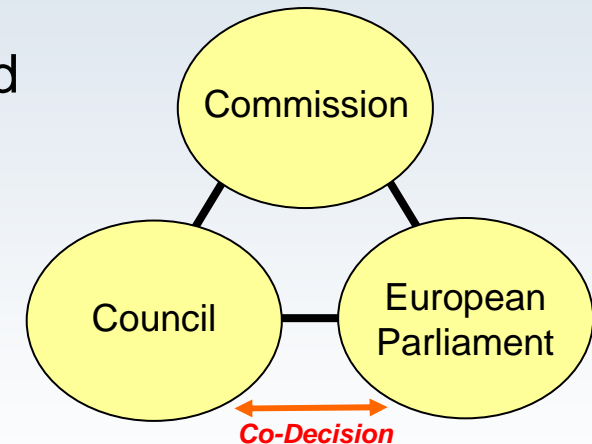
EU Future Framework



Revision of Directive 91/414

Results of 2nd reading by European Parliament, January 13, 2009

- Evaluation of data according to guidance documents in place at time of submission (not “latest science”).
- Data protection: 10 years for first registration (at country level), 2,5 years for data needed for renewals, 3 additional months (max. 36) for each minor use.
- Introduction of Cut-offs.
- Introduction of Comparative Assessments and Substitution.
- Limitations for provisional national approvals.
- Zonal authorizations and mutual recognition.



Cut-off criteria




- **Human Health**
 - CMR classification (carcinogenicity, mutagenicity, reproductive toxicity, categories 1 and 2)
 - Endocrine Disruption effects
- **Environmental Safety and Persistence**
 - POP, PBT, vPvB
- **Ecotoxicology**
 - Endocrine Disruption effects on non-target organisms



Cut-off Criteria - *CMR, ED*

	Category 1 Evidence of effects in humans	Category 2 sufficient evidence based on animal testing	Category 3 evidence based on animal testing not sufficient for Cat 2
Cancerogenicity	C1*	C2	C3
Mutagenicity	M1	M2	M3
Reprotox	R1*	R2	R3

Endocrine Disruption (Tox and Ecotox)	
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-  Banned, (*unless exposure is negligible)
-  Banned, unless exposure is negligible or phytosanitary need („serious danger to plant health“) can be demonstrated, approval for 5 years, renewable
-  Performance of risk assessment

Cut-off criteria – *Endocrine Disruption* (1)

- **Definition of EU Commission:**

- *Endocrine disruptors are exogenous substances that alter functions of the endocrine system and consequently cause adverse health effects in an intact organism, or its progeny, or (sub)populations.*

- Test guidelines, endpoints, guidelines for risk assessment and risk management are not in place.
- Room for interpretation and uncertainties.

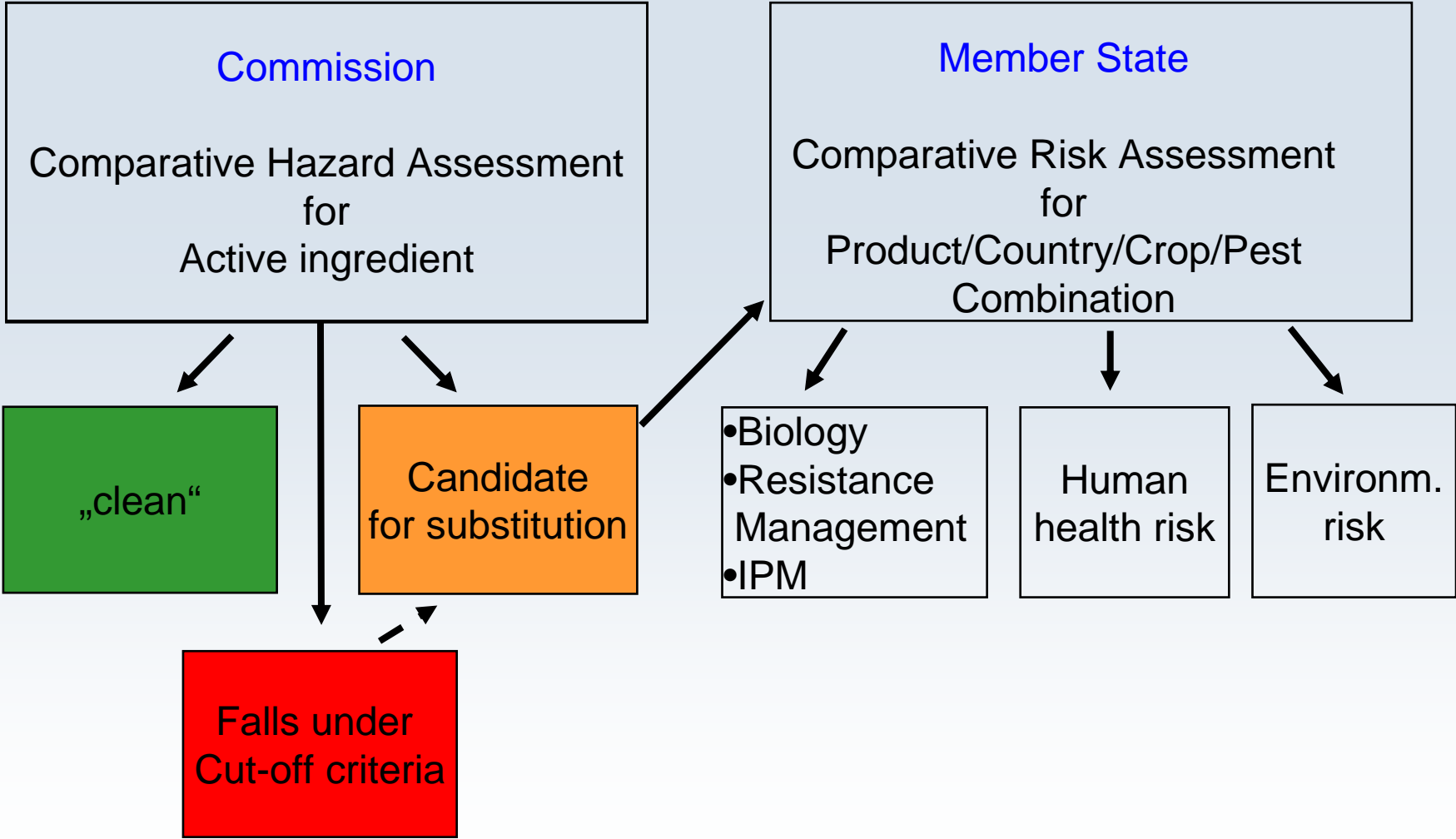


Candidates for Substitution (CfS)

- Candidates for substitution are defined at EU-level.
- Criteria:
 - ADI, ArfD or AOEL are significantly lower than for the majority of the approved substances
 - Two of the PBT Criteria are met
 - Critical effects (e.g. Developmental-Neurotox, Immunotox) which could still cause concern even with very restrictive risk management measures
 - Substances classified as C1, C2 or R1 bzw. R2 (if not banned)
 - Possible endocrine effects on humans (if not banned)
- Approval for 7 years only, can be renewed.
- Candidates for substitution are subject to comparative assessments (Product / Country / Pest / Crop).

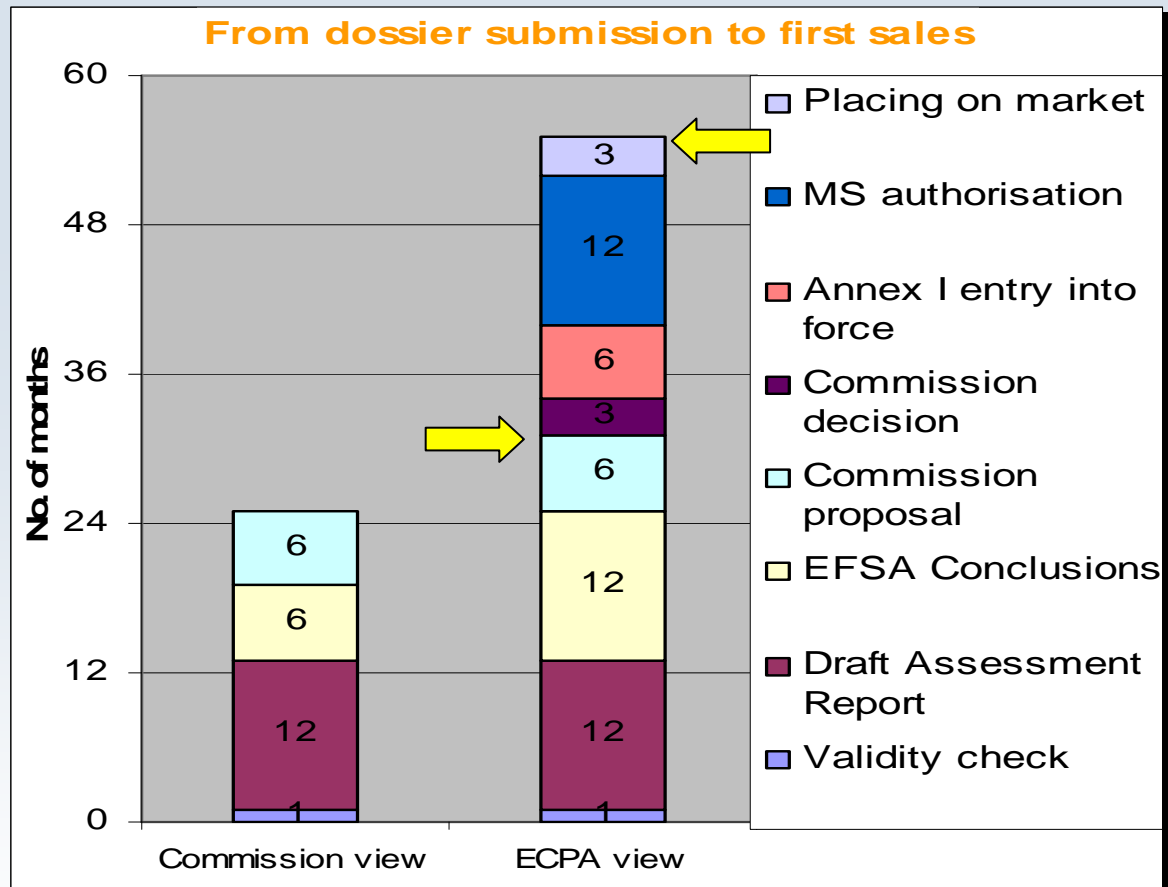


Comparative Assessments (CA)



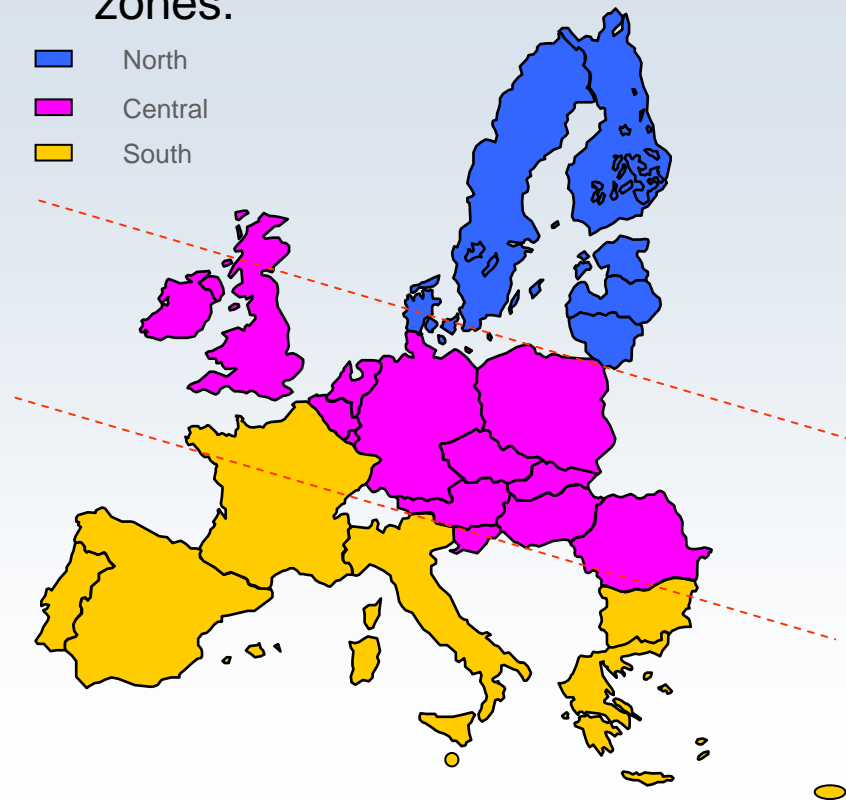
National Provisional Authorizations

- **COM believes that Annex I inclusion is possible in 25 months.**
- **ECPA believes that the process will take longer:**
 - Over 30 months is needed for Annex I inclusion proposal
 - Two more years are required before first sales
 - A problem free evaluation will take at least **55 months**, but delays are likely...



Zonal Authorizations

- Authorizations granted by one Member State should be accepted by other MS (when ecological and climatic conditions are comparable), but MS can reject.
- Mutual recognition possible between zones (as long as this mutual recognition is not used for further approvals within that zone).
- Mutual recognition for greenhouse and post-harvest treatments, irrespective of zones.



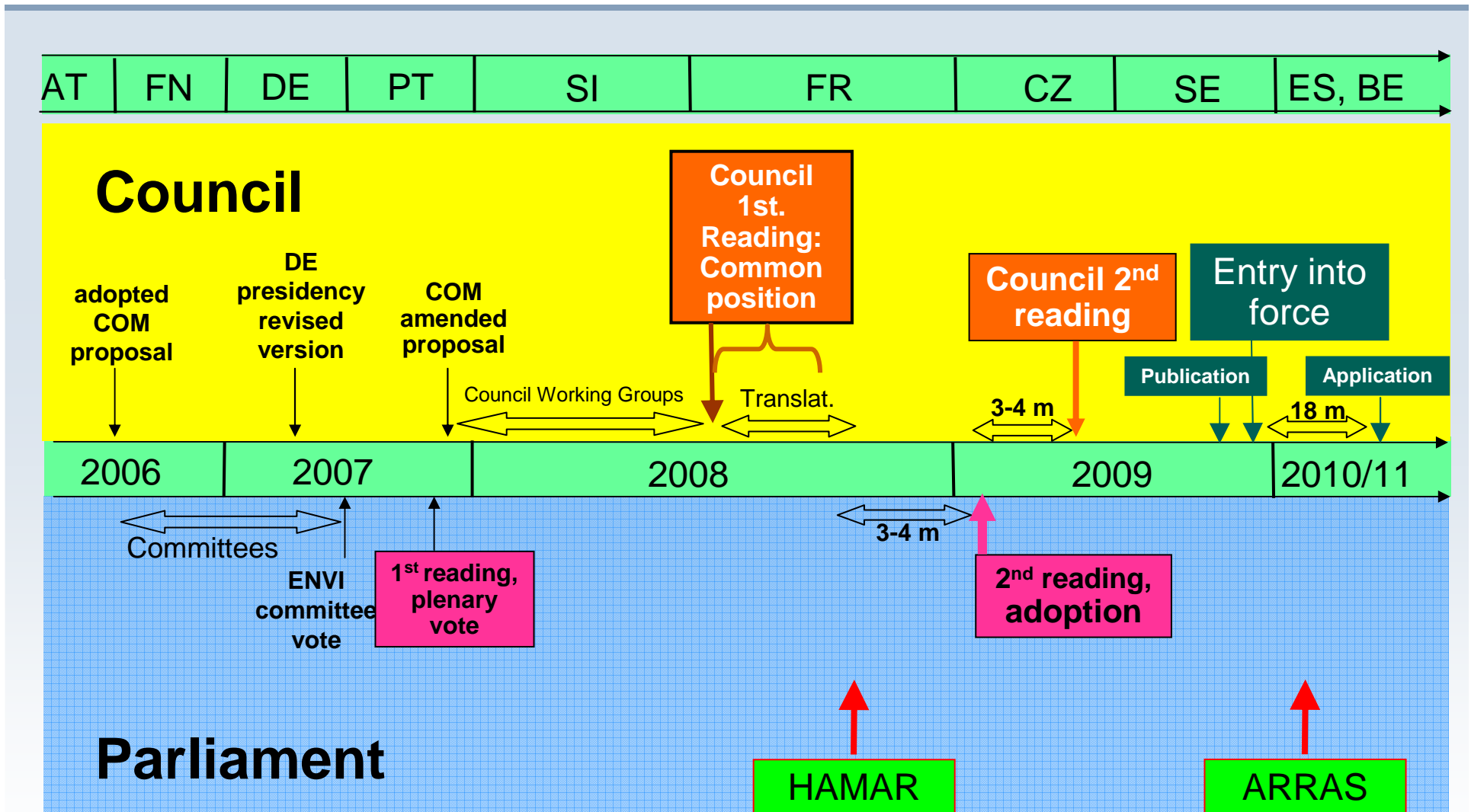
Germany	29	Austria	10
France	29	Bulgaria	10
United Kingdom	29	Finland	7
Italy	29	Denmark	7
Spain	27	Slovakia	7
Poland	27	Ireland	7
Romania	14	Lithuania	7
The Netherlands	13	Luxembourg	4
Greece	12	Estonia	4
Czech Republic	12	Latvia	4
Belgium	12	Slovenia	4
Hungary	12	Cyprus	4
Portugal	12	Malta	3
Sweden	10		

Safeners and additives (already on the market)

- Within **5 years** of the entry into force of the Regulation, a program of work shall be adopted and established for the gradual review of synergists and safeners on the market when the Regulation enters into force.
- Shall include the establishment of data requirements, notification, evaluation, assessment and decision-making procedures.
- It shall require interested parties to submit all the necessary data to the Commission, the Authority and the Member States within a specified time period.
- In the interim period safeners and synergists are regulated under REACH.



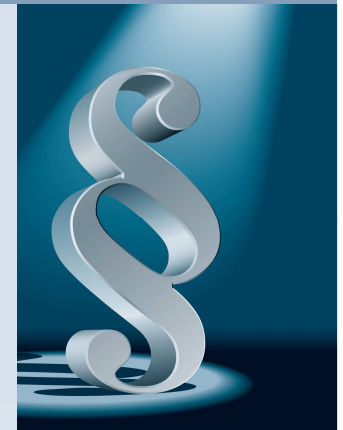
Timelines for replacing Directive 91/414/EEC



Other relevant EU legislation

- **REACH**

- Chemicals > 1000t/year have to be registered in first tranche.
- New Authority (European Chemicals Agency, ECHA) established and involved in evaluation as well as classification and labeling process of active ingredients.



Other relevant EU legislation

- **Sustainable Use Directive (SUD)**

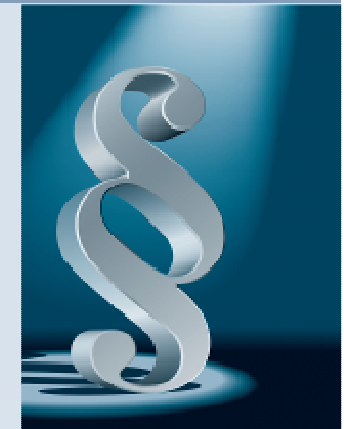
- Regulates **how** Crop Protection Products are used
- Call for ‚National Action Plans‘ to reduce risks of Plant Protection Products (e.g. ‚Grenelle‘ in France)
- Priority is given to non-chemical crop protection measures
- Development of IPM principles at EU level and implementation by all professional users by 2014

- **Maximum Residue Level (MRL) Regulation**

- New process of harmonisation at EU-level
- Pre-requisite for national product approvals
- First experiences: process slow, risk of longer time-to-market

- **Water Framework Directive**

- Publication of more monitoring data



Several new legislations, but lack of definitions, guidance and experience

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SUD - National Implementation – Industry view



Achieving the Sustainable Use of Pesticides / NAPs

- **Focus needs to be on further risk & impact reduction during the use phase of plant protection products**
 - **Main goal of the Framework Directive**
 - **Registration of products covers risk assessment and products are considered safe for use**
 - **Loss of many PPP solutions due to review process and expected due to new 91/414**

- **Diversity in cropping systems requires a diversity of plant protection product solutions**
- **Agriculture has to respond to many external factors (climatic, pest pressures, markets)**
- **Resistance management**
- **Implementation of IPM principles by ALL professional users**

SU - National Implementation – Industry view

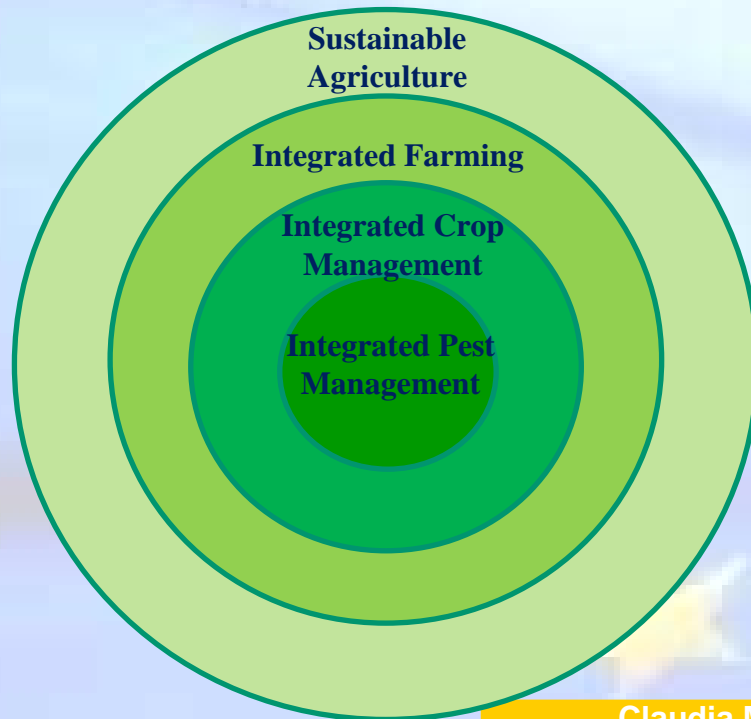
Achieving the Sustainable Use of Pesticides / NAPs

- **NAPs / Measures to be focused on improving practices**
 - **Progress can be measured by indicators: such as uptake of IPM, sprayers passing the inspection, uptake of PPE, use of modern technologies (e.g. spray drift reduction nozzles)**
- **NAPs / Measures envisaged need to consider the economic, social & ecological aspects**
 - **This a part of sustainability**
 - **Economic and social indicators to be included in the NAPs**
- **The way forward is responsible use & impact reduction!**
 - **No direct link between the amount used and the risk involved**
 - **Allow agriculture producing high quality food for all consumers**
- ➔ **Training on responsible practices is one of the key tools**
 - **Industry open to contribute and provide its expertise**

SU - National Implementation – Industry view

Achieving the Sustainable Use of Pesticides / NAPs (cont.)

- Appropriate implementation of IPM offers opportunities to fulfil the goals of the SUD
- IPM a holistic concept, part on Integrated Crop Management & Integrated Farming as the path for sustainable agriculture
- IPM implementation needs a variety of plant protection tools





Thank you for your kind attention