



EU MRLs procedures



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European Commission

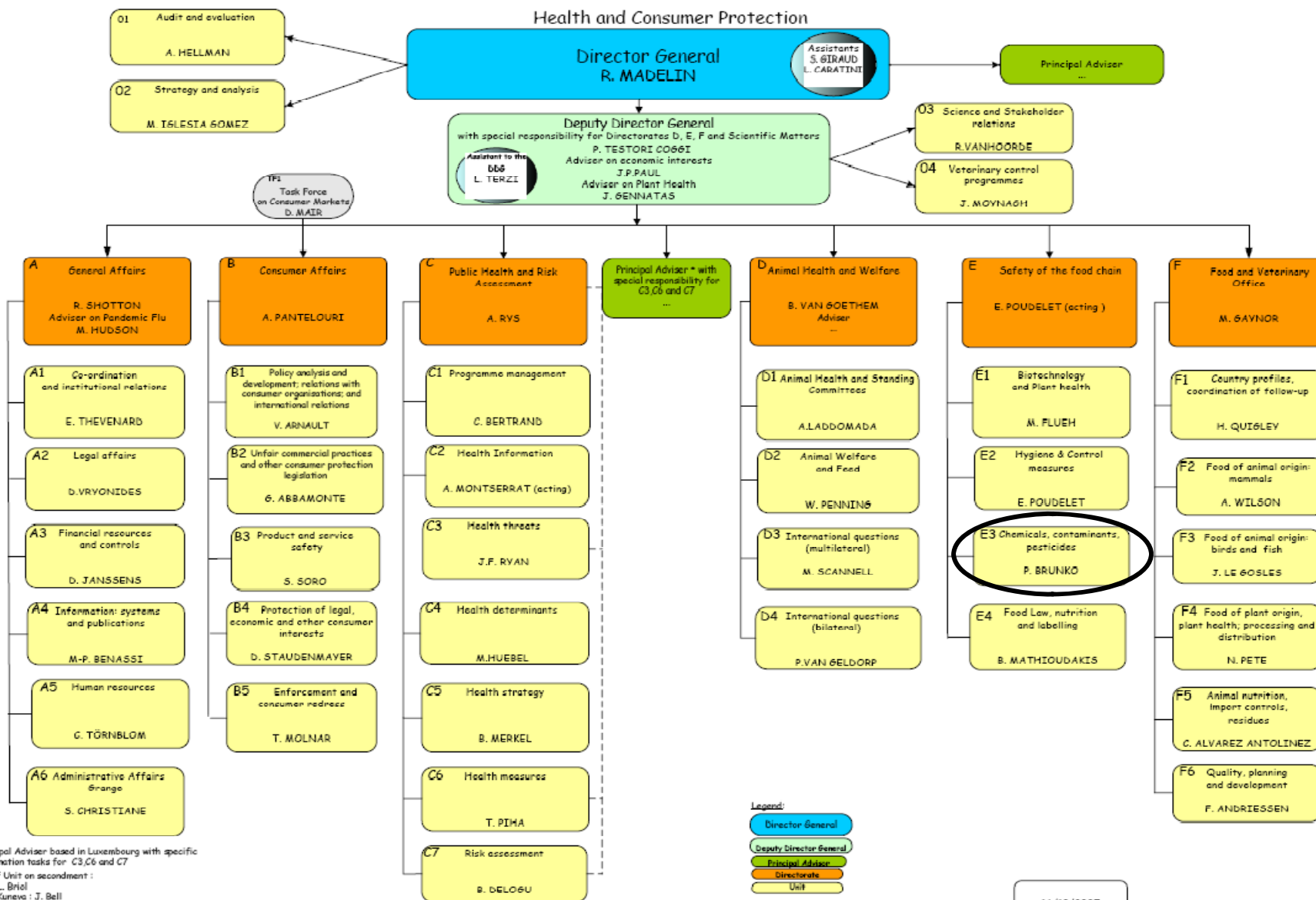
Health and Consumer Protection Directorate General

Unit E3 - Chemicals, Contaminants and Pesticides



Outline presentation

- ❖ DG SANCO
- ❖ Overall regulatory framework for pesticides
- ❖ Regulation (EC) N. 396/2005
 - ❖ On-going implementation
 - ❖ MRL setting
 - ❖
- ❖ Future challenges



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Cabinet Kuneva: J. Bell
Adviser on secondment
Cabinet Kyriacou: D. Spanou



Unit E3

Chemicals, contaminants, pesticides



Pesticides EU Regulatory Framework



Placing of plant protection products on the market

Directive 91/414/EEC

**Pesticide residues:
EU MRL settings**

Directives
76/895/EEC
86/362/EEC
86/363/EEC
90/642/EEC



Replaced by
Regulation (EC) No 396/2005



Directive 91/414/EEC

Basic objective

- Establishment of a Community Positive List of Active Substances (Annex I)
- Once a substance is on the Community list, Member State may grant authorisations for plant protection products which contain a listed active substance.

European Commission



**Approval of
active substances**

Member States



**Authorisation of
plant protection products**



Directive 91/414/EEC

Approval of active substances

1. **Industry:** submit dossier (data requirements: Annexes II and III)
2. **Rapporteur Member State:** evaluate dossier
3. **European Food Safety Authority (EFSA):** co-ordinate peer review
4. **EU Commission:** decision for inclusion in Annex I

“New” substances:

- 75 evaluated and approved

Review programme of “old” substances:

- More than 600 eliminated
- 92 approved
- Review to be finalised by the end of 2008
(ca. 230 substances)

Pesticide Residues MRLs setting

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**



Regulation (EC) N. 396/2005

of the European Parliament and of the Council of 23 February 2005

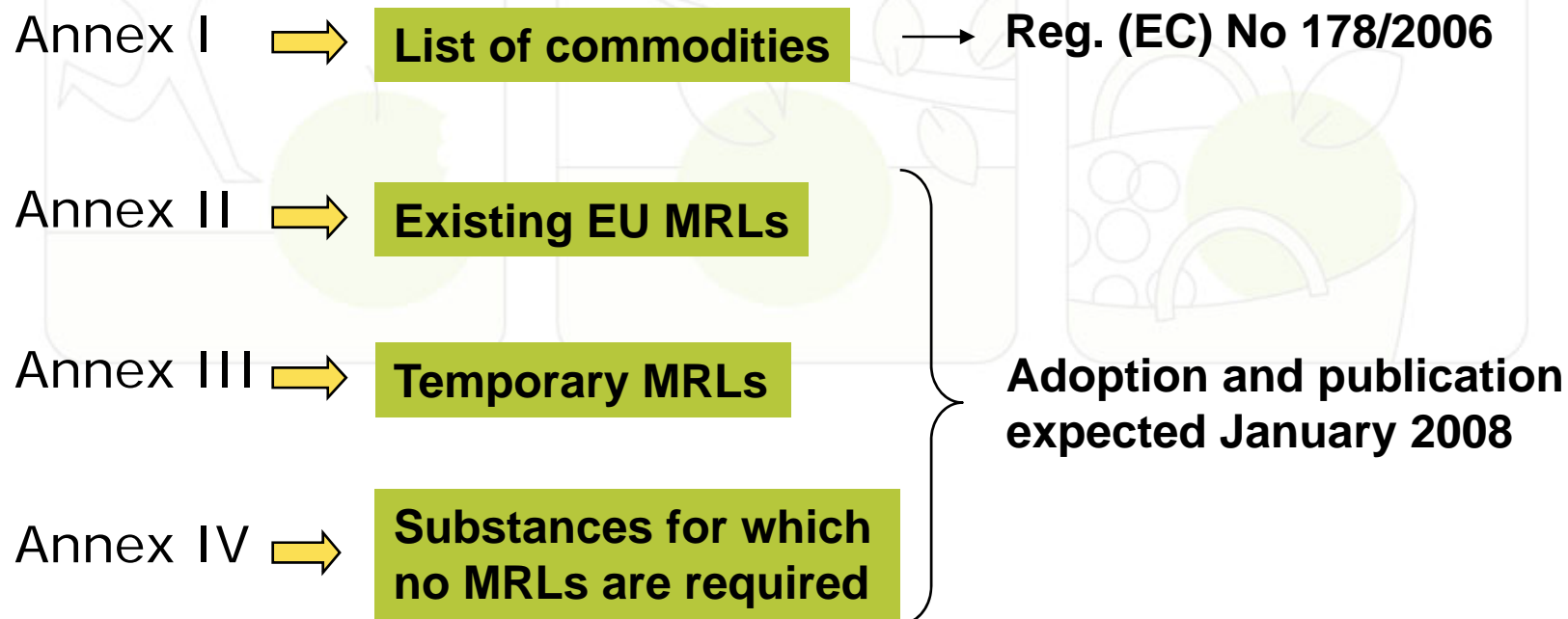
**on maximum residue levels of pesticides in or on food and feed
of plant and animal origin**

Key points

- High and consistent level of consumer protection across EU
 - Community harmonised MRLs
 - Consumer risk assessment reviewed by EFSA
- No authorisation of a PPP without an established EU MRL

Implementation of Reg. (EC) 396/2005

Reg. 396/2005 will be 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 foreseen: July 2008



ANNEX II: EU-MRLs

First establishment

- **238 pesticides** from current MRLs Directives.
 - ± 45000 MRLs
 - only existing crops under current Directives
 - combinations new crops/238 pesticides in Annex III B
- Mostly pesticides for which EU risk assessment has been completed under Dir. 91/414/EEC.
- Voted in the Standing Committee on the Food Chain and Animal Health (October 2007). Publication expected **January 2008**.



ANNEX III: temporary EU-MRLs

First establishment

- **National MRLs** collected until May 2006 on all the non-harmonised substances.
- EFSA asked for an opinion (September 2006).
- **EFSA** delivered a **reasoned opinion** (March 2007).
- COM-EFSA-MS: refinement risk assessment (March-September 2007).
- SPS notification (July 2007)
- Voted in the Standing Committee on the Food Chain and Animal Health (October 2007). Publication expected **January 2008**.



ANNEX I: List of commodities

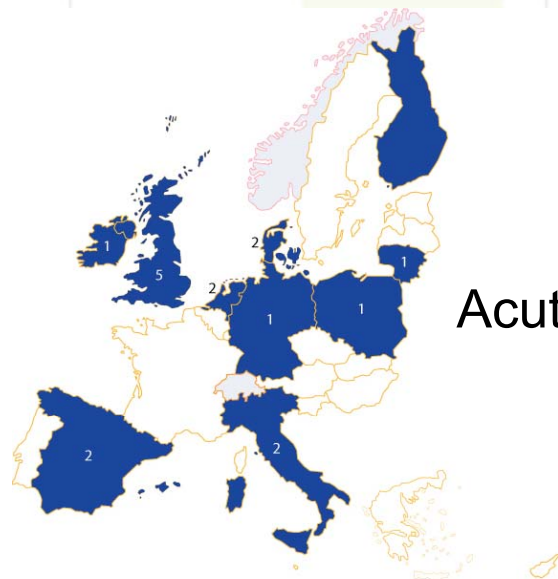
Regulation (EC) N. 178/2006

- **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).

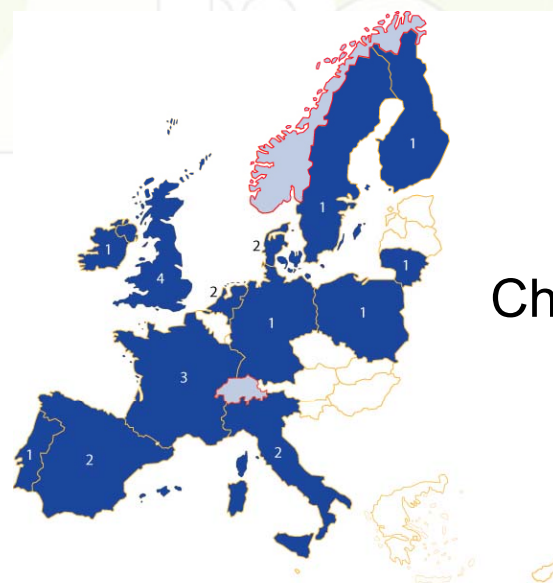
EFSA model

EFSA developed a model to perform the risk assessment:

- Harmonised food consumption database:
 - Data collected from Member States: 22 chronic diets, 19 acute diets
 - Data from WHO (GEMS Food) also considered: 3 cluster, 1 regional
 - Consumption data organised by sub-groups of population



Acute diets



Chronic diets



EFSA model Chronic RA

Active substance		
Status of the active substance:	non-included	Code no. 14
proposed LOQ (mg/kg bw):	0,05	
Toxicological end points		
ADI (mg/kg bw/day):	0,006	ARfD (mg/kg bw):
Source of ADI:	JMPR 1987, BfR 1991, BE	Source of ARfD:

Chronic risk assessment						
		TMDI (range) in % of ADI minimum - maximum				
		7	262			
		No of diets exceeding ADI:				
		7	7			
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)
261,7	DE child	257,3	Citrus fruit	1,9	PRODUCTS OF ANIMAL ORIGIN-	
232,3	NL child	227,4	Citrus fruit	2,6	PRODUCTS OF ANIMAL ORIGIN-	
152,0	IE adult	149,5	Citrus fruit	0,5	CEREALS	
136,3	FR toddler	131,0	Citrus fruit	3,5	PRODUCTS OF ANIMAL ORIGIN-	
134,4	UK Toddler	129,3	Citrus fruit	1,9	PRODUCTS OF ANIMAL ORIGIN-	
133,8	ES child	131,1	Citrus fruit	1,4	PRODUCTS OF ANIMAL ORIGIN-	
105,6	NL general	103,9	Citrus fruit	0,7	PRODUCTS OF ANIMAL ORIGIN-	
91,0	WHO Cluster diet B	87,5	Citrus fruit	1,0	CEREALS	
82,6	ES adult	81,1	Citrus fruit	0,6	PRODUCTS OF ANIMAL ORIGIN-	
80,8	UK Infant	75,3	Citrus fruit	3,4	PRODUCTS OF ANIMAL ORIGIN-	
80,7	SE general population 90th percentile	77,7	Citrus fruit	1,4	PRODUCTS OF ANIMAL ORIGIN-	
65,3	WHO Cluster diet F	63,4	Citrus fruit	0,6	PRODUCTS OF ANIMAL ORIGIN-	
64,4	FI adult	63,3	Citrus fruit	0,5	PRODUCTS OF ANIMAL ORIGIN-	
62,7	FR infant	59,2	Citrus fruit	2,2	PRODUCTS OF ANIMAL ORIGIN-	
60,1	UK vegetarian	58,8	Citrus fruit	0,3	Sugar beet (root)	
49,0	WHO cluster diet E	46,7	Citrus fruit	0,5	PRODUCTS OF ANIMAL ORIGIN-	
47,8	WHO regional European diet	45,7	Citrus fruit	0,6	PRODUCTS OF ANIMAL ORIGIN-	
44,3	PT General population	42,9	Citrus fruit	0,4	CEREALS	
42,6	IT toddler	41,3	Citrus fruit	0,7	CEREALS	
40,4	UK Adult	39,0	Citrus fruit	0,4	PRODUCTS OF ANIMAL ORIGIN-	
37,9	FR all population	36,5	Citrus fruit	0,4	PRODUCTS OF ANIMAL ORIGIN-	



EFSA model Acute RA

Acute risk assessment / children	Acute risk assessment / adults / general population
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The acute risk assessment is based on the ADI as no ARfD was available.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight in the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities exceeded (IESTI 2):		
	12			8			---			---		
	IESTI 1 *) **)			IESTI 2 *) **)			IESTI 1 *) **)			IESTI 2		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	223,1	Melons	0,5 / 0,22	223,1	Melons	0,5 / 0,22	77,8	Pumpkins	0,5 / -	77,8		
	209,6	Watermelons	0,5 / 0,23	209,6	Watermelons	0,5 / 0,23	62,0	Watermelons	0,5 / -	62,0		
	195,0	Oranges	0,5 / 0,25	148,8	Pineapples	0,5 / 0,33	58,0	Melons	0,5 / -	58,0		
	148,8	Pineapples	0,5 / 0,33	140,9	Oranges	0,5 / 0,35	52,5	Chinese cabbage	0,5 / -	52,5		
	144,1	Apples	0,5 / 0,34	131,2	Grapefruit	0,5 / 0,38	46,7	Table grapes	0,5 / -	46,7		
	133,9	Pears	0,5 / 0,37	128,6	Scarole (broad-leaf)	0,5 / 0,38						
	131,2	Grapefruit	0,5 / 0,38	125,3	Table grapes	0,5 / 0,39						
	128,6	Scarole (broad-leaf)	0,5 / 0,38	106,2	Apples	0,5 / 0,47						
	125,3	Table grapes	0,5 / 0,39	97,2	Cauliflower	0,5 / -						
	122,9	Bananas	0,5 / 0,4	96,3	Pears	0,5 / -						
	115,7	Mangoes	0,5 / 0,43									
	108,0	Sweet corn	0,5 / 0,46									
	99,4	Kale	0,5 / -									
	97,2	Cauliflower	0,5 / -									
	93,2	Carrots	0,5 / -									
	92,6	Peppers	0,5 / -									
	No of critical MRLs (IESTI 1)			12			No of critical MRLs (IESTI 2)			8		

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	74,9	Apple juice	0,5 / -	14,8	Orange juice	0,5 / -
	72,8	Orange juice	0,5 / -	9,7	Apple juice	0,5 / -

ANNEX III: temporary EU-MRLs

Structure

■ Part A

- MRLs Harmonisation for 167 pesticides
- ± 50000 MRLs
- Mostly pesticides not yet evaluated under Dir. 91/414/EEC

■ Part B

- combinations new crops/238 pesticides in Annex II
- ± 30000 MRLs

Harmonisation = Simplification





Annex III

Forthcoming update

- Need for an update:
 - National MRLs set after May 2006
 - Comments received from non-EU Countries (SPS)
- Revised Annex III to be published before Regulation 396/2005 becomes applicable in July 2008.
- On-going update :
 - Data collected from the Member States
 - Changes requested for 112 substances:
 - 51 new entries (not covered by current Annex III – part A)
 - 61 already covered by first establishment Annex III –part A
 - EFSA asked for an opinion
 - Vote: March 2008



ANNEX IV: substances for which an MRL is not necessary

First establishment

- EFSA asked for an opinion on the risk to consumers.
- Only substances already evaluated under Directive 91/414/EEC
 - 3 Chemicals
 - 5 Micro-organisms
- Many substances candidate for Annex IV still under evaluation under Dir. 91/414/EEC.
- Voted in the Standing Committee on the Food Chain and Animal Health (October 2007). Publication expected January 2008.
- Update possible before July 2008.

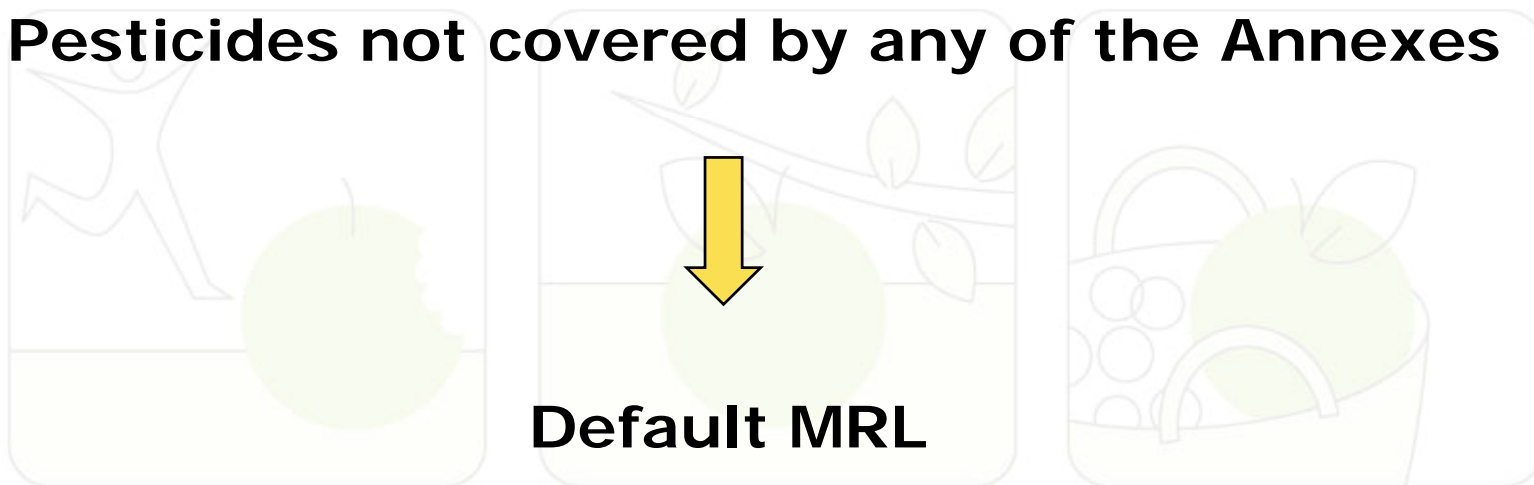


Complete list of Annexes Reg. 396/2005

Annex I	➔	List of commodities	➔	Reg. (EC) No 178/2006
Annex II	➔	Existing EU MRLs	}	Adoption and publication expected January 2008
Annex III	➔	Temporary EU MRLs		
Annex IV	➔	List of active substances for which no MRLs are required		
Annex V	➔	Substances for which a default MRL applies		
Annex VI	➔	Processed products		
Annex VII	➔	Fumigants	➔	Under development

Compliance with MRLs

Pesticides not covered by any of the Annexes

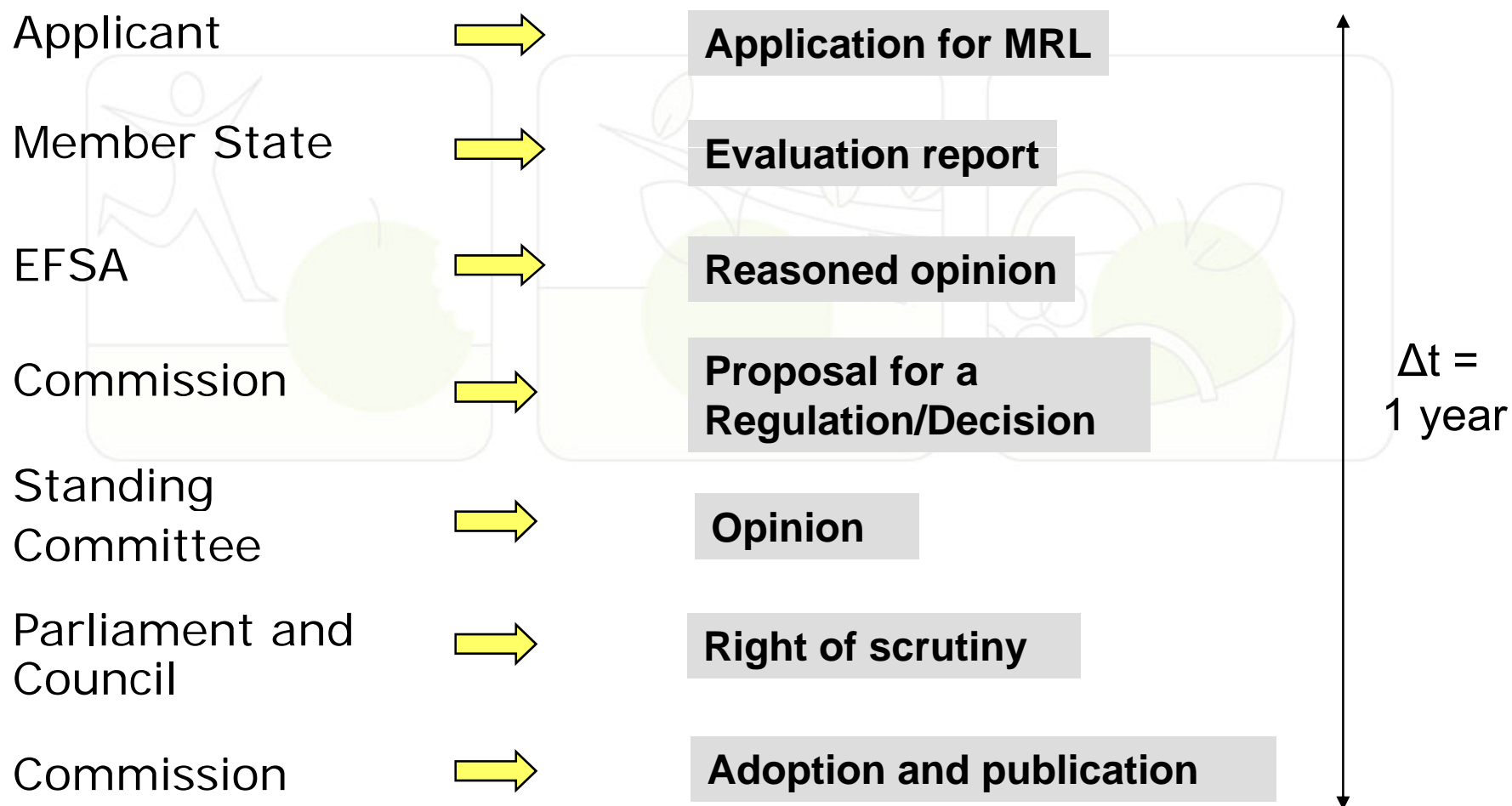


Default MRL

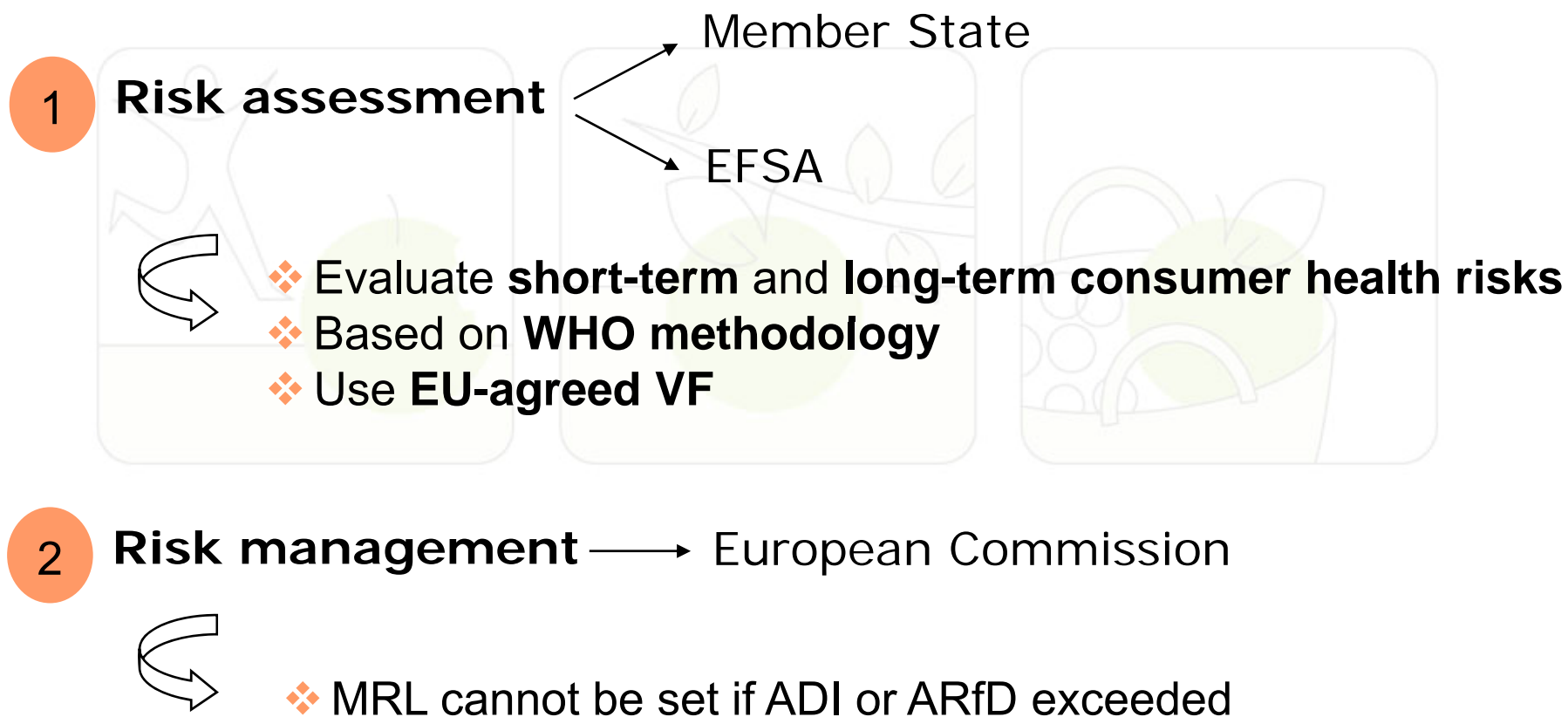
0,01 mg/kg

Regulation 396/2005

MRL setting



EU-MRL setting





Regulation 396/2005

MRL setting – Import tolerances

- When the request comes from outside the EU : Import tolerance.
- The **requirements are the same** as for applicants in the EU.
- A request for an import tolerance has to be submitted to the **Rapporteur Member State (RMS)**.
- If a RMS does not exist, a Member State is designated by the Commission.



Regulation 396/2005

MRL setting – data requirements

- Toxicology data to derive ADI/ARfD (**only for** substances not yet evaluated in the EU).
- Information on authorised use and **Good Agricultural Practice**.
- Supervised **residue trials** 8 for major crops 4 for minor crops (for minor crops, extrapolations may be possible). Plant metabolism data; processing studies; peel/pulp distribution.
- Animal feeding studies (if crop used for animal feed).

Current Directives Minor crops and very minor crops

Minor and very minor crops not always listed

Groups of products	Products included in the groups	Part of product to which maximum residue levels apply
1. Fruit, fresh, dried or uncooked, preserved by freezing, not containing added sugar; nuts		
(i) CITRUS FRUIT	Grapefruit Lemons Limes Mandarins (including clementines and similar hybrids) Oranges	} } Whole product



Legal uncertainty as regards MRLs for crops not covered by the Directives



Reg. 396/2005 Simplification for (very) minor crops

Clearer classification in Annex I

Code number ⁽¹⁾	Groups to which the MRLs apply	Examples of individual products within the groups to which the MRLs apply	Scientific Name ⁽²⁾	Examples of related varieties or other products included in the definition to which the same MRL applies
0100000	1. FRUIT FRESH OR FROZEN; NUTS			
0110000	(i) Citrus fruit			
0110010		Grapefruit	<i>Citrus paradisi</i>	Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids
0110020		Oranges	<i>Citrus sinensis</i>	Bergamot, bitter orange, chinotto and other hybrids

All crops covered by one code → same MRL

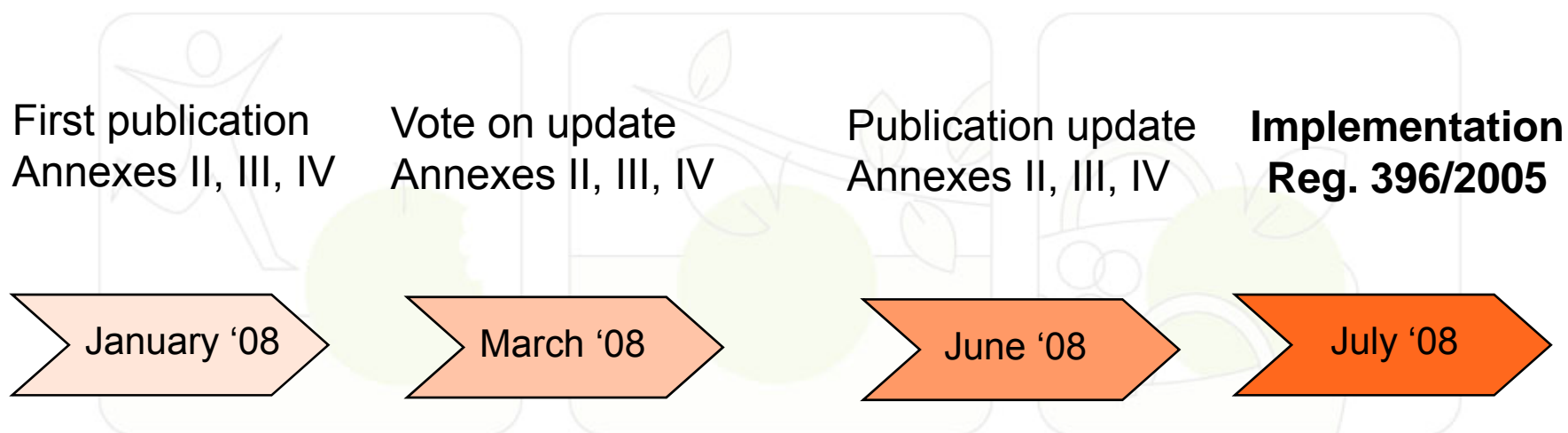


Next challenges

- **Annex I**: add fish and animal feed
- **Annex VI**: processed products
- **Database** on MRLs (DG SANCO website)
- **Database** on toxicological reference values, GAPs, dietary intake assessment (EFSA)
- Variables **ESTI equation** (EFSA opinion)
- Consider **cumulative and synergistic effects** (EFSA)



Timeframe entering into force Reg. 396/2005



Conclusions

1

Pesticide legislation in the EU

Approval active substances, autorisation PPP
Setting MRLs

2

MRL legislation

Full harmonisation on-going
Reg. 396/2005 applicable as from September 2008

3

MRL setting

EFSA involved in the risk assessment
Increased transparency



Documents on the Internet

DG SANCO webpage

http://ec.europa.eu/dgs/health_consumer/index_en.htm

Pesticide Residue Legislation

http://ec.europa.eu/food/plant/protection/pesticides/legislation_en.htm

Annexes II, III and IV (voted texts to be published in January 2008)

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

Approval of active substances

http://ec.europa.eu/food/plant/protection/evaluation/index_en.htm

EFSA model

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620776373.htm -

