

**List of Prohibited Substances and PL Registration Criteria for
Biomass-based Plastics and its Semi-finished Products**

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Japan BioPlastics Association

1. Introduction

Based on the classification of the materials used in BiomassPla shown below, a positive list system that will list all of the materials that have, upon application, been screened and approved for use in the manufacture of BiomassPla shall be adopted for “Biomass-based plastics (Category A)”, “Semi-finished Products (Category C)”, “Biomass-derived thermosetting plastic raw materials (Category E)” and “Semi-finished biomass-derived thermosetting plastic products (Category F)” while a negative list system that enables materials that do not correspond to designated prohibited substances to be used, in principle, shall be adopted for “Additives (Category B)”, “Other Materials (Category D)” and “Non-biomass-derived thermosetting plastic raw materials (Category G)”.

[List of Classifications of Materials Used]

Classification Code	Category	Remarks
A	Biomass-based plastics	This refers to high-polymer materials with a molecular weight (Mn) of at least 1,000 that can be obtained through chemical or biological synthesis from raw materials that contain substances derived from renewable organic resources. (Excludes chemically unmodified non-thermoplastic natural organic high-polymer materials.) The ratio of biomass-based plastics is to be specified.
B (Additives)	1 Stabilizers	Includes antioxidants, radical scavengers and ultraviolet absorbers, etc.
	2 Surfactants	Includes antistatic agents, antifog additives, dispersants and emulsifiers, etc.
	3 Lubricants	Includes mold release agents, organic antiblocking agents, plasticizers, waxes, rosins, etc.
	4 Inorganic Materials	Includes inorganic antiblocking agents and inorganic colored fillers, etc.
	5 Blowing Agents	Includes auxiliary blowing agents.
	6 Organic Materials	Food additives used under the Food Hygiene Law, etc.
	7 Adhesives, etc.	Adhesives, etc.
	8 Natural Organic Materials	Starch, cellulose, wood flour, natural rubber, etc.
	9 Color Materials	Includes organic pigments, dyes, masking agents, food dyes and inorganic pigments.
C	Semi-finished Products	Semi-finished products that include biomass-based plastics (A), for example films or compounds consisting of A + B + D. The degree of biomass plastic ratio is to be specified.
D (Other Materials)	1 Non-biomass Plastic Materials	Non-biomass-based plastics, compounds and films, etc.
	2 Other	Rubber, other materials.
E	Biomass-derived thermosetting plastic raw materials	Limited to the use applications of thermosetting plastic raw materials. The degree of biomass plastic ratio is to be specified.

コメントの追加 [e1]: この後に (plastics) が要ると思います。原文が (バイオマスプラスチック度) です。

F	Semi-finished biomass-derived thermosetting plastic products	Semi-finished products that include biomass-derived thermosetting plastic raw material (E), for example thermosetting plastic compositions (compounds) consisting of E + F + B. The degree of biomass plastic ratio is to be specified.
G	Non-biomass-derived thermosetting plastic raw materials	Limited to the use applications of thermosetting plastic raw materials.

2. List of Prohibited Substances and PL Registration Criteria for Biomass-based Plastics and its Semi-finished Products

- (1) Substances to which the following applies will be deemed to be prohibited substances; substances that contain these cannot be used as raw materials in the manufacture of BiomassPla.
 - a) Substances designated as a Class I or Class II specified chemical substance under the latest version of the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture (Chemical Substances Control Law).
 - b) Substances subject to a prohibition on their manufacture under the latest version of the Industrial Safety and Health Law.
 - c) Substances designated as poisonous under the latest version of the Poisonous and Deleterious Substances Control Law.
 - d) Chemical substances classified as Group 1 substances under the system of evaluation and classification of the carcinogenicity of chemical substances employed by IARC (International Agency for Research on Cancer).
 - e) Substances that this association has deemed to be particularly undesirable.
- (2) "Biomass plastics" (Category A) must be high-polymer materials with a mean molecular weight (Mn) of at least 1,000 (excluding chemically unmodified non-thermoplastic natural organic high-polymer materials) that can be obtained through chemical or biological synthesis from raw materials that contain substances derived from renewable organic resources, and must contain biomass-derived components that can be measured using the technique specified by the Japan BioPlastics Association (ASTM D6866-05).
- (3) In acute oral toxicity tests, the LD₅₀ of "biomass-based plastics (Category A)" must be at least 2,000mg/kg.
- (4) Substances that conform to the criteria (1) – (3) above shall be certified as "biomass-based plastics (Category A)", and a positive list specifying their ratio of biomass-based plastic shall be compiled and managed.
- (5) "Semi-finished products" (Category C) must contain "biomass-based plastics (Category A)".
- (6) A positive list specifying the ratio of biomass-based plastic of "semi-finished products (Category C)" shall be compiled and managed.

- (7) “Biomass-derived thermosetting plastic raw materials (Category E)” are thermosetting plastic raw materials derived from renewable organic resources and shall contain biomass-derived components that can be measured using the technique specified by the Japan BioPlastics Association (ASTM D6866-05).
- (8) “Biomass-derived thermosetting plastic raw materials (Category E)” or thermosetting plastics produced by reacting these raw materials using a typical formula shall achieve at least 2,000 mg/kg of LD₅₀ in acute oral toxicity tests.
- (9) Substances that conform to the criteria (1), (7) and (8) above shall be certified as “biomass-derived thermosetting plastic raw material,” and a positive list specifying their ratio of biomass-based plastic shall be compiled and managed.
- (10) “Semi-finished biomass-derived thermosetting plastic products (Category F)” shall contain a “biomass-derived thermosetting plastic raw material (Category E)”.
- (11) For “Semi-finished biomass-derived thermosetting plastic products (Category F),” a positive list specifying their ratio of biomass-based plastic shall be compiled and managed.
- (12) Substances that are free of the prohibited substances listed in item (1) above shall, as a general rule, be accepted for use as “Additives” (Category B), “Other materials” (Category D) and “Non-biomass-derived thermosetting plastic raw materials (Category G),” and no positive list of these shall be compiled.
- (13) Irrespective of the stipulation in item (7) above, only color materials that are not subject to restrictions in the latest version of the “Voluntary Restrictions on Printing Inks (NL restrictions)” issued by the Japan Printing Ink Makers Association shall be accepted for use.
- (14) Irrespective of the stipulation in item (7) above, only adhesives that are not subject to restrictions in the latest version of the “Voluntary Restrictions on Adhesives for Use in Food Packaging Materials” issued by the Japan Adhesive Industry Association shall be accepted for use.
- (15) With regard to materials consisting of multiple components (Category B and D), such as resin-treated products, the disclosure of all components of which the substance consists is required as a general rule; however, if a supplying manufacturer’s guarantee that the material does not contain any of the prohibited substances in item (1) above and a product safety data sheet, or materials equivalent to this, are submitted, the requirement to disclose the components other than the main component may be waived.
- (16) Regarding the above item (15), if a guarantee that any of the aforementioned prohibited substances is not used intentionally cannot be obtained from a supplying manufacturer, submitting a document that shows the acute oral toxicity value LD₅₀ is at least 2,000 mg/kg or non-toxicity against living body, e.g., documents that indicate the satisfaction to the Voluntary Restrictions of its industry group, alternatively may be allowed.
- (17) As for LD₅₀ in (3), (8) and (16), according to GHS classification, JBPA could regard that materials with acute toxicity estimate >2,000mg/Kg or acute toxicity hazard category 5 are equivalent to those with LD₅₀ >2,000mg/Kg.

3. Criteria Concerning Amendments and Additions

- (1) The addition to or amendment of the PL concerning “biomass plastics (Category A)”, “semi-finished products (Category C)”, “biomass-derived thermosetting plastic raw materials (Category E)” and “semi-finished biomass-derived thermosetting plastic products (Category F)” will be conducted in line with the criteria listed herein.
- (2) JBPA regular members, supporting members and mark members can apply for the addition to or amendment of the PL in line with the following procedure. The members who are approved to add or amend the PL should maintain the quality of the registered material.

However, applications concerning “biomass-based plastics” (Category A) and “biomass-derived thermosetting plastic raw materials (Category E)” as the key material can, as a general rule, only be made by regular members and supporting members.

- (3) Those who wish a new material not currently on the PL to be listed shall fill in the requisite sections of the application form in the format stipulated by this association and submit it to the Chairman of the Identification Committee, along with the required documentation. In case that applicers of the material are not the manufacturer, they shall submit also documents about the qualification certification of the manufacturer, the relationship with the manufacturer, etc. according to JBPA requests. Any change in those documents should be applied to amend the PL to the Chairman of the Identification Committee, as soon as possible.
 - i) Application for listing of a “biomass-based plastic” (Category A) on the PL
The requisite information shall be completed on Application Form I-2 and submitted along with a report on the biomass-derived carbon measurement of the biomass plastic, a biomass plastic ratio calculation sheet, a report on the acute oral toxicity test (LD₅₀) and a report on the analysis of specified toxic substances implemented by the prescribed institution and in the prescribed manner.
 - ii) Applications concerning “semi-finished products” (Category C)
The requisite information shall be completed on Application Form III-2, including the name of all components (materials) of which the product consists (substances and product names), the quantities thereof, the PL number (if using a material registered as Category A or C), the name of the manufacturer of the material, the ratio of biomass-based plastic, and content of specified toxic substances. If using an additive or other material, a supplying manufacturer’s guarantee that the item does not contain any of the prohibited substances designated by the JBPA and a product safety data sheet, or materials equivalent to this, shall be attached.
 - iii) Application for listing of a “biomass-derived thermosetting plastic raw material (Category E)” on the PL
The requisite information shall be completed on Application Form I-2 and submitted along with a report on the biomass-derived carbon measurement of the biomass-derived thermosetting plastic raw material, a biomass plastic ratio calculation sheet, a report on the analysis of specified toxic substances, and a report on the acute oral toxicity test (LD₅₀) or a report on the acute oral toxicity test (LD₅₀) for

thermosetting plastics produced by reacting these raw materials using a typical formula implemented by the prescribed institution and in the prescribed manner.

- iv) Application for listing of a “semi-finished biomass-derived thermosetting plastic product (Category F)” on the PL

The requisite information shall be completed in the “Raw Materials” field on Application Form V-2, including the name of all components (materials) of which the product consists (substances and product names), the quantities thereof, the PL number (if using a material registered as Category A, C or E), the name of the manufacturer of the material, the ratio of biomass-based plastic, and content of specified toxic substances. If using an additive or other material, a supplying manufacturer’s guarantee that the item does not contain any of the prohibited substances designated by the JBPA and a product safety data sheet, or materials equivalent to this, shall be attached.

- (4) If requesting the amendment of the information on the original application with regard to a substance already on the PL, the requisite information shall be completed on Application Form I-2 or III-2, and submitted to the Chairman of the Identification Committee with required documents.
- (5) For details of tests prescribed by this committee when applying for inclusion on the PL, please refer to the ancillary document “Testing Methods Required for Inclusion on the PL”.

4. Deletion Criteria

In the following cases, the relevant substance will be deleted from the PL after implementing the procedures prescribed separately.

- (1) If the criteria for inclusion on the PL change as a result of revisions to the legislation to which it refers, resulting in the substance in question no longer fulfilling the compatibility criteria.
- (2) If the safety of the substance concerned is called into question and it is deemed that it should be deleted from the list due to the social conditions or other situation.
- (3) If the properties of the substance concerned are found to differ from those listed in the PL application, and it is deemed that the substance does not fulfill the criteria prescribed by this association for inclusion on the PL.
- (4) In situations other than those listed above, if it emerges that the substance concerned is not actually being used.