Commission notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses

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Plenary meeting of the Advisory Group on the Food Chain and Animal and Plant Health

29 April 2016

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= Review of the 2005 Guidance document on the implementation of procedures based on the HACCP principles, and facilitation of the implementation of HACCP principles in certain food business

http://ec.europa.eu/food/safety/docs/biosafety_food-hygiene_legis_guidance_haccp_en.pdf

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Why a revision?

- *Outcome of a number of fact finding missions and questionnaire by former FVO:*
  - **Need to better explain de link between PRPs and procedures based on HACCP principles within a food safety management system**
  - **More harmonised implementation of PRPs**
  - **More harmonised implementation of HACCP principles**
  - **Need to clarify the flexibility on PRPs and HACCP in certain establishments**

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New structure

Current guidance:

- *Short introductory part on HACCP*
- *Annex I: HACCP and its application*
- *Annex II: Facilitation of implementation of HACCP in certain FBO*

New guidance:

- *More extended introduction part on FSMS*
- *Annex I: PRPs*
- *Annex II: HACCP and its application*
- *Annex III: Flexibility as regards FSMS, PRPs and HACCP*
- *Appendix 1: Glossary*
- *Appendix 2: Risk analysis procedure for hazard analysis*
- *Appendix 3: Decision trees*
- *Appendix 4: Comparison PRP, oPRP, CCP*
- *Appendix 5: Summary of flexibility*

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New approach

Current guidance:

- *Developed with experts of MS and in consultation with EU private stakeholders' organisations*
- *No formal status*
- *Guidelines (not binding)*
- *Published on SANTE website*
- *Available in all official languages*
- *Endorsement by SCOPAFF meeting*

New guidance:

- *Developed with experts of MS and in consultation with EU private stakeholders' organisations*
- *Formal status: Commission Notice*
- *Guidelines (not binding)*
- *Published in Official Journal, link from SANTE website*
- *Available in all official languages*
- *Adoption by the Commission*
- *More examples*

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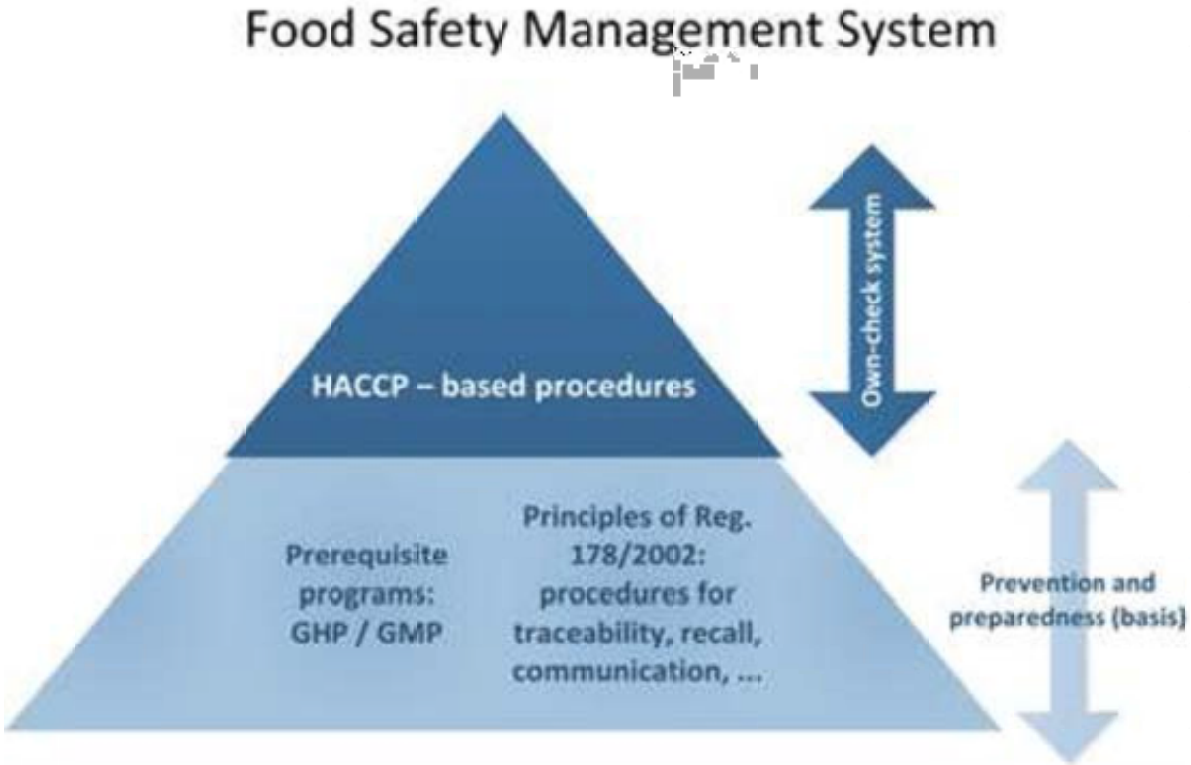
Main doc.: The link between PRPs and HACCP



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Main doc.: The link between PRPs and HACCP

- *A number of PRPs must always be in place*
- *A hazard analysis (HACCP principle 1) is always required (company specific or generic)*
  - **Identification of most relevant hazards**
  - **What control measures apply?**

- *If all hazards can be controlled by PRPs, no need to further elaborate HACCP*
- *If not, need for CCP and full HACCP*

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Main doc.: Other issues

- *Introduction of flexibility*
- *Guides to Good Hygiene Practice*
- *Relation with international standards*
- *Training*

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Annex I (PRP): Legislation based on Article 4 of Reg (EC) No 852/2004

- *Annex I of Reg. (EC) No 852/2004: PRPs at primary production and associated operations*
- *Annex II of Reg. (EC) No 852/2004: PRPs at later stages of the production chain*
- *Annex III of Reg (EC) No 853/2004: specific PRPs for food of animal origin.*

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Annex I: Examples of PRPs

- *Infrastructure*
- *Cleaning and disinfection*
- *Pest control*
- *Technical maintenance and calibration*
- *Environmental contamination*
- *Allergens*
- *Waste management*
- *Water and air control*
- *Personnel*
- *Raw material (supply)*
- *Temperature control*
- *Working methodology*

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Annex II: HACCP

- *Introduction: reference to Article 5 of Reg. (EC) No 852/2004*
- *General principles*
- *Preliminary activities*
- *Hazard analysis (Principle 1, P1)*
  - **Listing of relevant hazards: use of evaluation tool (Appendix 2)**
  - **Identification of control measures: PRPs and, if needed, CCPs**

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Annex II: HACCP

- *Identification of CCPs (P2): 2 examples of decision trees: Appendix 3, concept of operational PRPs*
- *Critical limits at CCPs (P3)*
- *Monitoring procedures at CCPs (P4)*
- *Corrective actions (P5)*
- *Verification procedures (P6)*
  - **Differentiation monitoring, verification and validation, with examples**
- *Documentation and record keeping (P7)*
- *Link with EU or national limits (e.g. microbiological criteria)*

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Annex III: Flexibility (1)

- *Within FSMS*
  - **Size and nature of the establishment**
  - **An integrated approach with the hazard analysis as central element**
  - **Overview in Appendix 5**
- *In the implementation of PRPs*
  - **Primary production**
  - **Exclusions from scope (e.g. retail from R 853/2004)**
  - **Adaptations under national law**
  - **Concrete examples on entrance control, water control, cleaning and disinfection**

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Annex III Flexibility: implementation of HACCP

- *Background*
- *Generic guides*
- *Examples of application of flexibility in*
  - **Preliminary activities**
  - **Hazard analysis and identification of CCPs**
  - **Critical limits**
  - **Monitoring procedures**
  - **Validation and verification procedures**
  - **Documents and records**

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Appendix 1: Glossary

Appendix 2: Example of hazard analysis approach

PROBABILITY					
High	4	4	5	6	7
Real	3	3	4	5	6
Small	2	2	3	4	5
Very small	1	1	2	3	4
		1 Limited	2 Moderate	3 Serious	4 Very serious
		EFFECT			

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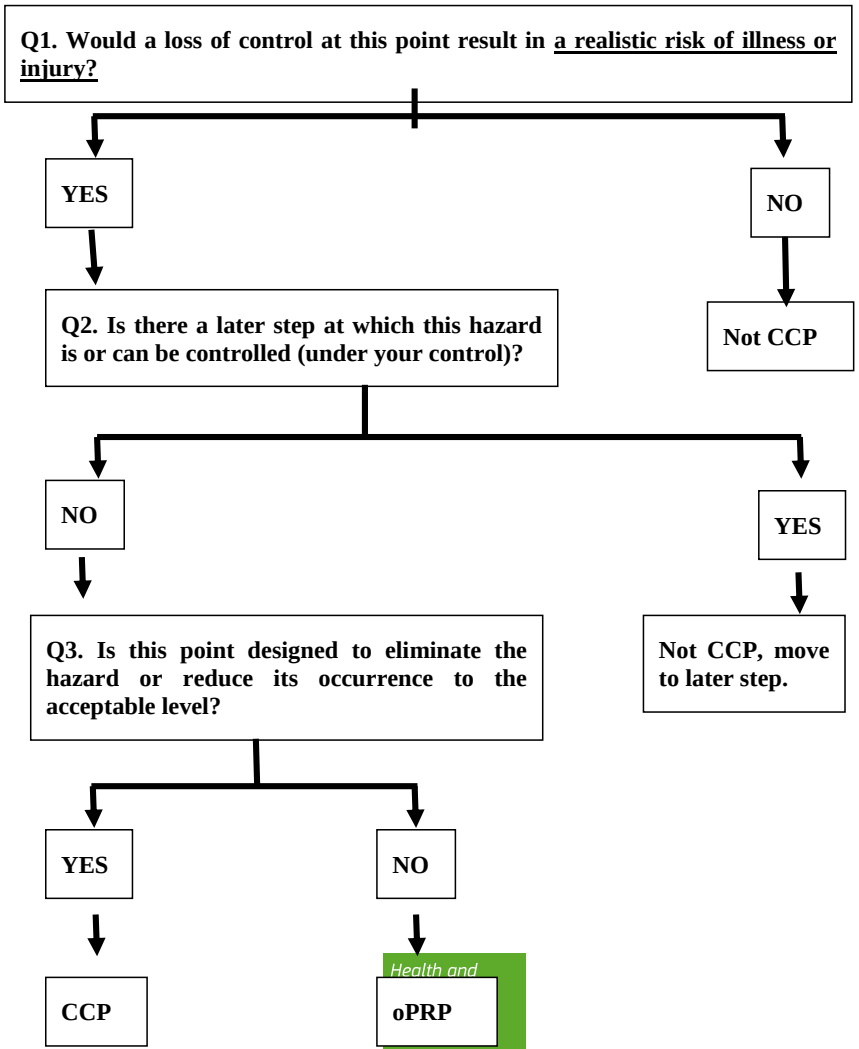
Appendix 3: Examples of decision trees



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Appendix 4: Comparison PRPs-oPRPs-CCP

Type of Control measure	PRP	OPRP	CCP
Scope	**Measures related to creating the environment for safe food**: measures impacting food suitability and safety	Measures related to the environment and/or product (or combination of measures) to **prevent the contamination, or to prevent eliminate or reduce hazards to an acceptable limit in the end product.** These measures are implemented after the implementation of PRP.	
Relation to hazards	Not specific to any hazard	Specific to each hazard or group of hazards	
Determination	Preliminary development based on: ✓ Experience, ✓ Reference documents *(guides, scientific publications,…)*, ✓ Hazard or hazard analysis.	Based on the hazard analysis taking PRPs into account. CCPs and OPRPs are product and/or process specific	
Validation	Not necessarily carried out by FBO. *(ie: cleaning products manufacturer has validated the efficiency of the product and determined product spectrum and instructions of use – FBO has to follow instructions ans keep technical specifications of product)*	Validation has to be carried out *(in many cases, guides to good pratice provide guidance on a validation methodology or gives ready to use validation material)*	
Criteria	/	Measurable or observable criteria	Measurable critical limit
Monitoring	Where relevant and feasible	Monitoring of the implementation of control measures: usually recorded	
Loss of control: Corrections/corrective actions[1]	Corrective actions and/or corrections on the implementation of PRP where relevant	Corrective actions on the process Possible corrections on the product (case by case) Records kept	Pre-set corrections on the product Possible corrective actions on the process Records kept
Verification	Scheduled verification of implementation	Scheduled verification of implementation, verification of achivement of planned hazard control	

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Appendix 5: Summary of flexibility

Flexibility as regards:

- **PRPs**
- **Preliminary HACCP activities**
- **Hazard analysis and CCP identification**

CCP identified

No CCP identified

Flexibility as regards:

- **Critical limits**
- **Monitoring procedure**
- **Documents and records**
- **Verification and validation**

Low risks: No need for further elaboration HACCP

Intermediate risk: consider oPRP

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Next steps on this Commission notice:

- *Translation in all official languages*
- *Publication in the Official Journal C*
- *Publication on or link from SANTE website, replacing the current guidance document*
- *Not binding, guidance only*

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Other initiatives: The webplatform on FSMS

- *See document uploaded in CIRCABC*
- *Final comments to kris.de-smet@ec.europa.eu by end of the month*
- *Publication on SANTE website*
- *Updates following requests/input of Member States remain posible*

Other initiatives: EFSA mandate on hazard analysis approaches for certain retail establishments in view of the application of their FSMS

Starting from generic flow diagrams with processing steps for respectively a butcher shop, a grocery, a bakery, a fishery shop and an ice cream shop, EFSA is requested:

- *(1) To formulate guidelines on how to identify the most relevant biological hazards and if relevant chemical, including allergens and physical at each step in the enterprises;*
- *(2) To provide guidance on methodology for hazard ranking (within HACCP) and select most appropriate method(s) for each type of the selected retail activities;*
- *(3) To provide guidance on how to select, implement and validate the most efficient approaches to control hazards (considering CCP, PRPs, critical limits and monitoring system);*
- *(4) Using the guidance developed in TOR 1, 2 and 3, to identify and rank the hazards in each of the five retail establishments and to describe appropriate control activities for the hazards identified including PRPs, CPs and CCPs and, where required, indicate critical limits and monitoring systems.*

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EFSA mandate on hazard analysis approaches for certain retail establishments in view of the application of their FSMS

- *When carrying out the analysis and making recommendations, EFSA should consider that mostly these small retailers are limited with regards to knowledge and resources. EFSA should take into account proportionality to the nature and size of the enterprise as laid down in Regulation (EC) No 852/2004.*
- *Deadline for opinion: end of 2016*
- *Similar mandates might be considered in future for other businesses*

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Thank you for your attention!

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