

**Biodegradable Plastics Positive List (PL) Formulation
Standards
(Includes Compostable Biodegradable Plastics)**

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Japan BioPlastics Association

1. Tabulation Policy

- (1) This shall be a positive list (hereafter referred to as the PL) by usage classification of materials.
- (2) The substances listed in the PL shall be limited to substances currently being used, the use of which has become determined, and which it is reasonable to use as biodegradable plastics.
- (3) The content of the PL shall conform to the following classification categories (see the appendix tables)
 - A: Biodegradable synthetic polymers and compostable synthetic polymers(Name, substance name and chemical structure to be specified. Includes copolymers and block copolymers.)
 - B: Additives that can be used (Substance name and, if necessary, restrictions on quality, usage and applications to be specified.)
 - C: Other materials (This refers to raw materials consisting of biodegradable synthetic polymers or compostable synthetic polymers to which additives have been added. Name (product name, etc.) and all constituent elements to be specified. Includes biodegradable adhesives.)
- (4) The additives that can be used are listed according to the classification by effect given below.

(PL Classification Table)

| Classification Code | PL Category | Remarks |
|---------------------|--|---|
| A | 1 Biodegradable Synthetic Polymers | Refers to biodegradable synthetic high-polymer materials with a molecular weight (Mn) of at least 1,000. This includes chemically modified starch- and polyamino-acid-based biodegradable high-polymer materials. |
| | 2 Compostable Synthetic Polymers | The plastics in A-1 category and be successful in the degradability tests and the reproduction inhibition tests |
| 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 Other (1) (Organic Materials) | Includes food additives used under the Food Hygiene Law, etc. |
| | 7 Other (2) (Organic Materials with Special Functions) | Includes specified functional materials, functional non-biodegradable high-polymer materials and non-biodegradable adhesives, etc. for exclusive use in biodegradable plastics |
| | 8 Natural Organic Materials | Includes starch, cellulose, wood flour, etc. |
| | 9 Color Materials | Includes organic pigments, dyes, masking agents, food dyes and inorganic pigments. |

| | | | |
|---------------------------|---|---------------------------------------|--|
| C (Other Materials) | 1 | Semi-finished Products | Refers to raw materials where the total amount of biodegradable synthetic polymers (Category A) and natural organic materials (Category B-8) accounts for at least 50.0% of the weight (or volume) of the product and to which additives (Category B) have been added. However, this does not apply where the item itself does not constitute a finished product, such as a master batch. Includes biodegradable inks. |
| | 2 | Compostable Semi-finished Products | Refers to raw materials where the total amount of compostable synthetic polymers (Category A) and natural organic materials (Category B-8) accounts for at least 50.0% of the weight (or volume) of the product and to which additives (Category B) have been added. However, this does not apply where the item itself does not constitute a finished product, such as a master batch. Includes biodegradable inks. |
| | 3 | Biodegradable Adhesives | Includes reactive biodegradable adhesives, etc. |

(5) The standards for listings on, additions and revisions to, and deletions from the PL are stipulated

Listing Standards

- (1) The PL shall be formulated in line with the Tabulation Policy.
- (2) The selection method shall be as follows.
 - a) The substance on the PL that consists of the single component shall demonstrate a biodegradability of at least 60% in biodegradability tests (OECD 301C, JIS K 6950, JIS K 6951, JIS K 6953, JIS K 6955) designated by the Identification Committee of the JBPA. (The testing period is the testing period stipulated for each testing method.)
 - b) In oral acute toxicity tests, the LD₅₀ shall be at least 2,000mg/kg.
 - c) The substance shall not be a Class 1 or Class 2 designated chemical substance in Clause 2 of the latest version of the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (1973 Law No.117; abbreviated to ‘Chemical Substance Control Law’).
 - d) The substance shall not be a substance subject to a prohibition on its manufacture under the latest version of the Industrial Safety and Health Law.
- (3) Biodegradable synthetic high-polymer materials with a molecular weight (Mn) of at least 1,000 shall be classified as biodegradable synthetic polymers (Category A-1).

Among A-1, the plastics that is successful in the degradability tests (ISO16929 or ASTM D5338) and the reproduction inhibition tests (OECD208 or “Plant Tests Using Komatsuna (Brassica rapa var. pervidis)” prescribed in General Administrative Agency Bulletin No.5005 (Silkworm Farming))shall be classified as compostable synthetic polymers (Category A-2).

Other substances shall be classified as additives (Category B (1-9)), according to the purpose of their use.
- (4) With regard to item (2) a) above, if the substance on the PL consists of multiple components, or is a processed plastic product (finished item), all components of which the substance subject to the PL consists must be disclosed, and it must be shown that each component satisfies the PL listing standards of this Committee.
- (5) Item (2) a) above does not apply to natural organic materials and inorganic materials (including natural inorganic materials). However, these materials are restricted to those that are added to biodegradable synthetic polymers (Category A). Moreover, the quantity of an inorganic material added (used) must be less than 50% of the total weight (the total of the biodegradable synthetic polymers and all additives).
- (6) In lieu of item (2) b) above, if it can be confirmed that the LD₅₀ is at least 300mg/kg, and that the values for all of the prescribed environmental and ecosystem toxicity tests (EC₅₀ in the case of alga and daphnia, LC₅₀ in the case of orange *Oryzias latipes*) are at least 100mg/l, the substance will be acknowledged to comply with this regulation.
- (7) With regard to item (2) above, part of the requirements can be omitted if the substance satisfies the following provisions.
 - ① With regard to organic additives (Category B other than B-4 and B-8), if the total content by weight of any additive components is less than 1% of the total weight (the total of the biodegradable plastic and all additives), there shall be no need for that additive to comply with item (2) a), on condition that the

additive is added to a biodegradable synthetic polymers (Category A).

- ② With regard to the total quantity of organic additives exempted from compliance in item (7) a), the content must represent less than 5% of the total weight (the total of the biodegradable synthetic polymers and all additives),
 - ③ Substances recognized in Japan and the USA as (direct) food additives shall be acknowledged to be substances with a safety level equivalent to item (2) b), and can be listed as long as they have a technical effect in manufacturing or processing.
 - ④ Biodegradable synthetic polymers (Category A) have a molecular weight distribution, so if item (2) a) is confirmed with regard to the substance with the greatest average molecular weight, the plastics with a smaller average molecular weight shall also be acknowledged to satisfy item (2) a).
- (8) Assuming that biodegradable synthetic polymers (Category A) have decomposed in the natural environment, findings that confirm the safety of the products (intermediates) that arise from the decomposition process must be disclosed to this Committee.
- (9) Color materials are limited to those that are not subject to NL restrictions in the latest version of the “Voluntary Restrictions on Printing Inks (NL restrictions)” issued by the Japan Printing Ink Makers Association.
- (10) With regard to other materials, semi-finished products (Category C-1) refers to raw materials where the biodegradable synthetic polymers (Category A) satisfies items (2) and (8) above, and where the additives (Category B) that form accessory components comply with item (2) or item (7) ①, ② or ③; moreover, in these raw materials, the total amount of biodegradable synthetic polymers (Category A) and natural organic materials (Category B-8) shall account for at least 50.0% of the weight or 50.0% of the volume of the product. However, this does not apply where the item itself does not constitute a final product, such as a master batch.
- (11) With regard to other materials, semi-finished products (Category C-2) refers to raw materials where the compostable synthetic polymers (Category A-2) satisfies items (2) and (8) above, and where the additives (Category B) that form accessory components comply with item (2) or item (7) ①, ② or ③; moreover, in these raw materials, the total amount of compostable synthetic polymers (Category A-2) and natural organic materials (Category B-8) shall account for at least 50.0% of the weight or 50.0% of the volume of the product. However, this does not apply where the item itself does not constitute a final product, such as a master batch.
- (12) Biodegradable adhesives shall be listed under Category C-3 and all raw materials prior to hardening must be registered in accordance with the PL classification and standards. However, registration is not required if less than 1% by weight of the volatile solvent (including water) remains after hardening. Moreover, applicants must prove that the adhesive satisfies the biodegradability standard in item (2) a) in its post-hardening state, and that the adhesive is not orally toxic (in oral acute toxicity tests, the LD50 shall be at least 2,000mg/kg).
- (13) Non-biodegradable high-polymer materials shall be listed in Category B-7; applicants must prove that the addition of a small quantity (less than 1% by weight of the final product) to biodegradable plastics has a useful function, such as improving the physical properties of the plastic.

(14) As for LD50 in (2)-b and (12), according to GHS classification, JBPA could regard that materials with acute toxicity estimate $>2,000\text{mg/Kg}$ or acute toxicity hazard category 5 are equivalent to those with LD50 $>2,000\text{mg/Kg}$.

(15) As for LD50, EC50 and LC50 in (6), according to GHS classification, JBPA could regard that materials with acute toxicity hazard category 4 and not classified in acute short time aquatic hazard are equivalent to those with LD50 $>2,000\text{mg/Kg}$.

2. Criteria Concerning Amendments and Additions

- (1) The addition to or amendment of the PL will be conducted in line with the criteria listed herein.
- (2) JBPA full members, supporting members and symbol members (including time-limited symbol 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 “biodegradable synthetic polymers” (Category A) as the key material can, as a general rule, only be made by full members and supporting members.

Moreover, applications concerning additives (Category B) may be accepted from non-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 the 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) Applications concerning biodegradable synthetic polymers (Category A-1)

Applicants shall complete the necessary sections of Application Form I-1 and append reports on biodegradability tests, oral acute toxicity tests (LD_{50}) and specified element analysis implemented by the prescribed institutions, as well as findings (test reports or copies of papers or review articles) concerning the safety or lack of environmental persistence of the decomposition products (intermediates) that result when the plastic degrades in the natural environment.

If the substance is not listed on the PL but is recognized as a biodegradable synthetic polymers by accredited institutions in other countries, applicants shall complete the necessary sections of Form I-1 and, after appending the requisite documentation, shall complete and submit details of the accreditation in Section 6 “Accreditation Already Acquired” (accreditation name and accrediting country, date of accreditation and validity period), with details of the accreditation standards being given on Application Form II-1.

- ii) Applications concerning compostable synthetic polymers (Category A-2)

Adding the degradability test report and the reproduction inhibition test report in addition to above 3(i)
iii) Applications concerning additives (Category B)

Applicants shall complete the necessary sections of Application Form I-1 or III-1 and append materials (LD₅₀ oral acute toxicity data, product safety data sheet, content of specified elements, etc.) proving the safety of the substance (material) for which the application is being submitted; in the case of substances (materials) that account for at least 1% by weight of the product, test reports proving the biodegradability of the substance (material) or materials officially recognizing its degradability shall also be provided.

iv) Applications concerning other materials (Category C)

Applicants shall complete the necessary sections of Application Form III-1, such as filling in the name, content and PL number of all components (materials) of which the material consists in the raw materials section of the form and content of specified elements.

- (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-1 or III-1, 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".

Deletion Criteria

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

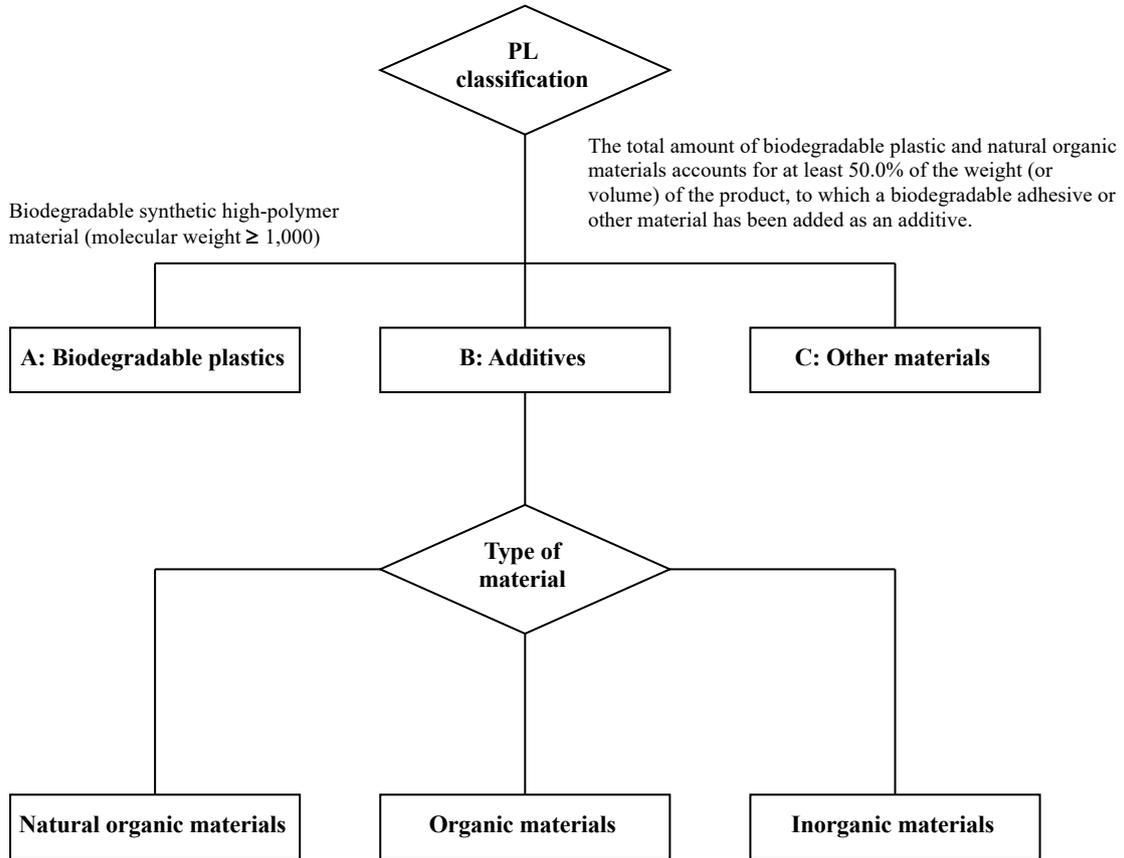
- (1) If the criteria for inclusion on the PL change as a result of revisions to the legislation to which it refers, resulting in the substance in question no longer fulfilling the compatibility criteria.
- (2) If the safety of the substance concerned is called into question and it is deemed that it should be deleted from the list due to the social conditions or other situation.
- (3) In the event that it is deemed difficult to recognize the relevant product as a biodegradable product, because the biodegradability of the substance does not control the overall biodegradability of the product that uses that substance.
- (4) 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.
- (5) Substances not granted a serial number based on the regulation concerning Outcomes of Judgments on New Chemical Substances in Clause 4, Item 1 of the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (1973 Law No.117). However, this does not apply if proof of confirmation by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry

under the provisions of Clause 4 of the Ministerial Decree Concerning Notification Regarding the Manufacture or Import of New Chemical Substances (1974 Ministry of Health, Labour and Welfare and Ministry of Economy, Trade and Industry Ministerial Decree No.1) is submitted.

- (6) In situations other than those listed above, if it emerges that the substance concerned is not actually being used.

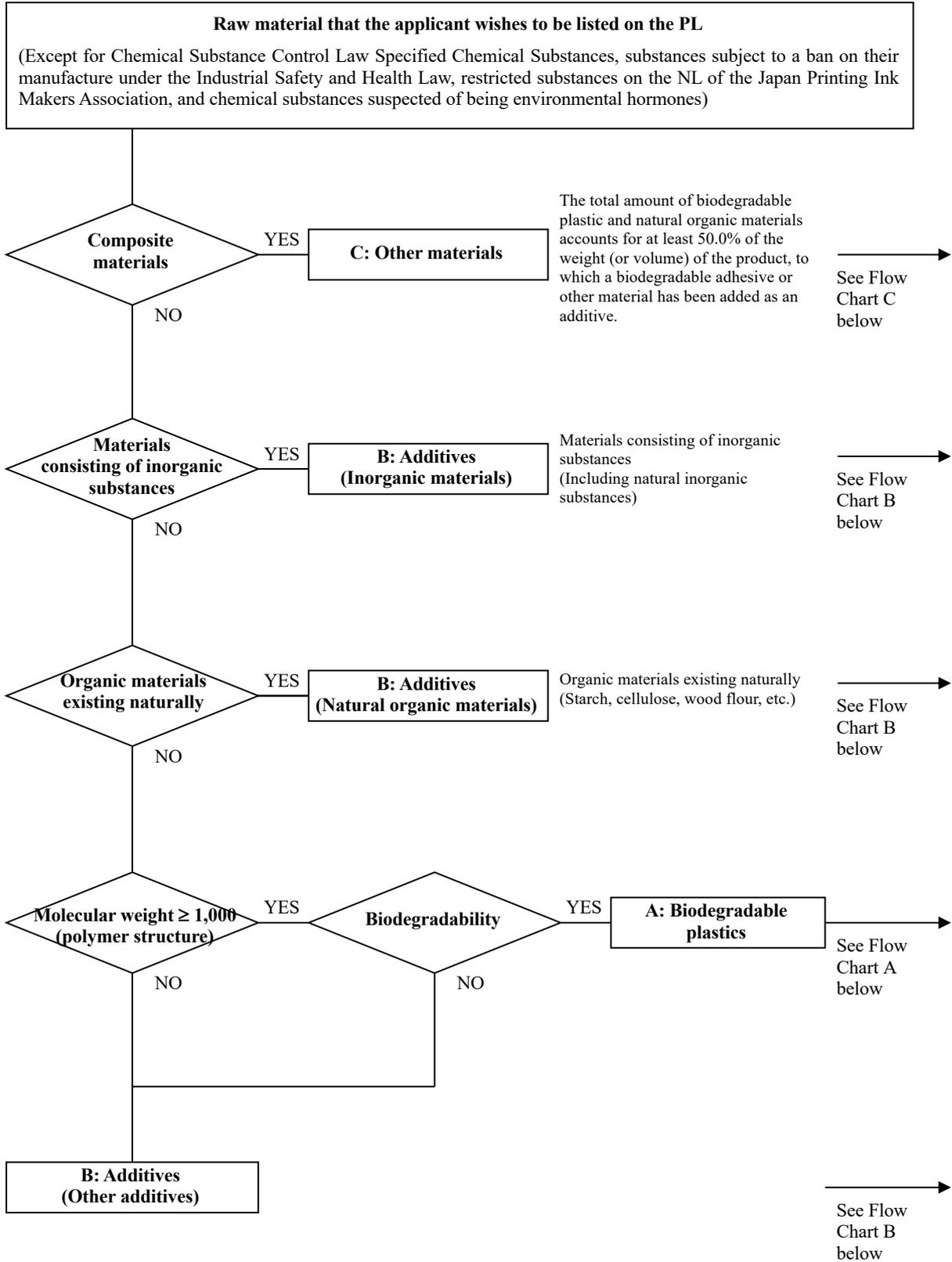
Appendix Tables: PL Classification Flow Charts

1. PL Framework Concept Diagram

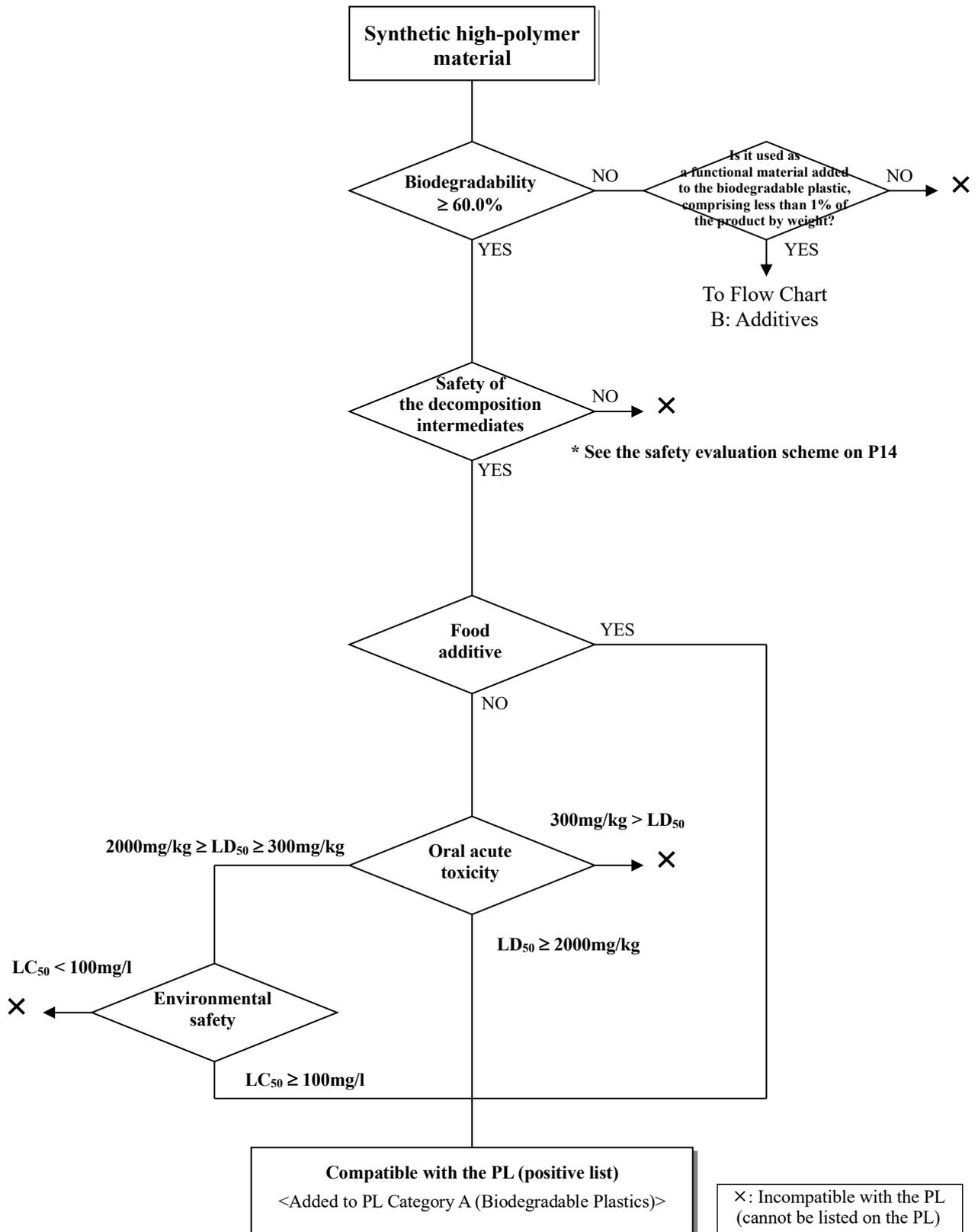


Note: Even in the case of synthetic high-polymer materials with a molecular weight of at least 1,000, non-biodegradable polymers are classified as additives.

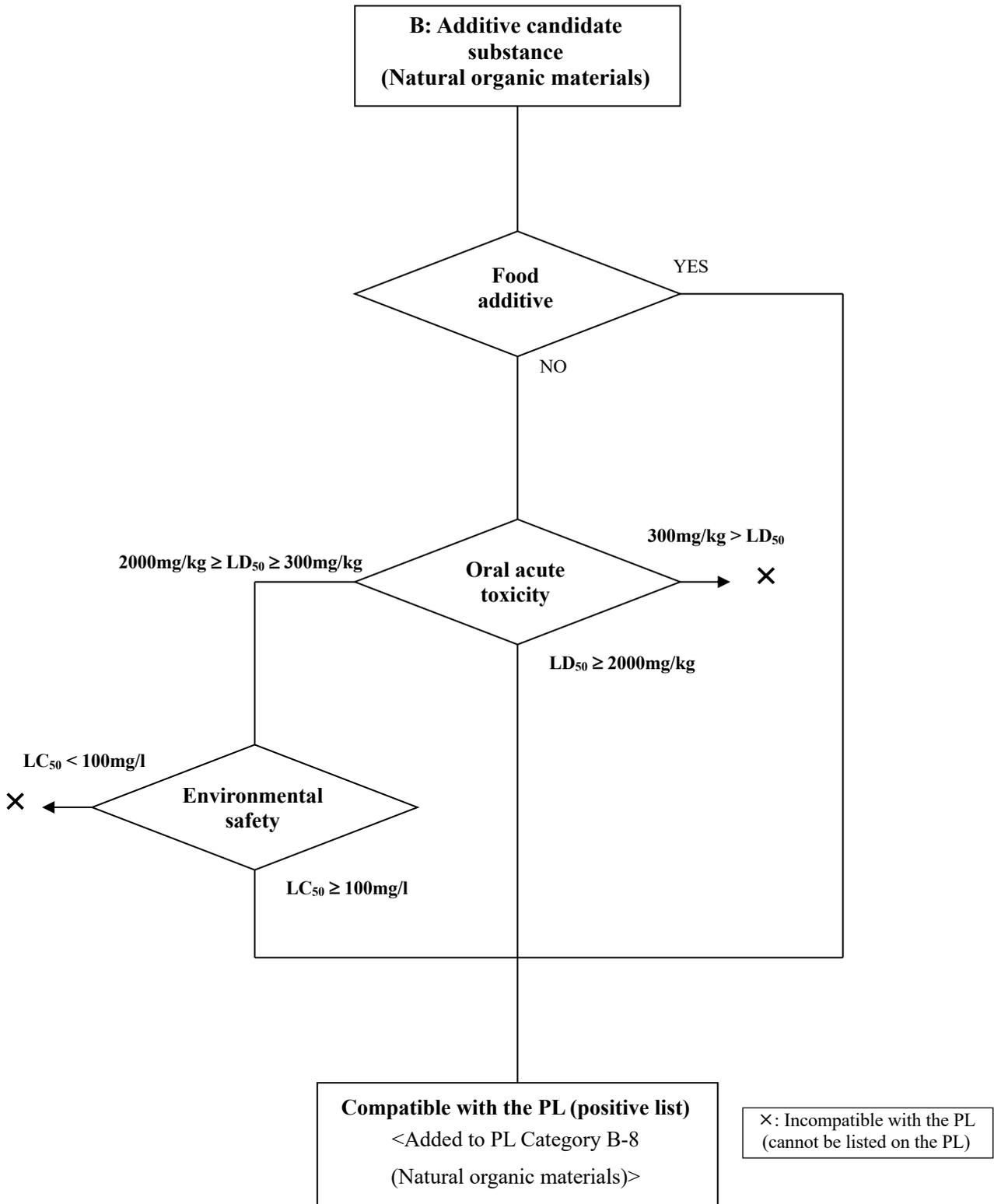
2. Basic Flow of PL

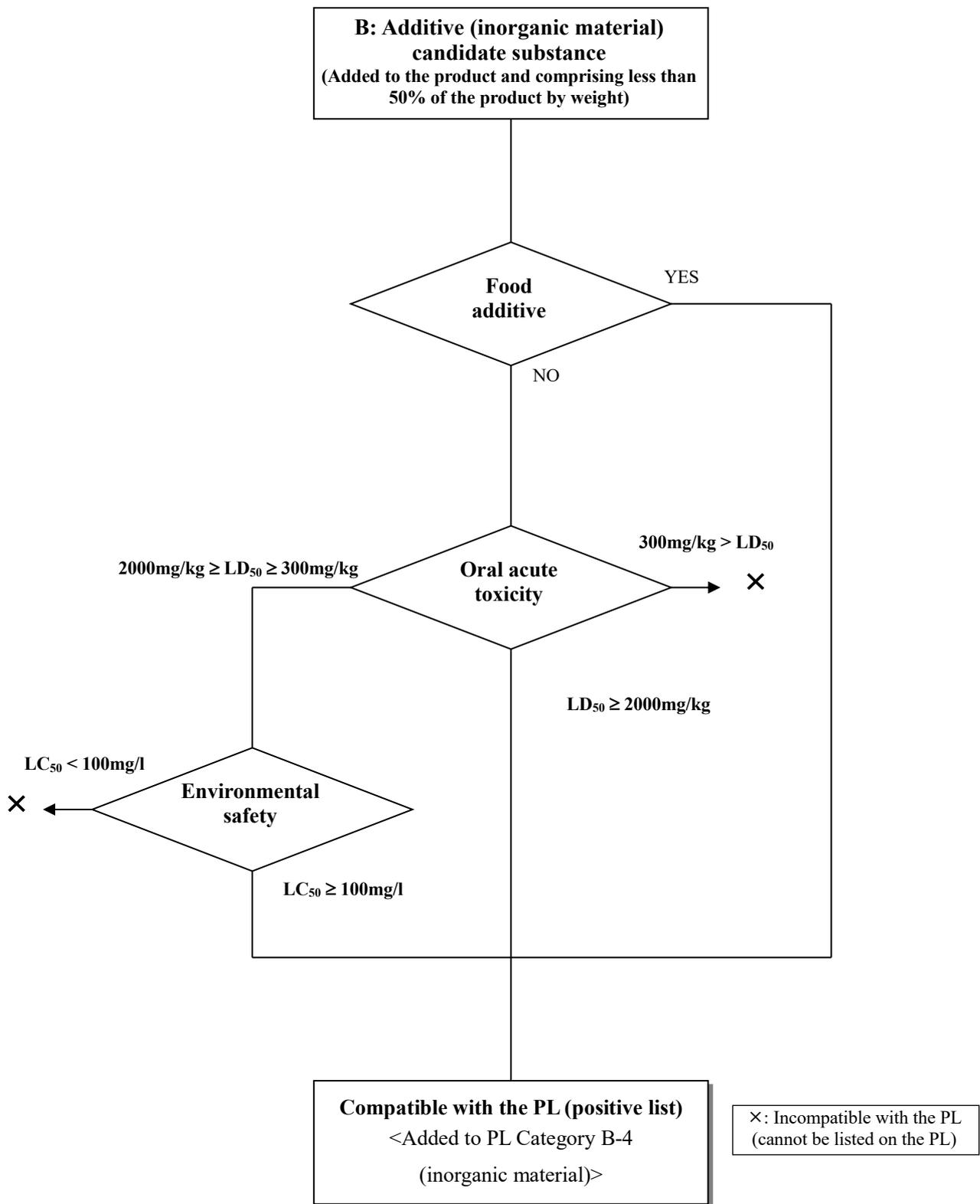


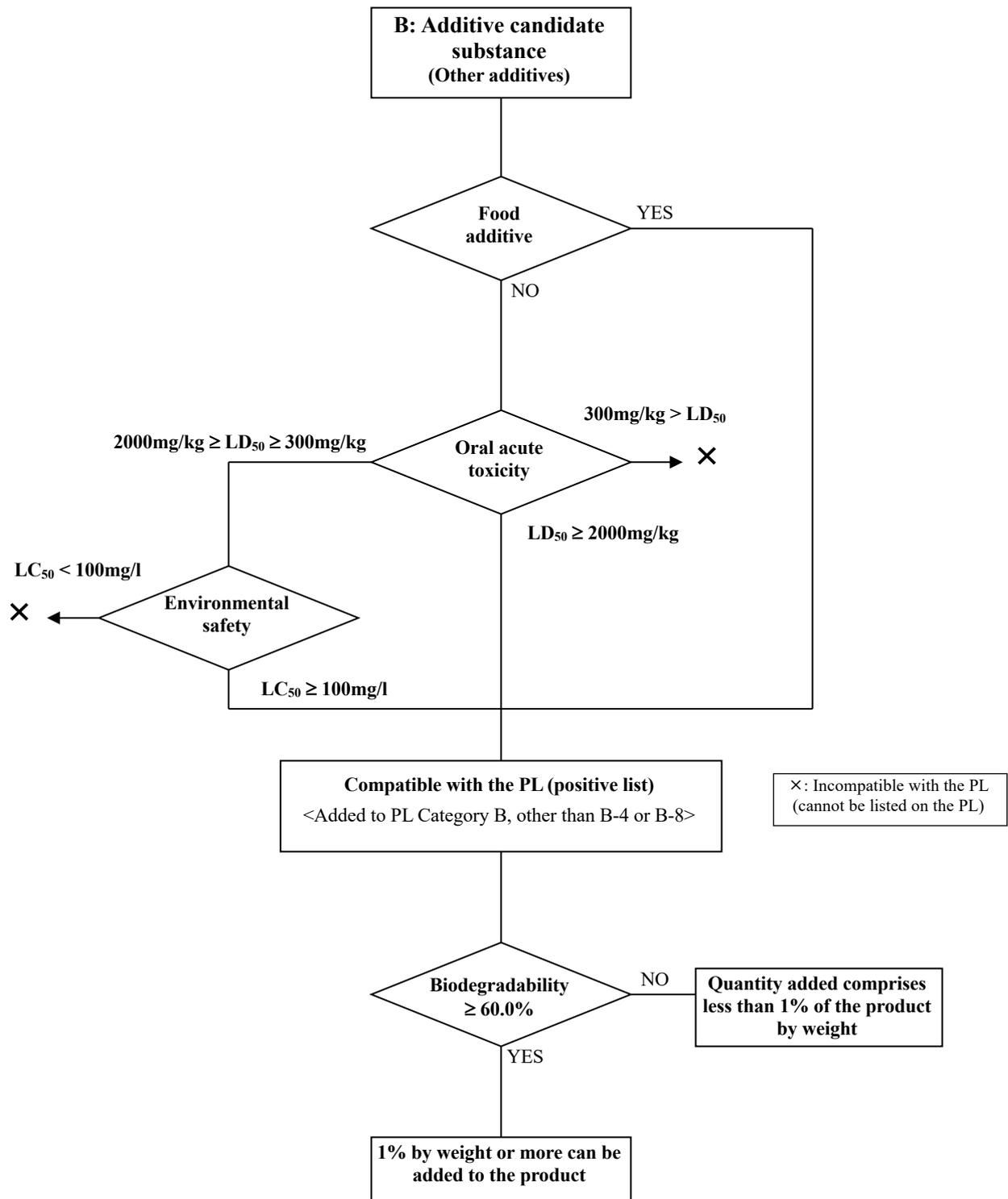
3. Flow Chart A: Biodegradable Plastics



4. Flow Chart B: Additives

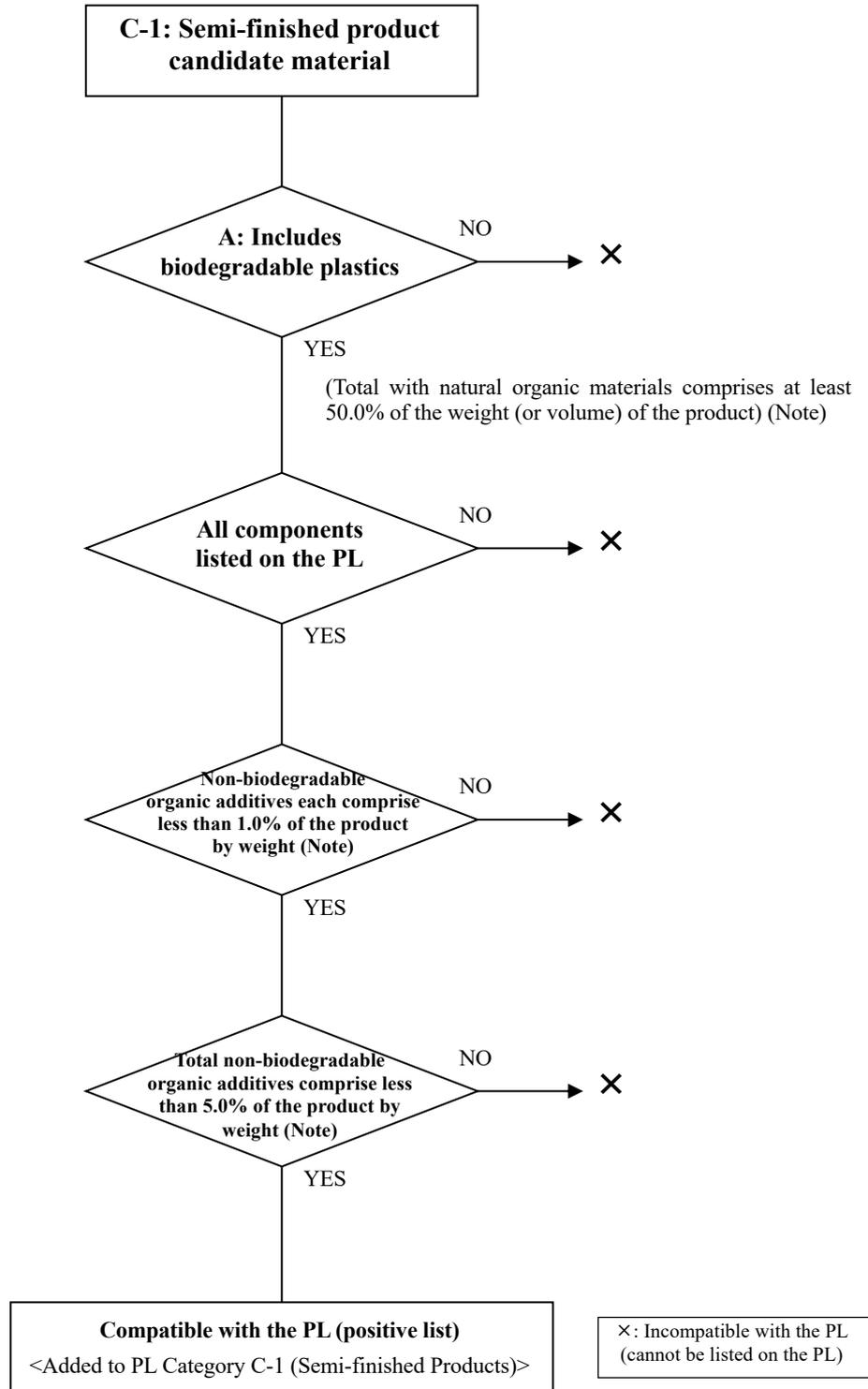






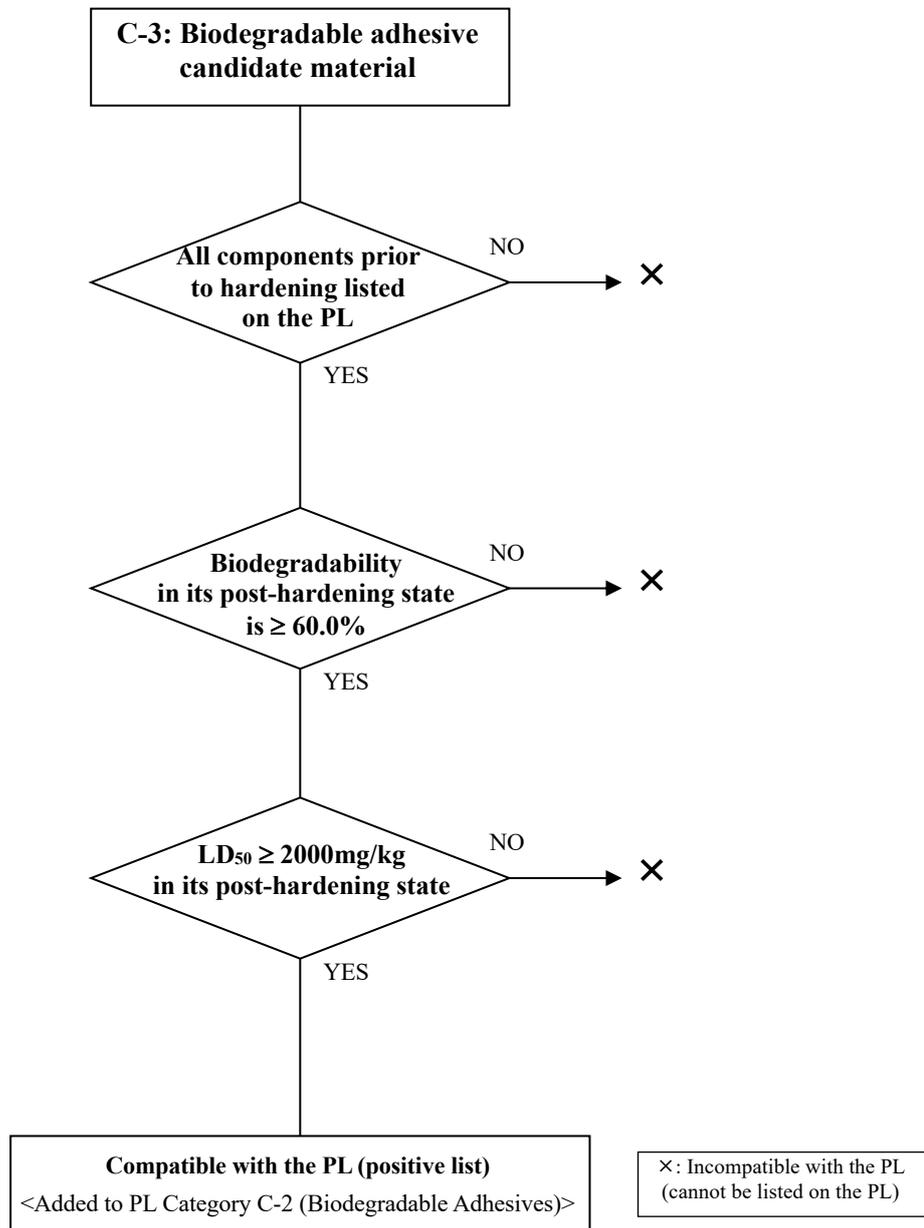
5. Flow Chart C: Other Materials

Category C-1 Semi-finished Products



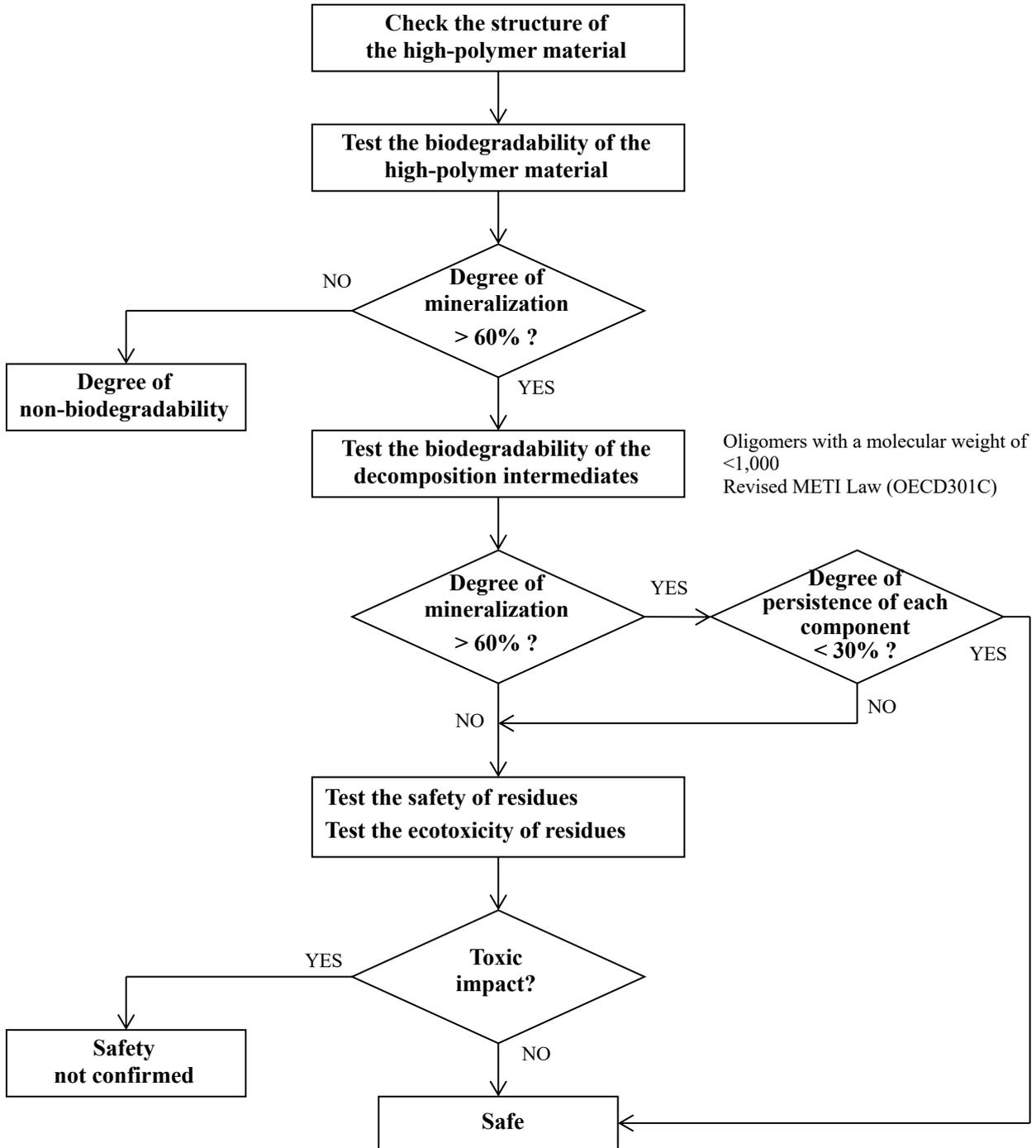
(Note) This does not apply where the item is not a finished product (such as a master batch)

Category C-3 Biodegradable Adhesives



***Table**
Safety Evaluation Scheme for
Biodegradable High-polymer Materials

(Concerning the safety of decomposition intermediates referred to in Flow Chart A on page 8)



Application Forms to be Used When Applying for Inclusion on the PL

In the following examples

→ Use application form _____

○ When adding a substance not listed on the PL

→ **Application Form I**: circle “Addition”

○ When changing the details regarding a substance already listed on the PL

→ **Application Form I**: circle “Revision”

○ When adding a substance that is not listed on the PL but has been accredited as a biodegradable plastic by an accredited institution in another country

→ **Application Forms I & II**

○ When adding biodegradable adhesives and semi-finished products, etc. consisting of biodegradable plastics and additives listed on the PL

→ **Application Form III**

For further details, refer to PL Formulation Standards section 3 (Criteria Concerning Revisions and Additions).