The guide to submitting application about the new draft of the Positive List

Scope of apparatus, containers, and packaging

Apparatus

Tableware

Cooking utensils

food contact machinery and others

Containers and packaging

Last opportunity for application on the Positive List

Check the following chart and if there are substances for which request about the Positive List (PL) should be made,
make sure to submit an applications within the due date.

This is the last opportunity for the applicants to submit application for request. After the due date, no application may be accepted.

Make sure to check that the substance satisfies the following.

- **The substance is used in food apparatus, containers, or packaging**
  * Not target of the PL for the substances contained in apparats, containers, and packaging that are used for food additives
  - No → Application is not needed
  - Yes ↓
- **The substance is subject to the PL of synthetic resin**
  - No → Application is not needed
  - Yes ↓
- **The substance has been used prior to June 1, 2020**
  - No → Application is not needed
  - Yes ↓

(See p. 5, 6)

Not covered by the scope of the PL

The substance is a base material (See p. 7-13)

Additional information needs to be added to the new draft of Table 1.
Refer to the code numbers of the previous draft of Table 1

Application (Base materials) (See P. 12, 13)

See P.7 for polymers. (Some polymers may fall under base materials. Such polymers are listed in Table "Pending.")

The substance is an additive (See p. 7,11, 14, 15)

Confirm that the additive is listed on the previous draft of Table 2
(Check the serial No., CAS No. and MITI No.)

Yes

When the following descriptions are given in the column "Sorting" of the previous draft of Table2:

New draft of Table 2	Table "To be deleted"	Table "Pending"
Additional information on the use limit and the requirements are needed		
Application about an additive (See P.14)	Application is not needed (Out of the scope of the PL)	Application about an additive (See P.14)

Please also check the Table "Integrated"

No

Application about an additive (See P.14)

Scope of substances to be listed in the Positive List

Table 1 (Base Materials)
- Synthetic **polymers**
- Synthetic **polymers** (Coatings **involving** chemical reactions)

More than 98% of a polymer should be composed monomers listed in Table 1

See P. 7-13 for the details

Table 2 (Additives)
- Synthetic polymers*
- Refined natural-derived substances
- Low molecular organic substances
- Food additives (collectively listed in the PL)

* Limited to those which are liquid at ordinary temperature and pressure; or those that have specific functional groups and whose functional groups exhibit characteristic effects on the base material (As a guide, substances with a molecular weight of about 2,000)

See P. 7, 11, 14, 15 for the details

Target substances listed in the Positive List

Not subject to management by the PL (Substances will not be listed in the restructured PL)
- Minor monomers
- Unrefined natural substances
- Natural polymers
- Inorganic substances
- Substances used for spreading application

Can be used as before (no restrictions by the PL)

Another standards
- Coloring agents

Note: Substances not subject to the PL: Those that are generated by chemical changes of the substances contained in raw materials.

ATTENTION:
Substances outside the scope of listing in the Positive List –1

Substances listed below and in next page (p. 6) are not subject to being listed in the restructured PL.
There is no need to submit application about these substances.
Note that the submitted information is not listed in the PL.

➢ Substances that do not fall under raw materials of synthetic resins

- Elastic bodies without thermoplasticity (substances that are raw materials of rubber)
- Inorganic substances (metals, non-metals, rocks, earth and sand)
- Natural products (extracts or distillates such as rosins, naphtha etc., excluding substances and related substance groups that are obtained by refining only specific components)
- Chemical reactants of natural products
- Substances used for the purpose of being released from apparatus, containers, and packaging; migrating into food; and acting on that food
- Coating agents: Liquid or powdered substances to be adhered on the surface of raw materials of apparatus, containers, and packaging for the purpose of antistatic, antifog, etc.

ATTENTION:
Substances outside the scope of listing in the Positive List – 2

Substances listed below and in the former page (p. 5) are not subject to being listed in the restructured PL.
There is no need to submit application about these substances.
Note that the submitted information is not listed in the PL.

- **Among additives, coloring agents used only for the purpose of coloring**
- **Substances generated by chemical changes of the substances contained in raw materials**
- **Substances that are not intended to remain in the final product**
  - Substances used on the assumption that they are removed during the manufacturing process
  - Impurities contained in raw materials (residual monomers, catalysts, polymerization aids, by-products, etc.)
- **Substances that are used in non-food contact parts and that are unlikely to be eluted or seep out at levels exceeding an quantity unlikely to cause harm to human health**
- **Minor monomers**

New draft of the Table 1 (Base Materials) and Table 2 (Additives)

【Table 1】 Base materials (base polymer)

: Polymers (molecular weight 1,000 or more) in synthetic resins

Notes on submission: The molecular weight is determined based on the intended molecular weight at the time of manufacturing design of the polymer regardless of number average or weight average.

【Table 2】 Additives

As a general rule, low molecular organic substances that have a molecular weight of less than 1,000 and that satisfy both of the following are those to be listed in the new draft of Table 2 (additives).

- **Substances that change the physical or chemical properties of a base material**
- **Substances used with intent to remain in the final product without chemical reaction**

* **The following substances are managed in the new draft of Table 2 as additives** because the same risk management as for **low molecular organic substances** is considered necessary for these substances: **Those that are liquid at ordinary temperature and pressure; or those that have specific functional groups and whose functional groups exhibit characteristic effects on the base material (As a guide, substance with a molecular weight of about 2,000).**

Confirm that based on the above, substances that had been listed as additives in the previous draft of Table 2 and that had been judged to be base materials are reorganized into the new draft of Table 1.

Overview of new draft of the Table 1 (Base Materials)

Polymer Group	Polymer Class	Name	Category no. of synthetic resins in the previous draft of Table 1 (1)
1	a	polymer composed of formaldehyde as the main monomer	25, 30, 31, 34, 71
	b	polymer mainly composed of sulfide bonds	59
	c	polymer mainly composed of ether bonds	45, 46, 47, 55, 60, 61
	d	polymer mainly composed of siloxane bonds	22
	e	polymer composed of fluorine-substituted ethylenes as the main monomers	32
	f	polymer mainly composed of imide bonds	36, 38, 44
	g	polymer mainly composed of carbonate bonds	39, 50
	h	cross-linking polymer of epoxy compound	17
	i	cross-linked polymer mainly composed of ester bonds	20
2	a	polymer composed of isoprenes or butadienes as the main monomer	62
	b	polymer composed of alkenes as the main monomer	2, 3, 4, 5, 6, 7, 10, 11, 12, 14, 15, 16, 18, 19, 40, 66, 67, 70
	c	polymer composed of styrenes as the main monomer	23, 54
3	a	hydrolysates of polymer composed of vinyl acetate as the main monomer	13, 58
	b	polymer mainly composed of urethane bonds	26, 28
	c	polymer mainly composed of amide bonds	35
	d	cross-linked polymer mainly composed of ester bonds	27, 29, 37, 41, 42, 43, 51, 52, 53, 56, 57, 63, 64, 65, 68
	e	polymer composed of acrylic acids as the main monomer	1, 8, 9, 24, 33, 69
	f	polymer with adsorptive or ion exchange ability	21
	g	synthesized cellulose or chemically modified cellulose	
4	a	polymer composed of chlorine-substituted ethylene as the main monomer	48, 49
5*	a	polymer used for coating that involves chemical reaction during film formation	Previous draft of Table 1 (2)

Includes polyethylene and polypropylene (group 5 and 6 of the previous list were integrated into material group 2 of the draft of the restructured PL)

Includes polyethylene terephthalate (group 7 of the previous list was integrated into material group 3 of the draft of the restructured PL)

* For the use limit, either of the percentage values in Polymer Groups 2 and 3 in the new draft of Table 2 is applied to each substance. Only for polymers with a heat-resistant temperature exceeding 150°C, one of the values in Group 1-3 is applied to each substance.

Examples of the new draft of Table 1 (Base Materials)

- The listing method was changed: Substances came to be managed by monomer not by source-based name.
- Codes were provided to monomers individually to link monomers listed in previous and new tables.
- Based on hearings on polymeric additives; essential monomers, optional substances, and optional chemical treatments were added.
- More than 98% of a base material should be composed of monomers listed in Table 1. (The previous draft (3) of Table 1 had been eliminated.)

【New draft of Table 1 (Base Materials)】

Unit: weight percent

1a polymer composed of formaldehyde as the main monomer		polymer composed of following one or more essential monomers and following one or more optional substances
Essential monomer		
1,3,5-trioxane	【1a-101】	
formaldehyde	【1a-102】	
Optional substance		Molecular weight of the part composed only of the following substances: Less than 1,000.
ethyleneglycol or oxirane	【1a-701】	Not more than 6% in the polymer components.
1,3-dioxolane	【1a-703】	Not more than 6% in the polymer components.
urea	【1a-704】	
phenol	【1a-705】	
Optional chemical treatment		Can be applied only for polymer.
methylated	【1a-901】	

The first digits of the three digit numbers in the above table indicate essential monomers (expressed as 1-5), optional substances (expressed as 7), and optional chemical treatments (expressed as 9), respectively. This rule, however, is not applicable to some substances because their category changed after the numbering. The last two digits indicate the order of registration in that category.

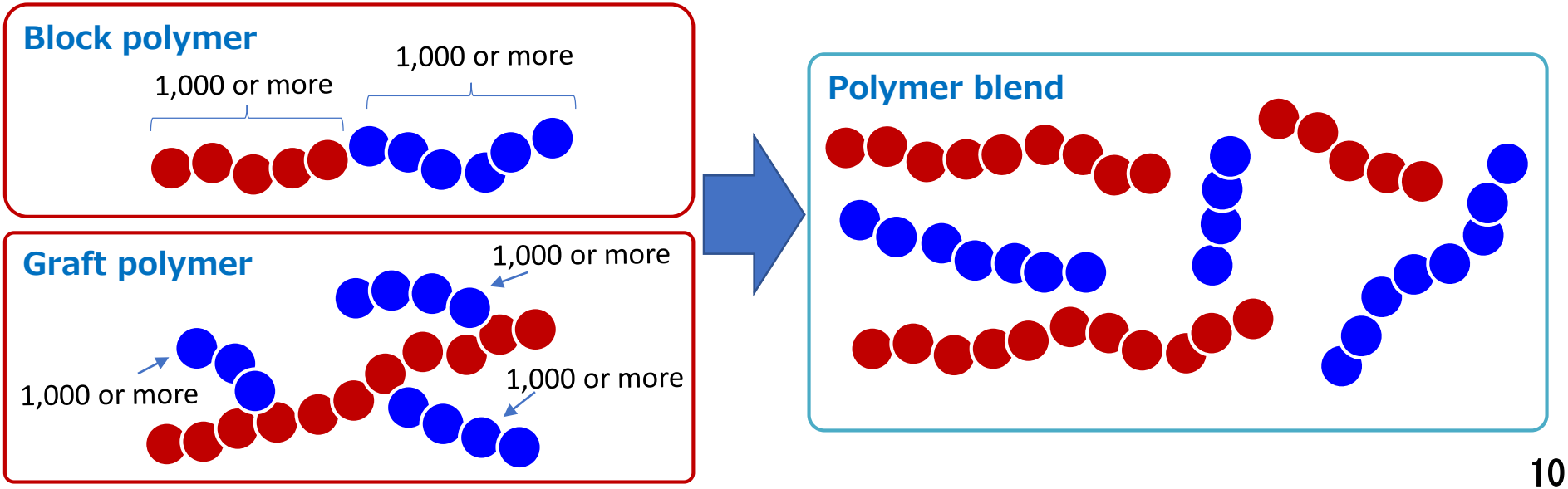
Mixture and bonding between polymers in different groups

When synthetic polymers (polymers of molecular weight 1,000 or more) categorized into different Polymer Groups are bonded (block polymer or graft polymer) or mixed, the use limit is set as one of the following.

- ✓ The value that is calculated proportionally from the weight ratio of the individual polymers used in the polymer obtained by bonding or mixture, based on the corresponding use limits of the groups into which these polymers are categorized. A combination of synthetic resins that individually satisfy the use limit by group is also treated as conforming to the PL.

- ✓ When the sum of each weight percentage of substances categorized in a group exceeds 50%, the use limit for the group concerned is applicable to the resulting polymer.

A short chain part (molecular weight less than 1,000) is treated in the same manner as an alternating polymer and a random polymer, and is considered as a polymerized part of a monomer. All constituent monomers of a short chain part should be listed as essential monomers or optional substances.



The format of new draft of the Positive List

【New draft of Table 1 (Base Materials)】 (Molecular weight: 1,000 or more)

1a. polymer composed of formaldehyde as the main monomer

Numbers by polymer group

物質code Substance Code	材質区分 Polymer Group	ポリマー分類 Polymer Class	モノマー分類 Monomer Class	モノマー番号 Monomer No.	物質名 Substance Name (JP)	物質名 Substance Name (EN)	CAS登録番号 CAS RN	特記事項 Requirements (JP)	特記事項 Requirements (EN)
1a-xxx	**1**	**1a**	**–**	**–**	**ホルムアルデヒドを主なモノマーとする重合体**	**polymer composed of formaldehyde as the main monomer**		**以下の必須モノマー（１種以上）と任意の[illegible]（１種以上）からなる重合体**	**Polymer composed of following one or more essential monomers and following one or more optional substances**
1a-1xx	**1**	**1a**	**1**	**–**	**必須モノマー**	**essential monomer**			
1a-101	1	1a	1	1	１，３，５―トリオキサン	1,3,5-trioxane	0000110-88-		
1a-102	1	1a	1	2	ホルムアルデヒド	formaldehyde	0000050-00-		
1a-7xx	**1**	**1a**	**7**	**–**	**任意の物質**	**optional substance**		**[illegible]00未**	**Molecular weight of the part composed only of the following substances: Less than 1,000.**
1a-701	1	1a	7	1	エチレングリコール又はオキシラン	ethyleneglycol or oxirane	0000075-21- 0000107-21- 0000111-46- 0000112-27- 0025322-68-	重合体の構成成分に対して６％以下であること。	Not more than 6% in the polymer components.
1a-710	1	1a	7	10	キシレン	xylene	0001330-20-		
1a-702	1	1a	7	2	１，３―ジオキサシクロヘプタン	1,3-dioxacycloheptane	0000505-65-	重合体の構成成分に対して６％以下であること。	Not more than 6% in the polymer components.
1a-703	1	1a	7	3	１，３―ジオキソラン	1,3-dioxolane	0000646-06-	重合体の構成成分に対して６％以下であること。	Not more than 6% in the polymer components.
1a-704	1	1a	7	4	尿素	urea	0000057-13-		
1a-705	1	1a	7	5	フェノール	phenol	0000108-95-		
1a-706	1	1a	7	6	１，４―ブタンジオールのジグリシジルエーテル	diglycidyl ether of 1,4-butanediol	0002425-79-	重合体の構成成分に対して６％以下であること。	Not more than 6% in the polymer components.
1a-707	1	1a	7	7	ベンゾグアナミン	benzoguanamine	0000091-76-		
1a-708	1	1a	7	8	４―メチルベンゼンスルホン酸アミド	4-methylbenzenesulfonamide	0000070-55-		
1a-709	1	1a	7	9	メラミン	melamine	0000108-78-		
1b-9xx	**1**	**1a**	**9**	**–**	**任意の化学処理**	**optional chemical treatment**		**重合体の処理に限る。**	**Can be applied only for polymer.**
1b-901	1	1a	9	1	メチル化処理	methylated			

Specific standards stipulated in the "Requirements"

【New draft of Table 2 (Additives)】 (Molecular weight: less than 1,000)

通し番号 Serial No.	物質名 Substance Name (JP)	物質名 Substance Name (EN)	CAS登録番号 CAS RN	特記事項 Requirements (JP)	特記事項 Requirements (EN)	材質区分１ Polymer Group 1	材質区分２ Polymer Group 2	材質区分３ Polymer Group 3	材質区分４ Polymer Group 4
948	セバシン酸ビス（２，２，６，６―テトラメチル―４―ピペリジル）	bis(2,2,6,6-tetramethyl-4-piperidinyl) sebacate	0052829-07-9	材質区分４に限り、100℃を超える温度で酒類に接触する部分に使用してはならない。	Only for Polymer Groups 4, not allowed to be used in the parts coming into contact with food at over 100°C.	5	5	5	0.5
1666	食品衛生法施行規則（昭和23年厚生省令第23号）別表第１又は既存添加物名簿（平成８年厚生省告示第120号）に掲げる添加物	Additives listed in Appended Table 1 of Regulations for Enforcement of the Food Sanitation Act (Order of the Ministry of Health and Welfare No. 23, 1948) or the List of Existing Food Additives (Public Notice of the Ministry of Health and Welfare No.120)	–			適量 proper dose	適量 proper dose	適量 proper dose	適量 proper dose

Substances composed of the same components as food additives are collectively listed as food additives on the list.

Substances whose use limit by group is specified as "proper dose" are as follows:

- Substances consumed as main components of food and beverages.
- Substances that qualify as food additives.
- Substances that are judged not to require special risk management based on their use in Europe and the United States.
- Other substances that are judged to be unlikely to cause harm to human health.

* **Proper dose**: The use amount (percentage) of an additive that is set **at** the designing of a synthetic resin as the minimum level at which the migration amount into food is reduced as far as possible from a safety perspective and at which the intended property is exhibited.

Application form for the new draft of Table 1 (Base Materials)

1				2	3	4		5	6				7	8	9
Mandatory						Mandatory									Mandatory
Corporate name	Contact person	Telephone number	E-mail	Application about:	Serial No.	Polymer group	Polymer class	Category	Substance name (Japanese)	Substance name (English)	CAS RN.	NITE-CHRIP MITI No.	Name or No. of the substance, which most accurately identifies the substance	Requirements	Reason for submitting an application
○○Co.	○○△△	xx-xxxx-xxxx	xxx@xxx.xx.jp	Addition Table "Pending" Revision	Only for application about Table "Pending"	1~5	a~i	Essential monomer Optional substance Chemical treatment			xxxxxxx-xx-x	x-xxxx	和名/Japanese name 英名/English name CAS RN.		

1. Submit an application on a company-by-company basis.
2. Select an appropriate item from the following:

   Addition: When the applicant wants a substance to be added.

   (Limited to the substances that fall under base material and have been commercially used as base material)

   Table "Pending": When the applicant wants a substance to be transferred from Table "Pending" to the new draft of Table 1, by adding missing substances or chemical treatments.

   Revision: When the applicant wants the information in the new draft of Table 1 to be revised.
3. When Table "Pending" was selected in above 2, enter "the number" of the substance concerned.
4. If any choice in Polymer Group and Polymer Class is not applicable, select the one that is considered most appropriate.
5. Select an appropriate item from the following:

   Essential Monomer: Main monomers linking to the name of a polymer.

   Optional substance: Substances that constitute a polymer and that do not fall under essential monomer.

   Chemical treatment: Treatments to incorporate only functional groups into a polymer or treatments that are applied under special conditions different from the polymerization reaction.
6. Confirm that there is no discrepancy between the Japanese and English names, and the CAS number is correct.
7. Select the name/CAS RN that most accurately identifies the substance to be added.
8. Enter the information when an applicant wants to revise descriptions in "Requirements."

   (Make sure to enter the name of the substance concerned)
9. Enter the reason for addition or revision.

In addition, please submit documents* showing that the substance has been used since before June 1, 2020.
***Any format is acceptable.**

Addition of monomers to the new draft of Table 1 (Base Materials)

The submission on addition is accepted only when the polymer has been used since before June 1, 2020

A polymer that the applicant is using or wants to use is not covered by the scope of the polymers listed in the draft PL;

Case 1. Monomers, etc. are not listed under the polymer.

→ **Essential monomers, optional substances, and chemical treatments that are not listed should be added.**

Case 2. The polymer does not comply with the descriptions in the "Requirement" column.

→ **The corresponding requirements should be revised.**
When the sum of essential monomers in the polymer is less than 50%:
Newly categorizing the polymer according to the following criteria, the scope of its use should be expanded or the polymer should be listed as an new polymer.

Polymer Group	Criteria for judgment	Essential monomer
4	Main monomer: Chlorine- substituted hydrocarbon	Vinyl chloride, Vinylidene chloride
2	Main monomer: Hydrocarbon	Ethylene, Propylene, Styrene, etc.
1	Heat resistant temperature: 150°C or higher	Specified for each polymer
3	Heat resistant temperature: Less than 150°C	Acid, Amine, Alcohol, Isocyanate, etc.
5	Polymers used for coating that involves chemical reaction during film	Not specified

Application form for the new draft of Table 2 (Additives)

1				2	3	4				5	6	7	8	9	10	11	12	13	14	15
Mandatory																				Mandatory
Corporate name	Contact person	Telephone number	E-mail	Application about:	Serial No.	Substance name (Japanese)	Substance name (English)	CAS RN.	NITE-CHRIP MITI No.	Name or No. of the substance, which most accurately identifies the substance	Polymer group 1	Polymer group 2 (PE)	Polymer group 2 (PP)	Polymer group 2 (Other)	Polymer group 3 (PET)	Polymer group 3 (Other)	Polymer group 4	Use	Requirements	Reason for submitting an application
○○Co.	○○△△	xx-xxxx-xxxx	xxx@xxx.xx.jp	Addition Table "Pending" Revision		○○△△	○○△△	xxxxxxx-xx-x	x-xxxx	Japanese name English name CAS RN.								XX agents		The substance is in liquid form and therefore falls under additives.

1. Submit an application on a company-by-company basis.
2. Select appropriate item from the following:

   Addition: When the applicant wants a substance to be added.

   (Limited to the substances that fall under additive and have been commercially used as additive.)

   Table "Pending": When the applicant wants a substance in Table "Pending" to be back to the new draft of Table 2.

   (Conditions must be met.)

   Revision: When the applicant wants the information in the new draft of Table2 to be revised.
3. Enter the number of the substance concerned. In the case of "Addition," enter "Addition."
4. Confirm that there is no discrepancy between the Japanese and English names, and the CAS number is correct.
5. Select the name/CAS RN that most accurately identifies the substance to be added.
6. Enter the amount that has actually been used in the market. (previous "Group 1")
7. Enter the amount that has been actually commercially used in the market. (previous "Group 5")
8. Enter the amount that has been actually commercially used in the market. (previous "Group 6")
9. Enter the amount that has been actually commercially used in the market. (previous "Group 2")
10. Enter the amount that has been actually commercially used in the market. (previous "Group 7")
11. Enter the amount that has been actually commercially used in the market. (previous "Group 3")
12. Enter the amount that has been actually commercially used in the market. (previous "Group 4")
13. When "Addition" or "Table 'Pending'" is selected, enter its use or effect.
14. Enter the information when the applicant wants to revise descriptions in "Requirements."

    (Make sure to enter the name of the substance concerned.)
15. Enter the reason for addition or revision.

In addition, please submit documents* showing that the substance has been used since before June 1, 2020.
***Any format is acceptable.**

Tables to be checked concerning the organization of Table 2 (Additives)

Previous Table 2
(Published on December 24)

New Table 2 was published together with the following two tables showing the organization status

New Table 2

Substances remaining in Table 2 as additives

Pending substances

Table "Pending"

Substances that may not qualify as additives and that require confirmation

- **Substances qualifying as base materials → should be transferred to Table 1**
- **Substances qualifying as components of a polymer → should be transferred to Table 1**
- **Substances qualifying as additives → should be transferred to Table 2**

If an substance is applicable to above, submission of application is required.
The substances on which no request is submitted will be delated from the PL.

Table "To be deleted"

Substances that will be deleted because they are not the targets to be listed in the restructured PL:

Unrefined natural substances, natural polymers, inorganic substances, Substances used for spreading application, etc.

Table "Integrated"

Substances integrated into other substances

Application form for inquiry about submission of request

1				2	3
Mandatory					
Corporate name	Contact person	Telephone number	E-mail	Slide No. of the guide	Inquiries
○○Co.	○○△△	xx-xxxx-xxxx	xxx@xxx.xx.jp	2～17	

1. Submit an application on a company-by-company basis.
2. Make sure to select the number(s) of the page outlining matters related to the inquiry.
3. Limited to the inquiries about information on substances.
   Inquiries about the PL System itself and inquiries about matters understandable from this guide are not accepted.

ATTENTION !

If there is any unclear point about application, please make inquiries first. Then, submit information in accordance with the responses from the MHLW.
Do not submit ambiguous application.

How to submit an application

As directed below, submit an application directly by the business who handles the substance concerned.
Email separately according to the purpose of submission: “base materials,” “additives,” or “inquiry.”
Please do not submit the application on the name of trade association.

- **Email address**: packpl6@mhlw.go.jp
- **Subject**: Select appropriate one from below:
  - Request (Base materials)
  - Request (Additives)
  - Inquiry about request

  } and add corporate name, name of the contact person, and date.
- **Body text**: Select appropriate one from below and add the sender’s information at the end of the email.

[Corporate name] hereby submits application about base polymers.
[Corporate name] hereby submits application about additives.
[Corporate name] hereby makes an inquiry about application.

Please do not provide other information.

- **Attachments**: Only the following two files are accepted.
  1. An Excel file in fixed Form (for Base materials, Additives, or Inquiries)
  2. When submitting application about base polymers and additives, a file of documents* showing that the substance has been used since before June 1, 2020.
     *Any format is acceptable, but the documents should be put into one file.

ATTENTION !
Do not attach except above two files.

*At receiving an application, the MHLW provides a file number to the applicant.
*If there are plural applications, submit them in the order they were ready.