

Implementation of Reg. (EC) No 396/2005 On Maximum Residues Levels of pesticides



European Commission
Health and Consumer Protection Directorate General
Unit E3 - Chemicals, Contaminants and Pesticides

September 2008

Pesticide Residues MRLs setting

Until 1 September 2008 legislation partially harmonised

EU- MRLs
± 250 pesticides

Dir. 76/895/EEC (selected fruits and vegetables)
Dir. 86/362/EEC (cereals)
Dir. 86/363/EEC (animal products)
Dir. 90/642/EEC (fruits and vegetables)

National MRLs
± 850 pesticides

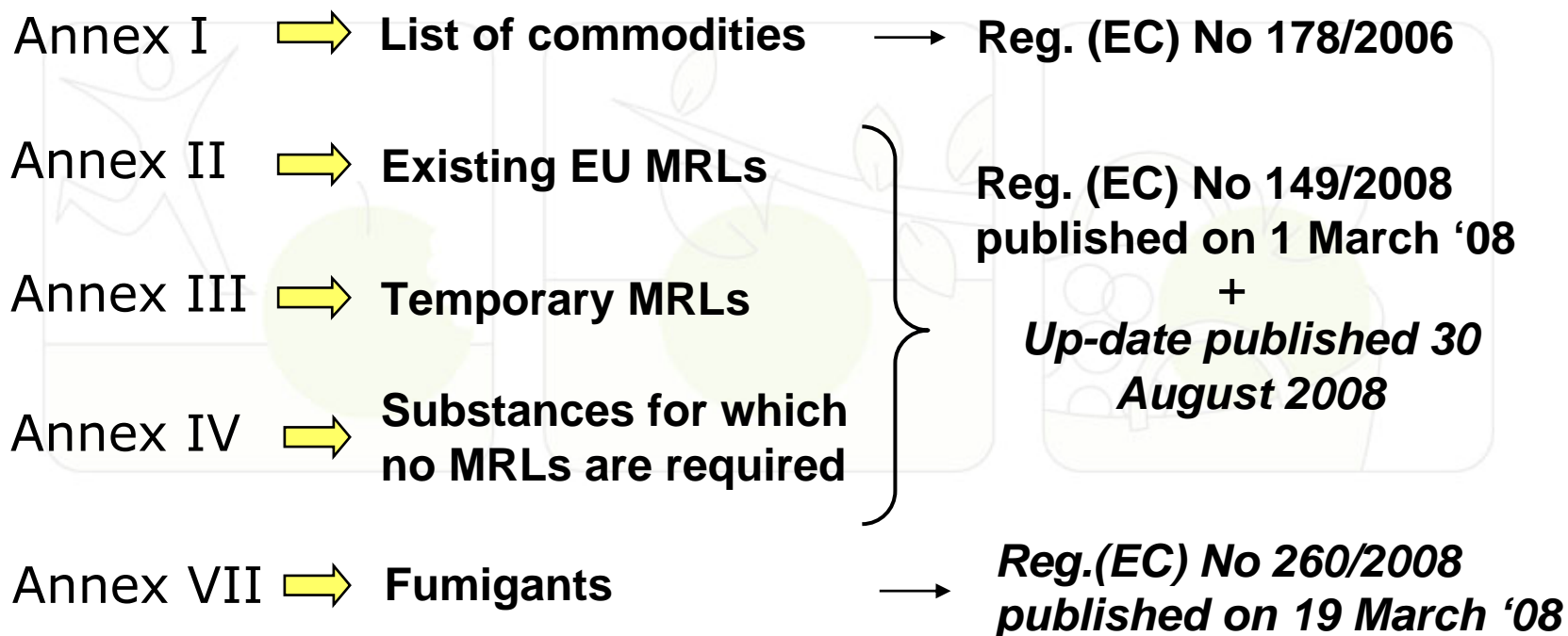
No harmonised risk
assessment for EU consumers
Trade problems



4 Directives → 1 Regulation 396/2005
completing process of harmonisation

Implementation of Reg. (EC) 396/2005

Reg. (EC) No 396/2005: fully applicable as from 6 months from the publication of the last of the Annexes I, II, III and IV.



Reg. (EC) N. 396/2005 → application date: 1 September 2008

ANNEX I: List of commodities

Regulation (EC) N. 178/2006

- **315 commodities** – 10 main groups.
- **190 existing** entries from current Directives.
- **125 new entries.**
 - Mainly minor crops (e.g. cassava, thyme, lupins), but also cocoa, coffee, sugar plants.
- **Fish and plants used in animal feed** listed, but for the time being exempted from MRL setting (not enough information).

ANNEX II: EU-MRLs

- **Covering 245 pesticides** from old MRLs Directives.
 - ± 45000 MRLs for 229 entries
 - only existing crops under old Directives
 - combinations new crops/245 pesticides in Annex III B
- Mostly pesticides for which EU risk assessment has been completed under Dir. 91/414/EEC.

ANNEX III: temporary EU-MRLs

■ Part A

- MRLs Harmonisation for 226 pesticides
- ± 70000 MRLs for 217 entries
- Mostly pesticides not yet evaluated under Dir. 91/414/EEC

■ Part B

- combinations new crops/245 pesticides in Annex II
- ± 30000 MRLs for 229 entries

ANNEX IV: substances for which an MRL is not necessary

- 52 entries
 - 6 micro-organisms
 - 46 chemicals (incl. plant extracts, pheromones, fatty acids)
- Many substances still under evaluation under Dir. 91/414/EEC. They are temporarily included in Annex IV, pending finalisation of their review under Dir. 91/414/EEC.

Reg. (EC) 396/2005

Alignment to new comitology rules

**Reg. (EC) No 299/2008
of the European Parliament and the Council**

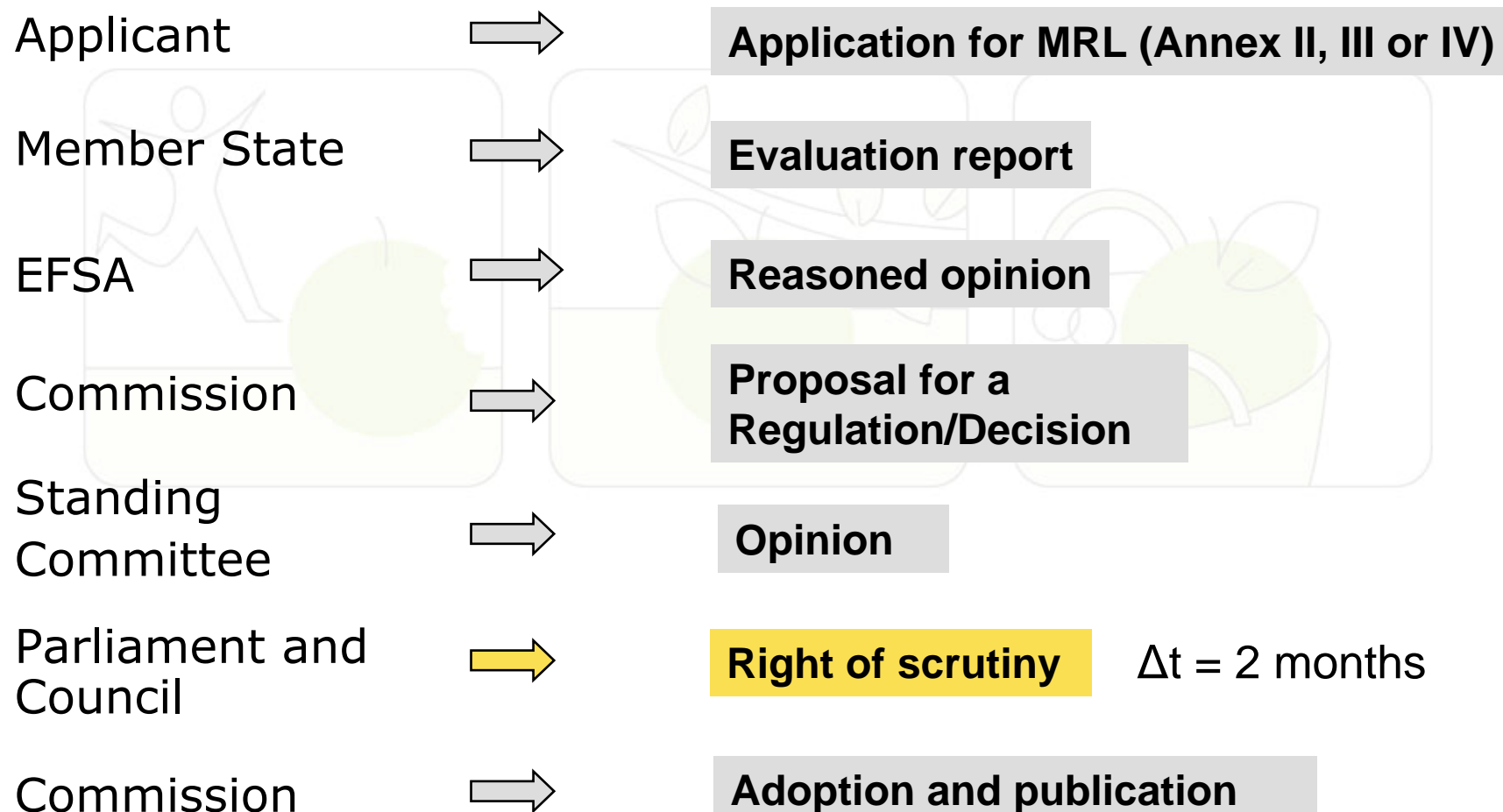
OJ L 97 of 9.4.2008, p. 67

Powers of EP widened.

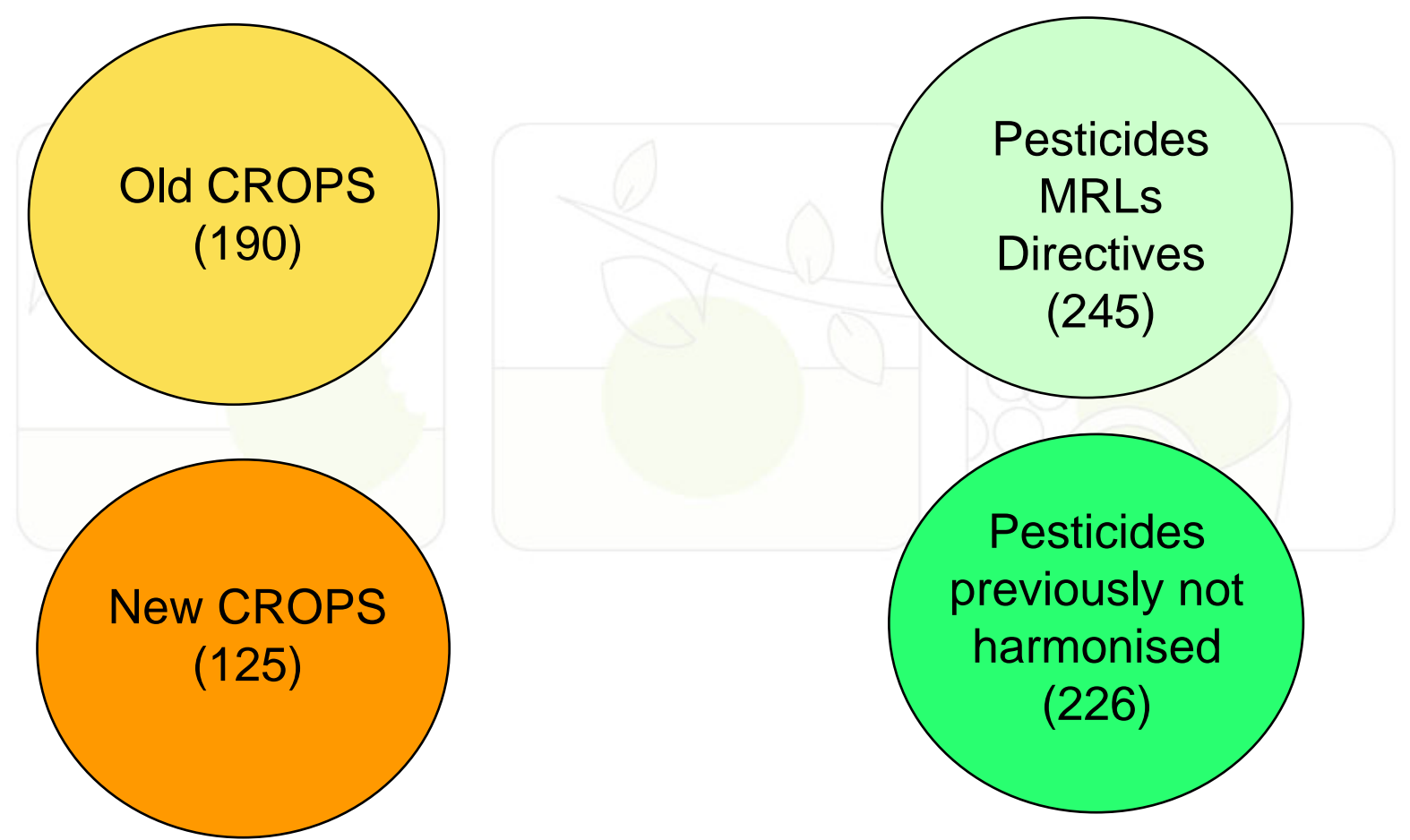
EP may oppose the adoption of a draft Commission proposal,
which received the favourable opinion of the Standing Committee.

Reg. (EC) 396/2005

Alignment to new comitology rules



Overview harmonisation exercise



Old CROPS
(190)

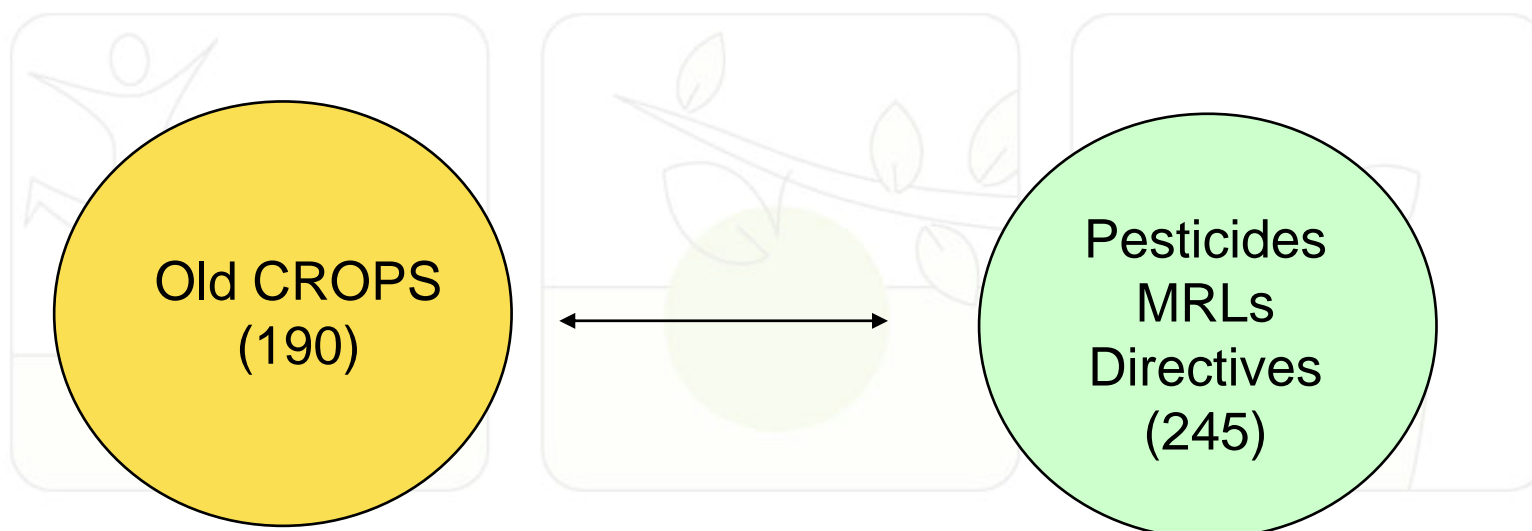
New CROPS
(125)

Pesticides
MRLs
Directives
(245)

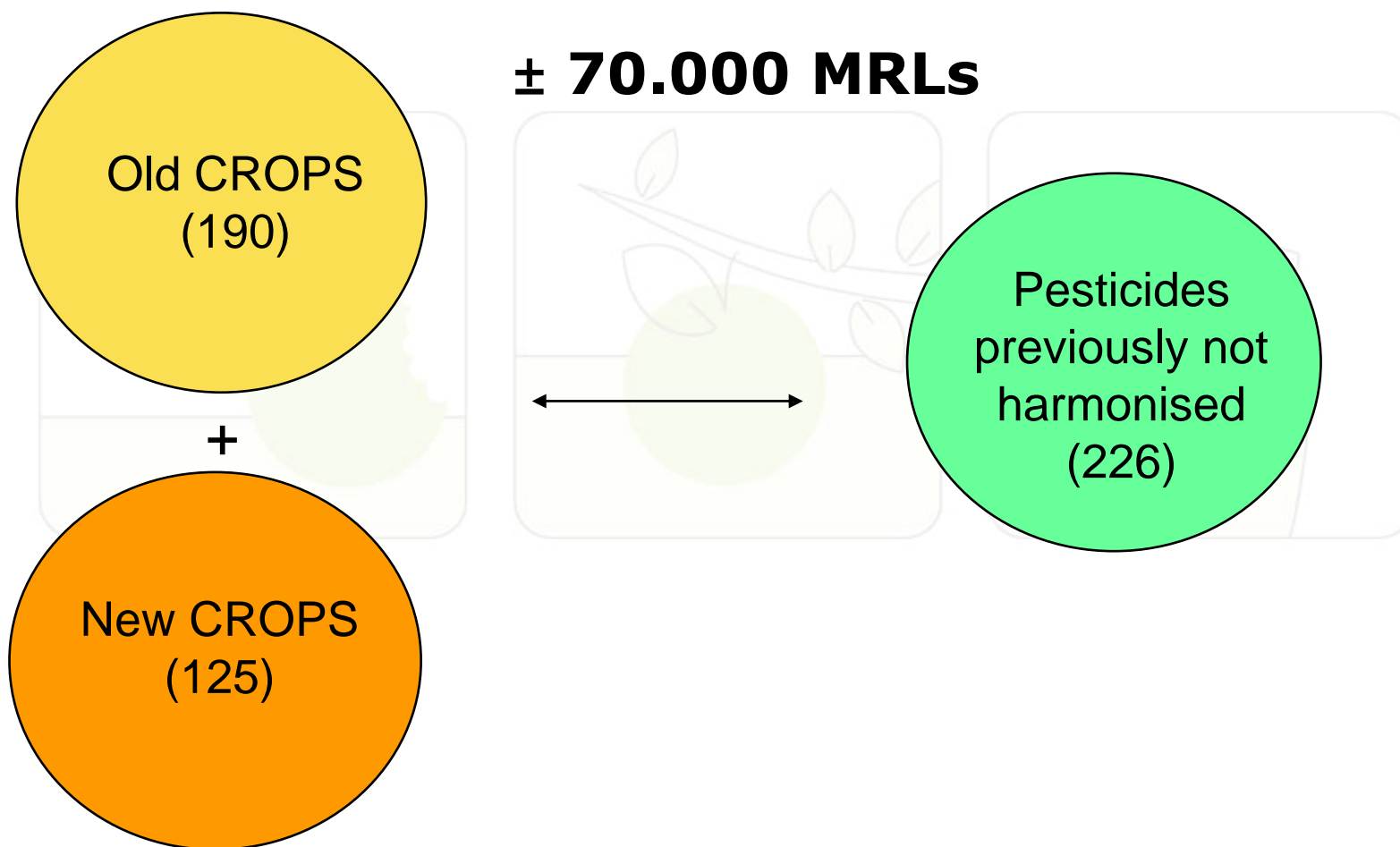
Pesticides
previously not
harmonised
(226)

Annexes II: EU definitive MRLs

± 45.000 MRLs

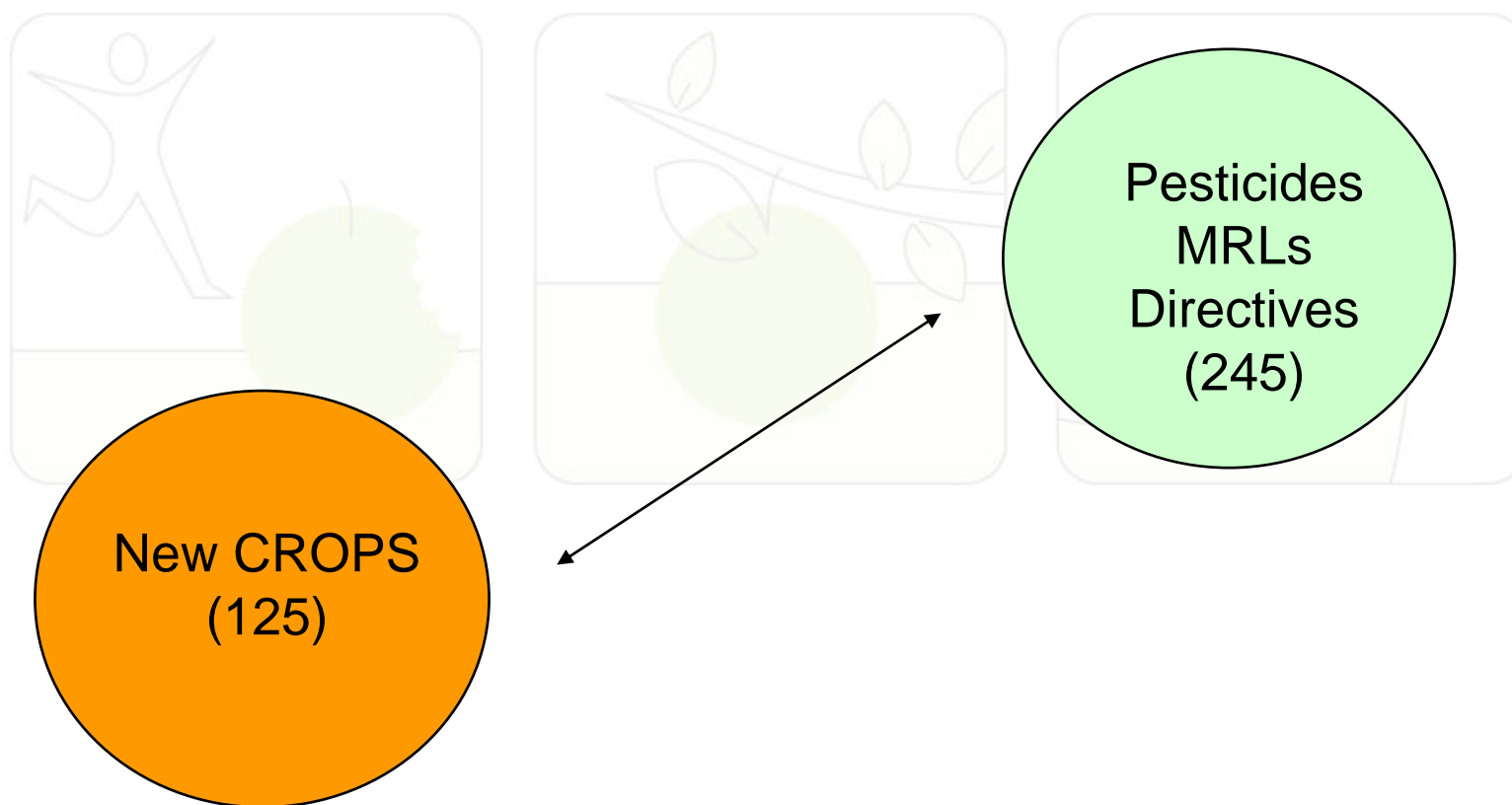


Annex III part A - temporary MRLs



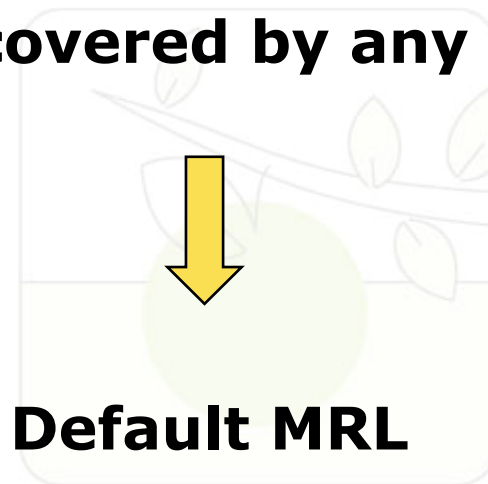
Annex III Part B - temporary MRLs

± 30.000 MRLs



Compliance with MRLs

Pesticides not covered by any of the Annexes



Default MRL
0,01 mg/kg

