COMPLIANCE SCHEME

FEBRUARY 2016

COMPLIANCE SCHEME REGARDING PRODUCTS OF CONTINUOUS FILAMENT GLASS FIBRE (CFGF) USED IN GLASS FIBRE REINFORCED PLASTIC (GFRP) INTENDED TO COME INTO CONTACT WITH FOOD

In relation with COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

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ABSTRACT

Glass fibre-reinforced plastics (GFRP) are composite materials made of a polymer matrix reinforced with glass fibres. The glass fibres therein are treated with a sizing to hold individual filaments together and to promote adhesion to the polymer matrix. Glass fibre-reinforced plastics are covered by Regulation (EU) No 10/2011. Until 31.12.2015, compliance of the sizing was solely based on a risk assessment in accordance with Article 19. This guidance document intends to assist the supply chain actors in determining compliance of sizing formulations with the new requirements of Regulation (EU) No 10/2011.

The main ingredients in glass fibre sizings are coupling agents and film formers.

Coupling agents as well as reactive polymers used in film formers, which are both intended to chemically react with the plastic matrix, are categorized as monomers and other starting substances in accordance with Article 5(2) of Regulation (EU) No 10/2011.

They require specific authorisation via the Union List or, in the case of polymers, regulation through their (already listed) monomers and starting substances, in accordance with the derogation in Article 6(3) of Regulation (EU) No 10/2011.

All other substances are considered polymer production aids defined in Art 3(8) of the Regulation. None of the substances used in glass fibre sizing are classified as *additives* as defined in Art 3(7). They have to be evaluated by performing a risk assessment in accordance with Article 19 of Regulation (EU) No 10/2011.

On the basis of the low migration from glass fibre-reinforced plastics and the low consumer exposure, there are no particular health risks to be expected from sizing agents.

About Glass Fibre Europe – EU Transparency Register n°635608817518-09.

Glass Fibre Europe, founded in 1987, is the voice of the European continuous filament glass fibre industry. It is composed of 7 companies: 3B the fibreglass company, FYSOL SAS, Johns Manville, Lanxess, Nippon Electric Glass, Owens Corning and Saint-Gobain Vetrotex. Glass Fibre Europe represents over 90% of the continuous filament glass fibre production in Europe.

TABLE OF CONTENTS

1. INTRODUCTION

Until 2011, glass fibre producers and their legal advisers have considered Glass Fibre Reinforced Plastic (GFRP) as composite materials and therefore not in the scope of the Plastics Directive 2002/72/EC. Legal advisers assessed Continuous Filament Glass Fibre (CFGF) products used in GFRP intended for food contact applications according to the requirements of the Framework Regulation (EC) No. 1935/2004.

The Plastics Regulation (EU) No. 10/2011 (repealing directive 2002/72/EC) clarified that CFGF products used in GFRP are in the scope of the Plastics Regulation and therefore have to comply with listing requirements.

Glass fibres are listed as an authorised additive to plastics in Annex I of Regulation (EU) No. 10/2011 under Ref. No. 55520.

Article 22 of the Regulation 10/2011 states that: *Until 31 December 2015 additives used in glass fibre sizing for glass fibre reinforced plastics which are not listed in Annex I have to comply with the risk assessment provisions set out in Article 19.*

Article 23 of the Regulation 10/2011 requires that: *The provision of Article 5 as regards the use of additives used in glass fibre sizing for glass fibre reinforced plastics, shall apply from 31 December 2015.*

However, the definition of *Additive* in Article 3(7) of the Regulation 20/2011 does not truly match all functions achieved by sizings.

The purpose of this document is to clarify how to apply the requirements of Regulation (EU) No. 10/2011 to sizing components of products used in GFRP intended to come into contact with food.

2. DEFINITIONS

2.1. Regulation (EU) No. 10/2011 (Article 3 definitions)

Additive	means a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article (Note: this definition is not applicable to sizing components)
Aid to polymerisation (AP)	means a substance which initiates polymerisation and/or controls the formation of the macromolecular structure
Monomer or other starting substance	means: (a) a substance undergoing any type of polymerisation process to manufacture polymers; or (b) a natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or (c) a substance used to modify existing natural or synthetic macromolecules
Non-Intentionally Added Substance (NIAS)	means an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product
Polymer	means any macromolecular substance obtained by: (a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or (b) chemical modification of natural or synthetic macromolecules; or (c) microbial fermentation
Polymer production aid (PPA)	means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article

2.2. CFGF specific definitions

CFGF	Continuous Filament Glass Fibre manufactured by continuous drawing of molten glass through a "bushing" (a device fitted with calibrated holes) which forms continuous glass filaments with a defined and precisely controlled diameter. A surface treatment (sizing) is applied onto the glass filaments which are then gathered into strands.
CFGF products	The different end products are: Single End or Direct Roving, Multi-end or Assembled Roving, Chopped Strands, Textile Yarns, Technical Fabrics and Milled Fibres. With the addition of a binder, other products like Chopped Strand Mats, Continuous Filament Mats and Veils can also be produced.
Sizing	A surface treatment (usually a mixture of organic substances) applied to the CFGF composed of coupling agents, film formers and processing aids. The functions of the sizing are to allow processing of the fibres, to hold the individual filaments together and to promote adhesion of the glass fibres to the polymer matrix.
Coupling agents	Chemical substances or mixtures that have the ability to bind inorganic materials such as glass fibres to organic resins. Typical examples for coupling agents are silanes.
Film formers	Chemical substances or mixtures that have the ability to bind the glass filaments together and to protect the filament bundles against abrasion during handling, processing and storage. They usually enhance the bonding properties between fibres and polymer matrix as well. Some film formers contain a reactive polymer intended to react with the plastic matrix.
Film former processing aids	Chemical substances or mixtures that are required to obtain stable film formers.
Sizing processing aids	Chemical substances or mixtures that maintain the stability of the sizing and allow its application on the glass filaments (antifoaming agents, thickening agents, surfactants, stabilizers, emulsifiers, dispersants, pH-adjusting agents, …)
CFGF processing aids	Chemical substances or mixtures in the sizing that allow the processing of the glass fibre strands like winding, chopping, weaving (lubricants, antistatic agents,…).
Binder	A mixture of chemicals (usually organic substances) applied to the glass fibre strands to bind them together and form mats (Chopped Strand Mats, Continuous Filament Mats and Veils).
Compound	Engineered plastic material made from two or more constituent materials which are homogenized and are only discernible on a microscopic level.
Composite material	Engineered (plastic) material made from two or more constituent materials which remain separate and distinct on a macroscopic level within the finished structure.
Glass Fibre Reinforced Plastic (GFRP)	Compound or composite material made of plastics and CFGF products.

3. COMPLIANCE REQUIREMENTS

3.1. Glass fibres

Glass fibres are listed as an authorised additive to plastics in Annex I of Regulation (EU) No. 10/2011 under Ref. No. 55520. There is no restriction applicable.

3.2. Sizing Components and their function in the reinforced plastic.

3.2.1. Coupling agents

Coupling agents have a clearly defined function in the finished plastic. They are intentionally applied to the glass fibre filaments in order to create an adhesive force between the fibres and the plastic matrix.

Coupling agents shall be listed in the Union List of Regulation (EU) No. 10/2011 as *monomers or other starting substances*. The given limitations shall be observed.

3.2.2. Film formers

The main constituents of film formers are either reactive or non-reactive polymers.

Reactive polymers are intended to react with the surrounding plastic matrix in order to improve the adhesion between the glass fibres and the plastic matrix. For reactive film former polymers, the monomers and starting substances shall be listed in the Union List of Regulation (EU) No. 10/2011according to Article 6(3)(d).

Non-reactive polymers are not intended to react with the plastic matrix and are functionally similar to polymer production aids (PPA) defined in Article 3(8)) of Regulation (EU) No 10/2011.

The film former commercial mixture is usually an emulsion which may also contain solvents (e.g. water) and other processing aids and aids to polymerisation (surfactants, lubricants, stabiliser, etc.).

All non-reactive polymers, aids to polymerisation (AP) and polymer productions aids (PPA) used in the manufacturing of the film formers and not listed on the Union List of Regulation (EU) No. 10/2011, shall be subjected to a risk assessment in accordance with article 19 of Regulation (EU) No. 10/2011.

Note: In the case where a substance (other than a coupling agent or a reactive film former polymer) is added to the sizing formulation for the purpose of delivering a specific function to the plastic material or article, this substance meets the definition of an additive (or possibly a monomer or starting substance) as defined by the Plastics Regulation, and must be listed as additive in Annex I of Regulation (EU) No. 10/2011.

The following table provides a summary of the compliance requirements applicable to the sizing and binder components according to their function in the plastic material.

Substance group	Function	Examples	Analogy	Risk management approach	Risk assessment
Coupling Agents	Create an adhesive force between the fibres and the polymer matrix, and therefore have an intended effect in the finished plastic material	Silanes	Similar substances already listed in annex I (e.g. FCM No. 142, 377, 453, 788)	Article 5, Annex I Union List	EFSA
Film Formers	-Tie single glass fibre filaments into strands -Protect strands during handling and storage -Disperse chopped strands into the polymer matrix during compounding	Polyester, Polyvinyl acetate, Polypropylene Polyurethane, Epoxy resins	Unreactive polymers (not capable of reacting with the plastic matrix) are functionally similar to polymer production aids (PPA) defined in Article 3(8) of Regulation	Article 6(1) and Article 19	Risk assessment by manufacturer

	-Bind fibres to polymer matrix, materials property improvement		(EU) No. 10/2011		
			Reactive polymers (substances capable of reacting with the plastic matrix) are functionally similar to polymeric starting substances and their monomers and other starting substances	Article 5, Annex I Union List or if not already listed, Article 6(3)(d)	EFSA
			Polymer production aids defined in Article 3(8)(a)	Article 6(1) and Article 19	Risk assessment by manufacturer
			Aids to polymerisation	Article 6(4)(b) and Article 19	Risk assessment by manufacturer
			Solvents	Article 6(4)(b) and Article 19	Risk assessment by manufacturer
Continuous filament glass fibre processing aids (CFGF)	- Maintain stability of sizing raw material preparations - Allow application of sizing to fibres - Allow mechanical processing of fibres	Antifoaming agents, pH regulators, process biocides, lubricants, antistatic agents	Similar to polymer production aids defined in Article 3(8)	Article 6(1) and article 19	Risk assessment by manufacturer

(a): See list in Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food available at http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/10–2011_plastic_guidance_en.pdf (page 12).

3.3. Sizing components acting as processing aids

Various processing aids may be present in the sizing:

- Film former processing aids
- Sizing processing aids
- CFGF processing aids

They have no function in the reinforced plastic and are not regarded as an additive to the reinforced plastic. Processing aids not listed on the Union List of Regulation (EU) No. 10/2011 are subject to a risk assessment according to internationally recognized scientific principles (article 19 of Regulation (EU) No. 10/2011).

3.4. Binder

The same compliance requirements as for sizings will apply also to binders.

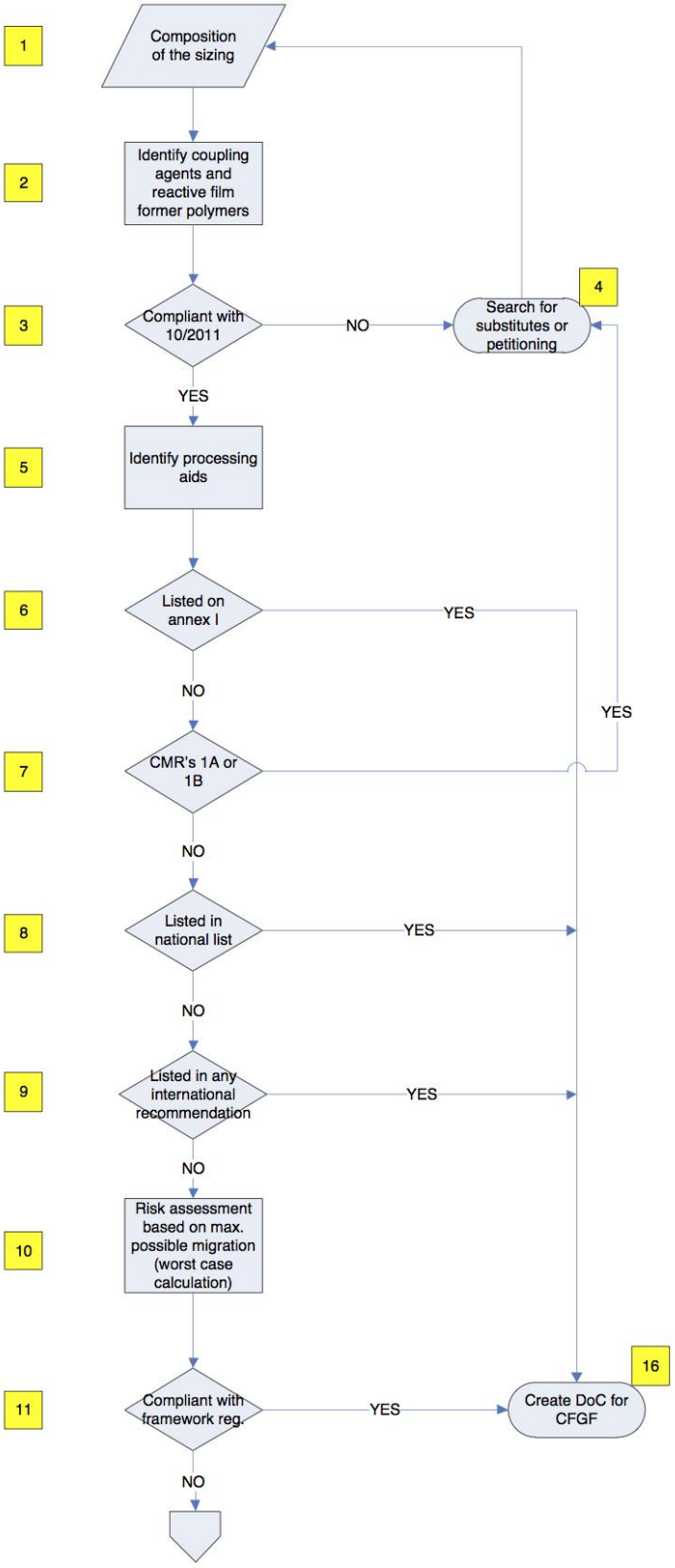
4. VERIFICATION OF COMPLIANCE AND SUPPORTING DOCUMENTATION

4.1. Overview

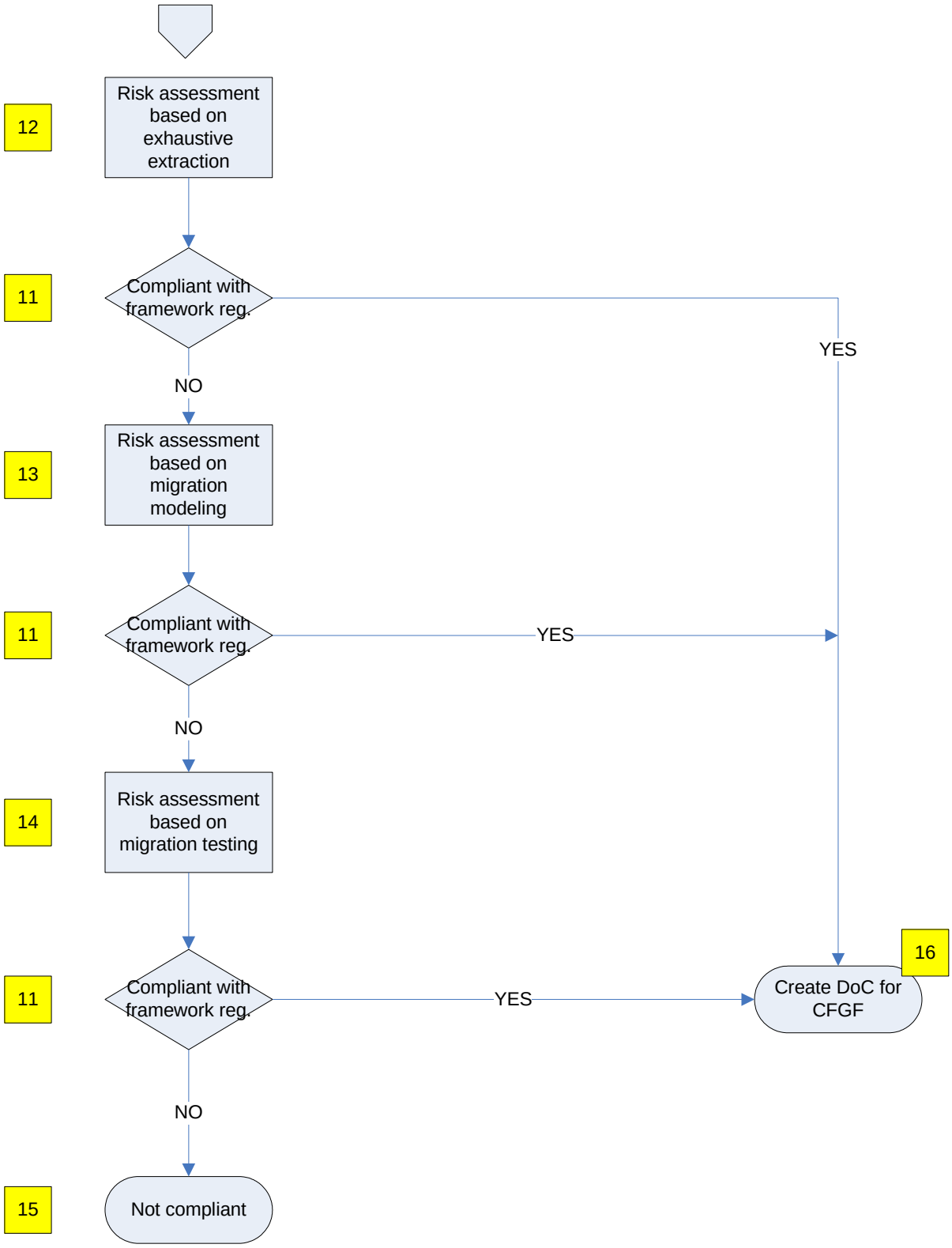
The following flow diagram gives a short overview on the different steps of a compliance check.

- Determine the function of sizing raw materials
- For coupling agents and reactive film formers reactive polymers, obtain Declara-tion of Compliance (DoC) from the suppliers
- For processing aids, perform a risk assessment according to internationally recognized scientific principles and verify the absence of non-authorised CMR substances of category 1A or 1B
- Transmit down the supply chain a certificate of compliance allowing the producer of the final GFRP to have access to required information for verifying compliance with the applicable specific migration limits (SML) and other restrictions or specifications.

4.2. Flow diagram



Continuation Flow diagram



4.3. Description of the compliance verification process

1	The CFGF manufacturer formulates the sizing from selected ingredients and knows the quantity of each ingredient applied on the CFGF product. Sizing ingredients are either substances (known identity) or commercial mixtures. Some commercial mixtures have a "supplier's proprietary" composition not fully disclosed to the CFGF manufacturer.
2	Identify sizing ingredients which are coupling agents and reactive film former polymers must be listed in Annex I of Regulation (EU) No. 10/2011. In case of proprietary information, a Third Party Expert evaluation is advisable.
3	Obtain a confirmation from the supplier that the relevant sizing ingredients (coupling agents and reactive film formers polymers) are compliant with Regulation (EU) No. 10/2011 (comply with listing requirements). Inform the supplier of this Guidance Document where necessary.
4	The CFGF is not compliant with Regulation (EU) No. 10/2011 and requires reformulation of the sizing or petitioning of the non-compliant monomers or starting substances.
5	Identify those substances that are processing aids.
6	Processing aids which are listed on Annex I of Regulation (EU) No. 10/2011 do not require further assessment. Compliance of a processing aid can either be certified by the supplier or by the CFGF manufacturer's own verification if the chemical identity (FCM-substance no., Annex I reference-no., CAS-no., substance name) of the processing aid is known. Processing aids not listed on Annex I have to undergo further compliance evaluation. Note: Some processing aids may be included in the Union List with purity criteria which were set in the context of a petition for their use in plastic. When used in a glass fibre sizing or binder, such purity criteria may be disregarded when certifying compliance and evaluated by a risk assessment based on their low concentration in the final plastic. The practical reason is that the supply chain does not provide separate food contact grades for all processing aids. Such high purity grades are not always available for CFGF sizing applications.
7	Processing aids containing substances classified as CMRs cat. 1A or 1B according to Regulation (EC) No. 1272/2008 are not authorized for food contact materials.
8	Verify if the substance is authorized at national level (NL: Warenwet; DE: BfR recommendations).
9	Verify if the substance is authorized by international recommendations (CoE coatings list, FDA CFR 21,…).
10	If the processing aid is not listed in one of the above lists, a risk assessment according to article 19 of Regulation (EU) No. 10/2011 is required. As an initial step the maximum possible migration (worst case migration) of the final GFRP part based on the known composition of the processing aid, its content in the CFGF and the known or assumed conditions of use (content of CFGF in the GFRP, repeated use, …) has to be calculated. The risk has to be estimated based on the toxicological properties of the different migrants and the calculated content in the food.
11	If the result of the risk assessment demonstrates compliance with article 3 of the Framework Regulation (EC) No. 1935/2004, the CFGF manufacturer is in the position to issue a Declaration of Compliance (DoC). If not compliant, the risk assessment can be refined by adjusting the migration potential of the different substances with more realistic figures which can be obtained by extraction, migration modelling and/or realistic migration tests.

Continuation Description of the compliance verification process

12	Extraction of the CFGF sizing: this approach is intended to provide more realistic figures for the actual quantities of substances available for migration.
13	Migration modelling based on extraction results simulates the ability of the plastic matrix to reduce the mobility of the different identified migrants and consequently to reduce their migration into food.
14	Migration testing with GFRP samples: the worst case conditions for the migration tests should be chosen according to Regulation (EU) No. 10/2011, Annex V, and should cover the foreseeable conditions of use for the intended application(s) of the FCM.
15	If none of the above methods allow demonstrating compliance with the frame work regulation, the CFGF product cannot be released for food contact applications under the conditions of use which have been considered in the risk assessment.
16	If the sizing is considered as compliant with the Framework Regulation (EC) No. 1935/2004, the DoC for the CFGF product can be issued. The presence of substances with restrictions and/or specifications should be mentioned in the DoC. For confidentiality reasons, their identity might not be included in the DoC; however, they shall be made available under a Non Disclosure Agreement to a third party institute mandated for verification purposes. Note: the DoC for CFGF does not discharge the manufacturer of the final material or article to verify and ensure its compliance with applicable regulatory requirements.

5. DESCRIPTION OF THE METHODS

5.1. Calculation of Maximum Possible Migration (Worst Case)

According to the Note for Guidance (EFSA 2008, chapter IV "Commission Explanatory Guidance for Migration Testing", subchapter 3 "Calculation of the maximum possible migration")[1], the maximum possible migration can be calculated on the basis of residual or actual content of the migrant in the polymer sample. The residual content of migrant in the polymer can be determined by e.g. exhaustive extraction or dissolution of the polymer. This procedure has the advantage that the results can be easily extrapolated to any other food contact article made of the same polymer, with only one test having to be performed.

This calculation is made by applying the following formula:

$$M = Q \times A \times Lp \times D$$

where:

M = is the maximum possible migration of the substance expressed in mg/kg foodstuff.

Q = is the quantity of the substance in the finished article in mg/kg polymer.

A = is area of the food contact material in dm²/kg foodstuff, conventionally set at 6 dm²/kg foodstuff. For repeated use applications a reduction factor can be applied to adjust the surface to food ratio.

Lp = is the thickness of the food contact material in dm.

Maximum thickness depends on the polymer and the diffusion coefficients of the components. In our example, we used the conventional thickness of 0,0025 dm.

D = is the density of the GFRP in kg/dm³.

The table below gives an example calculation with a GFRP of a density of 1.45 kg/dm³, a content of 40% glass fibre in the polymer and a sizing representing 1% of the CFGF mass. Instead of a specific substance, the calculation is made for the sizing as is. In knowing the composition of the dry sizing, the maximum migration of the different components of the sizing can be estimated.

Assumptions	**Value**	**Unit of measure**
density D of the GFRP	1,45	kg/dm³
thickness L_p for max. migration	0,0025	dm
standard food / surface ratio A	6	dm²/kg
reduction factor for repeated use	100	arbitrary hypothesis
adjusted food / surface ratio A	0,06	dm²/kg (factor 100 for repeated use)
max. content of glass fiber in the polymer	40	%
max. content of dry sizing	1	%
content of processing aid PA1 in dry sizing	0,5	%
content of processing aid PA2 in dry sizing	6	%
Calculations		
mass of GFRP in contact with food	217,5	mg
content of glass fiber in GFRP	87	mg
content of total dry sizing M available for migration	0,87	mg/kg food
max. migration of PA1	0,004	mg/kg food
max. migration of PA2	0,052	mg/kg food

The calculation shown above can easily be adapted to different polymers, glass fibre and sizing content.

Generally the assumption is that 100% of the sizing can migrate with the exemption of unreacted monomers which are calculated as being 1% of the total content.

5.2. Risk Assessment

Based on the calculated 100% migration and available toxicological data of the substance a risk assessment according article 19 of Regulation (EU) No. 10/2011 shall be conducted to determine compliance with article 3 of the Framework Regulation (EC) No. 1935/2004.

[1]European Food Safety Authority (30/07/2008) Note for Guidance for Petitioners Presenting an Application for the Safety Assessment of a Substance to be Used in Food Contact Materials prior to its Authorisation.

Annex IV lists selected literature containing detailed guidance for risk assessment procedures.[2] [3] [4]

In case compliance cannot be demonstrated, the following options should be considered:

- The maximum content of glass fibre in the GFRP has to be reduced.
- The maximum contact area of the GFRP in contact with food has to be reduced.
- The quantity of the substance in the GFRP has to be reduced.

5.3. Extraction Testing on Glass Fibre Samples

The curing process which the glass fibre sizing undergoes once it has been applied to the glass fibres (see also Annex II of this document for technical details) changes the chemistry of the sizing raw materials and eliminates most volatile ingredients; therefore it is important to know which potential migrants actually remain in the sizing.

In order to determine which low molecular weight compounds are present in the sizing, an exhaustive extraction in a suitable solvent can be carried out with the CFGF.

The ingredients in the extract are then identified and (semi-)quantified by chromatographic methods like GC/MS or HPLC/MS, depending on their volatility. An internal standard is added to the solution for semi-quantification. The most important peaks in the chromatogram need to be identified and semi-quantified, and the molecular weight of those peaks should be estimated (also by comparison to internal standards) for later use in the modelling calculation.

In case identified sizing ingredients are available as pure substances to be used for analytical standards, quantification should be done by generating full calibration curves.

Example screening method[5]:

1.0 g of the CFGF resp. 0.1 g of the pure sizing ingredient samples (in duplicate) are extracted by total immersion with 10 ml of dichloromethane for 2 d at 40°C and 10 ml of 95% ethanol for 2 d at 60°C. An internal standard of well-established and easily detectable substances like butylated hydroxyanisole (BHA) and Tinuvin 234 is added to an aliquot of the extracts and analysed by gas chromatography with flame ionisation detection (GC-FID) for semi-volatile compounds. The standard is also added to the rest of the extracts which is then reduced to approx. 1 ml to enhance the detection sensitivity.

The extraction solutions are analysed by gas chromatography with flame ionisation detection (GC-FID): DB-l-capillary column (length 30 m, inner diameter 0.25 mm, film thickness 0.25 pm) and the following temperature programme:

50°C (2 min isothermal) up to 340°C with a heating rate of 5°C/min, then 10 min isothermal at 340°C. Interesting peaks are identified and semi-quantified using the internal standard BHA.

The identification of the main compounds is done by GC analysis coupled with mass spectrometry. GC/MS-System: ThermoFinnigan SSQ, column: Optima-5-MS - 30 m length - 0.25 mm i.d. - 0.25 pm film thickness, temperature programme:

60°C (1 min), heating rate 10°C/min, 340°C (20 min), full scan mode, mass range m/z 40 - 800.

The identification of the spectra may be done by comparison with the NIST spectra library. A confirmation of the suggested spectra by analysis of a respective standard is also possible.

The detection limit of this screening method was found to be 5 ppm.[6]

5.4. Migration Modelling

There are several migration model programmes available on the market. Best known is MIGRATEST by Fabes Forschungs-GmbH in Munich, Germany (see also their website www.fabes-online.de). Another is AKTS-SML (www.akts.com) by AKTS AG, in Siders/Switzerland.

In order to select the best parameters for modelling, several aspects must be taken into account.

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[2] Guidance of the Scientific Committee on Transparency in the scientific aspects of risk assessment carried out by EFSA. Part 2: general principles. EFSA Journal (2009) 1051, 1-22.
[3] IPCS (1996) Principle for the safety assessment of food additives and contaminants in food. WHO, International Programme on Chemicals Safety (Environmental Health Criteria 70)
[4] Transparency in risk assessment carried out by EFSA: Guidance Document on procedural aspects. EFSA Journal 353, 1-16.
[5] Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4585/10 Part 1-3, chapter 3.
[6] Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4585/10 Part 1, table 1; Part 2, table 1+2; Part 3, table 1-3.

The typical application for a thermoplastic GFRP in food contact is a technical part, e.g. in a coffee machine or other kitchen food processing appliance. Repeated food contact with small contact surfaces at elevated temperatures is to be expected.

Reinforced thermosets usually have much larger contact surface areas, and in some cases storage containers are made from reinforced thermosets, which are then in direct long-term food contact at ambient temperature.

Since there are no validated migration models for thermosets to the authors' knowledge, it is recommended to verify migration by actual testing in cases where 100% migration calculations exceed the limits.[7]

Reinforced polymers contain on average 30% (5 – 65%) sized glass fibres. Thermoplastics like PA, PPS, PPO, PSU, LCP, PP and thermosets (e.g. unsaturated polyesters) are most commonly used as matrix for GFRP.

It is interesting to note that migration modelling parameters for most of the polymers given above are not available in the literature. Therefore worst-case assumptions need to be made for these polymers. It is recommended to perform preliminary migration tests on such polymers with selected well-known ingredients in order to refine the modelling parameters, before starting the calculations on any of the potential migrants.

The example calculation was performed using the programme MIGRATEST © Lite 2001 (Fabes GmbH, Munich, Germany).[8]

The parameters of the modelling calculation were set as follows:

The surface-to-simulant ratio was 0.2 dm² of surface to 1 l of simulant. The worst case contact conditions were 30 min at 100°C. As food simulants 3% acetic acid resp. 50% ethanol were applied.

A partition coefficient of K = 1 was used. This partition coefficient represents good solubility of the migrant in the food simulant (worst case).

A thickness of 0.8 cm was used for the food contact article.

For the food compliance evaluation a maximum concentration of 10 ppb was assumed.

The following table summarises the polymer specific parameters, which are published in the literature[9]. For polymers not included in this list worst-case assumptions need to be made.

Polymer type	Ap	τ	Polymer type	Ap	τ
LDPE	11.5	0	PS	-1.0	0
PA12	2.6	0	HDPE	14.5	1577
PA66	2.0	0	PP	13.1	1577
HIPS	1.0	0	PET	6.4	1577
PA6	0	0			

The modelling calculations carried out in the exemplary test programme[10] yielded the following results:

Sizing	Epoxy/PP	PP	PUR	PUR	PUR
Migrant Concentration	1.5 ppm	15 ppm	50 ppm	150 ppm	130 ppm
Mol. Weight	150 g/mol	300 g/mol	100 g/mol	200 g/mol	400 g/mol
Matrix	Calculated migration (ppb)				
High diffusive	1.9	8	90	134	40
Low diffusive	0.08	0.3	4	6	1.8

[7] Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4455/12, chapter 4.3.
[8] Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4585/10 Part 1-3, chapter 5.
[9] Applicability of generally recognised diffusion models for the estimation of specific migration in support of EU Directive 2002/72/EC, C. Simoneau (ed.), JRC Scientific and Technical Reports, EUR 24514 EN 2010.
[10] Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4585/10 Part 1-3, chapter 5.

Sizing	PVAc	PVAc	LM Epoxy	LM Epoxy
Migrant Concentration	50 ppm	50 ppm	50 ppm	600 ppm
Mol. Weight	100 g/mol	300 g/mol	100 g/mol	300 g/mol
Matrix	Calculated migration (ppb)			
High diffusive	90	25	90	304
Low diffusive	4	1.1	4	13

The details can be taken from the referenced test report. The main conclusion of this modelling exercise is that depending on measured residual concentration and molecular weight of each migrant, the typical range of sizing ingredient migration can be expected to be between 0.1 and 100 ppb. This means that in many cases migration modelling already allows the determination of the level of migration sufficiently to ensure compliance of migratable sizing ingredients.

It was also observed that compatible chemistries of film former polymers and matrix polymers reduce not only the available migrant concentration, but also the diffusivity of potential migrants. Such a chemical compatibility of film former and matrix is necessary to achieve the desired technical effect of the film former (see Annex II, chapter 6.2.2 for technical details).

Therefore commercially available GFRP are generally expected to yield low amounts of migratable sizing ingredients.

5.5. Migration Testing and Validation of Modelling Results in the Final GFRP

Screening analysis of migratable compounds by extraction

Either granules or plastic parts ground into particles of approximately 1-5 mm diameter (careful: powders in the µm diameter range would give non-representative results – any fine grinding dust should be removed by sieving) are exhaustively extracted and checked for recovery of any sizing ingredients. In order to subtract any peaks originating from the polymer matrix or additives, a reference sample of the same polymer without GF reinforcement should be analysed as well.

The chromatographic methods used for identifying and quantifying the migrants from the GFRP are basically the same as for the CFGF. In some cases adjustments may be necessary to accommodate for the additional migrants originating from the plastic material. Furthermore, the much lower concentrations of the sizing ingredients in the GFRP may require additional analytical method development in order to achieve lower detection limits.

Example screening method[11]:

1.0 g of granule samples (in duplicate for screening GC-FID analysis) resp. 2.0 g of ground plate samples (in duplicate for specific GC-MS analysis) are extracted with 10 ml of dichloromethane (DCM) for 3 days at 40 °C. The extraction is repeated with fresh solvent to show the exhaustiveness of the extraction. The first extraction can be regarded as exhaustive if the second extraction amount is less than 10 % of the first extraction amount.

An internal standard of butylated hydroxyanisole (BHA) is added to an aliquot of the extracts, and analysed by gas chromatography with flame ionisation detection (GC-FID) for semi-volatile compounds. The internal standard is also added to the rest of the extracts which is then reduced to 1 ml to enhance the detection sensitivity.

Key compound peaks are semi-quantified using the internal standard BHA.

The extraction solutions are analysed by gas chromatography with flame ionisation detection (GC-FID): DB-1-capillary column (length 30 m, inner diameter 0.25 mm, film thickness 0.25 µm) and the following temperature programme:

50°C (2 min isothermal) up to 340 °C with a heating rate of 10 °C/min, then 10 min isothermal at 340 °C. Interesting peaks are semi-quantified using the internal standard BHA. The identification of the main compounds is done by GC analysis coupled with mass spectrometry. GC/MS-System: ThermoFinnigan SSQ, column: Optima-5-MS - 30 m length - 0.25 mm i.d. - 0.25 µm film thickness, temperature programme: 60 °C (1 min), heating rate 10 °C min-1, 340 °C (20 min), full scan mode, mass range m/z

[11] Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4410/11 Part 1-3, chapter 3.

40 - 800. The identification of the spectra is done by comparison with the NIST spectra library. A confirmation of the suggested spectra by analysis of a respective standard may also be done.

The detection limit in the extraction solutions of this screening method was found to be between 5 ppm and 10 ppm. Depending on the expected concentration range of potential migrants, the substances of interest should then be targeted individually using specially developed analytical techniques designed to lower the detection limit into the ppb range. Methods have to be chosen according to the results of the sizing formulation check and the screening tests.

Migration estimation[12]

The detection limit of the applied chromatographic method (in this example 10 µg/g polymer or 10 ppm) can be used for the prediction of the migration of "non-detectable" compounds in the glass fibre reinforced samples.

For the following example of a migration calculation the standard migration model described in Annex I, chapter 5.4, is used. The calculation parameters are as follows: AP = 13.1, t = 1577 K, K = 1.

The volume of the simulant is assumed as 100 ml (case 1) and 1000 ml (case 2). The temperature is 78 °C (reflux temperature of ethanol) and the contact time 30 min. The thickness of the plate is 2 mm and the surface area 40 cm². The results are given in Figure 1.

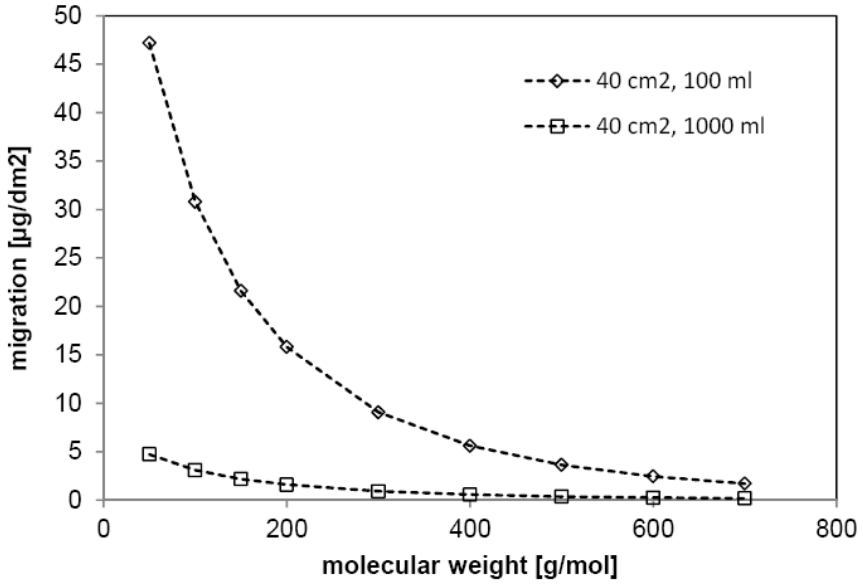

Figure 1. Migration calculation for the maximum migration assuming a concentration of a migrant in the sample of 10 ppm (detection limit)

This example illustrates the influence of various parameters like molecular weight or surface/volume ratio on the migration.

Depending on the analytical results of the extraction test, such a migration estimation based on detection limits may be used to decide whether actual migration testing is necessary or feasible, depending on the applicable Worst Case Conditions and the analytical capabilities available.

Migration test and validation of migration model

In case the concentrations of the potential migrants identified in the extraction tests are too low to be found in the migration solution, well-known "tracing substances" can be used to validate the migration experiments and the migration modelling calculations.

The actual concentration of the tracing substance in the polymer is determined by exhaustive extraction (see chapter 5.3) and then modelled acc. to its molecular weight and concentration (see chapter 5.4).

The prediction of the migration model is then compared to the measured migration value for that substance. Thus it can be determined whether the modelling calculation is likely to over- or under-estimate the migration. A corresponding safety factor can then be applied to all calculated migration

[12] Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4410/11 Part 1, chapter 4.2.

values, and the significance of each peak can then be determined e.g. by the Level of Interest (LOI) approach (only for NIAS).

Sizing ingredients found to have significant calculated migration can then be specifically targeted in the migration tests.

The methodology and various aspects of migration testing are described in the literature.13

Example screening method14:

Test method: European Standard EN 1186-3

Time and temperature: 30 min / reflux

Simulant: 100 ml of 50% ethanol

Surface area: 0.4 dm²

The test is carried out in triplicate, including a solvent blank.

The test plates are 2 mm thick. For the test both surfaces areas are taken into account.

An internal standard of butylated hydroxyanisole (BHA) is added to an aliquot of the migration solutions and analysed by gas chromatography with flame ionisation detection (GC-FID) for the fingerprint components. To enhance the detection limit the internal standard is added to 40 ml of the migration solutions which are then diluted with 160 ml distilled water and liquid/liquid extracted 3 times in series with dichloromethane. The dichloromethane is then reduced to approximately 1 ml under a nitrogen stream and analysed by GC-FID.

The migration solutions are analysed by gas chromatography with flame ionisation detection (GC-FID): DB-1-capillary column (length 30 m, inner diameter 0.25 mm, film thickness 0.25 µm) and the following temperature programme:

50°C (2 min isothermal) up to 340 °C with a heating rate of 10 °C/min, then 10 min isothermal at 340 °C. Interesting peaks are semi-quantified using the internal standard BHA.

In the example screening it was found that the aliquot migration solutions were too diluted to yield results. The liquid/liquid extracted and concentrated migration solutions yielded many interfering matrix peaks due to the sample preparation process. The detection limit was found to be between 150 ppb and 8 ppm. It is advisable to develop individual, more sensitive methods based on the chemistry of the target peaks identified in the screening analysis in order to reach the necessary 50 ppb resp. 10 ppb detection limit.

[13] Franz, R. and Störmer, A. (2008) Migration of Plastic Constituents, in Plastic Packaging: Interactions with Food and Pharmaceuticals, Second Edition (eds O. G. Piringer and A. L. Baner), Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim, Germany.

[14] Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4410/11 Part 2-3, chapter 3.

6. DESCRIPTION OF THE CFGF MANUFACTURING PROCESS

6.1. Overview

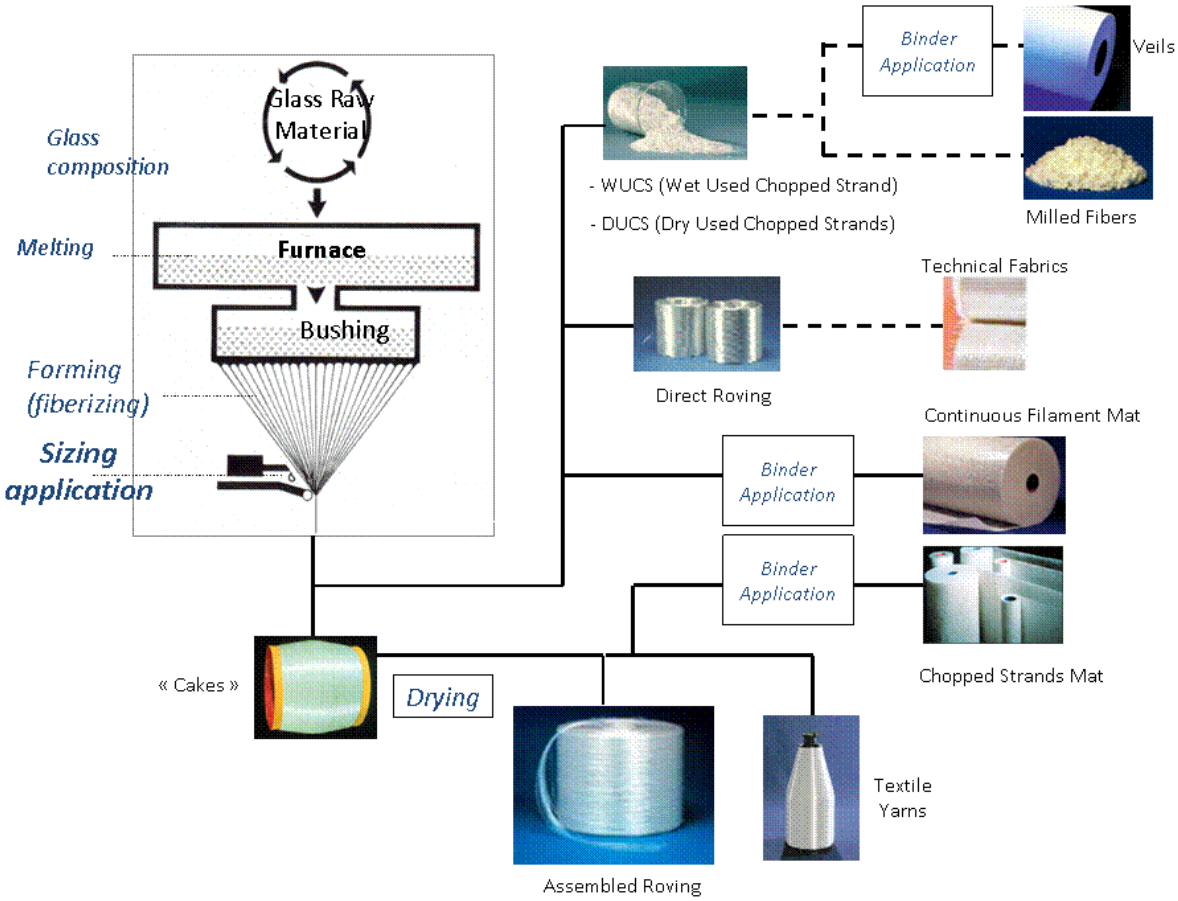

Figure 2. Schematic description of the CFGF manufacturing process

During the production of glass fibres for plastic reinforcement, molten glass flows to platinum/rhodium alloy bushings and then through individual bushing tips with orifices ranging from 0.75 to 2.0 mm. On exiting the bushing, the glass is rapidly quenched and attenuated (to prevent crystallization) into fine fibres with diameters ranging from 6 to 33 µm. As a result of the high linear speed of the glass fibres (mechanical winders or choppers pull the fibres at velocities up to 60 m/s), the very high cooling rates and the immediate interaction of the fibres with a coolant water mist, unique compositions and structures are created in the top layer of the fibre surfaces.

Within milliseconds of forming and cooling, a "sizing" is applied to the glass fibre surface - commonly by contacting an applicator roll carrying a layer of a mixture which may contain coupling agents, monomers or polymers and other processing aids.

The fibre sizing must supply the following characteristics to the strand of filaments:

- A good protection of the strand during its various processing stages
- A good cohesion between filaments within a strand
- Certain handling characteristics (e.g. hardness, softness, ability to be chopped, antistatic properties)
- A good bond between glass fibre and polymer matrix

Usually, sizings are aqueous chemical mixtures containing about 5% of "solids", (0.05-10%), with the rest being comprised of water. The "solids" generally consist of a number of multi-purpose components: coupling agents, film formers and processing aids.

To some CFGF products (Chopped Strand Mat, Continuous Filament Mat, Veil), a binder is added in a second production step to bind the strands together into the desired mat or veil shape.

The drying, respectively curing process, uses the following conditions:

CFGF Type	Oven Type	Curing T°	Drying + Curing Time	Type of Film Former	Final Matrix Type
Chopped Strands	Fluidized bed oven	150 - 280°C	2 - 5 min.	All	Thermoplastic, Thermoset
Direct Roving & Multi-End Roving	Hot air	110 - 140°C	24 - 36 hrs	All	Thermoplastic, Thermoset
	Radio Frequency	100 - 110°C	4 - 6 hrs	All	
Mat	Hot air	150 - 210°C	1 - 3 min.	Polyester	Thermoset

During the curing process, the solvents and other volatile ingredients of the applied sizing mixtures are removed completely. Moisture content after curing is usually < 0.05%.

6.2. Typical Composition of the Sizing

Sizing component type	Concentration (% of CFGF)
Coupling Agent	0.03 – 0.2
Film Former	0.05 – 1.0
Sizing / CFGF Processing Aids	0.001 – 0.25

6.2.1. Coupling Agent

The sizing generally contains an organo-functional silane commonly referred to as a coupling agent. One of the best known properties of the silane molecules is their ability to promote adhesion between the glass surface and the different plastic matrices. They have been reported to give improvements in interfacial strength and hydrothermal resistance of the interface.

The silane coupling agents have a general chemical structure of: $[\ R' - Si\ (OR)_3\ ]$.

The “OR” group will react with the glass surface.

The R’ reactive groups of the silane may either react with the reactive groups of the film former polymer (when needed and possible) during the CFGF manufacturing process or with the reactive sites of the polymer in the curing process (thermosetting polymers) or in the high temperature extrusion and injection moulding process (thermoplastic polymers) when the sized glass fibres are introduced into the plastic matrix that they have to reinforce.

This leads to a strong network “Glass – Sizing – Plastic“, in which all the partners are steadily linked through covalent and other bonds.

As to their function, coupling agents have to be considered as generating a significant effect on the properties of final reinforced plastic material.

6.2.2. Film Former

One of the most important components of the sizing is the film former which holds the filaments together in a strand after drying. The film former has a multifunctional role. By maintaining the strand integrity it protects the filaments from damage through fibre-fibre contact and fibre-process contact (winding, chopping etc.). Film formers are chosen to be as closely compatible to the intended polymer matrix as possible and still fulfil all the other requirements of a sizing.

The chemistry used in those film formers is generally similar to the one commonly found in adhesive applications. Film formers in their final fully reacted state are polymers.

Functions of the film former:

a) Primary function: Protection and Dispersion

Protection: Film formers bind the individual glass filaments together and protect them against abrasion during handling, storage and further processing.

The primary technological function of the film formers, shaping and protecting the filament bundles, may be more or less persistent and active upon compounding into the polymer or impregnating by the polymer to create the finished plastic material.

Dispersion: The nature and the quantity of the film former on the fibres will influence the dispersion of the glass fibre filaments into the matrix during compounding or impregnating.

This is illustrated by the picture below:

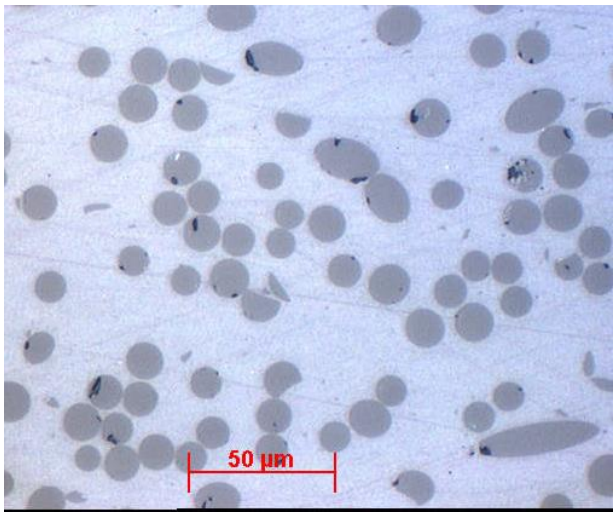

Figure 3. Polished micrograph of a typical GF reinforced plastic matrix

An optimized distribution of the fibres within the plastic matrix is essential for the manufacturing of reinforced plastics with technologically useful properties.

b) Secondary function: “Adhesive” i.e. interaction and interfacial bonding

The film former polymers are intended to remain at the interface between the glass fibre and the matrix. Many of these polymers are able to interact with the coupling agents on the glass fibre surface and/or the polymers of the plastic matrix. The type (Van der Waals, chemical bonds) of chemical link and the induced strength of adhesion have an influence on the properties of the reinforced plastic materials. The film formers are tailor–made in order to have the best compatibility with the specific type of plastics intended to be reinforced.

These two types of functions impact the properties of the reinforced plastic materials. By influencing the distribution of the fibres and/or interacting with the matrix or by chemically bonding the fibres to the matrix, the film formers may influence the mechanical properties and/or the ageing behaviour of reinforced thermoplastics. In reinforced thermosets, the ability to improve moisture content is important for the final properties.

However, it is very important to note that the interfacial bonding can only take place in combination with a suitable coupling agent. Without that, the film formers cannot sufficiently adhere to the glass fibre surface.

Examples of Film Former types

Poly Vinyl Acetate (PVAc) and Poly Vinyl Alcohol (PVA)

Polyurethane (PUR)

Unsaturated Polyester

Epoxy resins, partly modified

Polyolefin – maleic acid modified

Poly Carboxylic acid

Poly Vinyl Pyrrolidone

6.2.3. Sizing Processing and Curing Aids / CFGF Processing Aids

a) Sizing processing and curing aids

Beyond coupling agents and film formers, other chemical substances or mixtures can be added to the sizing formulation for various purposes including, but not limited to: maintain the stability of the sizing formulation, enhance the applicability of the sizing on the fibre, and protect the sizing from the high temperatures used in the oven.

Examples include: emulsifiers, pH adjusting agents, surfactants, antifoaming agents, antioxidants, and heat stabilizers.

b) CFGF processing aids

Beyond coupling agents and film formers, other chemical substances or preparations can be added to the sizing formulation to support mechanical processing of the fibres such as drawing and/or chopping.

Examples include: lubricants and antistatic agents.

The processing and curing aids have function only during the manufacturing process of the CFGF products and during their subsequent handling. Therefore they may be considered production aids as defined in Regulation (EU) No. 10/2011.

6.2.4. Binder

The binder is applied independently from the film former and at a later production stage. It is only required for certain CFGF products like mats and veils. Its main function is to bind the glass fibre strands together. The chemistry is generally chosen to be as compatible as possible to the final composite matrix.

Examples of Binder types

Poly Vinyl Acetate (PVAc) and Poly Vinyl Alcohol (PVA)

Polyurethane

Unsaturated Polyester

Epoxy resins, also modified

Polyolefin – maleic acid modified

Poly Vinyl Pyrrolidone

The binder is processed (dried and/or molten and/or cured) during a treatment step to fix the mats or veils into their intended shape (for more technical details see chapter 6.2.2).

***

ANNEX I: TEST REPORTS

The test reports attached here represent the work of the Joint Reinforced Plastics Working Group (JRPWG) in cooperation with Fraunhofer IVV, Germany.

The primary intention of the screening tests performed on selected, representative CFGF and GFRP samples was to illustrate the methods proposed in this Guidance Document and give members of the value chain a rough idea about what to expect when evaluating the suitability of CFGF sizings for reinforced plastics in food contact.

The complexity of the sizing compositions on one hand and the number of supply chain members involved in the manufacture of CFGF and GFRP on the other, made it necessary for the JRPWG to issue this Guidance Document and make it available to the entire industry.

It should not be presumed, however, that screening tests alone will suffice for the petitioning of an unlisted film former monomer or coupling agent. However, this Guidance Document shall serve as additional instruction to be used together with the EFSA Note for Guidance.[15]

Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4585/10 Part 1-3, 24.03.2011

Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4410/11 Part 1-3, 23.05.2012

Fraunhofer Institut für Verfahrenstechnik und Verpackung (IVV), Test Report PA/4455/12, 17.12.2012

[15] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4168.pdf

ANNEX II: DG SANTE'S LEGAL INTERPRETATION

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Innovation and Sustainability

Brussels,
SANTE/E6/GG/aj (2015)

Dr Axel Jorns
European Glass Fibre Producers
Association (AISBL)
Rue Belliard 199,
B-1040 Brussels.
Belgium

axel.jorns@glassfibreeurope.eu

Dear Dr Jorns,

Subject: Regulation (EU) No 10/2011 - end of transition period for additives used in glass fibre sizing for glass fibre-reinforced plastics

Ref.: Your e-mail of 23 October 2015

Thank you for the above-mentioned e-mail to which we provided a preliminary reply on 11 November 2015. In this e-mail you in essence ask us to extend the transition period for additives used in glass fibre sizing for glass fibre-reinforced plastics.

As you know we considered prolonging the transition period in draft proposals waiting for input from the European Food Safety Authority (EFSA) and in the analysis of EFSA opinion of July 2015 but we never provided specific assurances that the transition period would be extended.

After further analysis which comprised, amongst others, the discussion with AISBL of 21 October 2015 and consultation with Member States authorities on 4 December 2015 we concluded that we would not prolong the transition period. The decision was taken on the following background:

1. Glass fibre-reinforced plastics (GFRP) are covered by Regulation (EU) No 10/2011 *on plastic materials and articles intended to come into contact with food*[1]. Article 5(1) of that Regulation rules that only the additives and starting substances included in the *Union list* of authorised substances set out in its Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.

   "*Additives used in glass fibre sizing*" for GFRP were excluded from the Article 5(1) requirement for a transitional period[2]. This transitional period ended on 31 December 2015.

[1] The legislation of the European Union is available at http://eur-lex.europa.eu/homepage.html

[2] This has been achieved by Article 22 (Transitional provisions), paragraph 4 and 23 (Entry into force and application), paragraph 4 which read (emphasis added):

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111

2. The Regulation does not define "*additives used in glass fibre sizing*". Its recitals do explain neither the nature nor function of these additives, nor why a transition period was necessary for them.

3. The definition of *additives* in Article 3(7) of the Regulation does not truly match all functions achieved by sizing, it reads (emphasis added):

   "[...]a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article".

4. The term "*additives used in glass fibre sizing*" could refer either to the final coating on the glass fibre as a whole or to the individual substances used in glass fibre sizing.

   In case the sizing as a whole would be considered an '*additive*', each sizing would need to be listed in accordance with Article 5(2)(b) of the Regulation.

   Given the technical specificity and complexity of these mixtures, their evaluation is difficult. It would thus create a considerable burden for the industry, for EFSA and the Commission. Such additional burden would have to be justified by relevant safety concerns which, in the light of what will be further explained, does not seem to be the case here.

5. The understanding of the term "*additives used in glass fibre sizing*" as individual substances used in glass fibre sizing was favoured by AISBL who thus developed a draft guideline[3] in October 2013 classifying the components of the mixtures into the functional groups: coupling agents (binding glass fibres chemically to the polymer matrix), film formers (with several functions including binding glass filaments together and protecting them against abrasion), and aids to polymerisation.

   This classification allowed considering substances belonging to aforementioned functional groups in the light of the appropriate definitions set out in Article 3 of Regulation (EU) No 10/2011. In particular, coupling agents and certain substances used in film formers react with the polymers in the plastic. Hence, they meet the definition of *monomer or other starting substance* in Article 3(6) of the Regulation[4]. Other substances used in sizing are *polymer production aids* as defined in Article 3(8) of the Regulation. Notably, none of the substances used in sizing where classified as *additives* as defined in Article 3(7).

   Considering this the Commission asked EFSA whether the proposed classification would ensure that GFRP would satisfy the requirements of Article 3(1) of Regulation (EC) No 1935/2004, i.e. not pose a risk to human health.

   In its opinion of 23 June 2015 the EFSA concluded on the classification proposed and repeated on page 5 of its opinion that it did not see merit in deviating from risk management decisions taken earlier on the relevant substance classes. Thus according to EFSA's opinion only coupling agents (to be listed as starting substances) and reactive polymers (on the basis of their monomers) not yet listed in

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Article 22(4): *Until 31 December 2015 additives used in glass fibre sizing for glass fibre reinforced plastics which are not listed in Annex I have to comply with the risk assessment provisions set out in Article 19.*

Article 23, fourth paragraph: The provision of Article 5 as regards the use of additives used in glass fibre sizing for glass fibre reinforced plastics, shall apply from 31 December 2015.

[3] *Compliance scheme of CFGF used in GFRP intended to come in contact with food (copy attached,* see flow chart on page 6, step 4)

[4] Predictably, some of these substances are on the Union list.

the *Union list (i.e.* Annex I of Regulation (EU) No 10/2011) would have to undergo an assessment by EFSA[5] unless they fall under the scope of the provisions of Article 6(3)(d) of the Regulation.

6. EFSA states that it is likely that most of the substances are already on the *Union list.*

In consequence, of the above and in the light of the aforementioned EFSA opinion further transitional measures would not be justified.

In this context it should be clarified, that while EFSA opinions are not legally binding, the opinion at stake provides the technical elements to classify substances used for sizing under Regulation (EU) No 10/2011. In the other words, it provides technical input to apply the current legal framework and thus does not require any modification of the latter.

We recall that the 2013 AISBL guideline appreciates that if the approach through individual substances would be taken, coupling agents and film forming polymers would have to be authorised in accordance with Article 5(1) of Regulation (EU) No 10/2011, i.e. be on the *Union list* of authorised substances. Still AISBL signals that manufacturers may have difficulties to issue declarations of compliance as required by Article 15 of the Regulation after 31 December 2015 if the individual substances approach is applied as described above. AISBL neither identified the substances used in GFRP that would be caught by the Article 5(1) of Regulation (EU) No 10/2011 requirement nor explained why the necessary applications for coupling agents and film forming polymers have not been presented in due course.

We also recall that all substances used in glass fibre sizing that benefitted from the transitional period that ended on 31 December 2015 had to be assessed in accordance with Article 19 of Regulation (EU) No 10/2011.

Finally, we appreciate that the question arises whether glass fibres and glass fibre-reinforced plastics treated with sizing agents for which the transition period granted in Articles 22 and 23 of Regulation (EU) No 10/2011 *on plastic materials and articles intended to come into contact with food* applied, can legally be used to produce materials and articles beyond 31 December 2015.

Article 15 of Regulation (EU) No 10/2011 requires that a declaration of compliance is issued by business operators at all marketing stages other than retail and for all plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles.

Article 15(3) of Regulation (EU) No 10/2011 rules that such declaration of compliance

> *"shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available".*

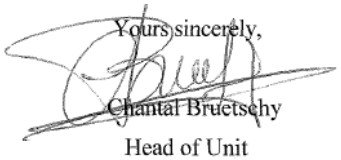
Given that, even where inclusion in the Union list is not required, any substance used in glass fibre sizing had to be assessed in accordance with Article 19 of Regulation (EU) No 10/2011 since it became applicable and the criteria of Article 15(3) of Regulation (EU) No 10/2011 cited above, it would seem plausible to presume that declarations of compliance issued in conformity with Regulation (EU) No 10/2011 before 31 December 2015 remain valid and can be relied on for the purpose of Article 16 of Regulation (EC) No 1935/2004 of the European *Parliament and of the Council on materials and articles intended to come into contact with food.*

[5] See in paragraph 3.2 of the EFSA Opinion (top of p. 8)

Please note that the above is purely to assist you. A final authoritative interpretation of Union law can only be given by the Court of Justice of the European Union.

We hope these explanations are helpful.

Yours sincerely,



Chantal Bruetschy
Head of Unit

Electronically signed on 20/01/2016 11:51 (UTC+01) in accordance with article 4.2 (Validity of electronic documents) of Commission Decision 2004/563

ANNEX III: EFSA OPINION (ABSTRACT)

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4168.pdf

SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 23 June 2015

PUBLISHED: 14 July 2015

doi:10.2903/j.efsa.2015.4168

Approach for safety assessment of glass fibre-sizing agents in glass fibre-reinforced plastics for food contact

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

Abstract

Following a request from the European Commission, EFSA was asked to review Commission proposals for classification of the substances used as sizing agents and provide an opinion on whether or not the proposed classifications could imply an unacceptable risk to human health. Glass fibre-reinforced plastics are composite materials made of a polymer matrix reinforced with glass fibres. The glass fibres therein are coated with a surface treatment ('sizing agent') to hold individual filaments together and to promote adherence to the polymer matrix. Glass fibre-reinforced plastic is covered by Regulation (EU) No 10/2011, which stipulates that substances used for its manufacture should be listed in the Union List. From January 2016, the Plastics Regulation will also apply to glass fibre-sizing agents, and these substances shall be included in the Union List. On the basis of the low migration from glass fibre-reinforced plastics and the low consumer exposure expected, the CEF Panel does not expect any particular health risks from sizing agents compared with other plastics. For substances classed as coupling agents and for the substances considered polymer production aids, aids to polymerisation or solvents used to make plastics, any use of glass fibre-reinforced plastics does not seem to merit deviation from risk management decisions that were taken earlier. For the reactive polymers used for sizing the glass fibres, two possibilities are presented: evaluation of these polymers by EFSA and then specific authorisation via the Union List or regulation through the starting materials, if already listed, in accordance with the derogation in Article 6(3) of Regulation (EU) No 10/2011. In either case, the data required and the risk assessment process used should be the same or equivalent. The difference will be in the data that are presented to EFSA, and this is a decision in the remit of the Commission.

Keywords: safety assessment, glass fibre-sizing agents, glass fibre-reinforced plastic, food contact materials

Requestor: European Commission

Question number: EFSA-Q-2013-00838

Correspondence: fip@efsa.europa.eu