Regulatories and certificates for semi finished products

EU-directives/regulations

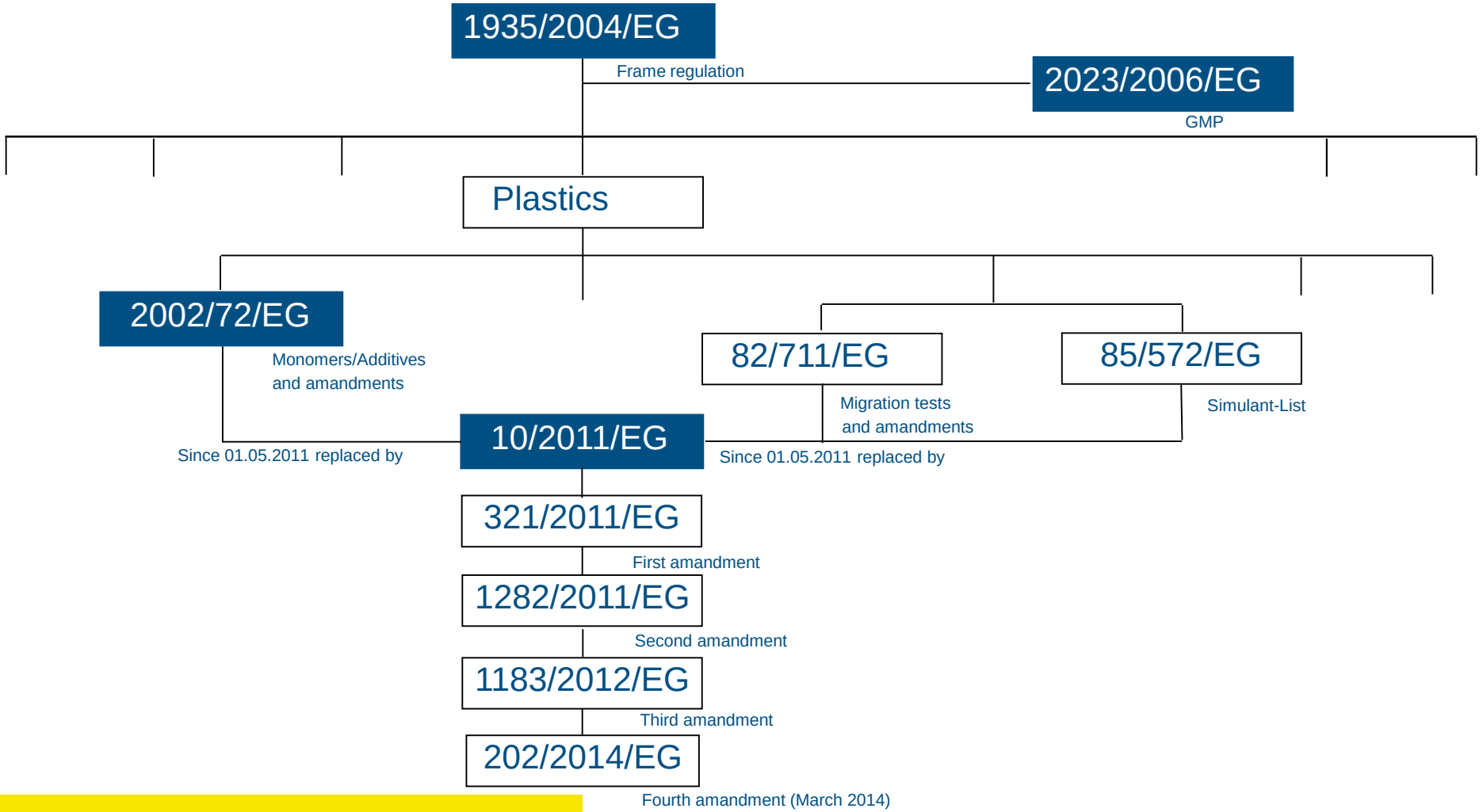
Regulations

- Legal acts of the EC
- Could be addressed to the EC, the member states or the citizens of the member states
- They are binding in all parts and apply directly in each member state.
- Don‘t have to be transfered into national law ->No modifications possible

Directives

- Have no direct validation
- Directives have to be transfered into national law

Structure of EU-directives/regulations for food contact



EU-directives/regulations for food contact

1935/2004/EC (Frame-regulation)

- Frame-regulation for materials and objects for direct food contact.
- Regulates materials and products for direct food contact.
- Regulates the labeling, traceability and single activities for articles and materials.
- Single activities:
  - Declaration of conformity
  - Positive list
  - Criteria of purity
  - application limitations
  - Migration- and residual content limits
  - Specifications for analytical verifications
- Transferred in the national law ->LFGB (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch).
- Status at Ensinger: Guideline of the 1935/2004 is generally implemented

EU-directives/regulations for food contact

2023/2006/EC (GMP-directive)

- → Directive for the good manufacturing practice (GMP) for material and products with direct food contact.
- → Regulates the implementation and application of a quality assurance systems with adequate documentation of all essential production processes.
- → Status at Ensinger: Guidelines of the 2023/2006 is generally implemented, last clarifications are currently in process.

EU-directives/regulations for food contact

2008/39/EC (and previous directives)

- Directive for the regulation of monomers and additives.
- Includes positive lists for monomers and additives.
- Limits for single substances (SML, GML).
- Purity specifications for some substances.
- Declaration of conformity
  - Simple identification of materials, products and substances.
  - Listing of norms, regulations and directives, parts have to correspond with
  - Has to be renewed with significant changes in the production, the composition or new scientific knowledge, which can affect the migration.
- Status at Ensinger: Migration testing on semi finished parts is not required; Confirmation of the suitability for the direct food contact.

EU-directives/regulations for food contact

97/48/EC - 85/572/EC (and previous directives)

- Directives for the operation of migration tests.
- The directives are linked to the 2002/72/EC. Herein the migration limits of substances are defined.
- 97/48/EC – Define the basis for the operations of migration tests.
- 85/572/EC - Define the simulant and solvents for the analysis.
- Compliance documentations of the migration limits
  - till 31.12.2012 testing rules according these norms
  - from 01.01.2016 according 10/2011
  - in between both methods are valid
  - Model calculations or scientific arguments. At the moment there is no special guideline how to perform the testing. Possibilities are checked constantly.

EU-directives/regulations for food contact

10/2011/EG -> so called PIM (Plastic Implementation Measure)

- Regulation for materials and objects out of plastics coming in direct food contact.
- Form 01.05.2011: summarizing all existing legal requirements for plastics into one regulation (positive lists, test conditions,…)
- 2002/72/EG and amendments get canceled within 01.05.2011
- transitional period:
  - until 31.12.2012 current testing rules applicable (82/711/EWG);
    from 01.01.2016 new testing rules apply only (10/2011);
    in between both old and new rules are applicable
- Declaration of compliance: is required for all production steps including basic materials
- Documents substantiating conformity of migration limits: results of the migration testing, modelling, other analysis, and scientific evidence ore other documents

EU-directives/regulations for food contact

10/2011/EG -> so called PIM (Plastic Implementation Measure)

- → Our declarations are appropriate to the current legal situation in the European Union and consider all requirements on stock shapes, but offer migration data measured on the resins.
- → We are closely monitoring changes in the regulatory surrounding with our compliance management and are doing our own strategic considerations.
- → We inform in time if there are any changes for you or our customers.

1907/2006/EC – REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)

- Regulation for the registration, evaluation, authorisation and restriction of chemicals
- Establishment of the European Agency for Chemical Substances (ECHA).
- The system is based on the policy of the individual responsibility of the industry for riscs.
- Chemical substances can display for the health and the environment.
- Regarding the principle „no data, no market“ only registered substances can be sold in the area of application.
- Optimisations of the previous valid lawful general requirements for chemical substances in the EU.
- Targets:
  - Better protection of the human health and the environment as well as the advancement of alternative methods for the testing of dangerous substances.
  - Increasing of the competitiveness of the European chemical industry.
  - Guarantees of the free transportation of substances in the European domestic market.

Further EU-directives/regulations

1907/2006 – REACH

- → The approval system should ensure that special worrying substances get adequate controlled or replaced.
- → Manufacturers and importers of chemical substances (raw materials and compounds) have to identify and handle the riscs of their products.
- → This is valid for the manufacturing and importing of substances from up to 1t per year and company.
- → Manufacturers/importers have to provide all necessary information relating to risks and safe operation to secondary users
  ->ENSINGER is a secondary user (we are reliant on the information of the raw material supplier)

2002/95/EG – RoHS (Restriction of the use of certain hazardous substances)

- Directive for the restriction of specific dangerous substances for the usage in electrical- and electronical devices.
- Regulates the usage of dngerous substances in devices.
- Target: Reduce or replace problematic substances in throw away electronic devices.
- Substances + limits:
  Cadmium ->0,01 weight%
  Lead, mercury, chromate 6, polybrominated biphenyle (PBB)
  and diphenylethers (PBDE) ->0,1 weight%

Further EU-directives/regulations

2002/96/EG - WEEE (Waste Electrical and Electronic Equipment)

- Directive for the handling of waste of electronic- and electrical devices
- Target:
  - Avoidance, reduction as well as an ecological waste disposal of the increasing amount of electronic waste through a advanced manufacturer responsibility.
  - Implementation of a national take-back system.
  - Recycling of 4kg electronic waste per year and citizen.
- Use of recyclable materials.
- Optimisation of the construction of devices for better material separations.

Further EU-directives/regulations

2000/53/EG (Directve for old cars)

- Directive of the recycling of scrapped vehicles.
- Regulates the material recycling of vehicals inbetween the EU.
- Includes also material prohibitions and directives.
- Strategy:
- Avoidance of waste formation though a better product construction.
- Expansion of recycling and reuse of waste.
- Target:
- Increasing of the reuse and recycling rates to 95% of the medium vehicle weight by 2015.
- Implementation of a take-back system for scrapped vehicles.

Further EU-directives/regulations

428/2009/EG (Dual-Use-Directive)

- → Regulation for the control of the exportation of products and technologies with a dual use application
- → The regulation defines dual use applications as products which can be used for civilian and military applications
- → Definition of materials, without an approval of the BAFA (Bundesamt für Wirtschaft und Ausfuhrkontrolle) for export into third party countries
- → Assignation of the approval depends on the country list (not dual use, „normal“ exportation control)
- → Different approval steps are possible (overall, singular case, cancellation)
- → List of the concerned materials from ENSINGER is in process

Further EU-directives/regulations

Ensinger

Directive and regulations of the restriction of substances

- → 76/769/EEC – General directive on the restriction of the use of dangerous substances
- → 2002/61/EC – Directive on the restriction of the use of azo dyes
- → 2003/11/EC – Directive on the restriction of the use of pentabromine and octabrominediphenylethers
- → 2005/69/EC – Directive on the restriction of the use of polycyclical aromatical hydrocarbones (PAK) and softener oils
- → 2005/84/EC – Directive on the restriction of the use of phtalates
- → 2006/122/EC – Directive on the restriction of the use of perfluoroctansulphones
- → 2009/251/EC – Directive on the restriction of the use of dimethylenfumarates (DMF)
- → 2037/2000/EC – Regulation of substances which lead to a degradation of the ozone layer

Food contact approvals

FDA (Food and Drug Administration)

- The FDA has a mission to protect public health in the USA. They control the safety and effectivity of human and animal drugs, biological products, medical products, food and radiation emitting devices
- This is valid for products which are produced or imported in the USA.
- Positive list of raw materials and processing aids for use with direct food contact
- The raw material suppliers are responsible for the approvals
- ENSINGER can only certificate the conformity.

BfR (Bundesinstitut für Risikobewertung)

- At the core of their work, the BfR sees the human as a consumer
- They look for safer food, substances and products to protect the health of consumers
- The BfR releases references and notifications relating to substances, compounds, etc.

3A Sanitary Standard Inc.

- Sanitation organisation of the USA food industry
- They define standards and specifications for the development, manufacture and use of sanitation devices manly in the dairy industry
- They define the requirements for food contact materials, which also have to be suitable for detergent and disinfection operations
- Thereby the following main criteria are valid:
  - FDA-conformity
  - Resistance for steam sterilisation
  - Resistance for milk fat and water
  - Minimum heat-aging properties
  - Physical minimum properties (tensile strength and elongation at break)
  - Resistance for acids and alkaline detergents
  - Resistance for disinfectants with a chloric basis
- Periodic annual testing

Drinking water approvals

NSF (National Science Foundation)

- Independent organisation in the USA for the promotion of research and education.
- Market leader for risk management services in the public health care.
- They test and certify all products in the drinking water system.
- Certification according NSF/ANSI standard 61 (NSF 61) for sanitary consequences of components of the drinking water system.

KTW (Plastics in drinking water)

- Guidelines of the federal environment agency for the hygienic evaluation of organic materials in contact with drinking water.
- Hot and cold water tests.

Drinking water approvals

WRAS (Water regulations advisory scheme)

- Institute in the UK for testings and certifications of products within the drinking water system.

DVGW (Deutsche Vereinigung des Gas- und Wasserfaches e. V.)

- They work on regulations, standards, testings and certifications in gas and water applications.
- Worksheet W270 „Increase of microorganisms on materials for drinking water contact“.
- Regulation of substances/surfaces with direct drinking water contact.
- Testing periode takes up to 6 month.

ACS (Attestation de conformité sanitaire)

- The French health authorities developed a system to certify the sanitary conformity of plastic materials and accessories containing at least one plastic component
- This system allows the evaluation of the suitability of a product to come into contact with water destined for human consumption

Medical approvals

USP (United States Pharmacopeia)

- Public agency for the analysis and registration of medical products.
- Function: protection of the product quality, preparation of standards, testing and approval of materials and products.
- USP class testings: In Vivo (Implantation) and In Vitro (Irritation) Screenings for the characterisation of the biocompatibility of plastics.
- Material classification: depending on the testings and results class 1-6.
- Periodic tests (every five years).

Medical approvals

ISO 10993

- Standards for the testing of the biocompatibility (biological evaluation of medical products).
- Analysis of substances and materials in laboratory trials to their compatibility to the human or animal body.
- Different tests: toxicity, cytotoxicity, genotoxicity, hemocompatibility, irritation.
- Periodic tests

Fire protection approvals

UL (Underwriters Laboratories)

- → Organisation in the USA for the testing and certification of products and their safety.
- → Method for the rating and classification of the flammability of plastics according to UL94.
  - → Classification take place through tested specimen thickness in different classes.
  - → HB, V2, V1, V0, 5VB, 5VA.
  - → periodic tests.
  - → Only valid for raw materials, not for semi finished products
  - → Conformity/UL-listening (yellow card)

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Responsibilities

- → The verification of the compliance of the requirements of the FDA, biocompatibility, EU regulations and directives, as well as further regulations , refers responsively to the user via declaration of conformity according to the directive 2002/72/EC
- → The verification of suitability for the intended application has to be provided from the user of the parts
- → To provide traceability, ENSINGER provides only order related certificates

Certificate of compliance

Declaration of compliance with the order 2.1

→ Declaration in which the manufacturer confirms, that the delivered goods meet the compliance of the order, without specifying any test results.

Certificate of compliance

Test report 2.2

- Declaration in which the manufacturer confirms, that the delivered goods meet the compliance of the order, including non-specific test results.
- Non-specific testing: A suitable testing process chosen by the manufacturer to make sure that the products meet the compliance of the order - such products have to be manufactured by the same product specification and by the same process.
- The tested products doesn‘t have to be based on the actual delivery

Certificate of compliance

Inspection certificate 3.1

- Certificates, issued by the manufacturer, in which he confirms that the delivered products meet the requirements of the order including specific test results
- The certificate has to be confirmed by a manufacturing independent authorised employee of the manufacturer
- Specific tests are applied on the specific ordered material
- The manufacturer is allowed to take over specific test results of the raw material whilst maintaining the traceability of the product.

Cerificate of compliance

Certificate or Declarations

→ Documents, which are declaring certain characteristics of the material (FDA, biocompatibility, cytotoxicity, ...), or its used precurser material.

Overview

	Order data	Material data	Tests	Confirmation
Declaration of compliance with the order 2.1	-Customer-No. -Order-No. -Customerorder-No.	-Material -DIN name -Piece name -Dimension -Quantity of delivery -Production-No.	none	complies with the agreements
Test report 2.2	-Customer-No. -Order-No. -Customerorder-No.	-Material -DIN name -Piece name -Dimension -Quantity of delivery -Production-No.	Values for the orientation, tested on the stock shape of the same material. i.e.: -density -crystalline melting point	complies with the agreements
Inspection certificate 3.1	-Customer-No. -Order-No. -Customerorder-No.	-Material -DIN name -Piece name -Dimension -Quantity of delivery -Production-No. -LOT-No. raw material	Mean values, testes on the stock shape* of the same production** i.e.: -density -crystalline melting point -tensile strength -elongation at break -impact strength	complies with the agreements
Certificates/ Declarations	-Customer-No. -Order-No. -Customerorder-No.	-Material -DIN name -Piece name -Dimension -Quantity of delivery -Production-No.	Tests according to the DIN standard: i.e.: -biocompability -FDA -cytoxizity	complies with the agreements

* or the precurser material, if the requested test results are available
** the test data comes from the material delivered

Thank you very much for your attention!