

FOOD
MICRO
SYSTEMS

REPORT ON THE EU REGULATORY SITUATION OF MICROSYSTEMS IN THE FOOD SECTOR

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FoodMicroSystems aims at initiating the implementation of microsystems & smart miniaturised systems in the food sector by improving cooperation between suppliers and users of microsystems for food/beverage quality and safety.

The project runs from September 2011 to November 2013, it involves nine partners and is coordinated by ACTIA (Association de Coordination Technique pour l'Industrie Agro Alimentaire, France). More information on the project can be found at <http://www.foodmicrosystems.eu>.

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1. Abbreviations

BfR	German Federal Institute for Risk Assessment
BMELV	Federal Ministry of Food, Agriculture and Consumer Protection
BVL	German Federal Office for Consumer Protection and Food Safety
EFSA	European Food Safety Authority
EU	European Union
FVO	Food and Veterinary Office
GDP	Gross domestic product
HACCP	Hazard Analysis and Critical Control Points

2. Executive summary: key findings from the report

1. There is no specific national specific regulation related to microsystem, the implementation of microsystem in the food sector is regulated by several EU regulations.
2. The most relevant regulations in regard to microsystems implementation in the food sector is the legislation on food contact materials (EC regulation no. 1935/2004 and 2023/2006, plus the legislation on specific materials). This regulation applies to microsystems directly in contact with food: for example in the case of a polymer-packaged sensor used for in-line monitoring of processes, the system has to comply with the regulation on plastic materials, which means that the components and additives of the polymer should be authorised and migrations limits of the material should be respected.
3. Another relevant regulation is the no. 450/2009 on active and intelligent materials and articles intended to come into contact with food. This regulation applies when the use of microsystems is intended in packaging. In that case of intelligent packaging application, a dossier for safety evaluation will have to be submitted to EFSA to comply with the regulation 450/2009.
4. In some specific cases, the regulation on Novel Foods 258/97 may apply: in the specific case of microdevices that enable new product and/or process innovation (for example micro-emulsification devices), the product will need to be evaluated by EFSA.
5. To conclude, microsystems should be evaluated case by case according to the nature of the microsystem materials in contact with food and their intended use. Other aspects such as end of life and waste management of microsystems may also have to be taken into account.

3. Introduction

The aim of this report is to describe the regulatory context on the utilisation of smart systems in the food sector at the European level. Because of the high emotional value of food related aspects, individual governments are in the process of setting up legislation to regulate the introduction and use of microtechnologies in various applications. Therefore there is a need to analyze and summarize the present regulation and to show expected developments in the close future.

4. Regulatory situation of smart systems in the food sector in EU

4.1 Overview

In EU, there are three regulation approaches to be considered:

- Mandatory regulations (i.e. food law);
- Standards required by independent organisations (e.g. DIN/ISO)
- Good food practices given by specific industry stakeholders

Guides to good practices are written according to the arrangements defined in the European regulation N°852/2004. Concerning the guides written according to the European directive CE/93/43¹, they remain appropriate as soon as they are compatible with the objectives set out in the new regulation.

- Microsystems manufacturers should contribute to the renewal of these guides².
- The guides are transmitted for approval to the National Agency in charge of food safety
- Non-member States must be sure that the guides respect the CE rules N°852/2004 and that their content could be applied to the field they are targeting.
- In the following summary, examples of reference standards resulting from the cooperation with another European country (e.g. Germany or United Kingdom) will be given.

In each EU country, Committees of Accreditation were created and nominated as unique national instances of accreditation, which are the recognition of the accreditation as an activity of the public authorities. They are also managing the Inter-Laboratories (national or international) Accreditation Comparison³.

Most of the recommendations highlight the topic of cleaning in the food chains, which could decrease the interest of the microsystems implementation in the domain. Indeed, even if a sensor is miniaturised, if its connection system is rather big it will not fit the good food practices requirements in terms of cleaning (perfect cleaning in all circumstances).

In a food packaging, even if a microsystem is placed on the face which is not in contact with the food, it could still present a risk because of the migration effect. It is at the expense of the industrial to prove that it is not true.

1 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/Directives/dir_93-43c.pdf

2 Le meilleur exemple provient des industriels de la filière papier-carton pour contact alimentaire : en l'absence et dans l'attente d'une réglementation spécifique complète, ces industriels réunis dans l'Association Club MCAS (Matériaux pour Contact Alimentaire et Santé), ont élaboré ce guide de bonnes pratiques de fabrication, avec la collaboration du CNERNA pour sa validation . Constituant un document transitoire jusqu'à la sortie d'un texte européen, il est destiné à améliorer la position des industriels papetiers français par rapports à leurs concurrents étrangers bénéficiant à ce jour d'une législation plus opérationnelle.

3 www.ilac.org/documents/ILAC_PT_Brochure.pdf

The European regulation N°852/2004⁴ (and its corrective text⁵) of the European Parliament and Council of the 29th of April, 2004, concerning the hygiene of food product is based on the provisions of the directive 93/43/CE. It prescribes the elaboration of guides of good practices, designed for the professionals of the food sector, which will be evolutive documents for the voluntary application of the regulation concerning hygiene of food products.

- Today it only concerns food packaging manufacturers;
- Tomorrow it will also concern the manufacturers of microsystems integrated or used in every steps of a transformed food.

The protocol of validation and revision of the guides and for the application of the HACCP principles (Hazard Analysis Critical Control Point)⁶ was published on the 27th of May, 2005.

The European regulation N°178/2002 consolidated⁷ of the European Parliament and Council, which establishes the general principles of the food legislation and institutes the European Food Safety Authority is mandatory in its entirety and directly applicable in all the member States.

- The consolidated version includes:
 - The basic regulation CE n°178/2002⁸
 - The regulation CE n°1642/2003⁹
 - The regulation CE n°575/2006¹⁰
- It must be applied to all the steps of the production, from the transformation and the distribution of the feed to the final food product. It sets procedures concerning all the points, which could have a direct or indirect impact on the safety of the food and the feed. It institutes the European Food Safety Authority.

4 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/Reglements_anglais/reg2004-852ang.pdf

5 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/Reglements_anglais/reg2004-852rectang.pdf

6 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/autres/protocoleGBP.pdf

7 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/Directives/reg2002-178c.pdf

8 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/Directives/reg2002-178b.pdf

9 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/Directives/reg2003-1642.pdf

10 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/Directives/reg2006-575.pdf

4.1.1 Historical evolution

- The complexity of the standards generated a need of normalization, with a progressive switchover from multiple European directives to synthetic European regulations. This juridical and regulatory change resulted in:
- The Food Law in 2002
- The application of the regulation of 2004/2005 which are the basis of the HACCP protocol and of the traceability
- The creation of EFSA (European Food Safety Authority)
- The DG-Sanco (Directorate General for Health and Consumer Protection) delivers the authorizations at the European level with the agreement of the Standing Committee on the Food Chain and Animal Health, when the opinion of the EFSA is favourable.

4.1.2 Codex Alimentarius¹¹ – Recommended international code of practice

General principles of Food Hygiene CAC / RCP 1-1969, Rev.. 4 (2003) represents the reference text on HACCP (Hazard Analysis Critical Control Point). The text contains:

- Formal definitions of the Codex Alimentarius for hygiene.
- In Annex 1 (System Hazard Analysis - Critical Control and guidelines for its application) are the 7 principles and 12 steps of the HACCP method.

This guide covers the packaging which is part of the food chain but, of course, can not itself be considered as a food product.

4.1.3 Hygiene Package

Hygiene Package is a set of five EU documents (base of European legislation on food from the regulatory reform made on the basis of the Commission White Paper of 12 January 2000). Texts are supplemented by Regulation 882/2004 April 29, 2004.

This package contains the following:

- EC Regulation N° 852/2004 of 29 April 2004 on the hygiene of foodstuffs.
- EC Regulation N° 853/2004 of 29 April 2004 laying down specific hygiene rules for food with an animal origin.
- EC Regulation N° 854/2004 of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.

¹¹ <http://www.codexalimentarius.org/>

- Directive 2002/99 of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin intended for human consumption.
- Directive 2004/61 of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Directives 89 / 662 EEC and 92/118 EEC and Council Decision 95/408 of the Council.

4.1.4 Microbiological Criteria (preliminary to application of new hygiene rule)

- Foodstuffs of animal and plant origin may present intrinsic hazards, due to microbiological contamination. Microbiological criteria are tools that can be used to assess the safety and quality of foods. However, microbiological testing of finished food products done alone is insufficient to guarantee the safety of a foodstuff tested due to reasons related to sampling, methodology and uneven distribution of microorganisms. The safety of the foodstuffs must principally be ensured by a more preventative approach, such as product and process design and by the application of Good Hygiene and Manufacturing Practices (GHP, GMP) and of the Hazard Analysis Critical Control Point (HACCP) principles.
- On 22 May 2011 Germany informed the Commission about a significant increase in the number of patients with hemolytic uremic syndrome (HUS) and bloody diarrhea caused by enterohemorrhagic Escherichia coli (EHEC). Investigations concluded that a Shiga toxin-producing Escherichia coli bacteria was responsible for this outbreak.

4.1.5 New hygiene rule: future field of development for microsystems?

Set of implementing measures and transitional arrangements adopted on 5 December 2005:

- (EC) No 2073/2005¹² sets down microbiological criteria for foodstuffs
- (EC) No 2074/2005 contains a set of implementing measures such as provisions concerning food chain information, recognised testing methods for detecting marine biotoxins (...)
- (EC) No 2075/2005 requires the examination for the presence of Trichinella parasite (...) a region can be officially recognised as a region where the risk in domestic swine is negligible
- (EC) No 2076/2005 lays down some transitional arrangements until 31 December 2009 (...)

¹² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R2073:EN:NOT>

4.2 Main principles of EU food legislation

The following main principles of EU food legislation are applied:

- The food chain principle
- The producers' responsibility principle
- The traceability principle
- Independent scientific risk assessment
- Separation of risk assessment and risk management
- The precautionary principle
- Transparent risk communication

4.2.1 The food chain principle

All actions and measures to assure food safety have to be performed along the complete food chain as faults occurring on a single step can have impacts on the whole chain.

This principle was implemented by the combination of the food and feed legislation into a combined Food and Feed Code (LFGB). So a homogeneous system of regulations was enabled which allows the control of food and feed from 'farm to fork'.

4.2.2 The producers' responsibility principle

Operators are responsible for the safety of the food and feed that they produce, transport, store or sell ('duty of care'). They have to ensure that their **products are safe** for consumption. Otherwise they are held liable for any loss and damage.

The responsibility of producers begins with the selection of raw materials and additives and only ends when their products leave their premises in excellent condition, well packaged and correctly labeled.

4.2.3 The traceability principle

Traceability is a main principle of the national and EU food and feed legislation. It permits to trace back food and feed item through all steps of their production, processing and selling/marketing. This allows rapid identification and elimination of hazards and fast withdrawal of problematic food and feed items from the market. So the possibility of traceability is an efficient risk management instrument.

4.2.4 Independent scientific risk assessment

Great emphasis was placed on the independence of scientific risk assessment. Experiences showed the need of risk assessment being independent from political, social and economic influences.

For this task in Germany the Federal Institute for Risk Assessment (BfR) was founded in the year 2002. The BfR statements are the basis of decisions of the political authorities and courts. The EFSA (European Food Safety Authority) is the corresponding authority on an European level.

4.2.5 Separation of risk assessment and risk management

A clear separation is established between scientific risk assessment on the one hand and risk management by policymakers on the other. First scientific statements have to be elaborated independently of any influence. Then risk assessment is performed considering all important parameters like environmental, social and economic perspectives.

4.2.6 The precautionary principle

From a scientific standpoint, risks cannot always be fully assessed, e.g. when previously unknown contaminants are discovered. Therefore the precautionary principle can be applied to allow risk management to take in precautionary measures in the interests of risk minimization. However, the measures taken have to be appropriate and be subject to review as soon as new research findings become available.

4.2.7 Transparent risk communication

Operators shall immediately inform the competent authorities if they have a reason to believe that their food or feed is not safe. Transparent risk communication includes the rapid exchange of information on the impact of a newly detected risk. Policymakers, industry and science discuss the scientific risk assessment and agree on suitable risk minimisation measures. Finally, the general public must be informed about new risks in an appropriate manner.

Rapid Alert System for Food and Feed (RASFF)

The European Rapid Alert System for Food and Feed (RASFF) allows rapid exchange of information between member states feed in cases where a risk to human health has been identified and measures have been taken. This exchange of information allows all Member States to check immediately whether they are also affected and if urgent action is needed.

If a risky food or feed product is already on the market and should not be consumed, the Member States' authorities have the power to take an array of emergency measures, including giving direct information to the public.

4.3 Regulation

- EC N°1935/2004: the European Regulation harmonized on contact materials which includes specific rules and specific guidelines
- Some specific directives have been transposed into French national law as decisions done by material (eg. plastics) including lists of authorized substances in Europe (positive lists) supplemented
- In the absence of specific regulations or guidelines for a specific material, the existing national provisions apply, which is the case in France for rubber, silicone, stainless steel, aluminum, for example.

When there is no specific requirement for a material, the inertia principle still applies: the industrial has to demonstrate compliance with these principles.

4.4 Standards

Standards related to materials and articles in contact with food intended primarily to provide tools to demonstrate regulatory compliance. The standards often describe analytical protocols.

- They are derived from the CEN TC 194 (Kitchenware) for methods to ensure the inertia of plastics (Methods for measuring the migration or the residual quantity of a substance in the material).
- Standards have also been developed within CEN TC 172 (Paper / Cardboard) for the analysis of cellulosic materials. Finally, a few methods have been published by CEN TC 261 (Packaging) for the analysis of packaging materials.
- There are analysis protocols to assess the microbiological quality of materials.
- There are also specification standards that deal with the ability for contact with food. They involve metals (Aluminium and aluminum alloys-CEN TC 132, steel BNAC 43-00) and finished objects such as tableware (ISO TC 186) and childcare (CEN TC 252).

The key standards are designed to help food businesses to implement dispositions for hygiene control whose scope extends to packaging (ISO TC 34).

4.5 Guides of good practices

- Each guide brings together the best practices recommendations specific to its referring sector. It helps to harmonize the rules of hygiene by industry sector.
- These documents recommend some means, appropriate methods and procedures whose implementation will lead to the control of health requirements (regulatory or otherwise) in preparation, processing, manufacturing, packaging, storage,

transportation, distribution, handling and sale or supply to the consumer of foodstuffs.

EC Regulation No. 1935/2004 of 27 October 2004 requires, in Article 3, that materials and articles intended to come into contact with food are manufactured in accordance with good manufacturing practices. Applicable since 1 August 2008, the EC Regulation No 2023/2006 of 22 December 2006 defines the rules on good manufacturing practice for materials and articles intended to come into contact with foodstuffs. It applies to all sectors and at all stages of production, processing and distribution of materials and also to the production of starting materials, which are not included.

EC Regulation No. 450/2004 extends the regulation No. 1935 with details on active and intelligent materials and articles intended to come into contact with food. 'Intelligent materials and articles' means materials and articles which monitor the condition of packaged food or the environment surrounding the food. The regulation defines requirements for active and intelligent materials and articles which are necessary for their placement on the market. They need to be suitable and effective for the intended purpose of use and must comply with the general and labelling requirements set out in Regulation (EC) No 1935/2004. The regulation defines composition and labelling and declaration requirements.

- Health Guides for Materials and Objects in Food Contact
 - Reference: FEFCO / ESBO (Fédération Européenne de Carton Ondulé / European Solid Board Organization)
- Guides to Good Manufacturing Practices
 - Code of practice for coated articles where the food contact layer is a coating¹³
 - To overcome the lack of a uniform regulation in Europe, coatings manufacturers gathered in the CEPE (European Council of the Paint and Inks) have taken the initiative to develop a code of good manufacturing practices (BPF in french).
 - 4th edition of the guide with the aim of describing good practices in the industry in order to respect the inertia principle described in the EC Regulation 1935/2004, so that the coatings in contact with food are not a risk for human health.
 - Guide EuPIA for printing inks applied on the non-contact with food side of packagings¹⁴
 - L'**EuPIA European Printing Ink Association** also published an inventory list of substances used for inks, which are intended to be on the non-contact food side.

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www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/guide/090202_Code_of_Practice_Edition_4_1_.doc

14

www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/guide/Guide_09091_1_trad_EuPIA_Guide_sept_09_des_encres_d_imprimerie_pour_emballages_alimentaires-rev_1_.pdf

- Good Manufacturing Practice for the Manufacture of Paper and Board for Food Contact¹⁵ Issue 1 - September 2010
 - Published by **CEPI (Confederation European of Paper Industries)**, for European paper and cardboard manufacturers to help them in the establishment of good manufacturing practices.
- Guides to Good Laboratory Practices
 - Guidelines on testing conditions for articles in contact with foodstuffs - with a focus on kitchenware¹⁶ - EUR 23814 EN 2009 (CRL-NRL-FCM Publication - 1st Edition 2009)
 - The content of this guide is the result of a collective effort of the National Reference Laboratories (NRL) of the European Laboratory for Food Contact Materials controlled by the Community Reference Laboratory (CRL). The representatives of DG SANCO (EU) approved it.
 - This guide explains the rules for testing migration mainly of plastic materials (Directives No. 82/711/CE, No 85/572/EEC, No 2002/72/EC). It describes migration tests conditions for articles in contact with food, such as kitchenware in order to set general or specific migration tests depending on the nature of the materials and articles in contact with foodstuffs (worst foreseeable conditions of use).
 - Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials¹⁷ - EUR 24105 EN - 1st edition 2009
 - The content of this guide is the result of a collective effort of the National Reference Laboratories (NRL) led by the Community Reference Laboratory (CRL). representatives of DG SANCO (EU) approved it.
 - Technical guidelines on testing the migration of primary aromatic amines from polyamide kitchenware and of formaldehyde from melamine kitchenware¹⁸ - EUR 24815 EN 2011 (1st Edition 2011)
 - This guide has been published by **JRC (Joint Research Center – Community Reference Laboratory for Food Contact Materials)**

15 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/guide/GMP_final-20100915-00027-01-E1.pdf

16 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/guide/Guidelines_CRL_conditions_final_ed2009.pdf

17 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/guide/Method_CRL_Perf_Guidelines_final_ed2009.pdf

18 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/guide/24815ENN_Guidelines_kitchenware_PAAAs-FA_2011_1_.pdf

- It was produced in collaboration with the European network of national reference laboratories in response to the publication of EU Regulation No. 284/2011¹⁹.

19 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/Directives/Rg_284-2011_fr.pdf

4.6 Certifications

1. ISO 22000 – Management systems of food safety

- Defines the requirements for a management system of food safety throughout the food chain companies, including suppliers of equipment, cleaning products, packaging materials and other materials in contact with food. ISO 22000 is compatible with ISO 9001:2000 or ISO 14001. The main objectives are:
 - Harmonize existing standards on food safety,
 - Provide to all food chain companies a single auditable document which can be certified;
- Includes the principles of the Hazard Analysis and Critical Control Point (HACCP) developed by the Codex Alimentarius and associates them dynamically with prerequisite programs (PRP) needed to control and reduce to an acceptable level the risks related to food safety.

2. BRC/IoP - Technical Standard and Protocol for Companies Manufacturing and Supplying Food Packaging Materials for Retailers Branded Products - (February 2011)

- « **Norme Mondiale pour les emballages et matériaux d'emballages** » (global standard for packaging and packaging materials) recognized by the majority of British retailers who require the certification from their packaging suppliers. Certifying bodies must be accredited according to the EN 45011 reference, by a national organization (such COFRAC in France or UKAS for Great Britain), and be recognized by the BRC.
- Standards developed by **British Retail Consortium** with the **Institute of Packaging** in order to give to food suppliers and manufacturers hygiene guarantees for their packaging production.
- 8 basic requirements: Commitment of management, internal audits, products specifications, traceability, maintenance and cleaning, process control, staff training and competence.

3. FEFCO²⁰/ESBO - International Guide for Good Manufacturing Practices for Packaging Corrugated and Solid Board: 1st edition officially published October 29, 2003

- **Fédération Européenne de Carton Ondulé / European Solid Board Organization**
- Corrugated and solid cardboard companies are facing a strong demand from their customers wishing to obtain guarantees of hygiene control on their production site.
- Certifying bodies must be accredited according to the EN 45011 reference by a national organization (COFRAC for France), and be recognized by FEFCO.

²⁰ <http://www.fefco.org/>

4. **EN 15593 – Management of hygiene in the production of packagings for foodstuffs** (April 2008)
 - specifies requirements for a hygiene management system for manufacturers and suppliers of food packaging including storage and transportation.
 - Standard currently under review (CEN TC 261).
5. **IFS (International Food Standard) - Version 6** applied from July 2012
 - Reference tool issued jointly by **FCD**²¹ (Fédération des entreprises du Commerce et de la Distribution) and **HDE**²² (Hauptverband des Deutschen Einzelhandels e.V)
 - It represents a standardized assessment system for auditing all food producers that supply to the retail trade. This certification does not apply for packaging manufacturing or process. Many retailers prefer the IFS standards in order to ensure the quality and safety of products manufactured by their suppliers²³.
6. **AIB - Consolidated Standards for Packaging Facilities - Version** published in December 2012.
 - The **American Institute of Baking**²⁴ has developed a specific certification for packaging manufacturing. The certificate is obtained with a given score.
 - Each non-compliance observed by the auditor is classified according to its nature and the potential risk for products (serious or unsatisfactory). The number of non-conformities in each category provides an overall score for the company. At each score there is a description of the company in terms of control of contamination, ranging from unsatisfactory deficiencies to no potential for contamination.
7. **Dutch Health Reference System CCvD-HACCP**²⁵ - Requirements for a HACCP based Food Safety System – 4th version, April 2007
 - The Dutch National Board of Experts (Dutch National Committee of HACCP Experts) has developed a certification standard in 1996, called CCvD-HACCP.

4.7 Assistance tools to ensure the compliance

The development of predictive approaches has been promoted at European scale (by DG-SANCO) and at the North American scale (by the FDA). These tools help guiding operators (polymers and packaging manufacturers, food industrial suppliers) in the choice of compliance control methods for plastics materials and articles in contact with food:

²¹ <http://www.fcd.asso.fr/>

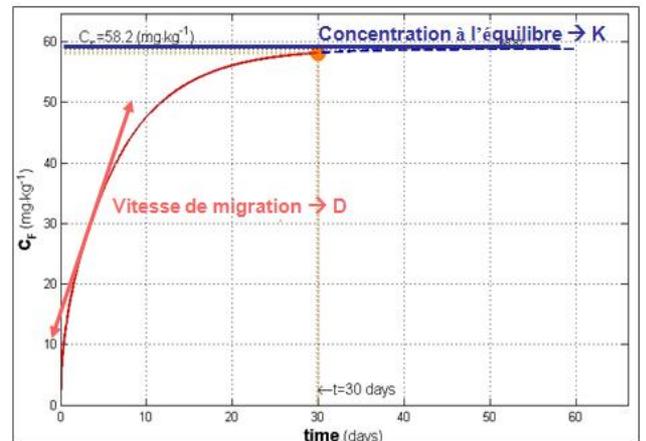
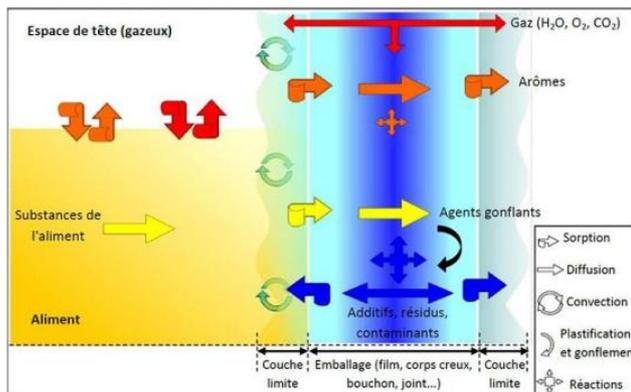
²² <http://www.einzelhandel.de/pb/site/hde/node/1243/Lde/index.html>

²³ [www food-care.info/](http://www.food-care.info/)

²⁴ <https://www.aibonline.org//>

²⁵ <http://www.foodsafetymanagement.info/net-book.php>

1. Tool for defining regulatory requirements for plastics materials and articles in contact with food ²⁶ (requirements and types of analyzes to be performed according to EU Regulation No. 10/2011).
2. Tool for the prediction of substances specific migration: approaches based on mathematical models of the phenomena of migration developed by French research organizations (authorized by plastics European regulations)
 - Migration Scenarios Database ²⁷ (Packagings / Food in real conditions).
 - Tools for modeling material transfers
 - Safe Food Packaging Portal (INRA, 2002) version 3 (SFPP3)²⁸ + European working group conclusions (SMT-CT98-7513).
 - Physico-chemical database for plastics and molecules involved;
 - Mathematical Modelling for material transfers (update from research):
 - Models of migration for monolayer and multilayer packagings,
 - Models of the phenomenon of permeation and 3D modeling for real packagings,
 - Simulations of diffusion coefficients.
 - Material transfers phenomenon²⁹



Migration of high weight molecules (200 to 2000 g / mol) is only possible after a prolonged contact (typically several hours to several days at room temperature) between the package and the food.

Migrant concentration increases in the first phase at a rate described by the diffusion coefficient D. The second phase is the contaminant balance between two settings determined by the partition coefficient K.

Source : Olivier Vitrac & Catherine Joly, 2008

²⁶ <http://www.contactalimentaire.com/index.php?id=187>

²⁷ <http://www.contactalimentaire.com/index.php?id=683>

²⁸ <http://modmol.agroparistech.fr/>

²⁹ <http://www.contactalimentaire.com/index.php?id=682>

4.8 Annex

List of resolutions of the European Council³⁰

- 23/09-2005 ResAP (2005) 2 for packaging inks used on surfaces that are not in contact with food and packaging materials for food intended to come into contact with foodstuffs.
- 12/07-2005 ResAP (2004) 2 for cork stoppers and other cork materials and articles intended to come into contact with foodstuffs (French and English)
- 12/07-2005 ResAP (2004) 4 for rubber products intended to come into contact with foodstuffs. (French and English)
- 12/07-2005 ResAP (2004) 3 for ion exchange resins and adsorbent used in the treatment of foodstuffs (French and English)
- 12/07-2005 ResAP (2004) 5 for silicones used for applications in contact with food (French and English)
- 12/07-2005 Résolution-cadre ResAP (2004) 1 for coatings intended to come into contact with foodstuffs (French and English)
- 21/06-2004 AP (89) 1 on the use of colorants in plastic materials coming into contact with foodstuffs (French and English)
- 21/06-2004 AP (92) 2 on a control system of aids to polymerisation (French and English)
- 21/06-2004 AP (96) 4 on maximum and indicative rates and at the source measures to reduce the food contamination by lead, cadmium and mercury
- 21/06-2004 AP (96) 5 for coatings intended to come into contact with foodstuffs (French and English)
- 21/06-2004 AP (97) 1 for ion exchange resins and adsorbent used in the treatment of foodstuffs
- 21/06-2004 AP (99) 3 on silicones intended to come into contact with foodstuffs (French and English)
- 21/06-2004 Guidelines on metals and alloys used as material expected to be in contact with foodstuffs (13.02.2002)
- 21/06-2004 ResAP (2002) 1 for materials and articles in paper and cardboard intended to come into contact with foodstuffs (French and English).

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<http://www.contactalimentaire.com/index.php?id=520&L=1\%22%20onfocus%3D\%22blurLink%28this%29%3B&task=listarticles&category=32&target=4>

5. Specific Provisions in Germany

5.1 Overview

In Germany the ‚Lebensmittel- und Futtermittelgesetzbuch (LFGB)‘ came into force on 01 January 2005. It represents the implementation of the European Commission Regulation (EC) No. 178/2002 into German legislation and combined the old ‚Lebensmittel- und Bedarfsgegenständegesetz (LMGB)‘ and ‚Futtermittelgesetz‘ to a single law.

The reformation aimed - in line with the Commission's "farm to fork" approach - to establish a new transparency along the food chain. The main goals of the food safety law were:

- To protect human health: Only safe food may be placed on the market.
- To safeguard consumers from deception.
- To ensure the public receives accurate information.

These three aims are enshrined in German as well as in EU law.

The LFGB is the German main Food and Feed Safety Law. It deals with all the topics that are not regulated by the EC community law.

To coordinate the implementation of the LFGB regulations in the German states (‘Bundesländer’) the German government (‚Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz, BMELV) has founded the ‚Bundesanstalt für Verbraucherschutz und Lebensmittelsicherheit (BVL)‘. The main task of BVL is the coordination between the German government and the German states especially in the field of risk management. Further tasks of BVL are:

- Coordination of monitoring programs of the states (‘Bundesländer’)
- Operation of the European Rapid Alert System for Food and Feed
- Crisis management and prevention
- Issuing of individual exemptions/permits
- Handling of tasks in the registration/authorization of pesticides and veterinary medicinal products

Besides the BVL the German ‚Bundesinstitut für Risikobewertung (BfR)‘ was founded. Its main tasks are risk assessment and risk communication. It is independent from political instructions and gives advice to BMELV, BVL and the public based on a scientific and research-oriented background.

The LFGB contains regulations for food and feed monitoring to ensure compliance with legislation. A main goal of the regulations is to harmonize the monitoring between the German states, which are responsible for the performance of the controls.

5.2 Regulation

LFGB	,Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch‘
HdIKIG	,Handelsklassengesetz‘
MitÜbermitV	,Verordnung zu Mitteilungs- und Übermittlungspflichten zu gesundheitlich nicht erwünschten Stoffen‘
RZV	Regulation on reference laboratories Regulation on following up and prosecuting regulatory offences in accordance with food and feed and animal welfare legislation Act on implementation of new food and feed law
2012/154/EU	Recommendations for monitoring of ergot alkaloids in feed and food.
AVV LM	General administrative provision for data transfer in food monitoring
(EU) 16/2011	Regulation laying down implementing measures for the Rapid alert system for food and feed
AVV SWS	General administrative provision for implementation of the Rapid alert System for food and feed
BGV	Consumer Goods Ordinance
VIG	Consumer information act Food penalty ordinance
BfRG	Act establishing the Federal Institute for Risk Assessment (BfRG)
BVLG	Act establishing the Federal Office for Consumer Protection and Food Safety
BVLÜV	Regulation on the Transfer of Powers to the Federal Office for Consumer Protection and Food Safety
DiätV	Dietary Regulation
FertigpackungsV	Finished pack regulation
 <u>Cosmetics</u>	
(EG) 1223/2009	,VO - über kosmetische Mittel‘

Food monitoring

AVV RÜB	,Allgemeine Verwaltungsvorschrift über Grundsätze zur Durchführung der amtlichen Überwachung der Einhaltung lebensmittelrechtlicher, weinrechtliche,- und tabakrechtlicher Vorschriften‘
KZV	,Kontrollstellen-Zulassungsverordnung NRW‘ ,Verordnung über die Weiterbildung und Prüfung von Lebensmittelkontrolleuren‘
ErukasäureV	,Erukasäure-Verordnung‘
EWMV	,Ernährungswirtschaftsmeldeverordnung‘ ,VO zur Festsetzung der Höchstgehalte für bestimmte Kontaminanten in Lebensmitteln‘
KmV	Regulation for contaminants
LMEV	Regulation on importation of food
LKV	,Los-Kennzeichnungs-Verordnung‘
LMBestrV	,Lebensmittelbestrahlungsverordnung‘
LMHV	,Lebensmittelhygiene-Verordnung‘
AVV LmH	,Allgemeine Verwaltungsvorschrift - Lebensmittelhygiene‘
Tier-LMUEV	,Tierische Lebensmittel-Überwachungsverordnung‘
Tier-LMHV	,Tierische Lebensmittel-Hygieneverordnung‘
LMKV	,Lebensmittel-Kennzeichnungsverordnung‘
LSpG	,Lebensmittelspezialitätengesetz‘
LSpV	,Lebensmittelspezialitätenverordnung‘
MOWG	,Gesetz über Meldungen über Marktordnungswaren‘
NemV	,Nahrungsergänzungsmittelverordnung‘
NKV	,Nährwert-Kennzeichnungsverordnung‘
2009/32/EG	Directive on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients
(EC) 258/97	Regulation concerning novel foods and novel food ingredients ,Liste über neuartige Lebensmittel/neuartige Lebensmittelzutaten gemäß der VO(EG) Nr. 258/97‘
NLV	Regulation novel foods and novel food ingredients
PAngV	,Preisangabenverordnung‘

PrüflabV ,Gegenprobensachverständigen-Prüflaboratorienverordnung'
 GPV ,Gegenproben-Verordnung'
 RHmV Regulation on maximum residue limits

,Bekanntmachung über neue Datenanforderung zu Analysenmethoden für Überwachungszwecke für die Festsetzung von Rückstandshöchstgehalten in pflanzlichen Matrices (BVL 08/02/16) '

ZoonUEV ,Verordnung mit lebensmittelrechtlichen Vorschriften zur Überwachung von Zoonosen und Zoonoseerregern'
 ,AVV über die Erfassung, Auswertung und Veröffentlichung von Daten über das Auftreten von Zoonosen und Zoonoseerregern entlang der Lebensmittelkette'

Deep frozen food

(EG) Nr. 37/2005 Regulation on the monitoring of temperatures in the means of transport, warehousing and storage of quickfrozen foodstuffs intended for human consumption

92/2/EWG Commission Directive laying down the sampling procedure and the Community method of analysis for the official control of temperatures of quick-frozen foods intended for human consumption

89/108/EWG Commission Directive on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption

TLMV Regulation on deep frozen food

Tobacco

VorlTabakG Preliminary tobacco law

TabakProdV Tobacco product regulation

TabakV Tobacco regulation

Tobacco framework convention

Auxiliaries and additives

VO 10/2011 Plastic materials and articles intended to come into contact with food

VO 257/2010 Setting up a programme for the re-evaluation of approved food additives

VO 450/2009 Active and intelligent materials and articles intended to come into contact with food

VO 1331/2008	,VO Einheitliches Zulassungsverfahren für Lebensmittelzusatzstoffe, -enzyme und –aromen DurchführungsVO (EU) Nr. 234/2011‘
VO 1332/2008	,VO Lebensmittelenzyme‘
VO 1333/2008	,VO Lebensmittelzusatzstoffe‘
VO 1334/2008	,VO Aromen und bestimmte Lebensmittelzutaten mit Aromaeigenschaften zur Verwendung in und auf Lebensmitteln, DVO Nr.: (EU) 872/2012‘
RL 2008/84	,zur Festlegung spezifischer Reinheitskriterien für andere Lebensmittelzusatzstoffe als Farbstoffe und Süßungsmittel‘
VO 2032/2006	,Herstellungspraxis für Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen‘
VO 1935/2004	,über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen‘
RL 97/48	,Zur zweiten Änderung der Richtlinie 82/711/EWG des Rates über die Grundregeln für die Ermittlung der Migration von Materialien und Gegenständen aus Kunststoff, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen‘
RL 94/62	,Verpackungen und Verpackungsabfälle‘
RL 93/10	,Materialien und Gegenstände aus Zellglasfolien, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen‘
BGV	,Bedarfsgegenständeverordnung‘
AromenV	,Aromenverordnung‘
THV	,Technische Hilfsstoff-Verordnung‘
	,Verordnung über vitaminisierte Lebensmittel‘
ZZuV	,Zusatzstoff-Zulassungsverordnung‘
ZVerkV	,Zusatzstoff-Verkehrsverordnung‘
	,Zugelassene Lebensmittel-Zusatzstoffe‘
<u>Eco</u>	
(EG) 834/2007	,VO über die ökologische/biologische Produktion und die Kennzeichnung von ökologischen/biologischen Erzeugnissen und zur Aufhebung der VO (EWG) Nr. 2092/91‘ ,VO (EG) 1235/2008 - Durchführungsvorschriften zur VO (EG) 834/2007‘ ,VO (EG) 889/2008 - Durchführungsvorschriften zur VO (EG) 834/2007‘
ÖLG	,Öko-Landbaugesetz‘

ÖkoKennzG	,Öko-Kennzeichengesetz‘
ÖkoKennzV	,Öko-Kennzeichenverordnung‘
BLEÖLGKostV	,BLE-ÖLG-Kostenverordnung‘
ÖLGKontrollStZuV	,Verordnung über die Zulassung von Kontrollstellen nach dem Öko-Landbaugesetz‘ ,RL über die Förderung der Beratung landwirtschaftlicher Unternehmen vor und während einer Umstellung des Betriebes auf ökologischen Landbau‘

Specific regulations

Meat

(EG) 2075/2005	,VO mit spezifischen Vorschriften für die amtlichen Fleischuntersuchungen auf Trichinen‘
FleischG	,Fleischgesetz‘ ,Fleischgesetz-Durchführungsverordnung: 1. FIGDV; 2. FIGDV‘ ,Fleischgesetz-Gebührenverordnung‘ ,Verordnung über den Erlass eines Besonderen Gebührenverzeichnisses für amtliche Kontrollen im Rahmen des Fleischhygienerechts‘
AVVFIH	,Allgemeine Verwaltungsvorschrift über die Durchführung der amtlichen Überwachung nach dem Fleischhygienegesetz und dem Geflügelfleischhygienegesetz‘
FIH-BelV	,Fleischhygiene-Beleihungsverordnung (By) ‘
BSEUntersV	,Verordnung zur fleischhygienerechtlichen Untersuchung von geschlachteten Rindern auf BSE Durchführung‘ ,TSE-Vorsorgeverordnung‘ ,TSE-Überwachungsverordnung‘
EG-TSE-AV	,EG-TSE-Ausnahmeverordnung‘ ,Verordnung über das Verbot der Abgabe bestimmten Fleisches von Rindern an Verbraucher‘
FleischV	,Verordnung über Fleisch und Fleischerzeugnisse‘
FIUStatV	,Fleischuntersuchungsstatistik-Verordnung‘
SchwHKIV	,Schweineschlachtkörper-Handelsklassenverordnung‘ ,Verordnung über gesetzliche Handelsklassen für Schaffleisch‘
RindHKIV	,Rinderschlachtkörper-Handelsklassenverordnung‘
RiFIEtikettG	,Rindfleischetikettierungsgesetz‘

(EG) 1760/2000	,VO zur Einführung eines Systems zur Kennzeichnung und Registrierung von Rindern und über die Etikettierung von Rindfleisch und Rindfleischerzeugnissen sowie zur Aufhebung der VO (EG) Nr. 820/97‘
RiFLEtikettV	,Rindfleischetikettierungsverordnung‘
RiFIEtikettStrV	,Rindfleischetikettierungs-Strafverordnung‘
<u>Poultry</u>	
LegRegG	,Legehennenbetriebsregistergesetz‘ ,Legehennenbetriebsregisterverordnung‘
VOVNEier	,Verordnung über Vermarktungsnormen für Eier, Eier- und Eiprodukte-Verordnung‘ ,Verordnung mit Übergangsregelungen zur Einführung der Informationen zur Lebensmittelkette‘ ,Verordnung über Stoffe mit pharmakologischer Wirkung‘
<u>Fish</u>	
FischEtikettG	,Fischetikettierungsgesetz‘
FischEtikettV	,Fischetikettierungsverordnung‘
<u>Milk</u>	
MilchFettG	,Milch- und Fettgesetz‘
MilchFettVerbrV	,Milchfett-Verbrauch-Verbilligungsverordnung‘
<u>Milk and margarine</u>	
MargMFV	,Margarine- und Mischfettverordnung‘
ButterV	,Butterverordnung‘
KäseV	,Käseverordnung‘
(EU) 605/2010	,VO zur Festlegung der Veterinärbedingungen und Veterinärbescheinigungen für das Verbringen von Milcherzeugnissen und Rohmilch zum menschlichen Verzehr in die Europäische Union‘
MilchErzV	,Milcherzeugnisverordnung‘
MilchGV	,Milch-Güteverordnung‘

ThürVV Milchhygiene ,VwV zur Durchführung des gemeinschaftlichen und nationalen Lebensmittelhygienerechts auf dem Gebiet der Milchhygiene in Thüringen‘

MilchKennzV ,Konsummilch-Kennzeichnungs-Verordnung‘

Beverages

,Verordnung über Kaffee, Kaffee- und Zichorien-Extrakte‘

,Verordnung über koffeinhaltige Erfrischungsgetränkes‘

,Verordnung über die Berufsausbildung zum

,Milchtechnologen/zur Milchtechnologin‘

2011/634/EU

,Beschluss über die Unterzeichnung des Internationalen Kakao-Übereinkommens von 2010 im Namen der Europäischen Union und seine vorläufige Anwendung ‘

,Internationales Kakao-Übereinkommen von 2010‘

KakaoV

,Verordnung über Kakao- und Schokoladenerzeugnisse‘

FrSaftErfrischGetrV

,Fruchtsaft- und Erfrischungsgetränkeverordnung‘

Vorl. BierG

,Vorläufiges Biergesetz‘

BierV

,Bierverordnung‘‘

,Verordnung über EG-Normen für Obst und Gemüse‘

,EG-Obst- und Gemüse-Durchführungsverordnung‘

Water

TrinkwV01

,Trinkwasserverordnung TrinkwV90vgl. "Wasser"‘

2003/40/EG

,RL Festlegung des Verzeichnisses, der Grenzwerte und der Kennzeichnung der Bestandteile natürlicher Mineralwässer und der Bedingungen für die Behandlung natürlicher Mineralwässer und Quellwässer mit ozonangereicherter Luft‘

MinW

,Mineral- und Tafelwasser-Verordnung‘

VwVMinW

,Allgemeine Verwaltungsvorschrift über die Anerkennung und Nutzungsgenehmigung von natürlichem Mineralwasser‘

Wine

WeinG

,Weingesetz‘

WeinV

,Weinverordnung‘

WeinÜbV

,Wein-Überwachungsverordnung‘

(EG) Nr. 110/2008

,VO zur Begriffsbestimmung, Bezeichnung, Aufmachung und Etikettierung von Spirituosen sowie zum Schutz geografischer

Angaben für Spirituosen und zur Aufhebung der VO (EWG) Nr. 1576/89‘

AGeV	‚Alkoholhaltige Getränke-Verordnung‘
EssigV	‚Verordnung über den Verkehr mit Essig und Essigessenz‘
HonigV	‚Honigverordnung‘
KonfV	‚Konfitürenverordnung‘
ZuckerAV	‚Zuckerartenverordnung‘ ‚Zucker-Produktionsabgaben-Verordnung‘ ‚Verordnung zur Abweichung von der Zucker-Produktionsabgaben-Verordnung für das Wirtschaftsjahr 2009/2010‘ ‚Zucker-Quoten-Verordnung‘
LmChemG	‚Gesetz zum Schutz der Berufsbezeichnungen "Staatlich geprüfte Lebensmittelchemikerin" und "Staatlich geprüfter Lebensmittelchemiker"‘

Feed

FutMG	‚Futtermittelgesetz (aufgehoben vgl. LFGB: Abschnitt 3‘ ‚Leitlinien für eine gute Verfahrenspraxis im Futtermittelsektor‘
FutMV	‚Futtermittelverordnung: Verwendung und Kennzeichnung bestimmter Futtermittel-Zusatzstoffe‘ ‚Futtermittelherstellungs-Verordnung‘
FutMPAV	‚Futtermittel-Probenahme- und -Analyse-Verordnung‘
FuttMkontrV	‚Futtermittelkontrolleur-Verordnung‘
VerfVerbG	‚Verfütterungsverbotsgesetz (aufgehoben vgl. LFGB)‘
VerfVerbV	‚Verfütterungsverbots-Verordnung (aufgehoben vgl. LFGB)‘
EGVerfVerbDV	‚EG-Verfütterungsverbotsdurchführungsverordnung‘
FuttEinfVerbV	‚Futtermittelleinfuhrverbotsverordnung‘ ‚Zweite Futtermittel-Verwertungsverbotsverordnung‘ ‚Speiseabfallverordnung‘
EURHGAusnahmV	‚Verordnung über Ausnahmen hinsichtlich des Inverkehrbringens und der Verfütterung von bestimmten Erzeugnissen mit Pestizidrückständen‘

6. Specific provisions in France

A report on the regulatory situation of smart systems in the food sector in France was prepared by COMMISSARIAT À L'ÉNERGIE ATOMIQUE ET AUX ÉNERGIES ALTERNATIVES (CEA) and ASSOCIATION DE COORDINATION TECHNIQUE DES INDUSTRIES AGROALIMENTAIRES (ACTIA).

6.1 Regulation

The **EC N°1935/2004**, European Regulation harmonized on contact materials which includes specific rules and specific guidelines is not implemented in France and is applied such as it is.

- Some specific directives have been transposed into French national law as decisions done by material (eg. plastics) including:
 - Lists of authorized substances in Europe (positive lists) supplemented;
 - Lists of authorized substances in France (Ex: rubbers).
- In the absence of specific regulations or guidelines for a specific material, the existing national provisions apply, which is the case in France for rubber, silicone, stainless steel, aluminum, for example.

EC Regulation N°1935/2004 resulted in France in the information note N° 2004-64 dated 6 May 2004 DGCCRF, revised on 18/05/2009 for the French version (+ English version). France has extended the scope of materials in contact with feed. These measures are recalled in the Decree N°2008/1469 and in Articles 4 and 5 of Decree No. 92/631. Note N°2004-64 provides:

- A detailed description of the responsibilities of the different actors in the chain;
- Application of the principle of inertia (one form per material) on:
 - Migration testing (testing the validity of migration is 5 years maximum);
 - Organoleptic tests.

When there is no specific requirement for a material, the inertia principle still applies: the industrial has to demonstrate compliance with these principles.

6.2 Guides of good practices

- Each guide brings together the best practices recommendations specific to its referring sector. It helps to harmonize the rules of hygiene by industry sector.
- These documents recommend some means, appropriate methods and procedures whose implementation will lead to the control of health requirements (regulatory or otherwise) in preparation, processing, manufacturing, packaging, storage,

transportation, distribution, handling and sale or supply to the consumer of foodstuffs.

- Development of Hygiene guides:
 - Protocol validation and revision guides to good hygiene practices and HACCP principles (DGA, DGS, DGCCRF) of 27 May 2005.
 - NF V01-001 (March 2006) - food and feed Health - Methodology for the development of guides to good hygiene practices and HACCP principles
- Health Guides for Materials and Objects in Food Contact
 - Guide to Good Hygiene Practices and manufacture of boxes, packaging and metal closures for foodstuffs.
 - This guide (regularly revised according to the evolution of the regulation) has been the subject of a notice of ANSES (French Agency for Food Safety) the 1st of March 2005, and was published by the SNFBM (National Union of Manufacturers of Metal boxes).
 - The Committee was composed of representatives of manufacturers of metal (steel, aluminum), varnishes, sealants and metal packaging. Apart from the manufacture and delivery of raw materials (steel, aluminum, joints and varnishes), the steps of the manufacturing process are all covered from cutting reels to shipping empty boxes and ready to use lids.
 - Guide to Good Practice for Hygiene Packaging Plastics and Packaging Flexible Complexes (Editions of the Official Journals - 2001)
 - This guide covers the packaging, which is part of the food chain but, of course, cannot itself be considered as a food product.
 - Good Practice Guide for the Manufacture of Paper, paperboard and Articles made with paper and cardboard transformed, intended for food contact (Lavoisier Tech & Doc-1998)
 - Pending specific and complete regulations, paperboard for food contact manufacturers gathered in the Club Association MCAS (Materials for Food Contact and Health) have developed this guide for good manufacturing practices, with collaboration of CNERNA for validation.
 - Constituting a transitional document until the output of an European one, it is intended to improve the position of the French paper industry with regard to their foreign competitors who so far have a legislation more operational.
- Guide of relationship Customers / Suppliers

- Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact³¹
- Guide ANIA - CLIFE of customer / supplier relationships for packaging materials and articles in contact with foodstuffs³²
- Lavoisier Librairie
 - Food hygiene: elements of control, HACCP (Collection)
 - Good Laboratory Practices (B.P.L in french) special fascicle 84/17 B
 - Guide to good hygiene practices for the production and refining of comté cheese
 - Raising, storage, marketing and transport of cereals, oilseeds and protein crops (Coll. Guides to good hygiene practices)
 - Brochure n° 5951 – Manufacturers of fresh or chilled delicatessen products (Guides of good hygiene practices. Legislation & regulation 2012)
 - Brochure n° 5946 – Canned and appertized fish and shellfish (Guide of good hygiene practices. Legislation et regulation 2011)
 - Brochure n° 5950 - Transformation of waterfowl in foie gras in craft and farm workshops (Guide of good hygiene practices)
 - Brochure N° 5942 – Cured meat industry (Legislation et regulation, guide of good hygiene practices 2011)
 - Brochure N° 5936 - Guide of good practices for mineral feed fabrication 2010
 - Brochure N° 5932 Guide of good hygiene practices: transformation et marketing of poultry and pork
 - Guide of good hygiene practices Réf 359300000 : fabrication of dairy and farm products
 - Guide of good hygiene practices for the pastry sector
 - Guide of good hygiene practices Réf.5909. Vine sector
 - Guide of good practices for the fabrication of papers, cardboards, paper processed articles and cardboards for foodstuffs contact
 - Brochure N° 5918 Guide of good hygiene practices Chocolate, confectionary
 - FD V 46008 : meat production : good breeding practices

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www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/guide/Paper_Board_Industry_guideline-final_2010.pdf

32 www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/guide/CLAC_10-0201_guide_relations_CF.pdf

7. Specific provisions in Estonia

Report prepared by TARTU BIOTEHNOLOOGIA PARK AS (TBP)

Estonia's accession to the European Union (1st May 2004) and other international organizations are profoundly influenced local food industry and regulations but also relations between industry, regulators, policy makers and public authorities.

In Estonia the food sphere (incl. handling of raw material for food and food, self-control of a food handling operator and governmental supervision) is regulated by the Estonian Food Act (<https://www.riigiteataja.ee/akt/750600>, in Estonian) and Directive of the European Parliament and the European Council 178/2002/EEC, establishing general legal principles and requirements in food area, founding European Food Safety Administration and establishing the procedures, connected with food safety. The food sphere is, in addition to the Food Act and its implementing acts, regulated by numerous other laws and regulations and the EU legislation that is directly applicable.

As provided by the Food Act, food control or governmental supervision shall be performed in Estonia by the Veterinary and Food Board, the Health Protection Inspectorate, the Estonian Consumer Protection Board and the Estonian Tax and Customs Board.

As provided by the Food Act and the Statutes of the Veterinary and Food Board the Veterinary and Food Board shall organize and conduct governmental supervision in all the spheres of handling and over the materials and objects, specified in Article 1 (12) of the Regulation of the European Parliament and European Council No. 1935/2004/EC. In the process of supervision the Veterinary and Food Board shall assess the conformity of the food, materials and items intended to be in contact with food, manufacturing, processing and marketing of such materials and items and the operator and handling procedures. By general rule, supervision is conducted without giving the entity a prior notice.

In Estonia there is no legal document, which regulates especially smart systems in the food sector.

8. Case study: regulation related to the implementation of RFID systems in Germany

The Fraunhofer Institute for Material Flow and Logistics IML, Dortmund has published an investigation on the 'MeatRFID; Use of RFIDs in beef processing'. It gives an overview over the legal framework and the effects of the regulations in regards to the use of RFID technology. As it treats also the use of microsystem technologies in other food and feed sectors the main results will be given in the following.

8.1 Analysis of legal frame works relevant for meat industry

8.1.1 Traceability

- **European Parliament and Council regulation EC 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety**
- **European Parliament and Council regulation EC 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC**
- **European Parliament and Council regulation EC 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC**

The regulations mentioned above demand full traceability from 'farm to fork' including identification of all persons/ companies involved and documentation of all product relevant information. Mostly the necessary information is not defined in detail.

The RFID technology fulfills the requirements as it enables the traceability of products along the complete food chain. It allows unique labelling of products, packaging or transport containers. As automated control and documentation is possible this technology adds some additional values in relation to traditional techniques. The necessary information can be stored directly at product and can be updated continuously.

- **DIN EN 12830, Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice-cream - Tests, performance, suitability**

Section 4.4.2 demands the registration of temperature, time, location and date. The data has to be stored for a minimum of one year.

Temperature sensors can be used for continuous temperature recording enabling a complete and automated temperature control. The technique would replace the measurements of core temperature usually performed.

- **EN ISO 22000:2005, Food safety management systems - Requirements for any organization in the food chain**

The standard defines requirements for a food safety management system. The transponder technology fulfills the requirements of the standard in respect to communication and documentation of relevant data of product and raw materials. The automated data recording ensures traceability.

8.1.2 Hygiene rules

- **German law on epizootic diseases (LFE)**
- **German Foodstuffs hygiene regulation (LMHV)**
- **German regulation for meat and hygienics (FIHV)**
- **European Parliament and Council regulation EC 852/2004 on the hygiene of foodstuffs**

The law demands that food-producing facilities including their instrumentation have to be constructed in such a way that cleaning and disinfection is possible. Temperatures have to be controlled. Especially for the meat industry there is a considerable number of hygienic rules.

Microsystems for use in these areas have to comply with the hygienec rules, too. The main demand is that all equipment has to be resistant to cleaning and disinfection procedures. In addition the equipment has to be free of microbiological contaminants.

8.1.3 Labelling requirements

- **European Parliament and Council regulation EC 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety**

Food has to be labelled in such a way that misleading of consumers is avoided. But the regulation only relates to the content of a food product not to the packaging. The labelling of possibly used transponders is therefore not necessary. But is advisable considering the obligation of consumer information.

- **European Parliament and Council regulation EC 853/2004 laying down specific hygiene rules for food of animal origin**
- **German Food Labelling Ordinance (LMKV)**
- **European Parliament and Council regulation EC 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC**

- **European Parliament and Council regulation EC 1760/2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97**

The regulations define requirements for labels to identify food items. In most cases the labels have to be printed on the product or its packaging.

The use of RFID technology simplifies the labelling by the possibility of updating product data while the processing along the food chain. This enhances the traceability. The demand of direct printing (in readable form) of information on products cannot be fulfilled by transponder microsystems. Here the traditional labelling method has to be applied. But transponders can be used complementary as further information regarding product properties; environmental conditions and traceability can be saved in the chip.

- **European Parliament and Council regulation EC 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption**
- **German regulation on commercial categories for beef**

Both regulations define requirements for the health marking of the products and for classification in commercial categories. This has to be accomplished by stamps on the product. Obviously this is not possible using transponders.

- **German law on beef labelling**
- **German regulation on beef labelling**

The 'Federal Office for Agriculture and Food BLE' is in Germany responsible for the approval and withdrawal of labelling systems. The introduction of a new labelling system (for example including the use of transponders) is probably subject to authorisation.

The modalities of the application of a labelling system are given in the 'Regulation on beef labelling'.

- **European Parliament and Council regulation EC 1829/2003 on genetically modified food and feed**
- **German Genetic Engineering Act (GenTG)**

The regulations define requirements for labels. It is not explicitly required that these are directly readable. In principle it is possible to indicate genetically modified food item by readable label and store relevant further information in a transponder.

- **European Parliament and Council Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs**

The regulations define requirements for labels. The use of transponders is well possible and has the advantage of automated recording, storage and administration of information.

- **German regulation for meat and hygienics (FIHV)**

The regulation defines requirements for labels for packaged meat. As the label has to be destroyed and discarded together with the packaging material only one-way transponders can be used in these cases.

- **Commission regulation EC 2073/2005 on microbiological criteria for foodstuffs**

The regulation defines requirements for labels for special food items which were heated before marketing. This information can well be stored in a transponder, but a printed (readable) label is still necessary to ensure customer information.

8.1.4 Regulations for cold chain monitoring

- **German Regulation on Deep-Frozen Goods (TLMV)**
- **Commission regulation EC 37/2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quickfrozen foodstuffs intended for human consumption**
- **German Minced meat regulation (HFIV)**

The regulations define requirements for temperature control for food products, facilities and packaging materials.

The use of microsystems allows the continuous temperature recording during the complete supply chain. If transponders are placed at the packaging material they have to comply additionally to the regulations for the packaging materials.

- **DIN EN 12830, Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice-cream - Tests, performance, suitability**
- **DIN EN 13485, Thermometers for measuring the air and product temperature for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice cream - Test, performance, suitability**

These standards regulate the technical and functional properties of air and product (core) temperature monitoring devices. The use of microsystems can support the devices. To comply with the standards transponder in form of labels should be used.

8.2 Analysis of legal frame works relevant for fish and seafood

8.2.1 Traceability

- **Council Directive 91/493/EEC laying down the health conditions for the production and the placing on the market of fishery products**

The directive defines requirements for the identification of fishery products. The use of transponders facilitates the identification and traceability by storage of the required data on the product.

8.2.2 Hygiene rules

- **German regulation on fish diseases**
- **German fish hygiene regulations**
- **Council Directive 92/48/EEC laying down the minimum hygiene rules applicable to fishery products caught on board of certain vessels in accordance with article 3(1) (a) (I) of Directive 91/493/EEC.**
- **Council Directive 91/493/EEC laying down the health conditions for the production and the placing on the market of fishery products**

The regulations define hygienic requirements for fishery industry. All used equipment, vehicles including ships, transport containers, storing rooms etc. must easily to be cleaned and disinfected.

RFID technology is well suited to meet the requirements as data documentation and storage is facilitated. But all used microsystems have to be resistant to cleaning and disinfection procedures and must not emit any substances hazardous to health.

8.2.3 Labelling requirements

- **German law on fish labelling**
- **German regulation on fish labelling**
- **Council Regulation (EC) No 104/2000 on the common organisation of the markets in fishery and aquaculture products**
- **Commission Regulation (EC) No 2065/2001 laying down detailed rules for the application of Council Regulation (EC) No 104/2000 as regards informing consumers about fishery and aquaculture products**
- **German fish hygiene regulations**
- **Council Directive 91/493/EEC laying down the health conditions for the production and the placing on the market of fishery products**

The regulations define requirements for labelling of fish and fishery products. Labelling includes ensurance of traceability.

The use of RFID technology is well suited. However transponders in label form are necessary, as stored information has to be directly readable.

8.2.4 Regulations for cold chain monitoring

- **German fish hygiene regulations**
- **Council Directive 92/48/EEC laying down the minimum hygiene rules applicable to fishery products caught on board of certain vessels in accordance with article 3(1) (a) (I) of Directive 91/493/EEC.**
- **Council Directive 91/493/EEC laying down the health conditions for the production and the placing on the market of fishery products**

The regulations define requirements for temperature control for fishery products, facilities and packaging materials including storage conditions.

The use of microsystems allows the continuous temperature recording during the complete supply chain.

If transponders are placed at the packaging material they have to comply additionally to the regulations for the packaging materials.

8.3 Analysis of legal frame works relevant for dairy products

8.3.1 Traceability

- **German law on milk and fat**

The law defines requirements for the examination of milk and dairy products. The use of transponders facilitates the traceability by storage of the required data on the product.

8.3.2 Hygiene rules

- **German regulation on milk**
- **Council Directive 92/46/EEC laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products**

The regulations define hygienic requirements for milk processing companies. All used equipment must easily to be cleaned and disinfected.

The use of microsystems is well suited to meet the requirements as data documentation and storage is facilitated. But all used transponders have to be resistant to cleaning and disinfection procedures and must not emit any substances hazardous to health.

8.3.3 Labelling requirements

- German regulation on milk
- German regulation on cheese
- German regulation on butter
- German regulation on milk based products
- Council Regulation EC 2991/94 laying down standards for spreadable fats
- German regulation on margarine and blends
- German regulation on quality inspection of milk

The regulations define requirements for labelling of milk and dairy products including transport. Labelling includes ensurance of traceability.

The use of RFID technology is well suited. However transponders in label form are necessary, as some regulations require direct readability of stored information.

8.3.4 Regulations for cold chain monitoring

- Council Directive 92/46/EEC laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products

The regulations define requirements for the temperature control of milk and dairy products along the complete supply chain.

The use of microsystems allows the continuous temperature recording as required.

8.4 Analysis of legal frame works relevant for fruits and vegetables

8.4.1 Traceability

No relevant regulations

8.4.2 Hygiene rules

No relevant regulations

8.4.3 Labelling requirements

- Council regulation EC 2200/96 on the common organization of the market in fruit and vegetables
- Marketing standards
- Commission regulation EC 85/2004 laying down the marketing standard for apples
- Commission regulation EC 1757/2003 laying down the marketing standard for courgettes and amending Regulation (EEC) No 1292/81
- Commission regulation EC 1148/2001 laying down the controls regarding compliance with marketing standards for fresh fruits and vegetables
- German regulations on commercial categories for fresh fruits and vegetables
- German law of commercial categories
- German regulations on commercial categories for potatoes

The regulations define requirements for labelling of fruits and vegetables including transport. Labelling includes ensurance of traceability.

The use of RFID technology is well suited. However transponders in label form are necessary, as some regulations require direct readability of stored information.

8.4.4 Regulations for cold chain monitoring

No relevant regulations

9. Conclusion

This report provides an overview over the regulatory situation of smart systems in the EU and specific provisions in France, Germany and Estonia.

The most relevant regulation in regard to microsystems implementation in the food sector is the legislation on food contact materials. It is documented in EC regulation no. 1935/2004 (inertie principle) and 2023/2006 (Good Manufacturing Practice) which are completed by the legislation on specific materials (for example the legislation 10/2011 on plastic materials intended to come into contact with food). The regulation no. 450/2009 on active and intelligent materials and articles intended to come into contact with food is also relevant when the use of microsystems is intended in packaging applications. Finally the regulation on Novel Foods 258/97 is relevant to devices enabling the development of new food products.

On the basis of these legislations, microsystems should be evaluated case by case according to the nature of the microsystem materials in contact with food and their intended use.

- For exemple, in the case of intelligent packaging application, the microsystem will have to comply with the regulation 450/2009: a dossier for safety evaluation will have to be submitted to EFSA prior to its commercialisation.
- In the case of a polymer-packaged sensor used for in-line monitoring of processes, the system has to comply with the regulation 10/2011 on plastic materials. In that case, the components and additives of the polymer should be authorised and migrations limits of the material should be respected.
- In the specific case of microdevices that enable new product and/or process innovation (for example micro-emulsification devices), the regulation on Novel Foods applies and the product will need to be evaluated by EFSA.

Even if not covere by this report, other aspects such as end of life and waste management of microsystems will also have to be taken into account.

This report will be used in FoodMicroSystems for the construction of three technological roadmaps. These reports will provide a more detailed framework to guide researchers and entrepreneurs of microsystems solutions in the development of applications for the food sector. For more information, please visit www.foodmicrosystems.eu.