

New MRL legislation in the EU

Lutz Alder

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(Acts whose publication is obligatory)

**REGULATION (EC) NO 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 and
amending Council Directive 91/414/EEC
(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37 and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and

cereals⁽¹⁾, Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin⁽²⁾, and Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on products of plant origin, including fruit and vegetables⁽³⁾, have been substantially amended several times. In the interests of clarity and simplicity, those Directives should be repealed and replaced by a single act.

New situation since September 1 2008

- All national MRL regulations in EU member states are withdrawn
- Entry into force of MRLs of Regulation (EC) 396/2005
- MRLs are listed in annexes II and III
- Annexes II and III are published (and amended) in separate regulations

Actually in force:

Regulation (EC) 149/2008

Regulation (EC) 839/2008

Regulation (EC) 256/2009

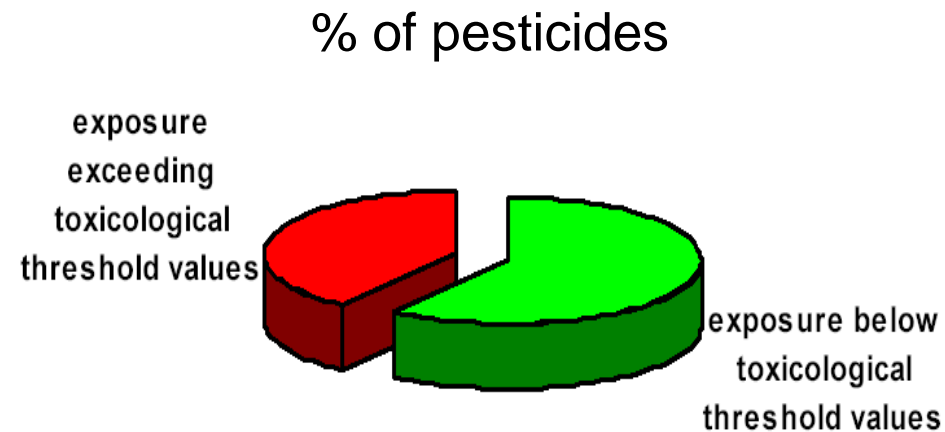
Advantages of the new regulation for MRL enforcement (for residue analysis and for monitoring)

- > 400 pesticides explicitly mentioned
- Default MRL of 0.01 mg/kg introduced for all substances not explicitly mentioned
- Nearly all fruits, vegetables etc. separately mentioned (>300 commodities separately listed)
- 66 kinds of food of animal origin directly listed
- Definition of the required LOQ (if no GAP or no residues)
- Additional list of pesticides for which no MRLs are necessary (Annex IV)

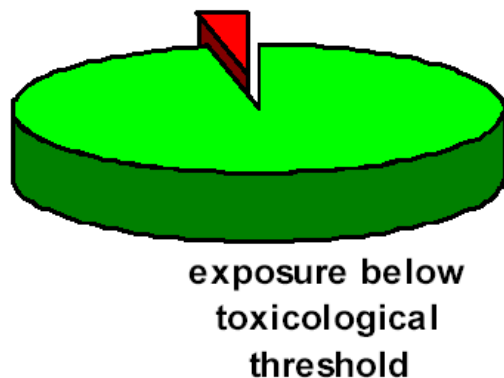


Advantages of the new regulation for consumers

- All former European regulations considered
- All MRLs checked in chronic and acute intake assessments based on different European diets



2500 pMRLs
exposure
exceeding
toxicological
threshold



- 2500 unsave (old national) MRLs withdrawn
- Last barriers in food trade inside the EU disappeared
- Reduced number of MRL violations observed now

Disadvantages of the new regulation and open points

- Compared to old national MRLs new EU MRLs are often set at higher levels (provided that there is no consumer risk)
- Approx. 50% of MRLs are provisional (not based on GAP and results of residue trials)
- Analytical methods which correspond to the required LOQs not generally available (new methods or higher LOQs required)

Note:

Assessment of provisional MRLs is in progress!

Thank you very much for your attention

Lutz Alder

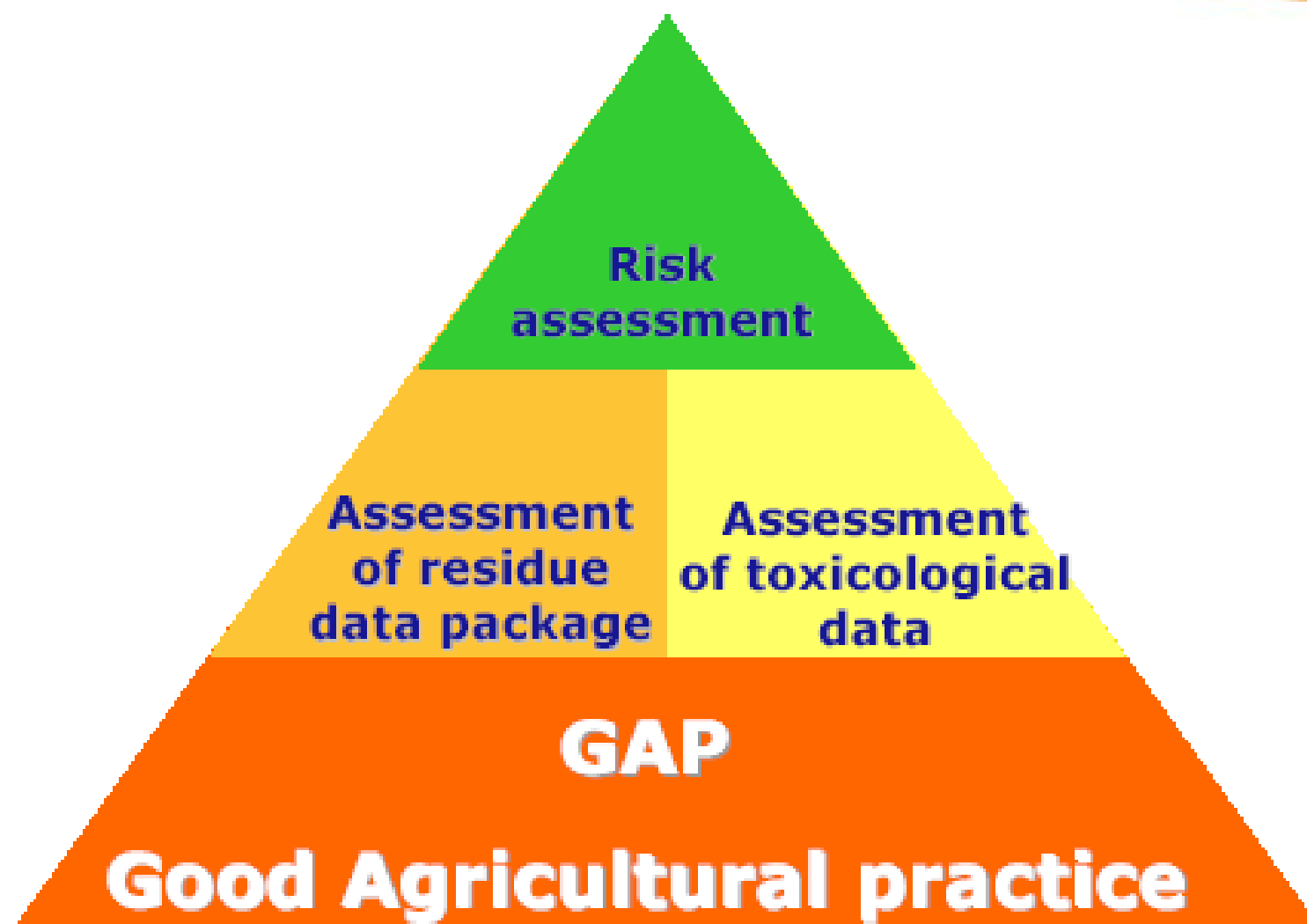
Bundesinstitut für Risikobewertung

Thielallee 88-92 • D-14195 Berlin

Tel. +49 30 84 12 33 77

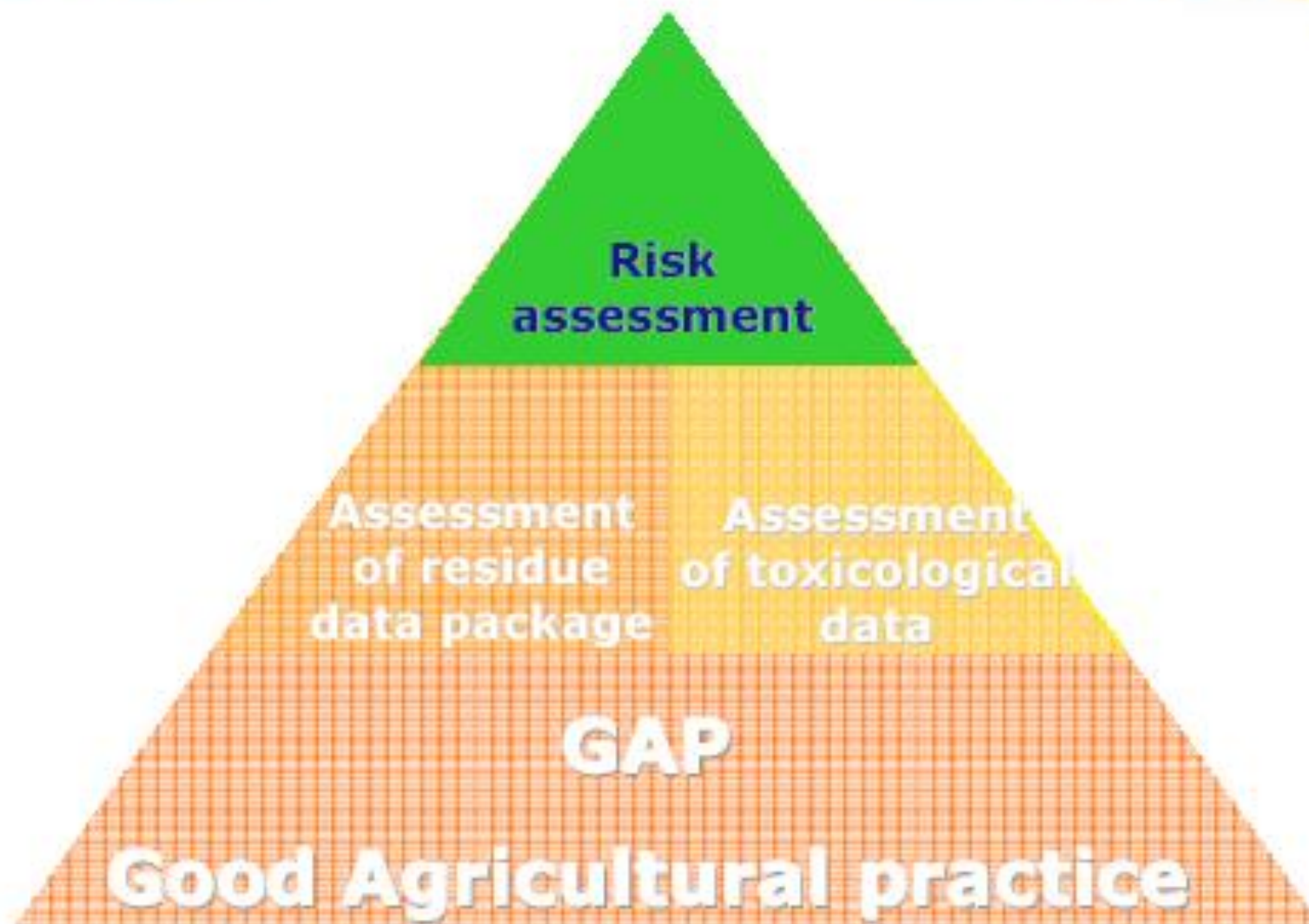
lutz.alder@bfr.bund.de

Standard MRL setting procedure



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Procedure for setting temporary MRLs



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Risk management decision



+ Member States

