

Developments on MRL's Harmonization and Food Monitoring in the EU

Experience from Greece

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Produce

- The production and consumption of plant and animal products play a very important role in the Community. The yield from plant production is continually being affected by harmful organisms.





Plant protection

It is essential to protect plants and plant products against such organisms in order to prevent a reduction in yield or damage to them, and ensure both the quality of the products harvested and high agricultural productivity. To this end, different methods are available, including use of plant protection products



Plant protection products

- Plant Protect Products **formulations have to be registered by each Member State** according to **91/414/EEC Directive** before entering the market
- **Their use is according to label which corresponds to GAP**

Plant Protection Products residues

- A possible consequence of the use of registered plant protection products according to the Good Agricultural Practice, may be the presence of residues of the parent substance or its metabolites may be detected in the treated commodity, residues that **have been evaluated and found to have no potential adverse effects** for the consumer.



Definitions: MRL

- According to Regulation 396/2005 '*maximum residue level*' (MRL) means the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers.



Maximum Residue Levels (MRLs)

- MRLs are often **mistaken for toxicological safety limits**.
- MRLs are safe limits that define the maximum expected levels of a pesticide on a food commodity after proper and authorized use of that pesticide.
- They serve both to prevent illegal and/or excessive use of a pesticide (e.g. to prevent damage to the environment or to the health of workers and bystanders) and to protect the health of consumers of the harvested products.



Maximum Residue Levels (MRLs)

- If an MRL is exceeded **it takes an additional assessment to establish whether the toxicological limit is exceeded**. MRLs must be and always are toxicologically acceptable.
- However, in many cases they are much lower than the toxicological limit simply because no more is necessary to achieve adequate control of the pest.

MRLs - what was the disharmony in the past?

- Member States had set own their national MRLs in absence of Community MRLs for all plant protection products
- National MRLs were in a lot of cases different from country to country.

TRADE BARRIER



Pesticide Residues MRLs setting

Until 1 September 2008 when legislation partially harmonised

National MRLs

- ± 850 pesticides
- No harmonised risk assessment for EU consumers
- Trade problems

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)

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



Regulation (EC) No 396/2005

*on maximum residue levels of pesticides in or on food of plant
an animal origin and amending Council directive 91/414/
EEC*

- The regulation establishes the maximum quantities of pesticide residues permitted in products of animal or plant origin that are intended for human consumption. These maximum residue levels (MRLs) include, on the one hand, MRLs that are specific to particular foodstuffs that are intended for human consumption and, on the other hand, a general limit that applies where no specific MRLs has been set.




Regulation (EC) No 396/2005

The maximum pesticide residue level in foodstuff “by default” is 0,01 mg/kg i.e. in all cases where no

MRL has not been set.

*(MRLs are set at the lower level of analytical determination where
authorised uses of plant protection products do not result in detectable
levels of pesticide residues and where uses of pesticides are not authorised
at Community level, in order to protect the consumer from the intake of
unauthorised or excessive levels of pesticides)*



Regulation (EC) No 396/2005

- **Annex I**
List of product groups including examples of products within the groups the regulation concerned.
- **Annex II**
List of Specific MRLs
- **Annex III**
List of provisional MRLs



Regulation (EC) No 396/2005

- **Annex IV**
List of active substances for which no MRL was considered necessary
- **Annex V**
Detection limit above 0,01 mg/kg
- **Annex VI**
specific factors concerning concentration and dilution of certain processed and/or composite products



Regulation (EC) No 396/2005


- **Setting, amending and removing MRLs** : The European Food Safety Authority (EFSA) is responsible for the risk evaluation. It makes a decision on each intended new MRL, amendment of removal.
- **Checking of MRLs**
Member States **carry out checks on pesticide residues** to ensure compliance with the MRLs. The Member States get the **possibility to publish the names** of **retailers, traders or producers**, concerning products where MRLs exceedance found.



Important clarification

- Regulation 396/2005 came into force September 1st 2008
- In foodstuffs where PPPs had been applied before 1st Sept 2008 e.g. in cases of olive oil, wine, grape leaves, etc. marketed today but produced prior to Sep 1st, 2008, according to article 49 of the regulation the regulation is not applied.





MRL exceedance: How to evaluate the acute risk to consumers?

- To evaluate whether an observed violation of an MRL can lead to a risk to the consumer, it is necessary to estimate the actual risk to the most critical consumer group. Therefore we should combine the toxicity (the hazard) and the exposure.
- ADI and ARfD are measures for the chronic and acute toxicity of a pesticide.
- The ADI is based on chronic or acute toxicity studies, the ARfD on acute studies only. These toxicological parameters are supposed to protect all consumer groups including infants and children.



Exposure

- Toxicity is not the only factor in determining the risk of a pesticide residue in food, it should be combined with the amount of the foodstuff that is expected to be consumed, resulting in the exposure.
- For the acute exposure a deterministic approach was developed. To see if eating such an apple would lead to a risk to a consumer, the model can best be applied to the most critically exposed consumer (e.g. children)

Greek legislation

According to the Greek legislation **no infringement** exists only if laboratory analysis shows that food of plant origin :

- **does not contain** PPP's residues or
- **contain residues of PPP's registered for use in the specific crop in a concentration not exceeding MRL value.**

The above simply means that only registered PPP's are used according to their label.



Food monitoring

- **Coordinated multiannual Community control programme**
- Multiannual **national control programme** for pesticide residues



Samples

- Samples are taken from imports and from the local market according to the monitoring program or after a claim
- Sampling does not distinguish among Globalgap certified, ICM, biological production or non certified products



Laboratories

- Samples are sent to 9 Official Residues Laboratories, ISO 17025 accredited.
- Results are sent to the sampling authority and the MRDF.
- Actions needed and sanctions in case of infringements are decided by the central authority and imposed by the local authorities.



Laboratory analysis

- Each positive laboratory finding (residue) is compared to the **EC MRL** database and checked also by the relevant regulations.
- Also it is checked if PPP's containing the specific substance are registered for **use in the crop** where it was detected.
- The value of residue used versus MRL is the concentration value detected **minus uncertainty**.
- If needed, even below MRL, a dietary risk evaluation is conducted.



Laboratory analysis



- In case of **MRL exceedance** always a dietary risk evaluation is conducted.
- Farmer, in case of local produced food, is **asked to justify** the presence of illegal residues.
- Residues statistics are recorded by the central authority.
- They are taken into account for the next year monitoring program and to advise farmers and official inspectors.



RASFF system

- The **Rapid Alert System for Food and Feed (RASFF)** was established by Council Directive 92/59/EEC on General Product Safety. In February 2002, new provisions entered into force as laid down in Regulation (EC) 178/2002 of the European Parliament and of the Council.

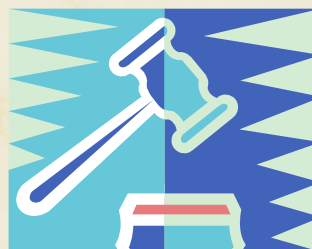


RASFF system

- Member States shall immediately notify the Commission under the Rapid Alert System whenever they have any information relating to the **existence of a serious direct or indirect risk to human health** deriving from food and feed and whenever they adopt measures to prevent the use of products entailing a serious risk to the health and safety of the consumer.
- Such notifications are classified as **ALERT notifications**.

Additional controls contributing to food safety monitoring

- Controls for counterfeit products
- Controls on PPP's guaranteed composition
- Controls on PPP's label
- Controls on PPP's sale
- On site farmer inspection




Sanctions results during last three years (2006-2008)

Illegal cases	2006	2007	2008
Illegal use of PPP's	36	49	65
Imports >MRL residues	0	2	1
Illegal sale of PPP's	9	20	22
Illegal PPP label	10	19	15
Illegal PPP composition	12	1	3
Not registered products	8	14	34
Other cases	8	6	5



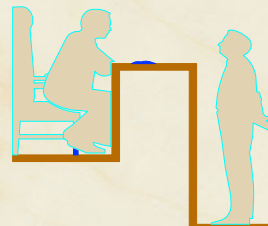
Do not forget...
New EC legislation

- Proposed **Regulation** of the European Parliament and of the Council concerning the **placing of plant protection products on the market.**
- Proposed **Directive** of the European Parliament and of the Council establishing a framework for Community action to achieve a **sustainable use of pesticides.**



GlobalGap and official controls

- Following the increase of GlobalGap certified farmers and farmer groups, it is not rare to find illegal residues. Farmers **use the GlobalGap certificate** to defend themselves and prove that they are not guilty of illegal use of plant protection products.




Real example



- Laboratory analysis in a strawberry sample taken by the Central Market, showed residues of two PPPs, not permitted in strawberry cultivation.
- Copies of invoices proved that a substantial quantity of strawberries were sold by the farmer (10,400 boxes of 1 kg) to the Central Market.
- The farmer insists that he did not use the PPPs. He copied and submitted the GlobalGap certificate and he is questioning the origin of the sample without providing any justification.

Questions

1. If the aim was to sell to the Central Market, why is there a GlobalGap certificate?
2. Is certificate enough to prove no illegal use?
3. Is CB informed by the farmer?




How can private and public service cooperate aiming food safety?

- **Is it possible GLOBALGAP to inform official authorities about at least MRL exceedances?**

These cases may show that a product, not allowed to be marketed, is marketed and a dietary risk evaluation has to be conducted.

Producer who did the illegal actions should have a effective, proportionate and dissuasive sanction in order to prevent new law violations.



How can private and public service cooperate aiming food safety

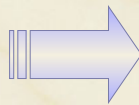
- **Is it possible official authorities to inform GLOBALGAP about MRL exceedances?**

Yes, every citizen or organization, even if he is not an interested party, has the right to be informed about official decisions, such as decisions for penalties after notification of interest.

Producer who use as an excuse the GlobalGap certification to defend from official sanctions should know that they will search his own data.



Aiming food safety from farm to fork...



Thank you!

