

Acceptance of alternative toxicological methods in the Croatian legislative framework

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Authorization for placing on the market in Croatia

- Plant protection products
- Biocides (public health pesticides, Pt 14 & 18)
- Consumer products/cosmetics
- Industrial chemicals
- Pharmaceuticals

Basic legislation before harmonization with the EU *Acquis*

- Toxic substances act (OJ 27/1999)
 - Toxic substances list (OJ 30/2005)
 - Classification and labeling regulation (OJ 47/1999)

Characteristics of the “old” authorization process

- Focused primarily on health safety issues - under the responsibility of the Ministry of Health
- Evaluations performed by independent experts from several scientific/academic institutions, final decisions made by the expert committee
- Authorization or marketing restrictions based on hazard evaluation
- Only data requirements provisions in the secondary legislation

Problems with the “old” authorization process

- No list of approved testing methods
- No GLP requirements
- Inconsistency in decision making
- Responsibility for evaluation of studies and acceptance of data obtained with different testing methods dependent on the opinion of the individual expert/members of the registration committee
- Some data requirement provisions not flexible enough to allow use of modern or alternative methods

Consequences of the “old” authorization process

- Mandatory animal testing of acute toxicity/irritancy for all PPP and biocidal products (but no repetition of testing!)
- Acceptance of data from non-GLP laboratories
- Reluctance to replace LD50 test by fixed dose/toxicity class/up and down methods
- LLNA test readily accepted !
- C&L based on hazard assessment of the individual components allowed for industrial chemicals and consumer products only
- No animal testing for cosmetics

Transposition/implementation of the EU chemical safety legislation

- PPP Directive 91/414 fully transposed, new authorization process in force January 2008.
- Biocidal Products Directive 98/8 transposed but not implemented, national authorization system still in place
- Dangerous Chemicals/Products Directives transposed (including Annex V)

Problems of harmonizing with EU chemical safety legislation /implementation of new regulatory system in Croatia

- Human resources
- Education of experts and regulatory staff
- New EU Regulations? REACH?
- Limited access/involvement in the work of EU regulatory bodies