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Kompetenz rund um die Frucht

PROGNOSFRUIT 2008

Ashford (Kent), August 8, 2008

MRLs and Active Substances Legislation and Implications

Wolfgang Ahlers

Legal Adviser

ATLANTA Aktiengesellschaft, Bremen, Germany



Current MRL Legislation (before September 1, 2008)

27 Member States

EC directives only

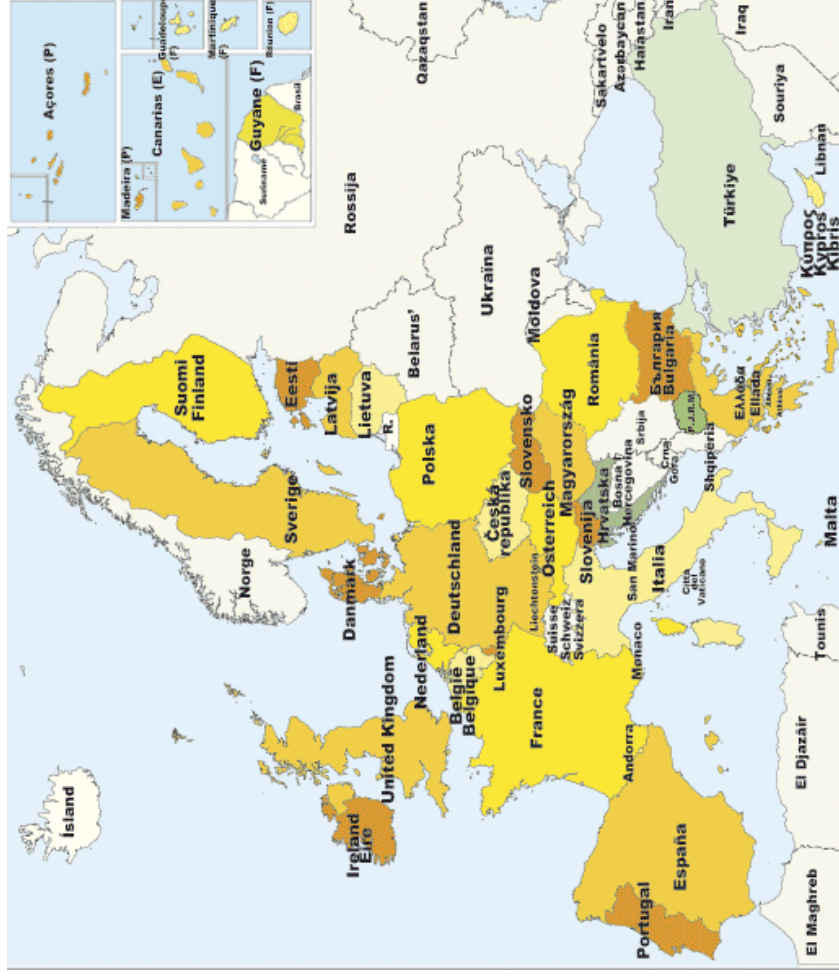
MRLs are subject to

Member States' legislation

Legal systems are not compatible

No automatic approval

Trade barriers (lawful?)



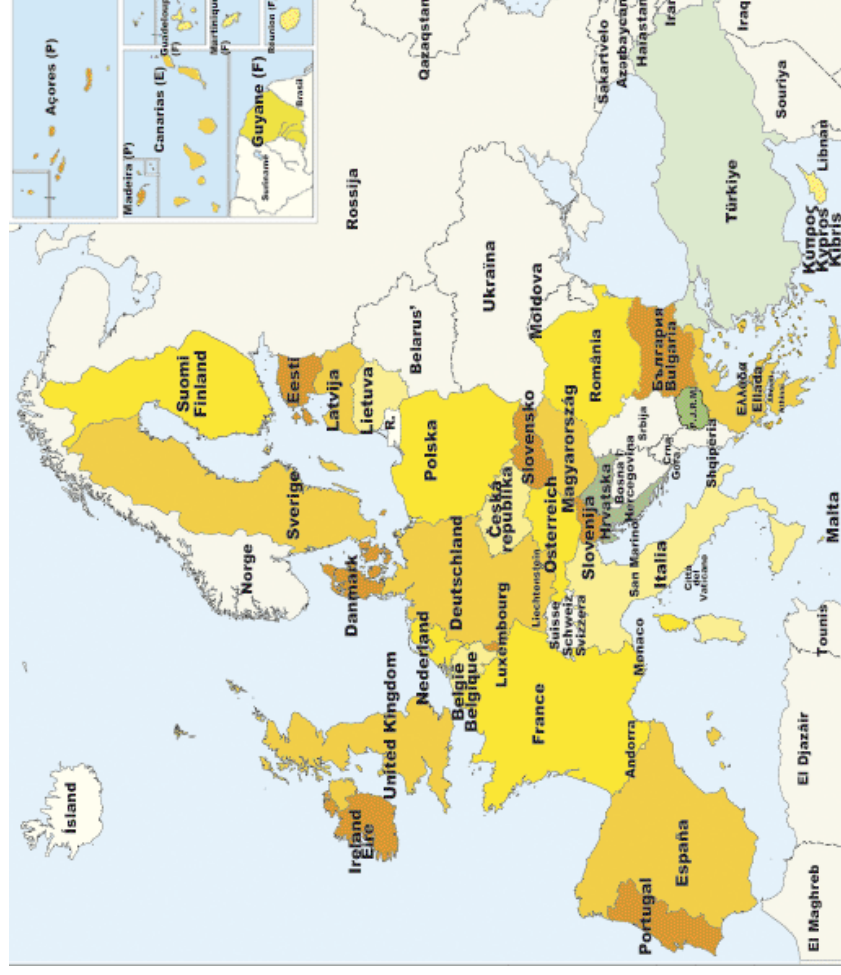


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Future MRL Legislation (as of September 1, 2008)

27 Member States
One harmonised MRL
legislation





Regulation (EC) no. 396/2005

- **One structured general list of crops (Annex I)**
- **MRLs as already set by EC Directives (Annex II)**
- **MRLs collected from Member States' Law (Annex IIIA)**
- **MRLs for new crops, honey, tea, infusions (Annex IIIB)**
- **List of substances that do not need MRLs (Annex IV)**

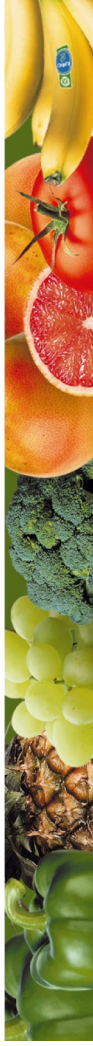
Annexes II, III and IV issued in the OJ of March 1, 2008

Regulation in force as per September 1, 2008



Regulation (EC) no. 396/2005

- National residue law is becoming obsolete
- No longer problems with German MRL system
- Less problems for third country suppliers



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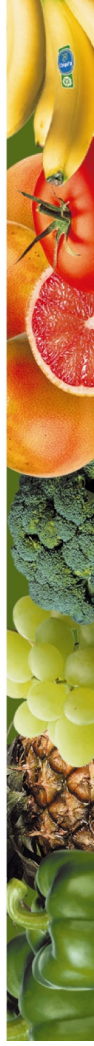
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Regulation (EC) no. 396/2005

New Problems:

- **Several substances are not yet listed**
- **No current risk assessment for Annex II substances**
- **Some Annex III MRLs differ from former rules**
- **Public perception (NGOs)**
- **Retailers' specifications (German situation)**
- **Transitional period ?**



Regulation (EC) no. 396/2005

Transitional Measures (Regulation 396/2005, art. 49)

„The requirements of Chapter III shall not apply to products lawfully produced or imported into the Community before“ (September 1, 2008)

„produced“ == „cultivated“ or „harvested“ ?



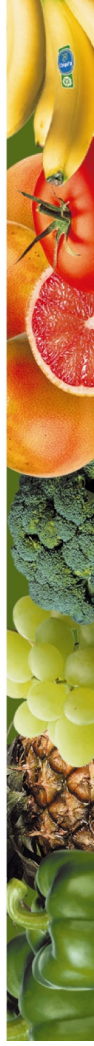
Regulation (EC) no. 396/2005

Transitional Measures (Regulation 396/2005, art. 49)

„produced“ == „cultivated“ or „harvested“ ?

EU Commission paper says „harvested“

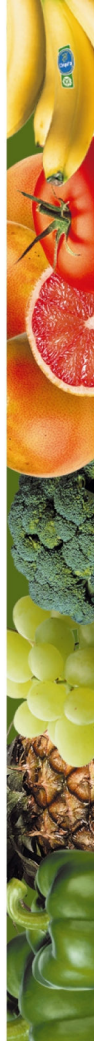
German ministry refers to 6 months‘ transitional period



Regulation (EC) no. 396/2005

Transitional Measures (Regulation 396/2005, art. 49)

Produce should comply with new MRLs, if harvested after September 1, 2008



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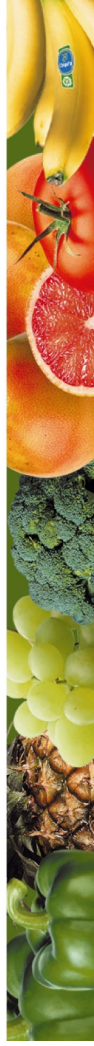
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Regulation (EC) no. 396/2005

Public Perception

NGOs like German Greenpeace branch say

- that consumer protection is being sacrificed**
- that most MRLs are being raised**

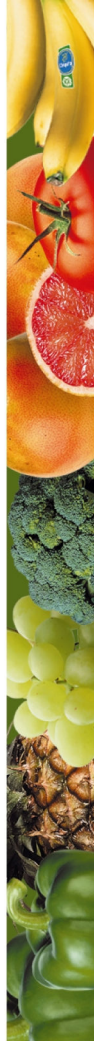


Regulation (EC) no. 396/2005

Public Perception

Factually, consumer protection on an EC level has never been better than today

**Factually, most MRLs do not change (in Germany):
Annex II MRLs have already been in force before
MRLs were applicable via „Allgemeinverfuegungen“**



Regulation (EC) no. 396/2005

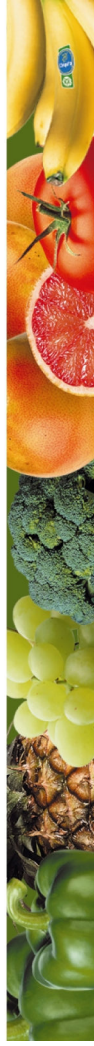
Annex II MRLs

- were checked and approved in the nineties
- do not reflect ARfD issues properly



ARfD Exceedances at MRL Level

Incompatible MRL's - Pome Fruit					
Substance	MRL	ARfD		ARfD (HR) in %	
Formetanat	1,00 mg/kg	0,0050	mg/kg BW	2035,4	
Imazalil	5,00 mg/kg	0,0500	mg/kg BW	1017,7	
Methomyl	0,20 mg/kg	0,0025	mg/kg BW	814,2	
Fentin	0,05 mg/kg	0,0010	mg/kg BW	508,9	
Fluquinconazol	1,00 mg/kg	0,0200	mg/kg BW	508,9	
Pyrazophos	0,05 mg/kg	0,0010	mg/kg BW	508,9	
Phosmet	2,00 mg/kg	0,0450	mg/kg BW	452,3	
Flusilazol	0,20 mg/kg	0,0050	mg/kg BW	407,1	
Azafenidin	0,01 mg/kg	0,0004	mg/kg BW	254,4	
Dinocap	0,10 mg/kg	0,0040	mg/kg BW	254,4	
Fenpyroximat	0,50 mg/kg	0,0200	mg/kg BW	254,4	

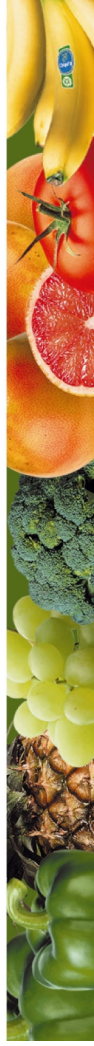


Regulation (EC) no. 396/2005

Annex II MRLs

- were checked and approved in the nineties**
- do not reflect ARfD issues properly**

Annex II substances will have to be re-checked



Regulation (EC) no. 396/2005

German Retailers' Specifications

- max. 70% of legal MRL per substance (Lidl: one third)**
- max. 70% of ARfD per substance**
- max. 80% of cumulated MRL percentages (Aldi)**
- max. 80% of cumulated ARfD percentages (Aldi)**
- max. 3-5 detectable substances (Aldi)**

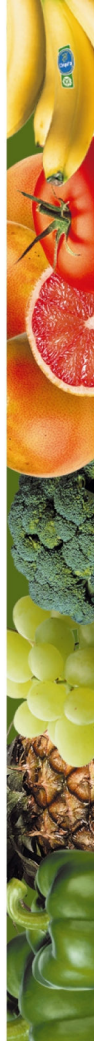
will be transferred to EC MRL legislation



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Things to come ...



Directive 91/414/EEC Revision

Commission proposal for „cut off“ criteria:

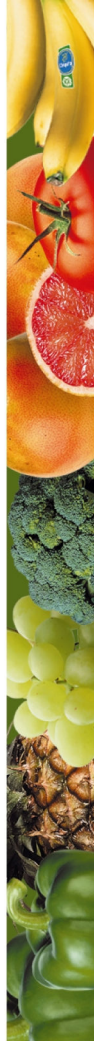
CMR carcinogenic, mutagenic, reprotoxic
POP persistent organic pollutant
PBT persistent, bio-accumulating, toxic
vPvB very persistent, very bio-accumulating
endocrine disruptor



Directive 91/414/EEC Revision

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Directive 91/414/EEC Revision

Commission proposal for „cut off“ criteria:

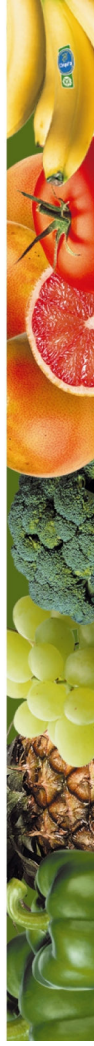
According to PSD report

6 to 10 % of insecticides

8 to 31 % of fungicides

4 to 10 % of herbicides

will not be re-approved



Directive 91/414/EEC Revision

EP Amendment to Commission Proposal:

CMR carcinogenic, mutagenic, reprotoxic

POP persistent organic pollutant

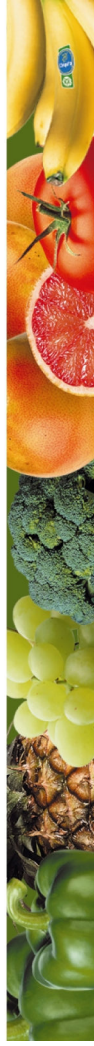
PBT persistent, bio-accumulating, toxic

vPvB very persistent, very bio-accumulating

endocrine disruptor

hazard quotient for bees

neurotoxic or immunotoxic



Directive 91/414/EEC Revision

According to PSD,

65 % of insecticides

31 to 43 % of fungicides

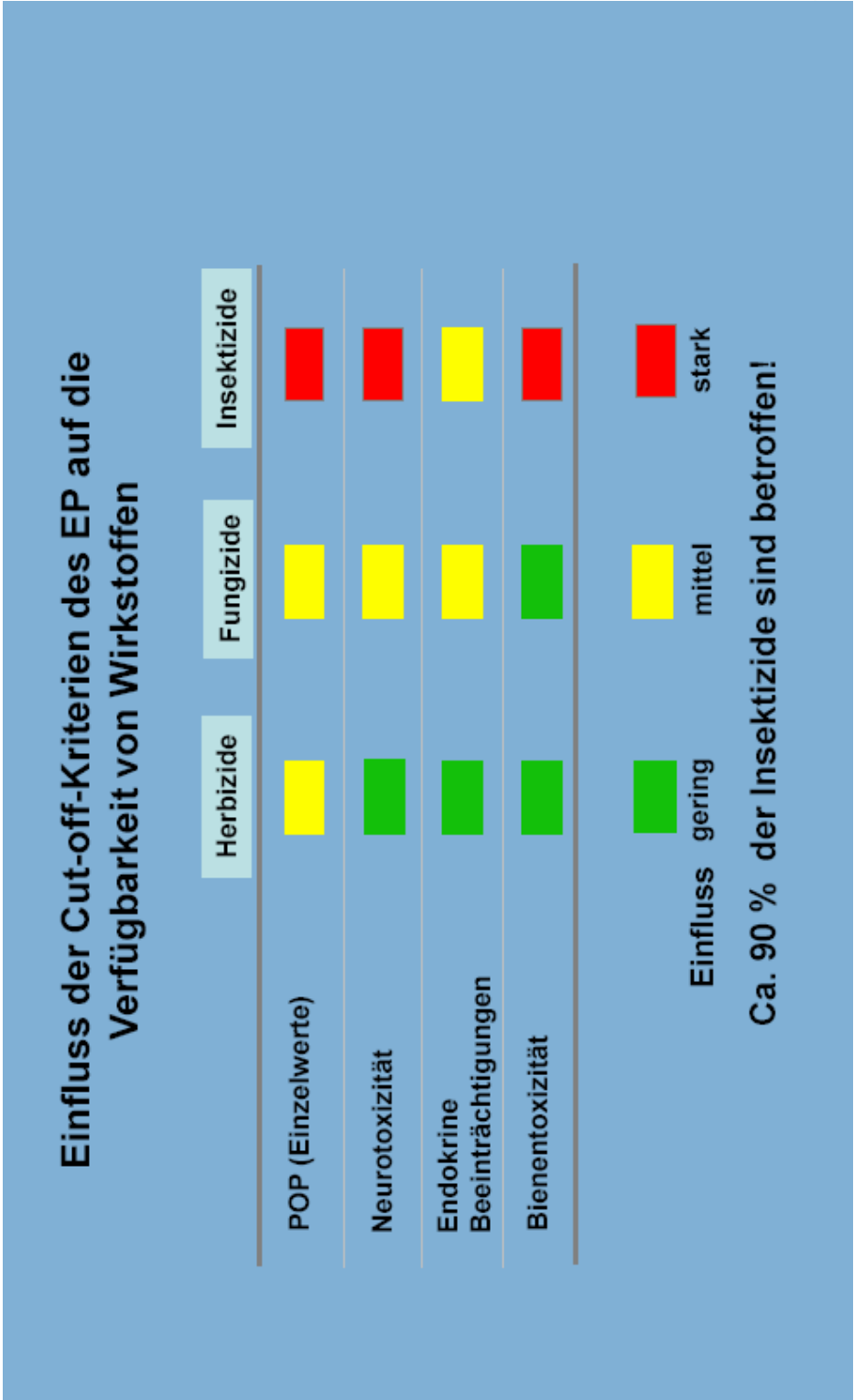
25 to 31 % of herbicides

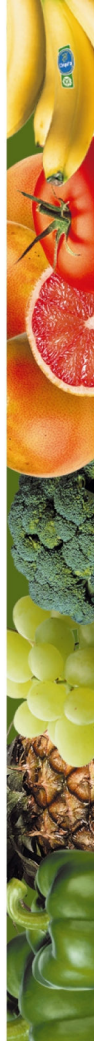
could fail re-approval under EP criteria

Possible overall loss of active substances: 82 %

Directive 91/414/EEC Revision

German Agency for Consumer Protection and Food Safety (BVL):

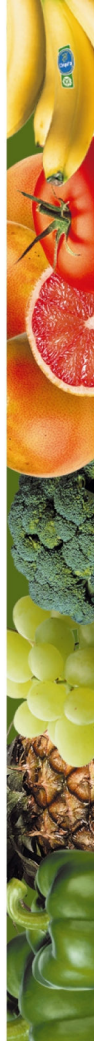




Directive 91/414/EEC Revision

Impacts for producers (according to PSD report)

- no substance change possible (GAP)**
- no specific agent against several pests**
- no appropriate protection for minor crops**
- severe crop yield losses**
- severe losses in food quality**
- medium and long-term resistances**



Directive 91/414/EEC Revision

PSD Conclusions

- EP does not consider world-wide production shortfall
- Retail customers demand maximum food quality
- impact on agricultural production is not assessed
- social impacts are not assessed



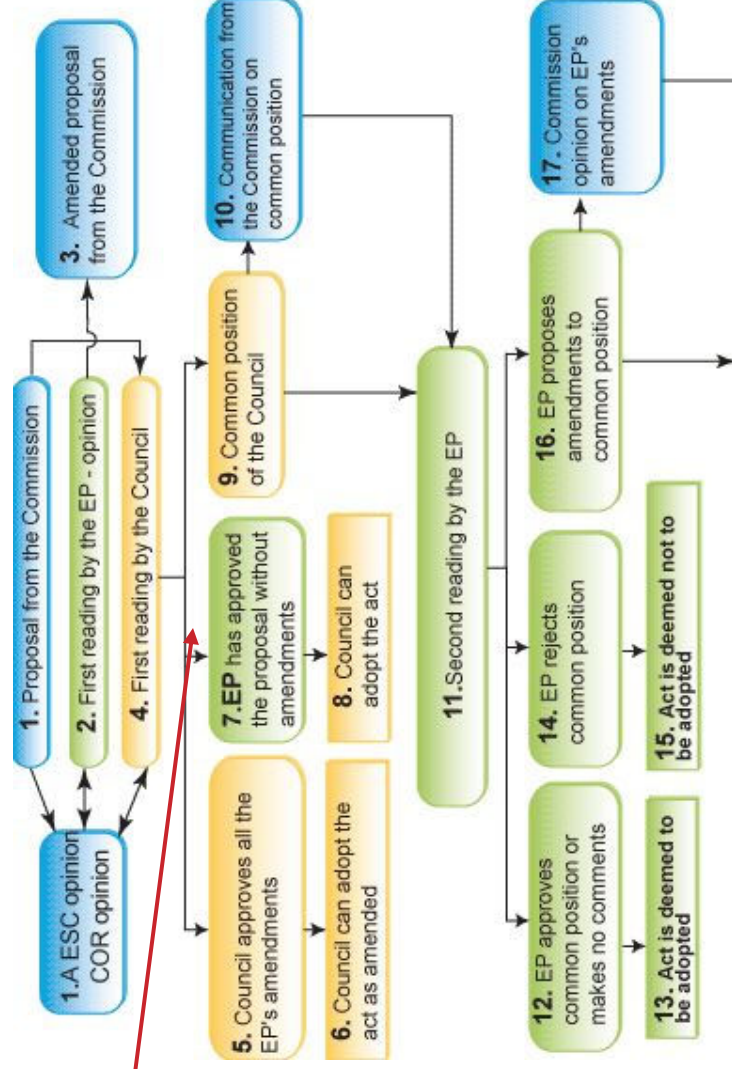
Directive 91/414/EEC Revision

Argumentation risks:

- **No approval in other Member States**
- **Former risk assessment is out-dated**
- **Producers' problems are no issue for NGOs**

Directive 91/414/EEC Revision

Where are we ?





Directive 91/414/EEC Revision

First EP reading has taken place

Council will have to set up „Common position“

EP will have to consider Council's arguments

Second reading in EP

Conciliation Committee, if approval fails

It's not too late to provide politicians with information



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Thank you for your attention !