

Implementation Guidelines for Notification on Producing Microorganisms for Enzymes as Food Additive and Its Disclosure

1. Substances targeted for notification

Seventy enzymes as food additive (See Attachment.)

2. Notifier

The notification must be filed by business entities who manufacture target enzymes.

- It is not necessary for business entities solely engaging in sales or import target enzymes to file a notification.
- When a target enzyme is manufactured by an overseas business entity and imported into Japan, the notification must be filed by the overseas business entity and not by the importer.

3. How to notify

(1) Business entities are not required to file a notification to the effect that they do not manufacture the target substances.

(2) When, for target substances, there are records of manufacturing as food additive, enter the required information into the following application form for them, and file a notification for each of them by December 31 (Wednesday), 2025.

Application Form:

https://www.nihs.go.jp/dfa/dfa_en/application_form_g_enzyme.html

4. Notes at entering information into the application form

Enter the information given below into the application form provided on the website of the Consumer Affairs Agency (“the CAA”). File a notification with a declaration to the effect that the information notified is free from mistakes and false under the responsibility of the representative of the business entity

(1) Information about the notifier

- i. Name of business entity
- ii. Job title of representative
- iii. Name of representative

iv. Address of business entity

v. Telephone number

(2) Information about the person responsible for notification

i. Name

ii. Job title

iii. Telephone number

iv. E-mail address

(3) Information about the target enzyme

i. Type of the enzyme

ii. This enzyme has been confirmed to conform to the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No.370 of 1959).

iii. Name of the enzyme

iv. Taxonomic category

v. Scientific name (genus and species name)

vi. Species and genus-level identification methods

vii. Name of the strain

viii. Sales start year

ix. Residue form in the final food product

x. Remarks

5. Matters to be confirmed after the transmission of the application form

(1) Acknowledgement of the confirmation email from the CAA

After the transmission of the application form, the confirmation email will be sent to the registered email address from the CAA's no-reply email address (enzyme.add.caa@pcresearch.jp). Please configure your email settings to receive the messages from the address and make sure to confirm the confirmation email.

(2) Confirmation of notification receipt form

Clicking the URL provided in the confirmation email enables access to the notification receipt for viewing and downloading. The notification receipt is to show that the notification is received but not to show that the enzyme notified complies with specifications and standards under the Food Sanitation Act. If any doubt arises concerning the information notified, the CAA may inquire of the notifier about the information and may decide not to consider the notified substance as an enzyme as food additive.

(3) Allocation of notification numbers

Notification numbers are allocated to each notification (each strain of producing microorganisms) and indicated on the notification receipt.

6. Disclosure of the notified information (List)

The list containing the information on the producing microorganism notified is disclosed on the CAA's website, considering the parts belonging to intellectual properties of the business entity.

(1) Information to be disclosed

The items given in i. to v. are disclosed. The contents may be modified as accordingly.

- i. The name of the enzyme
- ii. The genus and species names of the producing microorganism
- iii. Notification number
- iv. The date of notification
- v. Remarks (other information decided to be disclosed)

(2) The update of the list

The list will be updated regularly, approximately four times a year by the CAA.

7. Notification submission period and disclosure schedule

- (1) The information notified by December 31, 2025 is placed in the list and disclosed on the CAA's website within 2026.
- (2) The information notified in and after January 2026 is placed in the list at the time of regular updating of the list and disclosed on the CAA's website.

8. Notification of deletion of the producing microorganism already notified

When the producing microorganism notified is no longer used for manufacturing, the notification for deletion must be filed using the application form provided on the CAA's website. The producing microorganism notified for deletion will be deleted promptly from the notified data managed by the CAA, but the deletion from the list disclosed will be conducted at the time of updating of the list by the CAA.

9. Notification for the change of scientific name of the producing microorganism

When it is found that the scientific name of the producing microorganism notified needs to be changed, the business entity must promptly file a notification for the deletion of the notified producing microorganism and file a notification for the registration of the producing microorganism with the appropriate name. Furthermore, after transmission of the notifications, the business entity must promptly inform by email to the food additive section of the Food Safety Standards and Evaluation Division of the CAA that the scientific name of the notified producing microorganism has been changed.

10. Notification of change

When the name of the business entity has been changed, a notification for the change must be promptly filed to the CAA.

The page of food additives in the Food Safety Standards and Evaluation Division, the CAA:

https://cms.caa.go.jp/policies/policy/standards_evaluation/food_additives/research_003/

Contact: The food additive section of the Food Safety Standards and Evaluation Division, the CAA

Email address : g.enzyme.add@caa.go.jp