

A close-up photograph of a microscope's objective lenses and eyepiece, set against a blue background. The lenses are metallic and have some text on them, including "Plan" and "0.25".

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Regulatory Review for Food Contact Applications

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**PVC Plasticisers 2010,
10 February 2010, Brussels**

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OUTLINE

❖ **Overview of the Current Regulatory Regime**

- The Framework Regulation
- The Plastics Directive, as amended
- Regulation on Recycled Plastics
- Active & Intelligent Packaging Regulation
- Other Relevant Legislation

❖ **Relevant Future Developments**

- Recast of the Plastics Directive and related measures
- Nanomaterials in Food Contact Applications

❖ **Challenges Ahead**

- Demonstration of Safety
- Declaration of Compliance and Record Keeping

The Framework Regulation

- Regulation (EC) No 1935/2004. Applies to all food-contact materials, recycled materials, A&I systems
- Establishes general requirements (Art.3): safety, taste, composition, no deception of consumer
- Calls on the Commission to adopt specific “measures” for specific categories of materials (e.g. plastics, rubbers)
- Organises the procedure for the positive listing of substances under the specific measures, but leaves room for individual authorisations (recycling technologies ...)
- Establishes labelling, traceability, certification, and record-keeping requirements

General Safety Requirement (Art. 3)

- “Materials and articles must be manufactured in compliance with Good Manufacturing Practice (GMP) so that, under normal or foreseeable conditions of use, constituents are not transferred to food in quantities which could:
 - ✓ endanger human health
 - ✓ bring about an unacceptable change in the composition of the food, or
 - ✓ bring about a deterioration of the organoleptic characteristics thereof
- GMP Regulation (EC) No 2023/2006

The Plastics Directive

- Directive 2002/72/EC. Most comprehensive of all food-contact measures
- Amended by Directives 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC and 2008/39/EC
- Main Elements:
 - positive lists of authorized components (monomers, additives), sometimes with restrictions, SMLs, QMs
 - Overall migration limit
 - Written declaration of compliance
- Future of Plastics Directive:
 - Positive list of additives (since 1 January 2010)
 - Surface biocides?
 - Codification into Regulation? (PIM)
 - Extension to Multi-layer multi-material articles?

The Plastics Directive: Scope

➤ Applies:

- ✓ to food-contact materials and articles made entirely of plastic
- ✓ to multi-layer articles made of plastic and bound together by adhesives

➤ Does not apply:

- ✓ to multi-layers with both plastic and non-plastic layers – even if plastic is food-contact layer
 - ✓ to composite materials made of plastics and other materials
- 4th amendment extends scope to plastic layers and coatings forming gaskets in lids, even if the lid is not plastic (see infra)

Positive List Requirements for Plastics

- **Positive list for monomers and starting materials**
 - Only the substances listed can be used, with some exceptions
- **Positive list for additives (*NEW)**
 - Listed additives can be used throughout the EU
 - Various materials and their components are exempted from positive list requirements, subject to national law:
 - ✓ coatings, epoxy resins, adhesives, printing inks
 - ✓ colorants, solvents, aids to polymerization

Restrictions

- **Overall migration limit (OML)** 60 mg/kg or 10 mg/dm²
- Some substances listed with **specific migration limits (SML)** or maximum residuals (QM); sometimes as “not detected”
- Some substances have **purity specifications** (e.g. mineral oils) or compositional limits
- Some substances are subject to **specific use conditions** (e.g. not for contact with fatty foods) but authorities have the right to adopt any conditions
- The **transitional migration limits** established for **plasticisers** in gaskets in lids by Commission regulation (EC) No 372/2007 have been changed to the normal values of Directive 2002/72/EC on 30 April 2009

The Regulation on Recycled Plastics

- **Commission Regulation (EC) No 282/2008 of 27 March 2008**
- Framework Regulation calls for specific measure on recycled plastics as a priority (Intro § 24) and covers these materials (Article 5)
- **Objectives:**
 - ✓ Ensure that materials and articles produced from recycled plastics meet the general requirements of Framework Regulation
 - ✓ Ensure free movement of recycled plastics through harmonization
- Establishes approval for individual recycling processes

Recycled Plastics: Requirements

- Food contact materials containing recycled plastic must comply with the Framework Regulation and the Plastics Directive:
 - Safety (contaminants), no change in taste, odour, or composition of food
 - Positive lists of permitted components
 - OML, SMLs, QM, specifications
- Recycled plastic itself must be obtained from:
 - Recycling process that is authorised under the Regulation and supported by audited quality assurance system
 - Requirements for the quality assurance system are provided in the Annex to the GMP Regulation

Transitional Period

- 18 month transition period is established for submitting applications for recycling processes (*until December 2009)
- Authority issues opinion (no strict deadline)
- **Open-ended** procedure; no definitive deadline for Commission's decision to grant (or refuse) authorization of the recycling. Until that date national provisions continue to apply in Member States
- Trade and use of recycled plastic materials already placed on the market are permitted until:
 - Exhaustion of stocks if no application is submitted within the transition period
 - 6 months after adoption of final decision if valid application submitted within transition period

Active and Intelligent Packaging Regulation

- Commission Regulation (EC) No 450/2009 on active and intelligent (A&I) materials and articles intended to come into contact with food
- A&I materials are listed in Annex of Framework Regulation as subject to a specific measure
- A&I materials exempted from the principle of inertness (OML can be exceeded)
- Only covers the components causing the A&I function
- Subject to EU and national law on food until specific measures are adopted.

Active and Intelligent Packaging Regulation: Definitions and Requirements

- **Active materials and articles:** intended to extend the shelf-life or to maintain or improve the condition of packaged food, designed to release or absorb substances into or from the packaged food or its environment
- **Intelligent materials and articles:** monitor the condition of packaged food or the environment surrounding the food
- A&I are suitable and effective for the intended purpose
- Comply with general safety (Article 3) and specific requirements (Article 4) of the Framework Regulation
- Comply with compositional requirements of A&I regulation (Community List of authorized substances). Exemptions (Article 9)

Active and Intelligent Packaging Regulation: Timeline

- Before the Community List is set up (2012?) national provisions apply. Released Active substances need to comply with both the applicable provisions of Food Law and the Framework Regulation.
- Labeling and declaration rules apply from 19 December 2009 (***NEW**)
- A&I materials and articles labeled prior that date can be marketed until the exhaustion of stocks

Other EU Legislation indirectly applicable to food contact plastics

- 1. Regulation (EC) 764/2008 on Mutual Recognition**
- 2. Regulation (EC) 178/2002 on general principles of food law**
- 3. General Product Safety Directive 2001/95/EC**
- 4. Product Liability Directive 85/374/EC**
- 5. Construction Products Directive 89/106/EC**
- 6. Packaging and Packaging Waste Directive 94/62/EC**
- 7. REACH Regulation (EC) 1907/2006**

Chemical Control Legislation - REACH

- REACH (Regulation (EC) No 1907/2006) is in effect as of 1 June 2007
 - ✓ Registration of all substances > 1 MT/y when produced or imported in the EU as such or in preparations
 - ✓ Registration of monomers in imported polymers
 - ✓ Authorisation of substances of very high concern (SVHC)
 - ✓ Notification of SVHC present in plastic articles $> 0,1\%$ w/w
 - ✓ Several plastics additives (flame retardants - HBCDD, phthalates - BBP, DEHP, DBP, DIBP and pigments) are already listed
 - ✓ Only limited exemptions for food-contact substances

Specific Provisions: Food Contact Materials

➤ **Registration:**

- ✓ Substances used to make food contact materials are subject to Registration by their manufacturer/importer
 - ✓ They are only exempt from conducting a risk assessment for the health and safety aspects of the handling of these substances (human health part of the Chemical Safety Report)
- Other titles fully apply (e.g. Evaluation and Restrictions)
- By contrast, food additives and all other substances used in foodstuffs are exempt from REACH

Specific Provisions: Candidate List

- **Authorisation:**

“Substances of very high concern” used to make food contact materials are subject to Authorisation if they present environmental concerns (human health concerns are exempted)

- **Candidate List** substances in articles:

- Communication obligation (Art. 33) if $>0.1\%$ w/w
- Notification obligation (Art. 7(2)) if $>0.1\%$ w/w and $>1\text{MT}/\text{y}$

Specific Provisions: Polymers & Monomers

- Polymers are exempted from Registration and Evaluation but subject to Authorization (if they are CMRs, PBTs, vPvBs) and to Restrictions
- Polymers are subject to the classification and labelling provisions
- Monomers produced or imported into the EU for use in polymers are subject to Registration if above 1 ton and 2%
- Specific issues for imported polymers

Relevant Future Developments

- PIM (**Recast** of all measures related to food contact plastic materials and articles)
- Regulatory consideration for **nanomaterials** used in food contact applications

Recast of the Plastics Directive and related measures

- Aim is to simplify and clarify existing food contact plastic legislation
- Present draft includes several new elements; extending and amending existing scope and requirements

Recast: Main differences

- The Recast is a Regulation; will directly be in force in all MS
- Scope is extended to cover plastic layers in multi-material multi layer (MMML) applications (only for vinyl chloride monomers, VCMs?)
- Functional barrier is defined as “any type of material”; only relevant in MMML applications
- MMML is also covered if plastic layer is not in “direct” food contact
- All permitted substances (monomers, other starting substances and additives) are listed in the same Annex (Annex I)

Recast: Main differences (cont.)

- Substances behind a functional barrier with a deliberately engineered particle size providing different physical and/or chemical properties than their conventional analogues (nano?!) are NOT automatically exempted from compliance – ambiguous language
- Significant changes in food simulants:
 - ✓ Water is replaced by 10% ethanol as Simulant A
 - ✓ 10% ethanol is replaced by 20% ethanol as Simulant C
 - ✓ 50% ethanol is introduced as Simulant D1; vegetable oil as Simulant D2
 - ✓ Tenax (Modified Polyphenylene Oxides) is standardized as Simulant E

Recast: Observations

- While the aim to simplify and clarify the existing food contact regulatory provisions in one single regulation is understandable, the present draft goes far beyond a legal codification. The recommended changes need justification
- As plastics is already well regulated, it is questionable why further resources are needed to “improve” it
- Developments should rather concentrate on developing a “new approach” based on exposure to determine risks
- The more and more “engineered” food contact materials with special (and confidential) composition for specific uses call for the introduction of proprietary authorization

Nano-components in packaging - Introduction

- Nanotechnology: the ability to manufacture, manipulate and utilize nanometer-size (10^{-9} m) materials and structures with totally novel physico-chemical properties and functions
- Nano-particle improved products impact many consumer goods (particularly food packaging) providing products with novel functions
- 1 new nanotech product hits the market every 3-4 weeks. Over 600 nanotech products on the international market
- Nanocomponents subject to general requirements of current legislation (generally covered by scope, no regulatory distinction between conventional and nano materials)
- Specific recommendations and voluntary schemes in development for nanotechnology
- Potential new safety issues raised by nanotechnology

Potential Requirements to Address Nano Issues:

- Establish definition for nanoparticles
- Based on definitions and sufficient scientific understanding define proper descriptors which can serve the basis of regulation
- Not yet known whether
new endpoints (such as *in vitro* oxidative stress) or
new target organs (such as *in vivo* genotox studies for the respiratory tract) or
new mechanisms (such as translocation) might need to be considered for toxicological test
- Validate testing/detection
- Define complete life cycle and determine exposure
- **The use of nanoparticles requires case-by-case review**

Current approach: Voluntary Industry Measures

- Follow Due Diligence - reasonable reliance on existing regulatory requirements and scientific knowledge
- Assist authorities with relevant information – increase public confidence in both the industry and the technology
 - ✓ EU integrated projects (by DG Research) such as NanoSafe
 - ✓ REACH registration before deadline and under 1MT
 - ✓ Submit data for Trade Association calls
 - ✓ Submit data for Member States' initiatives
- Consider the merits of voluntary actions

Nano in food contact legislation

- No explicit reference to nanoparticles – except in new regulation on A&I materials and in draft PIM
- EFSA has published positive opinion on the direct application of a nanoparticles (TiN) in PET bottles. Basis of no concern: lack of any detectable migration into food
- Commission needs to act on this opinion to either include TiN in the positive list of permitted food contact additives or provide explanation to petitioner on lack of regulatory action

Recommended Industry Strategy

- Ensure compliance with existing legislation, standards and relevant industry guidelines
- Characterize applied nanoparticles (size distribution, shape, surface treatment etc) and define processing conditions
- Keep record of due diligence efforts, risk assessments & monitoring of risks; update knowledge
- Specify the added value of individual nanoparticles based products and distinguish between existing other applications in order to avoid generalization of the technology
- Engage in public dialogue
- Consider participating in “Voluntary Initiatives” supporting the safe use of your products

Challenges Ahead for the Food Packaging Industry

- Responsibilities in the Supply Chain
- Record Keeping
- Declaration of Compliance

Responsibilities in the Supply Chain

- Suppliers (monomer and additive producers, formulators for food-contact use) have the same responsibilities as finished packaging producers
- However, account will be taken of their position in the chain with respect to their compliance obligation and in particular their certification obligation:
 - ✓ Starting substance producer can only certify that the substance is positively listed and/or subject to a given restriction and produce that substance under GMPs
 - ✓ Intermediate producers (compounders, masterbatch producers, converters) must integrate and take account of cumulative requirements in their obligation to produce under GMPs and to ensure and certify compliance

Record Keeping: Adopt Suitable Policies

- **Labelling:** Ensure products are labelled as specified in Framework Regulation; use all EU languages
- **Certification:** Establish a “written declaration”, that:
 - ✓ Conveys the required information to your customers
 - ✓ Is flexible to cover all categories of your products with limited adaptation, if possible
 - ✓ Does not unduly increase your liability
- **Keep records** of all relevant information substantiating:
 - ✓ Compliance with positive list requirements, GMPs
 - ✓ Safety determinations
 - ✓ Traceability

Declaration of Compliance for Plastics

- Must accompany material or article and substances intended for their manufacture at all marketing stages other than the retail stage (unlike GMP Regulation, does not exclude starting substances!)
 - ✓ Ensure Compliance with GMPs
 - ✓ Collect necessary knowledge on the products in order to determine applicable regulatory requirements
 - ✓ Verify compliance with positive listings and other specific requirements (EU and national level)
 - ✓ Use all available elements (analytical data, scientific rationale) to demonstrate safety
 - ✓ Be reasonable → Only ask for information that you are prepared to handle

Be Reasonable?



...And if Something Goes Wrong?

- Unacceptable migration of substance in food → Food is injurious to health → Injurious food causes damage to consumer health

- Possible Consequences:
 - ✓ Legal actions by consumers against food packers and packaging producers (if identified) for damages
 - ✓ Recall (soft or hard) of packed food products and/or of packaging materials
 - ✓ Actions by enforcement authorities for non-compliance (breach of Regulation 1935/2004 and national criminal law)
 - ✓ Actions between food packers and packaging producers under contract law or tort for compensation/damages
 - ✓ Impact on brands/sales/stocks/product reformulations, etc.

THANK YOU

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advise you on the way forward!**