



# Flexibility in the Hygiene Package

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# Regulation (EC) No 178/2002 Food law

Competent authorities

Food business operators

**Regulation (EC)  
No 882/2004**  
General rules  
for official controls

**Regulation (EC)  
No 854/2004**  
Specific rules for official controls  
on products of animal origin

**Regulation (EC)  
No 852/2004**  
General rules  
on hygiene

**Regulation (EC)  
No 853/2004**  
Specific hygiene rules  
for products of animal origin



# Community provisions on flexibility

## Guiding principles

- Subsidiarity: Member States are best placed to find solutions to local situations
- Transparency: draft national measures must be notified to the Commission and to the other Member States



## Opportunities in 'Hygiene Package'

- Exclusions from the scope of the Hygiene Package (HP)
- Derogations / exemptions from certain requirements in the Annexes to the Hygiene Package
- Adaptations of certain requirements in the Annexes to the Hygiene Package



## Examples for exclusions

- Direct supply, by the primary producer, of small quantities of primary products to the final consumer and to local retail establishments directly supplying the final consumer i.e.
- Small quantity of honey sold at farm level of in a local market
- Small quantity of raw milk sold at farm level of in a local market;
- The harvesting of berries and mushrooms in the wild and their transport to the local market
- Private domestic consumption;



## Examples for derogation/exemptions from the Annexes

Watch out for phrases such as:

- If the competent authority so permits
- With authorisation of the competent authority
- Unless otherwise authorised by the competent authority

Example:

- Separate place for cleaning, washing and disinfecting means of transport



## Examples of adaptations

- The continued use of traditional **methods** of production;
- Needs of food businesses in regions subject to special geographical constraints;
- Adaptation of the requirements on the construction, layout and equipment of establishments;



## Background to mission series on flexibility

- Complaints that Hygiene package introduced too stringent rules
- In particular for 'small establishments' previously approved for the national market
- Six fact-finding missions to volunteering Member States (MS)
  - **CZECH REPUBLIC (2009-8361)**
  - **AUSTRIA (2010-8490)**
  - **FINLAND (2010-8492)**
  - **GERMANY (2010-8499)**
  - **SPAIN (2010-8485)**
  - **UNITED KINGDOM (2010-8491)**





## Conclusions from mission series

- Application of flexibility varies from MS to MS and within MS
- Notification not applied correctly
- Flexibility pragmatic, not leading to risk for consumers
- The MS are the best placed to apply and verify the flexibility arrangements



## Overview Report - Recommendations

1. MS should introduce flexibility measures more widely and to encourage their implementation.
2. MS should notify national measures as required.
3. MS should provide guidance to all levels of the competent authorities, in particular the CA in charge of approval and supervision of establishments.
4. MS should document in the establishment approval file or in official documents the flexibility granted to individual establishments.
5. MS should ensure that the objectives of the Hygiene Regulations are achieved despite implementation of flexibility measures



## Useful links

- Overview report 'flexibility small establishments'  
[http://ec.europa.eu/food/fvo/specialreports/index\\_en.htm](http://ec.europa.eu/food/fvo/specialreports/index_en.htm)
- Document for FBOs regarding flexibility and FAQ  
[http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/faq\\_all\\_business\\_en.pdf](http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/faq_all_business_en.pdf)
- Document for CA regarding flexibility and FAQ  
[http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/faq\\_all\\_public\\_en.pdf](http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/faq_all_public_en.pdf)