

(Unofficial)

Announcement of the Food and Drug Administration

Re: Application for Certification of Production System Standards under Regulated Criteria

Since the Food and Drug Administration has reviewed its duty by the virtue of Section 33 under Decree on Criteria and Procedures of Good Governance B.E. 2546 (2003) and Carbinet's resolution on 11th May B.E. 2553 (2001) agreed to transfer duty on promotion supporting food business operators in case that food business operators would like to apply for production premises inspection for issuing of certificate of production system standards under regulated criteria to inspection bodies that approved of competency assessment and registered with Food and Drug Administration for inspection of food production premises under legal criteria instead.

In order to make authorized officers and inspection bodies for food production premises under regulated criteria have consistent implementation, therefore announcement made as follows:

1. To repeal

1.1 Announcement of Food and Drug Administration, Re: Application for food production premises under regulated criteria prescribed in Annex of Notification of Ministry of Public Health (No. 193) B.E.2543 (2000) and (No.239) B.E. 2544 (2001) dated 14th September B.E.2548 (2005).

1.2 Announcement of Food and Drug Administration, Re: Issuing certificate of production system announced on 27th May B.E. 2556 (2013).

2. In this announcement, "Standard for production system under regulated criteria" means standards relevant to production methods, production equipments and storage of food that are issued by the virtue of Section 6(7) of Food Act B.E. 2522 (1979).

3. Anyone who intends to apply for certificate of production system standard under regulated criteria for food production premises located in Bangkok Metropolitan as of 1st October B.E. 2557 (2014) onwards and for food production premises located in other provinces as of 1st October B.E. 2558 (2015) onwards shall submit applications to inspection bodies that approved of competency assessment and registered with Food and Drug Administration with scope announced by Food and Drug Administration. The following actions shall be taken:

3.1 Submit an application for certificate to an inspection body with evidence documents as specified by such inspection body by submit at least the following documents:

(1) Copy of food production license (Orr. 2) or Application for requesting of food production premise number which not fall in a scope of a factory (Form Sorbor. 1).

(2) Correction Form of food production premises which not fall in a scope of a factory (Form Sorbor.2) (if any).

3.2 Procedure of application for certificate as in List No.1 enclosed with this announcement or as specified by a particular inspection body.

3.3 Criteria of certificate issuance is as follows:

3.3.1 Issue a certificate to food business operator when result of inspection of food production premises is complied with all categories of regulated criteria, no major defects, and total scores from all categories are not less 85.00%.

3.3.2 Certified scope shall specify food categories as have been approved and real produced.

3.3.3 Format of Certificate as specified in List No.2 enclosed with this announcement.

3.3.4 Certificate is valid for 3 years from the signing date on certificate.

3.3.5 An applicant shall agree to have officers of Food and Drug Administration join the inspection body to observe an on-site audit of the applicant's premises as specified in surveillance audit plan of Food and Drug Administration.

3.4 Expenditure for inspection and certification

3.4.1 In case of an audit for certification of a food production premises, rate of expenditure for conformity assessment shall be as agreement between a certification body and an applicant.

3.4.2 Expenditure for surveillance audit once a year for maintenance of a system operating during a certificate still valid to ensure that system is still complied with requirements, rate of expenditure shall be as agreement between a certification body and an applicant.

3.5 Surveillance of production system certified by certification bodies or by authorized officers under the Food Act B.E. 2522 (1979) of food production premises if the systems are not complied with certified requirements and have not been corrected within the specified period, the certificates issued by certification bodies shall be withdrawn or cancelled and shall be notified immediately to the Food and Drug Administration.

Therefore, the Food and Drug Administration has publicly announced and if there are any queries please contact with Bureau of Food, the Food and Drug Administration, Ministry of Public Health, Tel. 02-590-7257, 02-590-7214 and 02-590-7206 during office hours or via e-mail at food@fda.moph.go.th or qateam.food@gmail.com.

Announced on 8th July B.E. 2557 (2014)

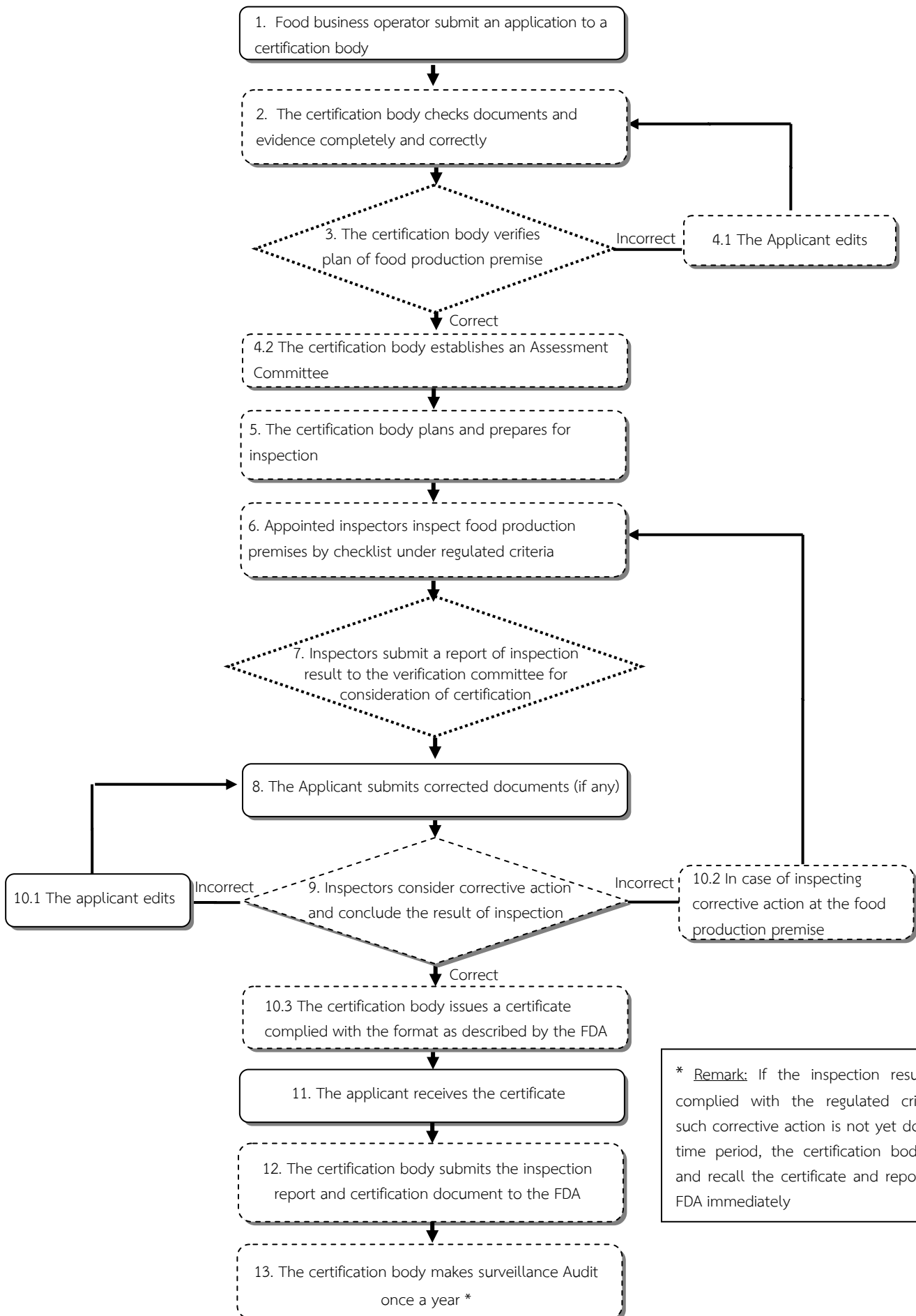
(Signed) Boonchai Somboonsuk

(Mr. Boonchai Somboonsuk)

Secretary-General of Food and Drug Administration

Note: This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.

Operation Procedures for applying for certification of food production system under regulated criteria



* Remark: If the inspection result is not complied with the regulated criteria and such corrective action is not yet done in the time period, the certification body repeals and recall the certificate and reports to the FDA immediately

**Format of a certificate for food production system under regulated criteria
issued by conformity assessment bodies
registered with the Food and Drug Administration**

1. Format of a certificate shall be as format prescribed by conformity assessment bodies issuing the certificate and shall have at least the following statements:

- 1) Name of certification body
- 2) Name of standard on food production system under regulated criteria certified
- 3) Name and address of a food production premise
- 4) Type of food certified (specify type of food as permitted by law)
- 5) Date of issuance of the certificate
- 6) Expiry date of the certificate
- 7) Number of the certificate
- 8) Signature of authorized person of conformity assessment agency
- 9) Certified registration mark of the Food and Drug Administration as format and conditions in No. 2 as below:

2. Format and conditions of displaying of certified registration mark of the Food and Drug Administration

1) Characteristic of Certification mark as displayed in figure 1 size of the mark as appropriate.

1.1) If background is white or light color, the symbol mark shall be blue only (FDA Blue - FDA PANTONE 661 and FDA Light Blue - PANTONE 279 C).

1.2) If background is dark color, the symbol mark shall be white or gold color by internal background of the symbol shall be the same color (see-through)

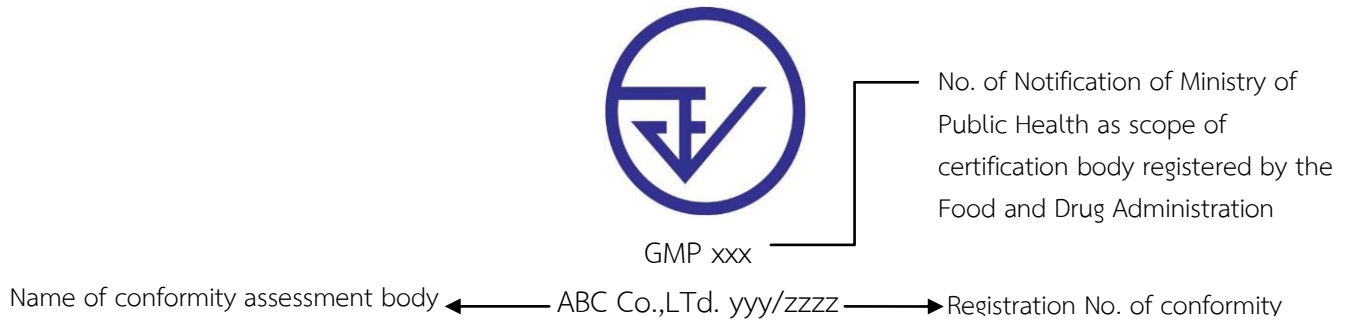
2) Only conformity assessment bodies registered with the Food and Drug Administration has right to use the certification mark on certificates.

3) Scope of registered inspection and registration number issued by the Food and Drug Administration shall be specified when display of certification marks and format shall be as in the figure.

4) Use of the certification mark with any products or services of the agencies is prohibited, if there are other products or services included, such those beyond the scope shall be clearly specified.

5) Displaying of the certification mark can be used for issuance of certificate only and shall not be used beyond the certified scopes or misleading of certified scopes.

6) Conformity assessment body shall describe to operators to not allow using the certification mark on product labels.



Certification mark registered with the Food and Drug Administration