

No. 552

September 10, 2025

To: Heads of bureaus and departments in charge of hygiene at all prefectures, cities with health centers, and special wards

From: Director of Food Safety Standards and Evaluation Division,  
Consumer Affairs Agency  
(Official seal omitted)

Notification of Producing Microorganisms for Enzymes as Food Additives  
and Its Disclosure

The enzymes that are used as food additive in Japan (“enzymes”) are as follows.

- ✓ Two designated additives listed in Appended Table 1 of the Ordinance for Enforcement of the Act (Ordinance of the Ministry of Health and Welfare No. 23, 1948).
- ✓ Sixty eight additives listed in the List of Existing Food Additives (Public Notice of the Ministry of Health and Welfare No.120 of 1996)

Specifications and standards for the above enzymes are specified in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No.370 of 1959, "the Public Notice No.370") based on Article 13, paragraph (1) of the Food Sanitation Act (Act No. 233 of 1947, "the Act"). In the Public Notice No.370, for enzyme producing microorganisms, which are origins of enzyme, the genus and species names of the microorganisms are specified in the definitions of Monographs.

In recent years, scientific names of enzymes and categorization into multiple names have been reviewed by related academic societies according to improvement of the microorganism identification technologies. It has been found that some scientific names of enzyme producing microorganisms are changed even though enzyme producing microorganisms themselves remain the same as before. This is likely to

cause concern that descriptive discrepancies may arise between the changed names and scientific names (genus and species names) specified in the definition in the Public Notice No.370.

Considering the situation, to grasp the actual status of the producing microorganisms, the Consumer Affairs Agency (“the CAA”) has decided to modify the methods of operation management. Under the modified methods, manufactures of enzymes are required to file notifications to the CAA on the producing microorganisms for enzymes currently being distributed, and when the scientific names are changed, with confirming that the producing microorganisms themselves remain unchanged, the CAA permits continued sale of the enzymes manufactured with such microorganisms. Information on producing microorganisms notified will be disclosed on the CAA’s website in the manner to ensure that the company’s intellectual property is protected.

Please inform manufacturers of the enzymes targeted for the notification listed in Appendix (70 substances) within your jurisdiction, with sending a copy of the implementation guidelines (Attachment), to make sure that they provide the information on the enzyme producing microorganisms via the application form available on the CAA’s website.

The CAA is informing relevant business operators of this matter, mainly with posting specific information on the websites of the CAA\*. The CAA has already requested the relevant associations to thoroughly disseminate this matter to their association members. Furthermore, the CAA asks you for your consideration to reach this information to non-association members because there are many cases that they manufacture the enzymes.

Even enzymes for which no notification has been filed will not be immediately subject to the prohibition of manufacture under the Act. However, please note that if there are changes in scientific names of enzyme producing microorganisms without prior notification, it is unable to confirm that the microorganisms themselves remain the same as before, which may give rise to doubt on the Act.

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

[https://www.caa.go.jp/policies/policy/standards\\_evaluation/food\\_additives](https://www.caa.go.jp/policies/policy/standards_evaluation/food_additives)