Approaches to EU's New Regulation on Chemicals Called "Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)"

Guidelines for Carbon Fibers and Carbon Fiber Products

(4th Edition)

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Japan Carbon Fiber Manufacturers Association
Committee,
Japan Chemical Fibers Association

Revision history

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1st Edition	August 2008	Publication of the 1st Edition
2nd Edition	October 2008	Amendments of Cautions about This Paper
3rd Edition	November 2008	Postscripts about released substances, amendments of wordings and others
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Cautions about This Paper

This document intends to provide guidance to members of the Japan Carbon Fiber Manufacturers Association Committee, Japan Chemical Fibers Association (JCFA) in order for them to consider their obligations under the REACH Regulation, and how to fulfill them. The content of this document is for informational purposes only and it does not constitute and/or replace legal advice or opinion or any legal texts.

Readers are reminded that the REACH Regulation is the only official legal reference. Any reference to carbon fibers and/or carbon fibers product included in this document is provided by way of example only and does not assess or guarantee compliance with the REACH Regulation for specific products. Japan Carbon Fiber Manufacturers Association Committee, JCFA does not accept any liability for decisions taken in consideration of the information provided in this guideline.

(Note) Japan Carbon Fiber Manufacturers Association Committee, JCFA was created to take over the operations and affairs of the former Japan Carbon Fiber Manufacturers Association (JCMA), when the Japan Chemical Fibers Association (JCFA) and JCMA were merged in July 2014.

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1. Purpose

The European Union (EU) enforced its new regulation on chemical substances on June 1, 2007, which is called REACH (Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals). EU European Chemical Agency (ECHA) was established on June 1 and practical operation of the regulation such as the pre-registration of phase-in substances (conventional chemical substances) started.

As for the classification of man-made fibers, it can be judged that the classification of carbon fibers and acrylic fibers (precursors), flame-resistant fibers come under articles because man-made fibers were classified into articles in the Guidance on Articles published in May 2008, which showed an example in which man-made fibers are classified into articles. As for other carbon fiber products, on the other hand, there is no accurate example decidedly mentioned, and they are classified based on the judgment flow of the guidance. But there are expected to be some cases where companies may waver in their judgment about “articles” or “intended releases” of individual products.

This paper shows the interpretation of the Japan Carbon Fiber Manufacturers Association concerning representative examples of carbon fibers and carbon fiber products in view of the definitions and examples of “articles” and “intended releases” as mentioned in the latest guidance (Guidance on requirements for substances in articles, June 2017 Version 4.0). We recommend that companies refer to this paper for their review.

2. Definitions of Major Terms and Acronyms

(1) Definitions of major terms

The definitions of major terms used in the REACH Regulation and this paper are shown as follows:

[REACH Regulation, etc.]

- Substance means a chemical element or its compound in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (Article 3(1) of REACH).

- Preparation means a mixture or solution composed of two or more substances (Article 3(2) of REACH).

- Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition (Article 3(3) of REACH).

- Monomer means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process (Article 3(6) of REACH).

- Polymer means a substance consisting of molecules characterized by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units (Article 3(5) of REACH). A polymer comprises the following:

  (a) A simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

  (b) Less than a simple weight majority of molecules of the same molecular weight.

  In the context of this definition a “monomer unit” means the reacted form of a monomer substance in a polymer.

- Phase-in substance means a substance which meets at least one of the following criteria:

  (a) It is listed in the European Inventory of Existing Commercial Chemical

Substances (EINECS);

(b) It was manufactured in the Community, or in the countries acceding to the European Union on January 1, 1995 or on May 1, 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this;

(c) It was placed on the market in the Community, or in the countries acceding to the European Union on January 1, 1995 or on May 1, 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first Indent of Paragraph 1 of Article 8 of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this (Article 3(20) of REACH).

- Non phase-in substance means "a substance which does not meet the criteria of phase-in substance" (defined above), that is, a substance which was not manufactured or marketed or put on the market prior to the entry into force of REACH.

- Intended release means that a release of substances from articles is intended: when the release contributes to an accessory function of the article, or, in other words, the release contributes to the added value of the article, which is not directly connected to the end use function thereof; or when the article would not work sufficiently without the release.

- The following substances are considered substances of very high concern (Article 57 of REACH):

(a) Substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;

(b) Substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;

(c) Substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;

(d) Substances which are persistent, bioaccumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII of REACH;

(e) Substances which are very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII of REACH;

(f) Substances such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfill the criteria of points (d) or (e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59 of REACH.

※ Substances of very high concern are specified as substances that meet the criteria referred to in Article 57 of REACH, and a list of candidates thereof was made for eventual inclusion in Annex XIV according to the procedures set out in Article 59. As a result, 6 substances were announced as substances of very high concern on February 24, 2011.

- Agency means the European Chemicals Agency (ECHA) that is established by this Regulation (Article 3(18) of REACH).

- Manufacturing means production or extraction of substances in the natural state (Article 3(8) of REACH).

- Manufacturer means any natural or legal person established within the Community who manufactures a substance within the European Community (Article 3(9) of REACH).

- Import means physical introduction into the customs territory of the Community (Article 3(10) of REACH).

- Importer means any natural or legal person established within the Community who is responsible for import (Article 3(11) of REACH).

- Downstream user means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user (Article 3(13) of REACH).

[Carbon fibers, etc.]

- Acrylic fiber (Precursor) is a fiber that is made by stretching a high polymer and applying a processing agent, etc. to it as a material of carbon fibers. For example, a rayon fiber is similar fiber, too.

- Flame-resistant fiber is an organic fiber that is made by processing a acrylic fiber in an air atmosphere at 200-300℃ in a high-temperature furnace and that has flame resistance of LOI (limiting oxygen index) of 50 or higher.

- Carbon fiber is defined by Japanese Industrial Standards as a fiber made from organic fiber precursors and whose carbon content is 90% or higher. From an industrial point of view, carbon fibers are represented by PAN-based carbon fibers, which are made by making acrylic fibers flame resistant and carbonized, and pitch-based carbon fibers, which are made by making pitches spun, infusible and carbonized. Their forms come under continuous fibers or filaments and short fibers or staples. In general, processing agents that are necessary to improve the functions of end products are applied to carbon fibers.

- Short-cut fiber is a carbon fiber that is cut or milled.

- Prepreg is “pre-impregnated fibers,” where tow-like carbon fibers are arranged in the form of a sheet or a weave, which is then impregnated with resin. Desired articles can be formed by cutting prepregs into necessary sizes or by laminating and winding them. Prepregs are made by the wet method that uses solvents when resin is impregnated and the hot melt method that does not use any solvent.

(2) Meanings of major acronyms

The meanings of major acronyms in the REACH Regulation are shown as follows:

- CMR: the acronym for Carcinogenic, Mutagenic, Toxic for Reproduction

- DU: the acronym for Downstream User

- EINECS: the acronym for European Inventory of Existing Commercial Chemical Substances. This is a list of chemical substances that were placed on the European Community (EC) market during the period from January 1, 1971 to September 18, 1981 (the list of EINECS can be seen at http://ecb.jrc.it/esis/).

- ELINCS: the acronym for European List of Notified Chemical Substances. This is a list of substances that have been reported based on Directive 67/548/EEC and placed on the market on and after September 18, 1981 (the list of ELINCS can be seen at http://ecb.jrc.it/esis/). The substances listed in ELINCS are judged to be registered.

- PBT: the acronym for Persistent, Bio-accumulative and Toxic

- SDS: the acronym for Safety Data Sheet

- SIEF: the acronym for Substance Information Exchange Forum

- SVHC: the acronym for Substances of Very High Concern

- vPvB: the acronym for very Persistent and very Bioaccumulative

3. REACH and Carbon Fiber Industry

Full-scale operation of the REACH Regulation started on June 1, 2008, and the preparations for research on and registration of chemical substances to be used are now under way by the industry as a whole with chemical businesses as the central figure.

REACH will make it mandatory for all businesses in the European Union to register chemical substances that they produce or import one ton or more thereof a year in the European Union, and unregistered substances will not be allowed to be produced and sold in the European Union even if they are existing chemical substances.

Therefore, when businesses outside the European Union export chemical substances themselves and preparations into the European Union, they must be registered by importers or designate their sole agent for registration.

The role of safety assessment that has been played by regulatory authorities will be transferred to businesses, and the scope of responsibility assumed by businesses will be substantially expanded. Businesses will have to input a large amount of cost in safety assessment and registration procedures.

Not only chemical businesses are involved, but also substances contained in other products such as automobiles, home electric appliances and textile will also be subject to the regulation.

Specifically speaking, ① if chemical substances are intentionally released from products (hereinafter referred to as “intended release”), such chemical substances must be registered. ② If products have toxicity such as carcinogenicity, and substances of very high concern (hereinafter referred to as “SVHC”) for impact on human health or the environment are contained in excess of one ton or more a year and in excess of 0.1% of weight ratio, such products must be notified (registrations and notifications are presented to ECHA). ③ If SVHC are contained in excess of 0.1% of weight ratio, such information must be provided in writing to downstream users (DU) for safe use of articles.

As for the classification of man-made fibers, which drew most attention in the carbon fiber industry, the judgment of “preparation” or “article” has been discussed as a borderline case. In the Guidance on Articles, which was presented in May 2008, a case of judgment of “textile and nonwoven fabric” was added, and it was clearly mentioned that man-made fibers and nonwoven fabrics were classified into articles (see 4.(2) “Classification of carbon fibers and carbon fiber products and interpretation of articles”).

According to the case of judgment mentioned above and the judgment flow in the Guidance on Articles, carbon fibers and carbon fiber products are classified into “articles,” and their registrations are considered unnecessary. However, ① as to the judgment of products on the borderline between “preparation” and “article” and whether products involve release of substances that can be considered as “intended release,” it is necessary to consider on a case-by-case basis by reviewing each product. Moreover, ② as to the

substances covered by the SVHC list to be announced by the EU European Chemicals Agency in 2018, it is necessary to check whether such substances are contained or not contained in carbon fiber products. The carbon fiber industry needs to continue to keep an observant eye on relevant developments.

4. Interpretation of Carbon Fiber Products in Terms of REACH

(1) Basic approaches to the Guidance on Articles

The REACH Regulation and the Guidance on Articles, which was published in May 2008 and revised as version 4.0 in June 2017, describe the definitions and examples of "articles" and "intended releases" as follows.

They must be understood as they constitute the information as the grounds for judgment of cases of carbon fiber products.

Table 1. Definitions and Examples of "Articles," "Intended Releases" and "Containers/Substances in Carriers/Preparations"

Mark	Item/source	Definition and standard	Example
A-1	Definition of article (Article 3(3) of REACH and the Guidance on Articles)	Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.	Chemical fibers (see 4(2) (Classification of Chemical Fibers and Interpretation of Articles), thermometers, batteries, adhesive tape for carpet stopper, tires, etc. are classified into articles.
A-2	Changes in chemical compositions due to treatment of articles (The Guidance on Articles)	Chemical compositions as a whole change due to surface treatment of materials (articles) but the status of materials remain the same as articles. Examples are printing, painting and coating on the surface.	Chemical compositions may change in the finishing process other than surface treatment. In dyeing fibers, for example, though chemical compositions change but the status of materials does not change, and it is shown that fibers after dyeing still remain as articles.
B	Definition of intended release (The Guidance on Articles)	It is considered that a release of substances from articles is intended: when the release contributes to an accessory function of the article, or, in other words, the release contributes to the added value of the article, which is not directly connected to the end use function thereof; or when the article would not work sufficiently without the release.	Examples of fragrant erasers and lotion-added pantyhoses are presented. As for fragrant erasers, their main function is to "erase" something, and fragrance is added as an additional function. In this case, the eraser itself does not have to be registered, but the

Mark	Item/source	Definition and standard	Example
			components (substances and preparations) of fragrance must be registered.
C	Containers/substances in carriers/preparations (The Guidance on Articles)	In the case where substances and preparations are released from articles for the purpose of having a certain function manifested, and the function to release is the main function of the products, it is considered that they are not intentionally released from articles but they are regarded as substances and preparations contained in containers and carriers. ・ This applies when all or most of the points mentioned in (a), (b) and (c) below: (a) An intended purpose is achieved even though such substances are removed/separated from such articles or such articles are replaced with other articles of similar types. (b) Such articles play the role of containers or carriers for release, or control the supply of substances/reaction products. (c) Most of such substances are consumed or removed, or discharged outside of such articles after they are used (before disposal).	Examples such as contents ejected from spray cans, ink of pens and ink cartridges (the same applies to toner cartridges), lotion impregnated in wet tissue paper, and wax peeled and separated from wax tapes for skis are presented.

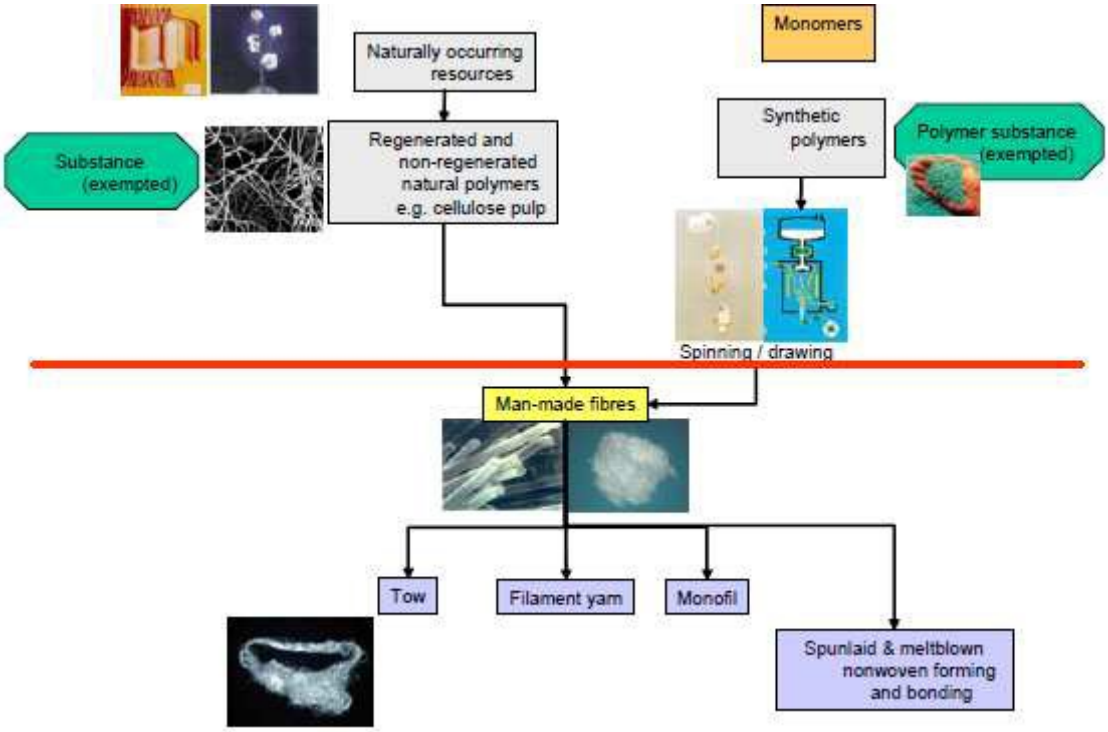
Table 2. Examples Not Regarded As Intended Release

Mark	Item/source	Definition and standard	Example
D-1	Dropping off in production process (The Guidance on Articles)	Removal (release) of impurities from a semi-finished or finished article during its production process is not considered to be an intended release.	An example of paste that is added to a fabric to improve its workability is dropped off (released) in the latter process (wet process) is presented as the interpretation of matters dropped off before articles are placed on the market as finished products.
D-2	Dropping off in use or maintenance (The Guidance on Articles)	A release that occurs during use or maintenance of a product and is meant to improve the product quality or the safety as a side effect but the released substances do not contribute to the function of the product is not considered to be an intended release.	An example that remnants of chemical substances (dye, softer, starch, etc.) from manufacturing process are dropped off (released) during washing of clothes by consumers is presented.
D-3	Secondary release (The Guidance on Articles)	A release that secondarily occurs when a product has its function manifested and that cannot be avoided (a release without which the product cannot function and is not intended) is not considered to be an intended release.	Examples of brake lining and tires are presented as the case where materials are contacted and torn off under friction conditions are presented.
D-4	Release caused by chemical reaction (The Guidance on Articles)	A release of substances formed during chemical reactions of any kind is not considered to be an intended release.	Releases that are unavoidable for having functions manifested like ozone released from photocopiers. Examples of substances released due to accidents and malfunctions of products like releases of combustibles from products due to a fire are presented.
D-5	Accidental release (The Guidance on Articles)	An accidental release caused by improper use or accident is not considered to be an intended release.	A release of substances from a thermometer that is dropped and broken. This also includes any form of misuse and inappropriate use which is not in conformity with the use instructions or functionality, even if it could have been anticipated.

(2) Classification of carbon fibers and carbon fiber products and interpretation of "articles"

Under the REACH Regulation, man-made fibers are discussed as the case of judgment on the borderline between "preparations" or "articles." In the Guidance on Articles, which was presented in May 2008, examples of "textile and nonwoven fabric" were mentioned, and it was clearly mentioned that man-made fibers and nonwoven fabrics are classified into "articles" (see Table 3).

Table 3. Examples of Textiles and Nonwoven Fabrics



(Source: The Guidance on Articles (published in May 2008))

As for carbon fibers themselves, though there is no specific description in the Guidance on Articles, the above-mentioned examples of man-made fibers are referred, and the Definition of Article (A-1 of Table 1) was referred. The carbon fibers and carbon fiber products mentioned in ①, ②, ③ and ④ below are considered to be "articles" as mentioned below (see Annex 1 and Annex 2). The judgment should be based on the latest ECHA Guidance. This document is based on the flowchart "Figure 2. Decision-making on whether an object is an article or not" on page 14 in the Guidance on requirements for substances in articles (version 4.0) issued in June 2017.

However, even though they are articles, response measures that comply with the REACH Regulation are additionally required in the case where there is an intended release or SVHC is included.

① Regarding acrylic fibers (precursors), flame-resistant fibers and carbon fibers:

- These are man-made fibers and classified into articles.

② Regarding short-cut fibers:

- Short-cut fibers are chopped or milled fibers, but both of them maintain the shape of fibers. As their shape (length, diameter, etc.) is more important in determining their function in use than their chemical composition, they are classified into "articles." Even when the carbon fibers are cut or deformed (cracked, etc.) during the use process, that is not considered to be an "intended release," and therefore short-cut fibers are classified into articles.

③ Regarding prepregs:

- Prepregs are integration of carbon fiber and resin in such shapes as sheet, tape and fiber. They can create desired shapes of articles by cutting, laminating, winding, etc. Therefore, as their shapes, surface conditions and designs are more important than chemical compositions to have their functions manifested, they are classified into articles.

④ Regarding other carbon fiber products:

- Textile goods, blades, nonwoven fabrics and carbon paper, which are made of carbon fibers and carbon fiber products, or processed goods made thereof such as heat insulating materials are also classified into articles.
- Composite products made of above-mentioned carbon fibers and carbon fiber products as their base materials are also classified into articles.

Furthermore, released substances from each product are considered as described below. However, this does not apply to the case where the purchaser of each product adds after purchase thereof any intended released substances to the product. (Please refer to Section 5. Q&A concerning Individual Examples of Carbon Fibers and Carbon Fiber Products.)

Table 4. Released Substances from Each Product

	Intended release	Interpretation of released substances
Acrylic fibers (precursors)	None	Processing agents such as oil solutions are integrated articles. Therefore, processing agents that are dropped off when they are used are not considered to be intended releases. Gases with H, N, C, etc. as a main composition are released when acrylic fibers are treated to be frame-resistant and carbonized. They are a release of substances formed during chemical reactions, but not considered to be an intended release. Also, the produced gases do not have functions.
Flame-resistant fibers, carbon fibers, short-cut fibers	None	Processing agents such as oil solutions are integrated articles. Therefore, processing agents that are dropped off when they are used are not considered to be intended releases.
Prepregs	None	There are cases where steam, high-volatility components or reactive condensation products are released when prepregs are made and hardened. Both are a release of substances formed during chemical reactions. Therefore, this is not considered to be an intended release. Also, the produced gases do not have functions.
Other products carbon fiber	None	Pursuant to the interpretation of the above mentioned product.

5. Q&A concerning Individual Examples of Carbon Fibers and Carbon Fiber Products:

Based on the definitions and examples of carbon fiber products in the Guidance on Articles (published in May 2008 and revised as version 4.0 in June 2017), the following shows interpretations on ① whether carbon fibers and/or carbon fiber products (both of which are themselves articles) can be considered as articles together with finishing agents or other agents used in them, and ② whether processing agents, functioning agents, etc., which drop off or are released from carbon fibers and/or carbon fiber products (both of which are themselves articles), are considered as intended releases, with regard to individual cases that can be expected for carbon fibers and carbon fiber products.

(Note: The marks in the "ground" column represent the marks in Tables 1 and 2.)

Q1) As for acrylic fibers (precursors), flame-resistant fibers and carbon fibers (including short-cut fibers) to which processing agents such as oil solutions, can they be considered to be articles, including processing agents? How about processing agents that are dropped off when they are used?

A1) They are considered to be articles in an integrated manner, including processing agents (ground: A-2 (Changes in chemical compositions due to processing of articles)). Processing agents that are dropped off when they are used are not considered to be intended releases (ground: D-1 (Dropping off in production process) and D-2 (Dropping off in use or maintenance)).

Q2) Taking an example, there is a fiber that contains a large amount of processing agent (5wt% for example). In this case, can the fiber be considered to be an article, including the processing agent? How about the processing agent that is dropped off when the fiber is used.

A2) The fiber is considered to be an article in an integrated manner, including the processing agent (ground: A-2 (Changes in chemical compositions due to processing of articles)). The processing agent that is dropped off when the fiber is used is not considered to be an intended release (ground: D-1 (Dropping off in production process) and D-2 (Dropping off in use or maintenance)).

Q3) Is the release of matters decomposed by combustion from carbon fiber products due to a fire and others applicable to an intended release?

A3) It is not considered to be an intended release (ground: D-4 (Release caused by chemical reaction)).

Q4) Is residual solvent (solvent used for wet spinning and dry spinning) that is dropped off in the production process of carbon fibers applicable to an intended release?

A4) It is not considered to be an intended release, including the case where acrylic fibers (precursors) produced outside of the European Union are exported into the European Union and such solvent is dropped off in the European Union (ground: D-1 (Dropping off in production process) and D-2 (Dropping off in use or maintenance)).

Q5) Is residual solvent (solvent mainly used for wet method) in prepregs, which is dropped off in use, applicable to an intended release?

A5) It is not considered to be an intended release, including the case where prepregs produced outside of the European Union are exported into the European Union and such solvent is dropped off in the European Union (ground: D-1 (Dropping off in production process) and D-2 (Dropping off in use or maintenance)).

Q6) Is the case, where a shape of article is made from prepregs and steam or solvent or condensation products are produced when the shape is hardened later, applicable to an intended release?

A6) It is not considered to be an intended release, including the case where prepregs produced outside of the European Union are exported into the European Union and steam or solvent or condensation products are produced at the time of hardening (ground: D-1 (Dropping off in production process), D-2 (Dropping off in use or maintenance) and D-4 (Release caused by chemical reaction)).

Q7) How are carbon-fiber-reinforced pellets classified?

A7) Pellets are considered to be classified into preparations (ground: there is an example of polyethylene pellet in the Guidance on Articles). However, carbon fibers contained in pellets are classified into articles.

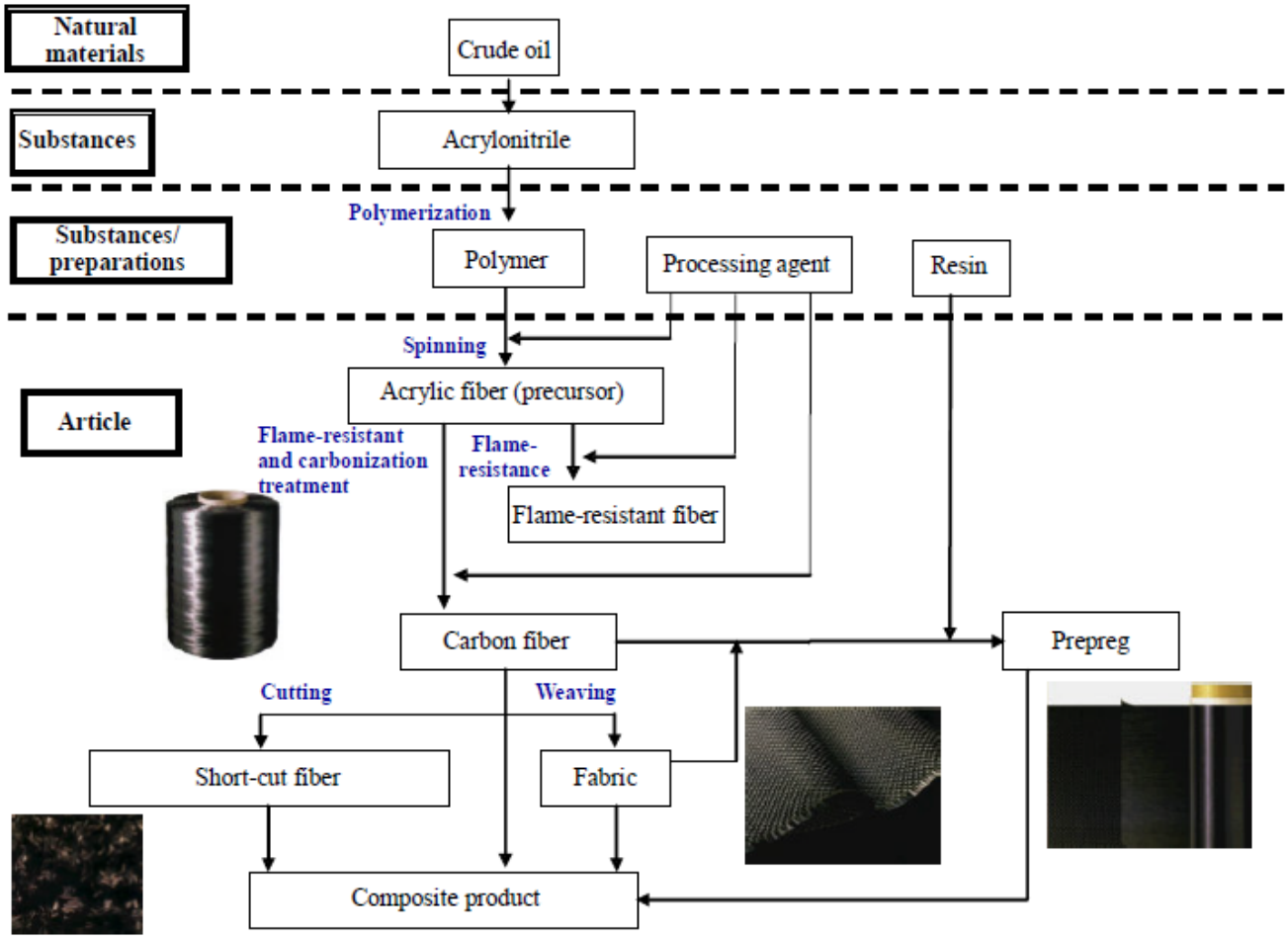
Q8) Do short-cut carbon fibers have adverse impact on human health when inhaled?

A8) Carbon fibers are distinguished from WHO fibers such as asbestos fibers by their size and shape. Their respiratory health risks are considered to be small because they are usually non-respirable, meaning that they are not easily inhaled deep into the respiratory organs (See Annex 3).

[Reference material] Refer to Item 13 on page 3 of WHO Workshop on Mechanisms of Fibre Carcinogenesis and Assessment of Chrysotile Asbestos Substitutes 8-12 November 2005, Lyon, France, SUMMARY CONSENSUS REPORT from World Health Organization (WHO) website http://www.who.int/ipcs/publications/new_issues/summary_report.pdf

Annex 1

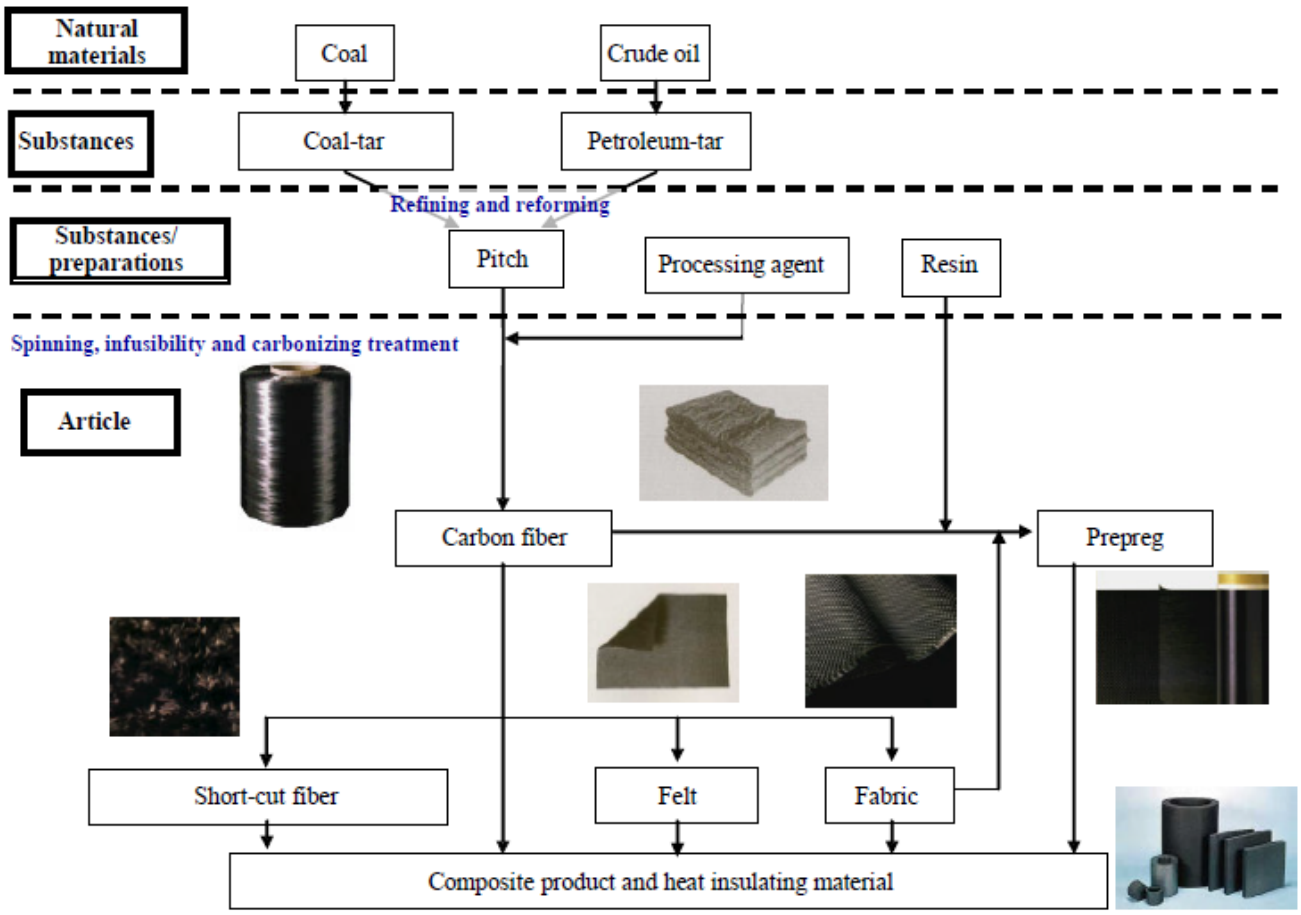
Classification of Applicable Substances of Carbon Fibers and Carbon Fiber Products
(Examples of PAN-Based Carbon Fibers)



[Interpretation of the Japan Carbon Fiber Manufacturers Association]

Annex 2

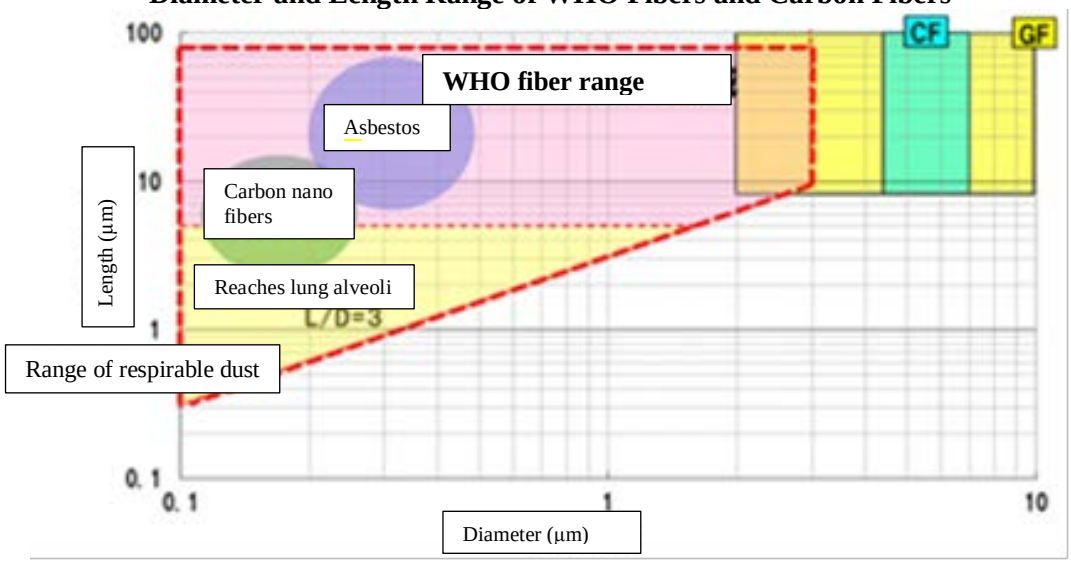
Classification of Applicable Substances of Carbon Fibers and Carbon Fiber Products
(Examples of Pitch-Based Carbon Fibers)



[Interpretation of the Japan Carbon Fiber Manufacturers Association]

Annex 3

Diameter and Length Range of WHO Fibers and Carbon Fibers



(Source: Prepared based on Determination of airborne fiber number concentrations, A recommended method, by phase-contrast optical microscopy, World Organization, Geneva 1997)