

Monitoring and **MoniQA** Quality Assurance

The Strong vs. Weak Regulatory Logic for Official Controls targeting Dioxins and dl-PCBs

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Cracow, 8nd June 2010*

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SIXTH FRAMEWORK PROGRAMME



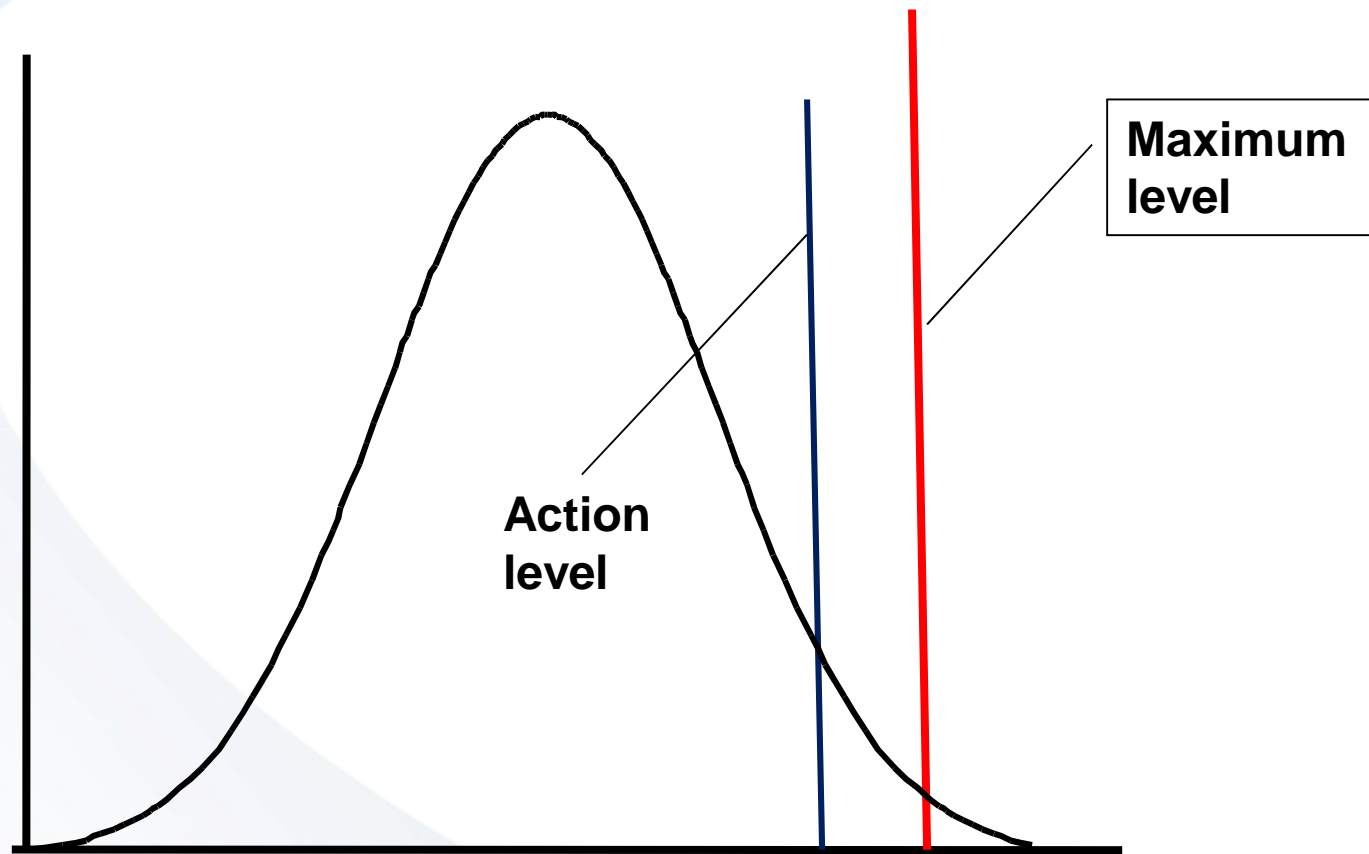
Regulatory Framework

- 2001 Commission Strategy on dioxins
- Regulation 1881/2006 on **maximum levels**
- Regulation 882/2004 on **official controls**
- Regulation 1883/2006 on **methods of sampling and analysis**
- *Recommendation* 2006/88/EC on **action levels** and announcement for setting of **target levels** in 2009
- *Recommendation* 2006/794/EC on **monitoring**

Regulatory Framework

- Logic of present regulatory framework:
 - Food of animal origin is the ‘predominant source of human exposure to dioxin and PCBs’; yet it will not be enough to define maximum levels unless the levels are set so low that a large part of the feed and food supply would be declared unfit for consumption’ (2001 Strategy, article 6.2)
 - Therefore...
 - Not so low ‘maximum levels’ (applicable to market) (Reg. 1881/2006)
 - Under the condition that Member States use stricter (lower) ‘action levels’ as part of their official controls or monitoring programmes (Reg. 882/2004 & Rec. 2006/88)
 - In parallel ...
 - New research (FP), improvement of guidance on analytical methods (Reg. 1883/2006) and monitoring of exposures (Rec. 2006/794)

Maximum vs. Action



So?

- EU has a very comprehensive system
- IN THEORY (*Regulatory framework*)
 - But
- What about IN PRACTICE? (*Implementation*)

Identifying the problem

- Empirical evidence suggests that not all Member States are in compliance with regulatory requirements
 - Expert interviews with public officials in MS
 - Austria, Sweden, UK, Germany, Ireland, Netherlands
 - Scope and quantity of dioxin testing in the framework of official controls for food & feed
 - Scope and quantity of dioxin testing in the framework of studies or monitoring
 - CRL Working Report 2009 on capacity of OFL and NRL on dioxin testing
 - EFSA Report 2010 Results on monitoring

Official controls vs. monitoring

- Official controls are controls performed by authorities to verify *compliance of enterprises* with food law
 - Enterprises to be controlled regularly and to be selected taking into account risks, past record, reliability of tests
- Monitoring delineates 'planned sequence of observations or measurements with a view of obtaining an overview of *state of compliance* with food law
- **Difference is small but significant**
- These are two different testing programmes governed by different statistical research designs

Official controls vs. monitoring

- Austria (*Source: AGES*)
 - Official controls for food guided by RASFF and target imports rather than enterprises
 - For instance, in 2008: 12 Indian imports of guar gum; 6 imports of Italian mozzarella and 14 imports of Irish pork
 - Official controls for feed more extensive – target feed producers
 - For instance 93 'samples' in 2008 as compared to 32 for food
 - Austria: monitoring targets according to EC recommendation and based on market samples (43 food, 50 feed)
 - Confirmatory method for all tests, € 800 / sample

Official controls vs. monitoring

- Sweden (*Source: NFA*)
 - **Official control** plan – stratification by region and past record of enterprises: fish checked throughout food chain; meat, milk and eggs at operator level and supermarkets
 - Checks carried out by Eurofins in Germany using UESPA method for feed and confirmatory methods for food.
 - Actions determined according to max levels (not action levels)
 - No separate **monitoring** plan

Official controls vs. monitoring

- Netherlands (*Source: Food Safety Authority*)
 - Few official controls
 - Systematic monitoring targeting feed and food
 - 300-400 samples for food; equal number for feed
 - Screening methods applied
 - Confirmatory methods only for suspected samples

Official controls vs. monitoring

- Germany (*Source: BVL*)
 - **Monitoring** targeting food at federal level
 - Dioxins are not part of the market-based monitoring programme, only of the project monitoring programme, i.e. they target specific foodstuffs (milk or sheep liver or vegetables)
 - Monitoring (market-based) according to EU recommendation (till 2009)
 - Data fed into Dioxin database (includes 8,569 samples cumulatively)
 - **Official controls** responsibility of Länder
 - Variation in approach and implementation.

CRL Survey 2009

- Capacity at 18,000 food samples (yearly) + 14,000 feed ... But
 - Some countries do a lot of tests, several only few
 - In several countries only NRLs able to carry out confirmatory tests
 - Official laboratories lack equipment and/or trained personnel
 - Unclear whether sampling / testing guidelines (Reg. 1883/2006) are followed
 - Preliminary results about validity and reliability of tests confirmed by EFSA in 2010

EFSA Report 2010

- Received 26,600 samples for 1999-2008 from 19 MS (+2)
- Around half concerned non-dl-like PCBs
- Of the 13,854 samples relevant for dioxin-testing only 7,270 could be retained for analysis
 - Austria, Denmark, Iceland, Ireland, Norway, Sweden, UK had **good quality** data
 - Germany, Belgium, Czech R., Finland, Slovenia, Spain had average quality
 - France, Netherlands, Greece, Cyprus, Poland had **poor quality**
 - **Worst situation** in Italy & Romania
 - Very few samples for Luxembourg, Estonia, Lithuania
- Problems: missing data, inconsistent data
- Final dataset still not representative

What does all this tell us?

- Tests give reasonable 'overall' results which suggest that exposure is within limits
- But: validity is questionable in view of
 - Lack of uniformity in interpretation and implementation of legislation
 - Lack of representativity
 - Extreme variation in quality of data provided
- **There is need for regulatory reform**

Four policy issues

- Lack or variation in compliance with regulatory framework
- Choice of analytical method
- Availability of trained personnel and necessary equipment
- Monitoring programme

Problem of compliance

- Existing situation means that MS are in breach of EU law
- This has legal implications for both MS and Commission
- Policy options
 1. Enforcing existing regulatory framework
 - Better audits of MS through FVO
 - Raising awareness campaign targeting MS officials
 - Assisting MS with upgrading of infrastructure
 2. Changing (downgrading) regulatory framework

Choice of analytical method

- Existing regulations allow for use of screening methods for establishing likelihood of risk
- Screening methods are cheaper (~ € 250) but unreliable; Confirmatory methods are expensive (~ € 800) but reliable
- **Policy options**
 - 1. Make confirmatory methods mandatory
 - 2. Validate screening methods and provide better guidelines as to their use

Training & equipment

- **At present, only 7 MS have official laboratories for dioxin testing. All others rely on NRLs or private laboratories**
- **Capacity might not suffice if compliance were to improve**
- **Policy options**
 - 1. Upgrade capacity of official laboratories through equipment and training
 - 2. Rely more on private sector and/or NRLs or OFLs of other countries

Monitoring Programme

- **Currently no monitoring programme at EU level. When it did exist, responsibility was assigned to MS through recommendations – but with no controls as to correct implementation**
- **Policy options**
 - 1. New Recommendation on Monitoring (by MS) with better auditing mechanisms
 - 2. Remodel monitoring to take place at EU level – MS collect samples but testing done centrally to ensure high data quality

Interrelations

- Clearly all four issues are interrelated
 - Correct implementation depends on MS technical capacities and choice of analytical methods
 - A question of costs:
 - Compliance with EU regulation will necessitate upgrading of capacities at national level in terms of both equipment and personnel in at least 20 MS with one-time investment costs of 10-15 million. Operational costs will also increase
 - Monitoring programme is in comparison much cheaper to implement (2 million per year)

Conclusions

- Assuming dioxins represent a public health risk ...
 - Official control capacity at MS level needs to be upgraded
- In the meantime ...
 - Need more monitoring to determine levels of exposure
- Maintaining status quo (comprehensive regulatory framework and ineffective implementation) is not tenable
- Transition from 'weak' to 'strong' model of implementation entails high transaction costs but cumulative emergency costs are potentially higher

Thank you for your attention!