

(Unofficial)

Announcement of the Food and Drug Administration

Re: Application for Certificate 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 Cabinet's resolution on 11th May B.E. 2553 (2010) agreed to transfer duty on promotion and supporting food business operators in case that food business operators would like to apply for food production premises audit for issuing of certificate of production system standards under regulated criteria to certification bodies that approved of competency assessment and registered with Food and Drug Administration for audit of food production premises under legal criteria instead.

In order to make authorized officers, certification bodies for food production premises under regulated criteria, and food business operators have consistent implementation, therefore the Food and Drug Administration has issued the announcement as follows:

1. To repeal

1.1 Announcement of Food and Drug Administration, Re: Application for food production premises under regulated criteria dated 8th July B.E.2557 (2014).

1.2 Announcement of Food and Drug Administration, Re: Application for food production premises under regulated criteria (No.2) B.E. 2557 (2014) dated 26th December B.E.2557 (2014).

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 the 1st October B.E. 2557 (2014) onwards shall submit applications to certification bodies that registered with Food and Drug Administration.

For food production operators located in regional area intend to apply for certificate of production system standard under regulated criteria as of the 1st October B.E. 2558 (2015) until 30th September B.E.2558 (2015) are able to submit applications at Provincial Health Office or certification bodies that registered with Food and Drug Administration so that all Provincial Health Office will cease the operation of issuing such certificates as of the 1st October B.E.2558 (2015), and food production operators located in regional area are able to submit the applications at certification bodies that registered with Food and Drug Administration.

4. Application for certificate of production system standard under regulated criteria at certification bodies that registered with the Food and Drug Administration shall comply with the scopes announced by the Food and Drug Administration, the following actions shall be taken:

4.1 Submit an application for certificate to a certification body with evidence documents as specified by such certification body as at least the following documents:

4.1.1 A 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).

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

4.1.3 Plant layout with details of machines and equipment located.

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

4.3 Criteria of certificate issuance are as follows:

4.3.1 Issue a certificate to food production operators when result of audit of food production premises is complied with all categories of regulated criteria, no major defects, and total scores from all categories are not less than 85.00%.

4.3.2 Certified scope shall specify food categories as have been approved and actual produced.

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

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

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

4.4 Expenditure for audit and certification

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

4.4.2 For Expenditure to surveillance audit and follow up 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.

4.5 Surveillance of production system of food production premises certified by certification bodies 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 to the Food and Drug Administration within 7 days from the date to consider to withdraw or cancel such certificate.

5. For authorized officers under the Food Act B.E.2522 (1979), application form, complemented evidences and operate under Work Instruction, Re Certification of system for legal GMP (P-F5-50) shall be used until the operation of issuing such certificate is ended.

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. 0-2590-7257 or 0-2590-7206 during office hours or via e-mail at food@fda.moph.go.th or qteam.food@gmail.com.

Announced on 29th May B.E. 2558 (2015)

(Signed) Boonchai Somboonsuk

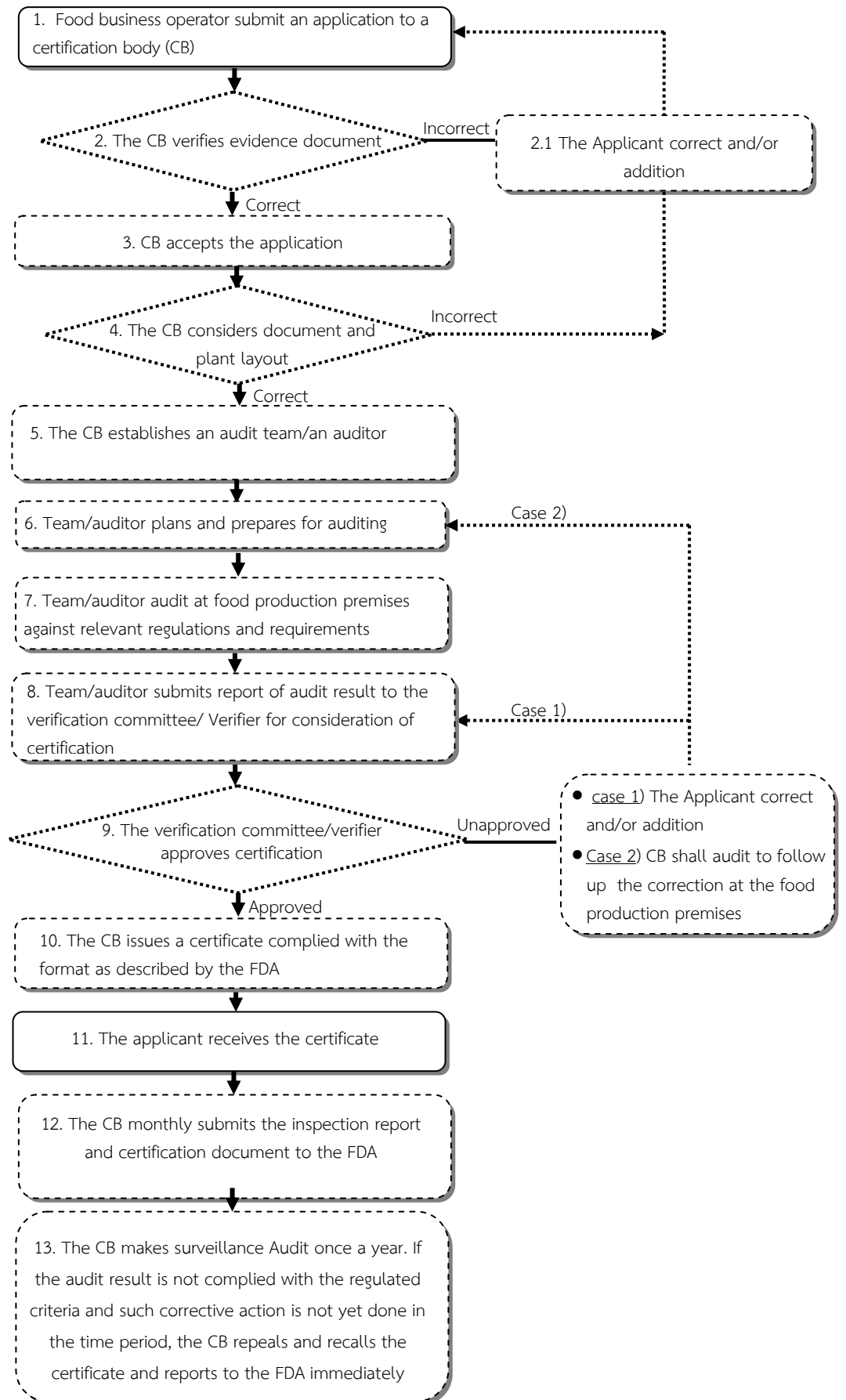
(Mr. Boonchai Somboonsuk)

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.

List no.1

Operation procedures of application for certificate of food production system under regulated criteria



List no. 2

A certificate format of production system standards 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:

1.1 Name of certification body

1.2 Name of standard on food production system under regulated criteria certified, scope of audit shall be specified to cover all standards as relevant to regulated criteria.

1.3 Name and address of a food production premise

1.4 Type of food certified (specify type of food as permitted by law)

1.5 Date of issuance of the certificate

1.6 Expiry date of the certificate

1.7 Number of the certificate

1.8 Signature of authorized person of conformity assessment agency

1.9 Certification mark registered with the Food and Drug Administration as format and conditions in No. 2 as below:

2. Format and conditions of displaying of Certification mark registered with the Food and Drug Administration

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

2.1.1 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).

2.1.2 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)

2.2 Only certification bodies registered with the Food and Drug Administration have right to use the certification mark on certificates.

2.3 Scope of registered audit standards 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 1.

2.4 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.

2.5 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.

2.6 Certification bodies shall describe to operators to not allow using the certification mark on product labels.

2.7 Food labeling shall follow the announcement of the Food and Drug Administration, Re: Criteria for declaration of texts on food labels relevant to receiving of audit of production premises dated 30th April B.E. 2550 (2007).

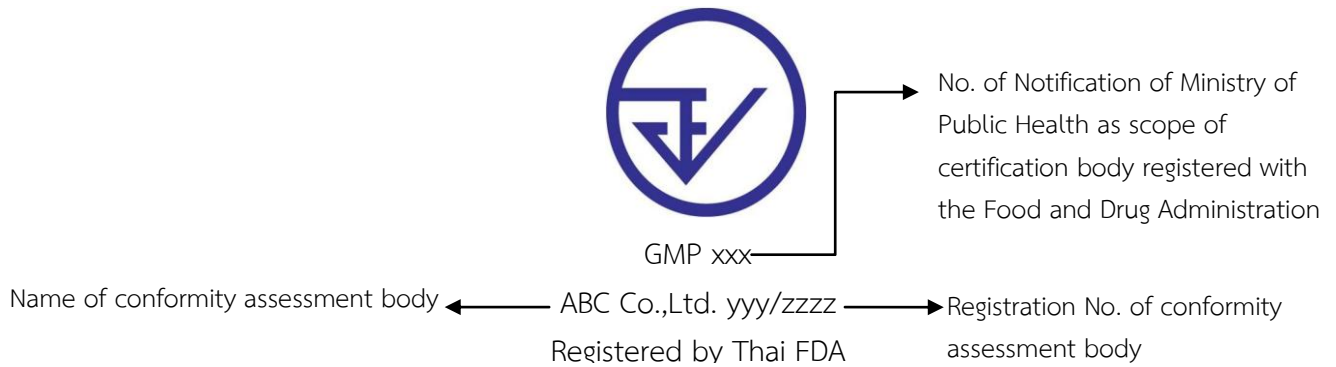


Fig. 1 Certification mark registered with the Food and Drug Administration