

EU legislation on the use and control of pesticides

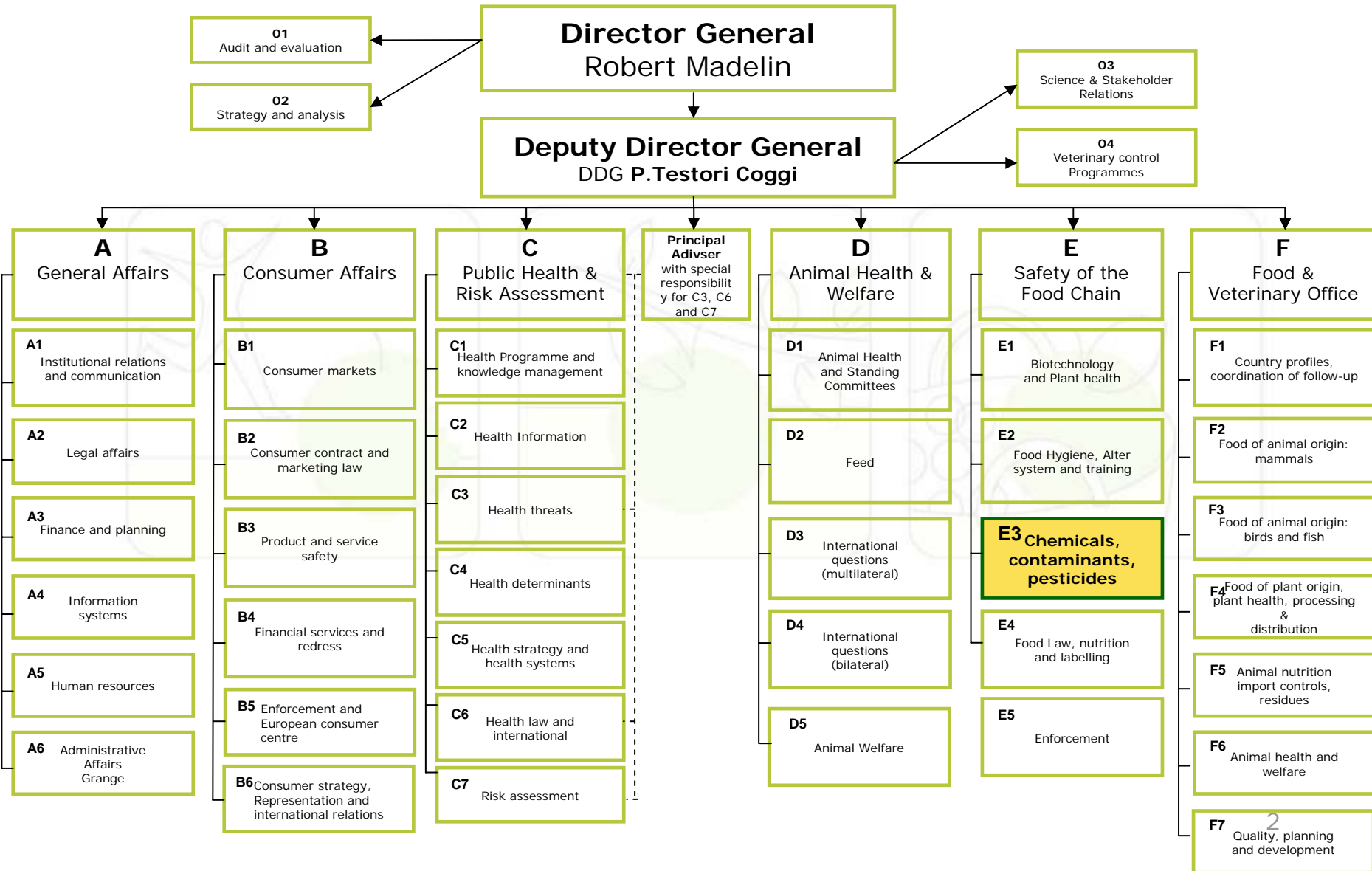


**Francesca Arena
European Commission
Health and Consumers Directorate General**

**Joint Regional Symposium on Regulation of Pesticide
Residues in Food
Hong Kong
27-28 March 2009**



DG SANCO: Our structure



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?

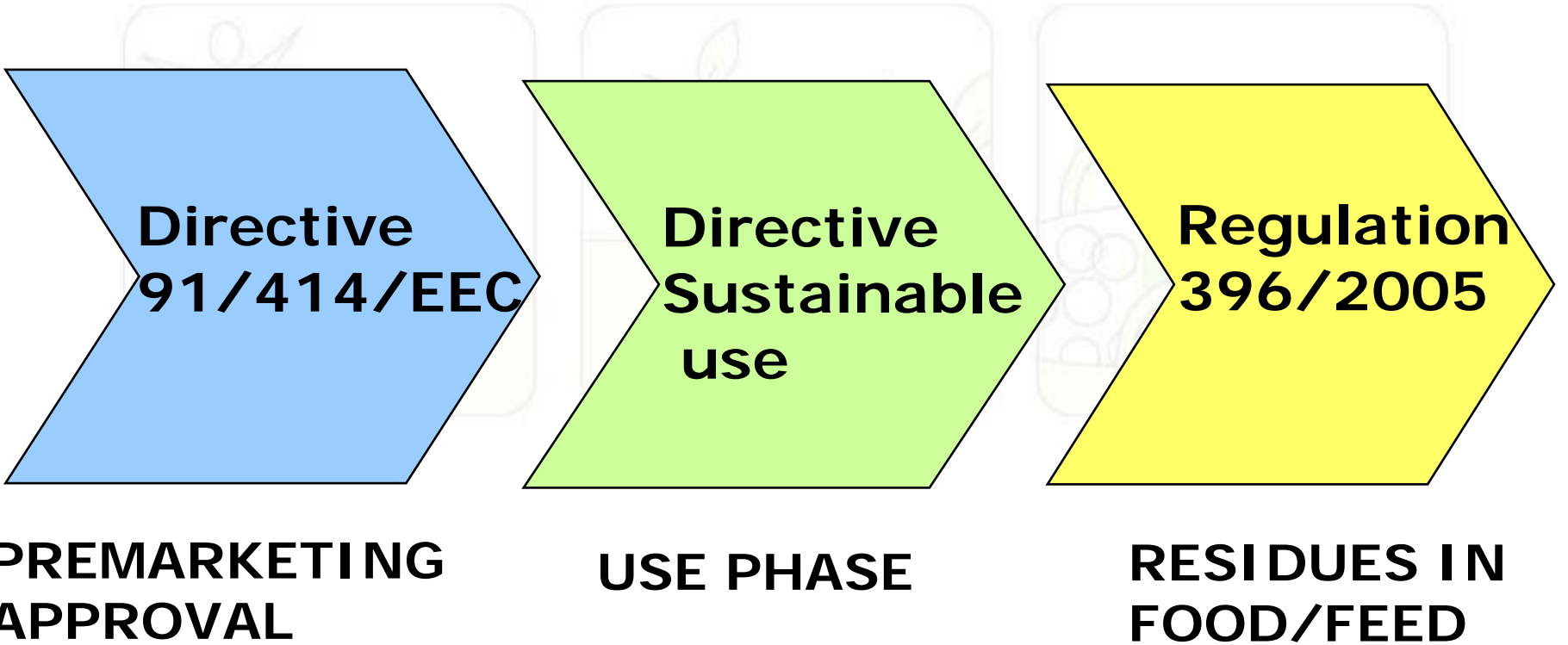
How much PCBs, dioxins?

Are these shrimps irradiated?

CHEMICAL FOOD SAFETY

UNIT E3 - CHEMICALS, CONTAMINANTS AND PESTICIDES

REGULATORY FRAMEWORK



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graph LR; A[Directive 91/414/EEC] --> B[Directive Sustainable use]; B --> C[Regulation 396/2005];
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**Directive
91/414/EEC**

**PREMARKETING
APPROVAL**

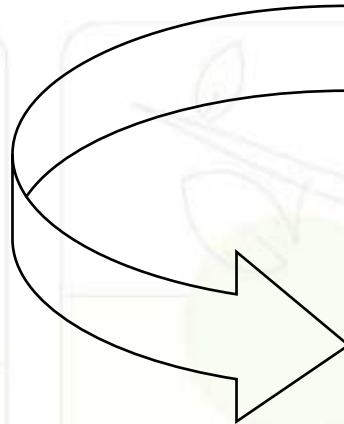
**Directive
Sustainable
use**

USE PHASE

**Regulation
396/2005**

**RESIDUES IN
FOOD/FEED**

SUBSTANCE A



**Approved at
Community level**



**One decision applying to all the 27
Member States**

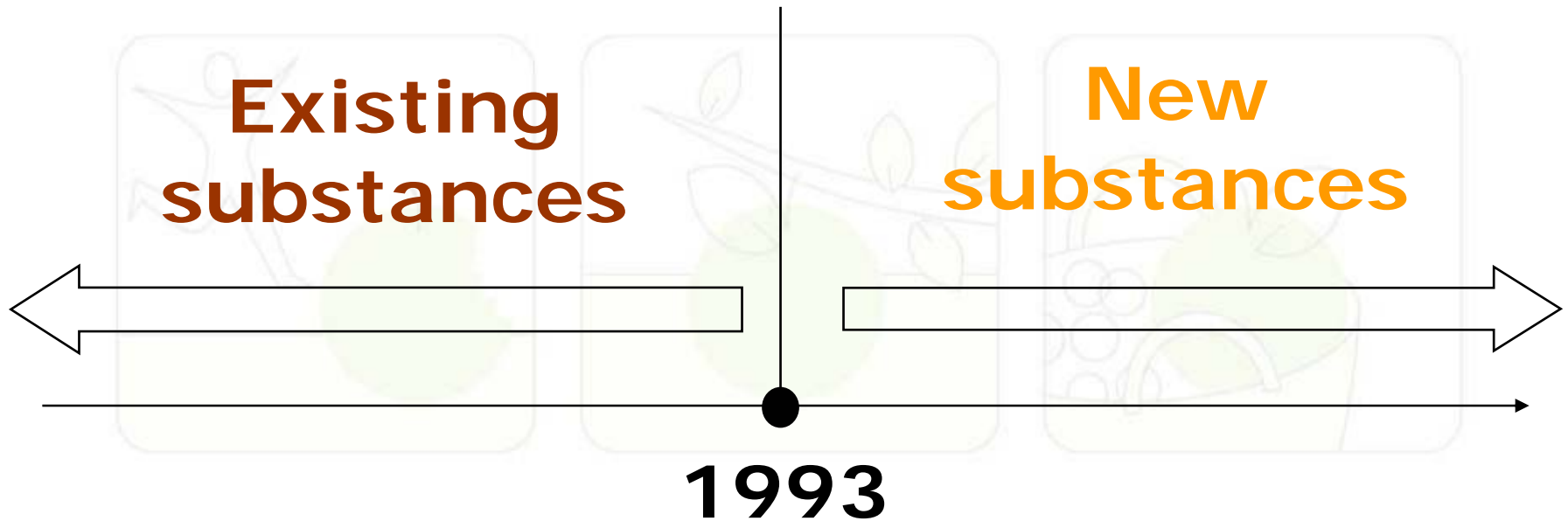


**Plant protection
products
(formulations)
containing the
substance A**

**Authorised at
national level**



2 Streams



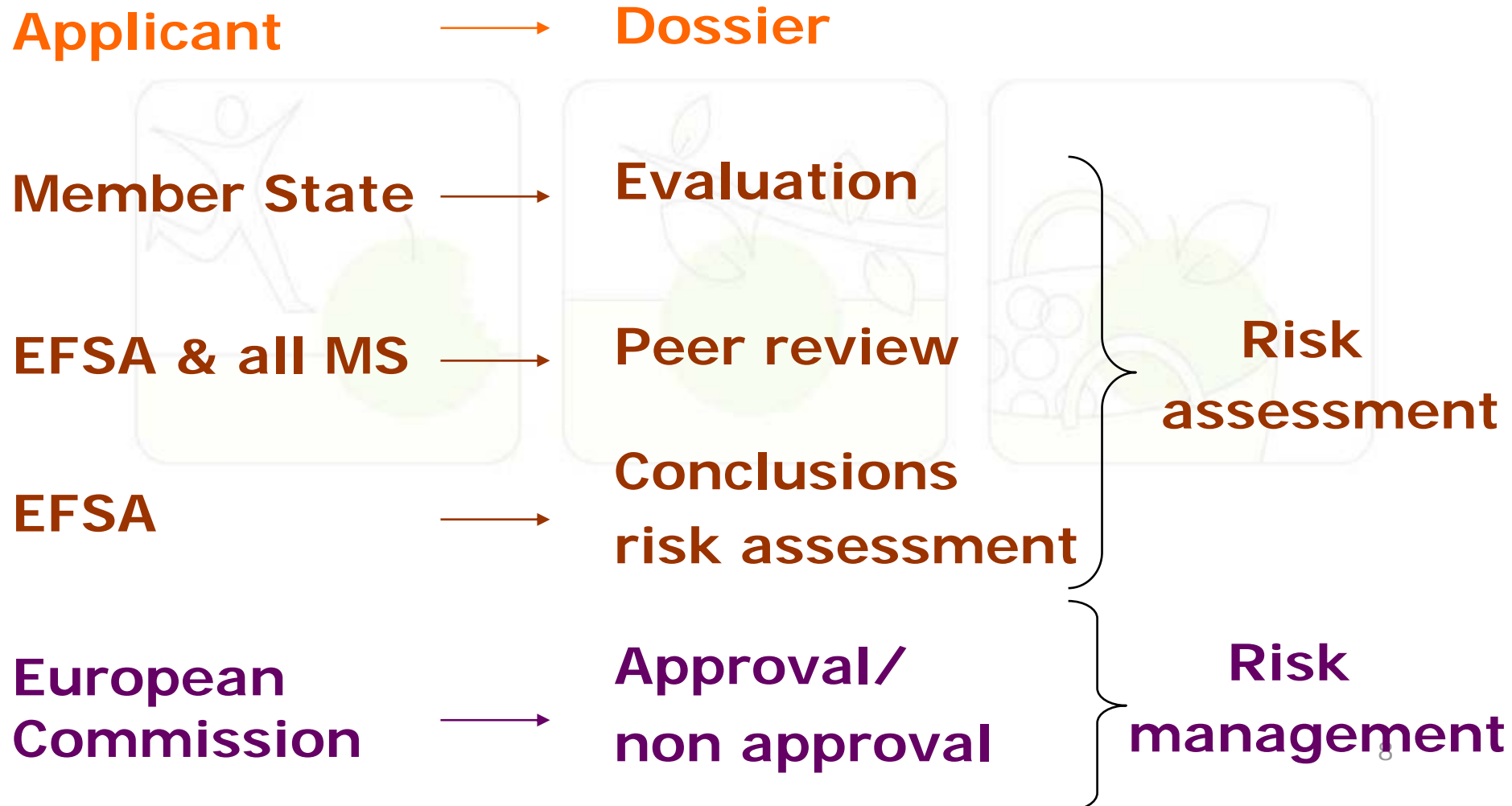
same evaluation criteria, but slightly
different procedures



Directorate-General for
Health & Consumers

Directive 91/414/EEC

Approval of active substances



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?

} Human health
Environment

YES

APPROVAL

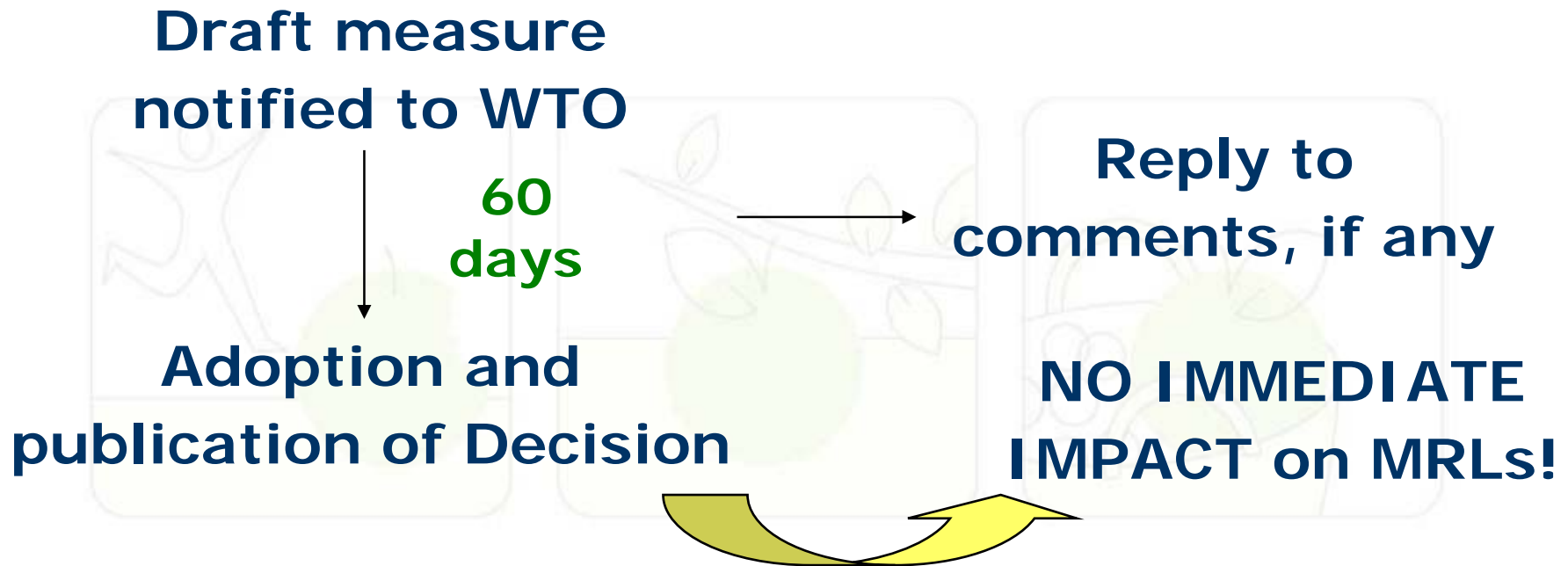
INCLUSION in EU
positive list (ANNEX I)
10 years

NO

NON APPROVAL

Uses to expire in the
EU at the latest 18
months after non
approval

What if a substance is not approved?

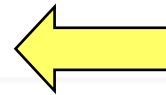


Although the substance is not approved in the EU, existing import tolerances can be kept or new ones can be set provided that they are safe

What if a substance is not approved?

Non approval Decision

1 year



**Submission of
MRLs underlying
data**

EFSA evaluates existing MRLs

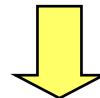
3 months

Commission proposal

But not final decision!

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

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!

Review programme on Existing active substances

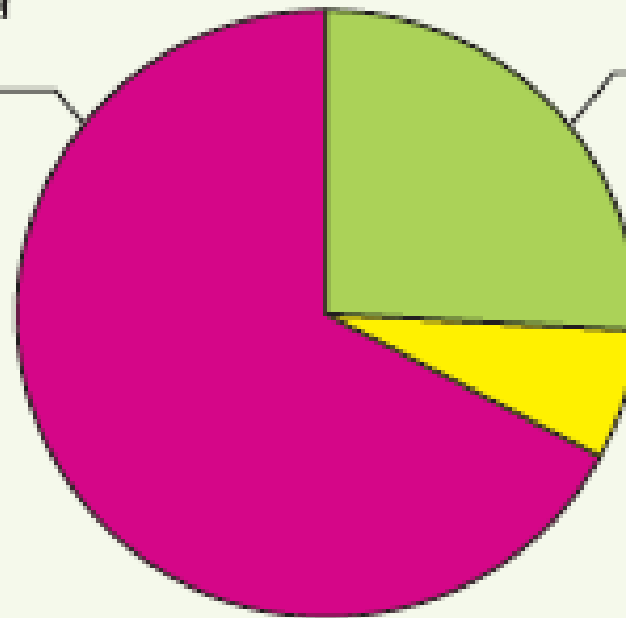
- Launched in 1993
- 983 substances, divided in 4 stages
- Finalised in March 2009



Review programme on existing active substances

Removed from market
(no dossier submitted,
incomplete dossier or dossier
withdrawn by industry)

67%



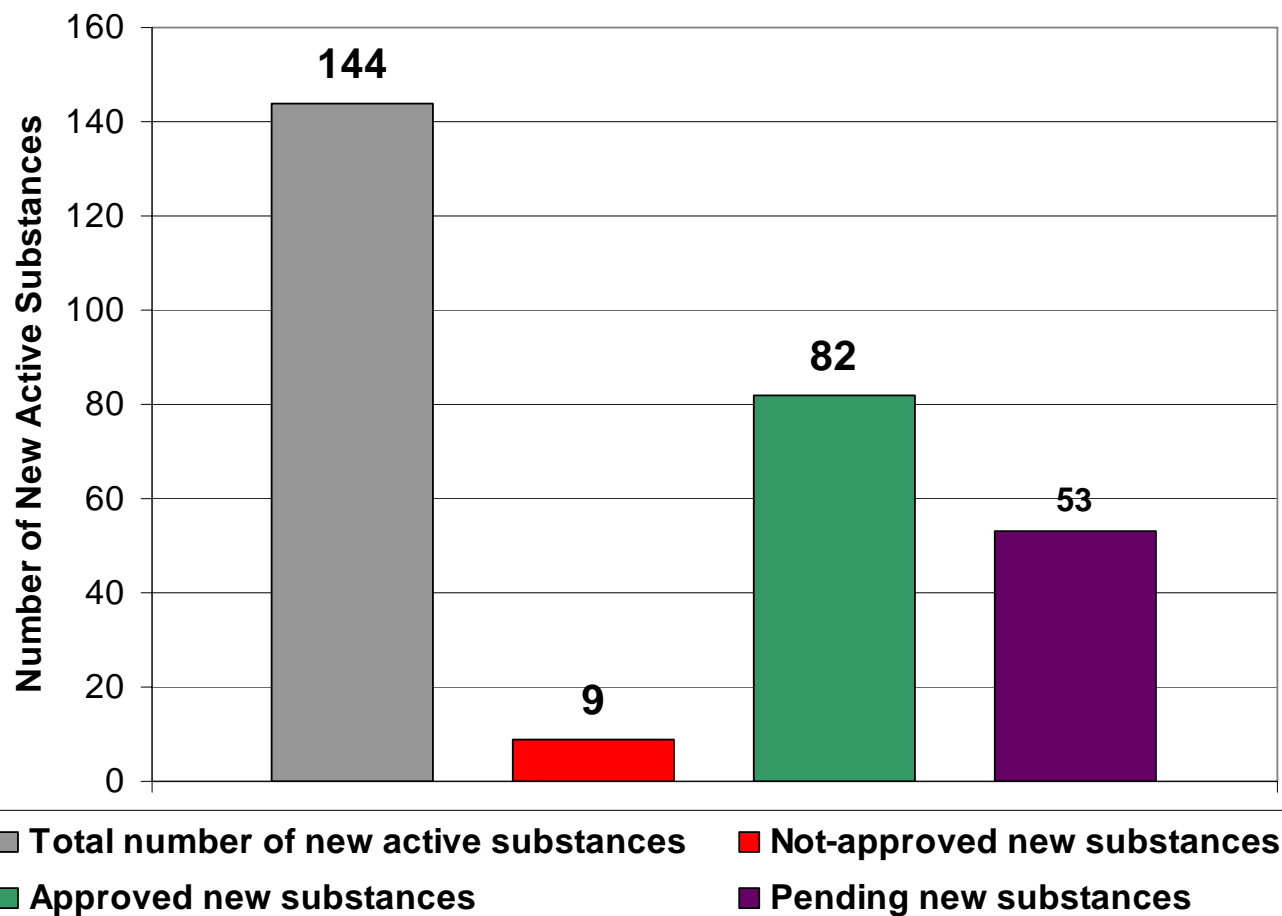
Approved

26%

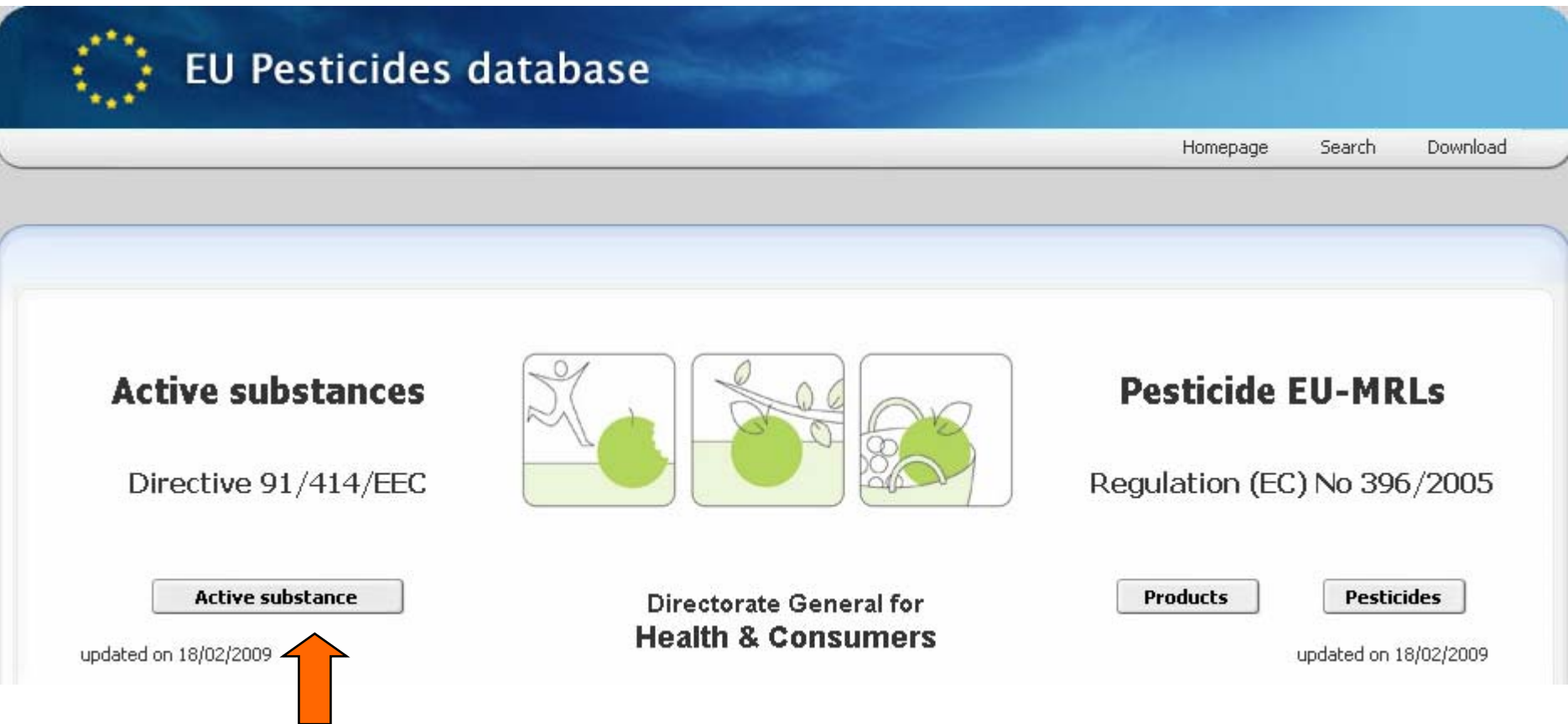
Not approved
after review

7%

Overview of Decisions on new substances 1993-2009



DATABASE on Active substances



The screenshot shows the homepage of the EU Pesticides database. At the top, there is a blue header with the European Union flag on the left and the text "EU Pesticides database" in the center. To the right of the header are three links: "Homepage", "Search", and "Download". Below the header, the page is divided into three main sections. The left section is titled "Active substances" and mentions "Directive 91/414/EEC". Below this, there is a button labeled "Active substance" and the text "updated on 18/02/2009". An orange arrow points from this text to the "Active substance" button. The middle section features three icons: a person running from a green apple, a green apple on a branch, and a green apple in a basket. Below these icons is the text "Directorate General for Health & Consumers". The right section is titled "Pesticide EU-MRLs" and mentions "Regulation (EC) No 396/2005". Below this, there are two buttons: "Products" and "Pesticides", with the text "updated on 18/02/2009" to the right.

Active substances
Directive 91/414/EEC

Pesticide EU-MRLs
Regulation (EC) No 396/2005

Active substance
updated on 18/02/2009

Products
Pesticides
updated on 18/02/2009

Directorate General for
Health & Consumers

DATABASE on Active substances



EU Pesticides database

[Homepage](#)[Search](#)[Download](#)

Active substances

Select your criteria

Category

Status

from

till

ADI

ARfD

AOEL

Inclusion date

Expiration date

Search

Reset

Find substance

Show details

Export list

alphabetically

1206 entries found

(2E, 13Z)-Octadecadien-1-yl acetate
(4E-7Z)-4,7-Tridecadien-1-yl-acetate
(4Z-9Z)-7,9-Dodecadien-1-ol
(7E, 9E)-Dodecadien 1-yl acetate
(7E, 9Z)-Dodecadien 1-yl acetate
(7Z, 11E)-Hexadecadien-1-yl acetate
(7Z, 11Z)-Hexadecadien-1-yl acetate
(8E, 10E) - 8, 10 - Dodecadiene 1-yl acetate
(9Z, 12E)-Tetradecadien-1-yl acetate
(E)-10-Dodecenyl acetate
(E)-11-Tetradecen-1-yl acetate
(E)-2-Methyl-6-methylene-2,7-octadien-1-ol(myrcenol)
(E)-2-Methyl-6-methylene-3,7-octadien-2-ol(isomyrcenol)
(E)-5-Decen-1-ol
(E)-5-Decen-1-yl-acetate
(E)-8-Dodecen-1-yl acetate
(E,E)-8,10-Dodecadien-1-ol
(E,Z)-8,10-Tetradecadienyl
(E/Z)-8-Dodecen-1-yl acetate
(E/Z)-9-Dodecenyl acetate (E/Z)-9-Dodecen-1-ol (Z)-11-Tetradecadien-1-yl acetate
(IR)-1,3,3-Trimethyl-4,6-dioxatricyclo[3.3.1.0^{2,7}]nonane (linestatin)
(Z)-11-Hexadecen-1-ol
(Z)-11-Hexadecen-1-yl acetate

DATABASE on Active substances

Pyraclostrobin

Category: FU, PG

N° Cipac:

Status under Directive 91/414/EEC

Status: **Included**

Directive: 04/30/EC

Date of inclusion: 01/06/2004

Rapporteur Member State: DE

Remarks:

[Back](#)

Review Report 

Expiration of inclusion: 31/05/2014

Toxicological information

Substance:	ADI:	Source:	ARfD:	Source:	AOEL:	Source:	Other:
Pyraclostrobin	0.03	04/30/EC	0.03	04/30/EC	0.015	04/30/EC	ARfD 0,05 - ADI 0,03 JMPR 2004

All values are expressed in mg/kg bw day

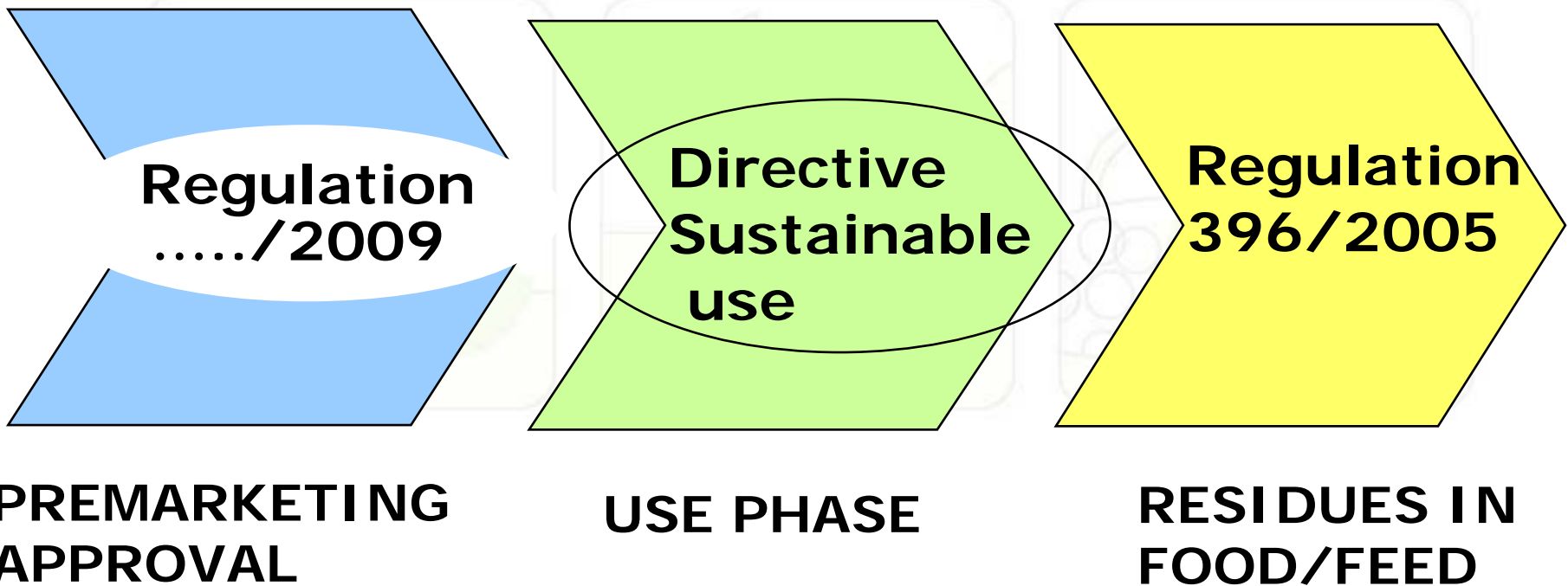
EU - Maximum Residue Levels (Reg. (EC) No 396/2005) (MRLs)

Legislation: **Pyraclostrobin**
Reg. (EC) No 839/2008
Reg. (EC) N°149/2008

Annexes: **Pyraclostrobin**
Annex II
Annex IIIB

[MRLs](#)

FUTURE REGULATORY FRAMEWORK



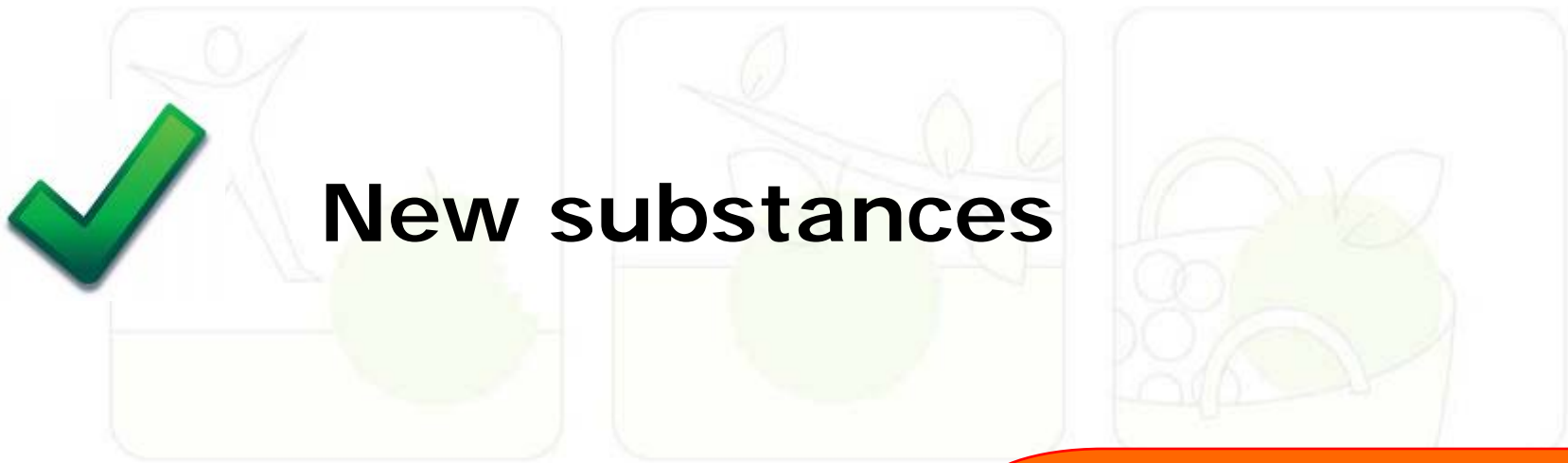
WHEN? WHAT CHANGES?

New Regulation on PPPs

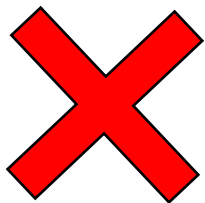
- Commission proposal: **July 2006**
- Co-decision procedure (European Parliament and Council): finalised January 2009
- **Publication:** expected **mid 2009**
- **Application:** expected **end 2010**



Will the new rules apply immediately to all substances?



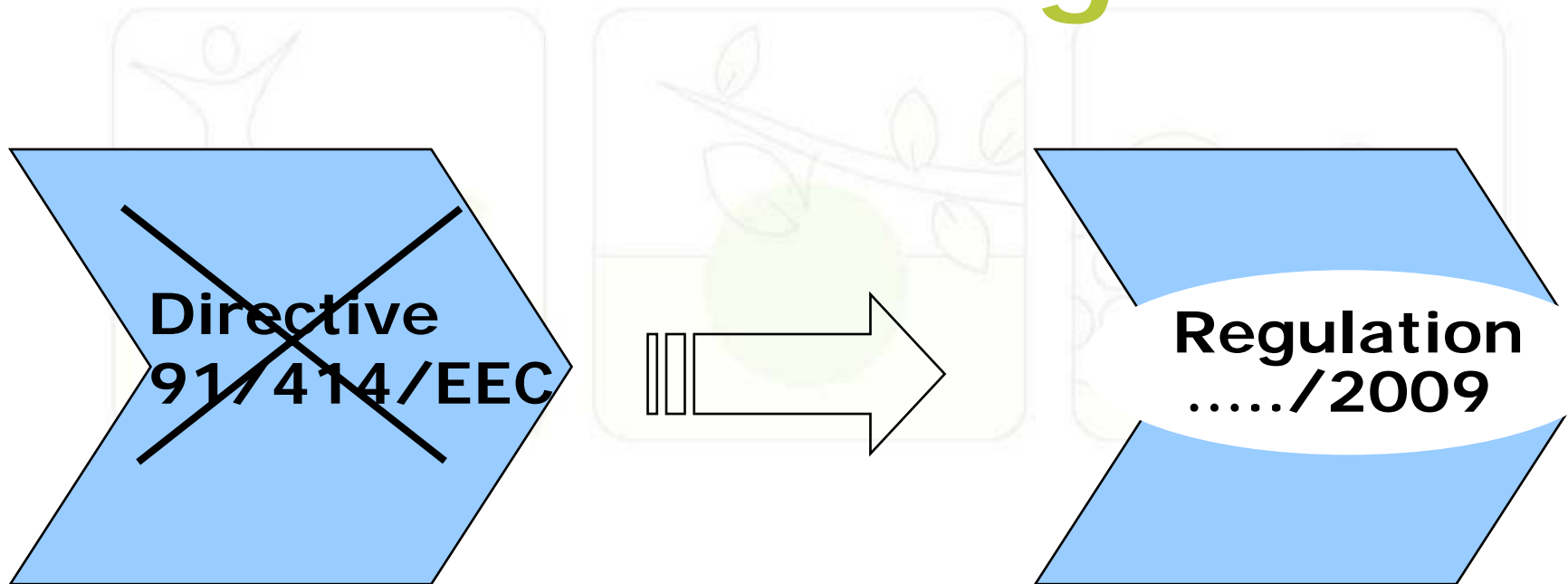
New substances



**Approved
substances or
substances
under evaluation**

**New rules will
apply at renewal
of approval**

Main changes






Dual system maintained

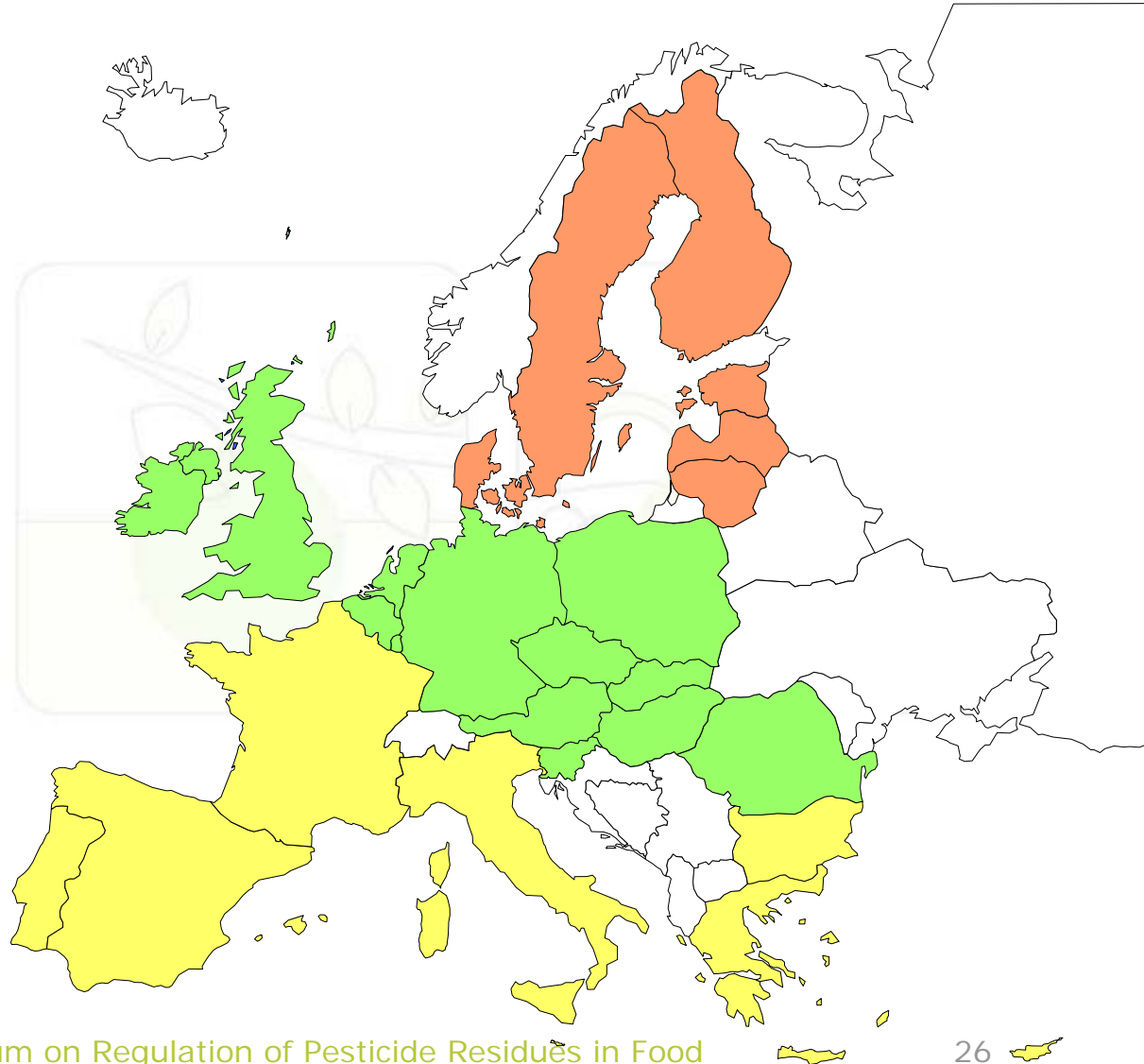
- Active substances approved at EU level
- Products approved at country level

with a change:

zonal system for authorisations of Plant protection products

Zonal system

-  North
-  Center
-  South



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

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

SYNERGYSTS, SAFENERS

- Subject to Community approval
- Data requirements and review programme to be defined by 2014

COFORMULANTS

- Negative list
- Detailed rules to be defined by 2014

CLEAR DEADLINES

APPROVAL SUBSTANCES

1. Risk assessment:

- Rapporteur Member State
- European Food Safety Authority

26-38
months

2. Risk management (Commission)

AUTHORISATION of PPPs

- Member State level

12-18
months

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!

ENVIRONMENT-FRIENDLY PESTICIDE