

Notification of Ministry of Public Health

No 386 B.E. 2560 (2017)

**Re: The Requirements for Production Processes, Production Equipment,
Storage and Labelling of Some Fresh Fruits or Vegetables"**

It is deemed appropriate to establish measure to regulate and control quality and safety of fruits and vegetables throughout the supply chain in a more effective way in order to ensure consumers get quality and safe fruits and vegetables.

By the virtue of provisions of the first paragraph of Sections 5 and 6 (5) (6) (7) (9) and (10) of the Food Act B.E. 2522 (1979), which restricts personal rights and liberties, in conjunction with section 26, 33, 34, 37 and 40 of the Constitution of the Kingdom of Thailand, the Minister of Public Health hereby issues the notification as follows:

Clause 1: Definition under this notification:

“Production” means the sorting, packing process of fruits or vegetables sourced from other parties or sorting and packing process of own grown fruits or vegetables in the buildings or premises dedicated for sorting and packing.

"Sorting and packing" means post-harvest process for fresh fruits and vegetables which covers from sorting, packing in any types of packaging for sales. The process may include cleaning, cutting, waxing or other processes which preserve quality of fruits or vegetables.

“Some Fresh Vegetable or Fruits’ means only fresh vegetables and fruits listed in Annex 1 of this notification.

Clause 2: Producer of fresh vegetables and fruits listed in Annex 1 shall follow the requirements regarding production process, equipment and storage, as follows:

- (1) In accordance with the requirements in Annex 2 of this notification; or
- (2) In compliance with other standards that are equivalent or higher than (1)

The inspection of the production premise under (1) shall follow the criteria in Annex 3 of this notification and be documented accordingly.

Clause 3: Importer of some fresh vegetables and fruits which has undergone sorting and packing process shall present certificate equivalent to or higher than the Annex 2 of this notification. The certificate may be issued by the following organisation:

- 1) Government authority of producing country, or
- 2) Other organisation accredited by government authority of the producing country, or

3) A certified Body, which is assessed and accredited by Accreditation Body recognized by International Accreditation Forum (IAF), or

4) Other organisations which Thailand Food and Drug Administration (FDA) specifies.

Clause 4: Packaging shall follow the MOPH Notification regarding packaging.

Clause 5: Irradiation shall follow MOPH Notification regarding irradiated food.

Clause 6: Producer under Clause 2 or Importer under Clause 3 intending to sell in the domestic market shall display product label in Thai language and may also contain other languages. Label should provide the following information, as minimum.

(1) Name and address of producer or importer or headquarters (where applicable)

(1.1) For domestically produced fresh vegetables and fruits, label shall display producer's name and address, or producer's name and headquarters' address. The description in the label should read

(a) Word 'Producer' or 'Produced by' for producer,

(b) Word 'Headquarters' for the producer intending to declare headquarters' name and address

(1.2) For imported fresh vegetables and fruits, label shall display importer's name and address, with a clear word 'Importer' or 'Imported by' as well as producing country.

(2) Registration number of food production premise or importer premise (where applicable); Font of this number shall not be smaller than 2 mm and be displayed in clearly defined white box.

(3) Any code or number that indicates production lot

Clause 7: Retailer, who sells fresh vegetables and fruits regulated by this notification from producer under Clause 2 and importer under Clause 3, shall display information required under Clause 6 or have a record of this information to inform consumers or responsible officials.

Clause 8: Those who were granted food production license or food production premise number under Clause 2 or those who were granted food import license under Clause 3 (where applicable), prior to the implementation of this notification, are given one year after the effective date to rectify any non-compliance from this notification.

Clause 9: The following products are exempted from notification:

(1) Some fresh vegetables or fruits that are sold directly to consumers

(2) Some fresh vegetables or fruits that are sold in a ready-to-cook and ready-to-eat form, as described in MOPH notification regarding labelling for ready-to-cook and ready-to-eat food

Clause 10: This notification shall enter into force after one year from the gazettal date.

Announced on 2 August 2017

Piyasakol Sakolsatayadorn

Minister of Public Health

This notification was published in the royal gazette on 25 August 2017.

Annex I

List of some fresh fruit or vegetables

List of Fruits	Scientific name
(1) Banana	<i>Musa spp.</i>
(2) Chestnut	<i>Castanea spp.</i>
(3) Dragon fruit/pitaya	<i>Hylocereus spp.</i> ; <i>Hylocereus undatus</i> (Haw.) Britton & Rose; <i>Hylocereus megalanthus</i> (K. Schum. ex Vaupel) Ralf Bauer; <i>Hylocereus polyrhizus</i> (F.A.C. Weber) Britton & Rose; <i>Hylocereus ocamponis</i> (Salm-Dyck) Britton & Rose; <i>Hylocereus triangularis</i> (L.) Britton & Rose
(4) Cantaloupe and melon	<i>Cucumis melo</i> L
(5) Rambutan	<i>Nephelium lappaceum</i> L.
(6) Java apple; wax jumbo; wax apple; rose apple	<i>Syzygium samarangense</i> (Blume) Merr. & L.M.Perry Syn. <i>Eugenia javanica</i> L.
(7) Watermelon	<i>Citrullus lanatus</i> (Thunb.) Matsum. & Nakai Syn. <i>Citrullus vulgaris</i> Schrad.; <i>Colocynthis citrullus</i> (L.) Kuntze
(8) Pomegranate	<i>Punica granatum</i> L.
(9) Guava	<i>Psidium guajava</i> L.
(10) Jujube, Indian	<i>Ziziphus mauritiana</i> L.; Syn. <i>Ziziphus jujuba</i> Mill.
(11) Mango	<i>Mangifera indica</i> L.
(12) Papaya	<i>Carica papaya</i> L.
(13) Sapodilla	<i>Manilkara zapota</i> (L.) P. Royen; Syn: <i>Manikara achras</i> (Mill.) Fosberg; <i>Achras zapota</i> L.
(14) Longan	<i>Dimocarpus longan</i> Lour. Syn: <i>Nephelium longana</i> (Lam.) Camb.; <i>Euphoria</i> <i>longana</i> Lam.
(15) Strawberries	<i>Fragaria × ananassa</i> (Duchesne ex Weston) Duchesne ex Rozier
(16) Mandarins and hybrids	<i>Citrus reticulata</i> Blanco and hybrids <i>nobilis</i> Lour.; <i>Citrus deliciosa</i> Ten.; <i>Citrus tangarina</i> Hort.; <i>Citrus mitis</i> Blanco Syn. <i>Citrus madurensis</i> Lour.; <i>Citrus unshiu</i> Marcow

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| (17) | Oranges and hybrids | <i>Citrus sinensis</i> Osbeck, <i>Citrus aurantium</i> L. and hybrids
<i>Citrus myrtifolia</i> Raf.; <i>Citrus salicifolia</i> Raf. |
| (18) | Pear, oriental; Chinese pear; nashi pear; sand pear; snow pear | <i>Pyrus pyrifolia</i> (Burm. f.) Nakai; <i>Pyrus lindleyi</i> Rehder; <i>Pyrus nivalis</i> Jacq. |
| (19) | Grapes | <i>Vitis vinifera</i> L. |
| (20) | Apple | <i>Malus domestica</i> Borkhausen |

List of vegetables

Scientific name

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|------|--|---|
| (21) | Garlic, Chinese onion | <i>Allium sativum</i> L. and <i>Allium chinense</i> G. Don;
Syn. <i>Allium bakeri</i> Regel |
| (22) | Cauliflower, romanesco broccoli | <i>Brassica oleracea</i> var. <i>botrytis</i> L. |
| (23) | Cabbages | <i>Brassica oleracea</i> L. var. <i>capitata</i> L. |
| (24) | Chives, chinese | <i>Allium tuberosum</i> Rottler ex Spreng. |
| (25) | Galangal | <i>Languas galanga</i> (L.) Stunz; Syn. <i>Alpinia galanga</i> Sw.; <i>Languas officinarum</i> (Hance) Farwell; Syn. <i>Alpinia officinarum</i> Hance
<i>Kaempferia galanga</i> L. |
| (26) | Chinese broccoli; Chinese kale | <i>Brassica oleracea</i> var. <i>alboglabra</i> (L.H. Bailey) Musil |
| (27) | Carrot | <i>Daucus carota</i> L. |
| (28) | Spring onion, onion, welsh; Japanese bunching onion; Chinese small onion; green onion) | <i>Allium cepa</i> L., White Portugal and <i>Allium fistulosum</i> L. |
| (29) | Bean sprout | <i>Vigna radiata</i> (L.) R. Wilczek |
| (30) | Ivy gourd | <i>Coccoloba grandis</i> (L.) Voigt |
| (31) | Cucumber | <i>Cucumis sativas</i> L. |
| (32) | Yard-long bean | <i>Vigna unguiculata</i> subsp. <i>sesquipedalis</i> (L.) Verdc. |
| (33) | Garden pea | <i>Pisum sativum</i> L. var. <i>sativum</i> |
| (34) | Broccoli | <i>Brassica oleracea</i> L. var. <i>italica</i> Plenck |
| (35) | Basil | <i>Ocimum basilicum</i> L.; <i>Ocimum x africanum</i> Lour.; <i>Ocimum basilicum</i> L. <i>Ocimum x citrodorum</i> Vis.; <i>Ocimum minimum</i> L.; <i>Ocimum americanum</i> L.; <i>Ocimum gratissimum</i> L.;
<i>Ocimum tenuiflorum</i> L. |

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| (36) Pennywort | <i>Centella asiatica</i> (L.) Urb. |
| (37) Spinach | <i>Spinacia oleracea</i> L. |
| (38) Chinese cabbage | <i>Brassica rapa</i> L. subsp. <i>pekinensis</i> (Lour.)
Kitam. Syn. <i>Brassica pekinensis</i> (Lour.) Rupr.,
<i>Brassica rapa</i> var. <i>pekinensis</i> (Lour) Olsson |
| (39) Amaranth | <i>Amaranthus</i> spp |
| (40) Kangkung/water spinach | <i>Ipomoea aquatica</i> Forssk. |
| (41) Chili | <i>Capsicum annuum</i> L. |
| (42) Peppers, sweet/ peppers, bell, prapika | <i>Capsicum annuum</i> var. <i>grossum</i> (Willd.) Sendt.
and <i>Capsicum annuum</i> var. <i>longum</i> (DC.)
Sendt. |
| (43) Pumpkins | <i>Cucurbita maxima</i> Duchesne; <i>Cucurbita</i>
<i>argyrosperma</i> C. Huber; <i>Cucurbita</i>
<i>moschata</i> Duchesne; <i>Cucurbita pepo</i> L.
and <i>Cucurbita pepo</i> subsp. <i>pepo</i> |
| (44) Tomato | <i>Lycopersicon esculentum</i> Mill.
Syn. <i>Solanum lycopersicum</i> L. |
| (45) Thai eggplant | <i>Solanum undatum</i> Lam. |
| (46) Potato | <i>Solanum tuberosum</i> L. |
| (47) Shallot | <i>Allium cepa</i> L. var. <i>aggregatum</i> G. Don. |
| (48) Mushrooms | <i>Agrocybe aegerita</i> ; <i>Hypsizygus tessellates</i> (Bull.)
Singer; <i>Auricularia auricular-judea</i> (Bull.) Quéf.;
<i>Ganoderma lucidum</i> (Curtis) P. Karst., and other
<i>Ganoderma</i> spp.; <i>Lentinula edodes</i> (Berk.) Pegler;
<i>Volvariella volvacea</i> (Bull.) Singer; <i>Tremella</i>
<i>fuciformis</i> Berk.; <i>Auricularia polytricha</i> (Mont.)
Sacc.; <i>Termitomyces</i> sp. |

Annex II

The good practices requirements for packing house

Areas	Criteria
<p>1. Premises and production buildings</p>	<p>Premise, its surrounding and building shall not pose risk of food contamination;</p> <p>1.1 Area of the premise and its surrounding shall not pose contamination risk to vegetables and fruits being packed in the premise;</p> <p>1.1.1 The surrounding area shall be clean from sewage and waste that could be a habitat for animals or insects that can be disease carriers</p> <p>1.1.2 There is no activity that produces too much dust happening near the premise.</p> <p>1.1.3 There is no unpleasant/ unhygienic place / activity near the premise.</p> <p>1.1.4 The area in the premise shall have good drain pipe connected to public sewage system. In the case that the premises are located next to the unsuitable surrounding, there shall be an effective measure to prevent any disease carriers, dust and other contamination.</p> <p>1.2 The premise and building shall be maintained in good sanitation;</p> <p>1.2.1 Production building shall be maintained its cleanliness and sanitation to reduce any risk of contamination and to facilitate the production operation.</p> <p>1.2.2 The production area shall be well separated from the residential area.</p> <p>1.2.3 There shall be sufficient light and air flow for the operation.</p> <p>1.2.4 There shall be good drain system connected to public sewage system. If chemical is being used in the production, wastewater shall be treated before releasing to public sewage system.</p> <p>1.2.5 There must be an effective measure for pest and animal control.</p>
<p>2. Tools and equipment used in the production process</p>	<p>Tools, equipment used in the production process shall be appropriately designed, for good sanitation, prevention of contamination and ease of maintenance.</p> <p>2.1 Tools and equipment shall be appropriately designed by factoring any potential contamination and how to maintain the cleanliness of equipment, tools and installation area thoroughly.</p> <p>2.2 Production equipment and facilities which come into contact</p>

	<p>with food shall be made of non-hazardous materials, cause no harm to consumers and be easy to clean.</p> <p>2.3 Surface of production equipment and tables shall be made of non-rusting materials, easy to clean and does not have any reaction that pose any risk to consumers' health. They shall be placed in the location that is easy to access for cleaning. Height of equipment shall be appropriate for operation. There shall be measure to prevent any contamination which may occur.</p>
<p>3. Production control</p>	<p>Every step in the production process shall maintain good sanitation, and prevent any aspects of harm (physical, chemical, biological). The control measure shall start from receiving of raw material from orchards or collection centers, packaging, preparation, washing, sorting, cutting, packing, storage, and transportation.</p> <p>3.1 ^(M) Fresh fruits and vegetables sourced into the production process shall have quality and be safe as per MOPH related requirements and at least follow these aspects:</p> <p>3.1.1 The fresh vegetables and fruits shall be sourced from the source where rely on good practice of pesticides application.</p> <p>3.1.2 There shall be a registration of grower, producer or collection agents of fresh vegetables and fruits.</p> <p>3.2 Packaging or packing material which directly contacts with fresh vegetables and fruits shall be clean, be cleaned prior to the usage, and made of non-toxin material. Packaging of toxic substance shall not be re-used for packing fruits and vegetables.</p> <p>3.3 Raw material and packaging/ packing material shall be stored appropriately to prevent any contamination and prolong durability of materials.</p> <p>3.4 Fresh vegetables and fruits shall be regularly tested for pesticide residue and ready-to-eat vegetables and fruits shall be regularly tested for microorganism. The on-site test may be conducted using simple test kit. It is required that product sample shall be tested by accredited laboratory at least once a year.</p> <p>3.5 Cutting, packing, transferring, packaging, and storage method of food products shall protect vegetables and fruits from contamination and deterioration.</p> <p>3.6 Transportation of vegetables and fruits shall protect from contamination and deterioration.</p> <p>3.7 ^(M) The cutting and packing method shall be appropriate for types of products.</p> <p>3.7.1 If food additive is applied, it shall strictly follow MOPH</p>

	<p>notification regarding Food Additive</p> <p>3.7.2 If chemical agent is applied in cleaning method, the application shall be appropriate and there shall be regular test for residue.</p> <p>3.8 (M) Water and Ice being used in washing process or directly contact with ready-to-eat vegetables and fruits shall be clean and fit for consumption. Quality of water shall follow MOPH notification regarding Water in Sealed Packaging and quality of ice shall follow MOPH notification regarding Ice. Water for basic washing shall be treated as appropriate and used in good sanitation.</p> <p>3.9 (M) There shall be traceability system which may record production lot, or production date.</p> <p>3.10 Records of raw materials, production process, finished products, and storage shall be well maintained and available for audit and traceability;</p> <ul style="list-style-type: none">3.10.1 Registration of collecting agents or growers.3.10.2 Record of raw material received3.10.3 Record of production control3.10.4 Record of water quality test3.10.5 Record of production and sales3.10.6 Certificate(s) assuring quality of raw materials3.10.7 Results indicating quality of finished products followed related MOPH notifications (e.g. pesticide residue (MRLs, EMRLs), microorganism, heavy metal).
<p>4. Sanitation</p>	<p>There shall appropriate measures to control factors that may affect the production:</p> <p>4.1 Water used in the production premise shall be clean and if required, the appropriate treatment shall be conducted.</p> <p>4.2 Trash cans and proper trash elimination systems for all types of trash must be available sufficiently.</p> <p>4.3 There must be an adequate number of toilets and sinks proportional to the number of workers, and these facilities must be maintained in sanitary conditions and in good working condition. Sinks for hand washing shall be fully equipped. Toilets shall be isolated from production areas and should not be directly exposed to production areas.</p> <p>4.4 Fully equipped hand washing sinks in the production area must be provided adequately.</p> <p>4.5 Proper and effective sewage systems for waste water well as dirt gutters for waste material which will not contaminate any part of the food production process or food products, must be instated.</p>

<p>5. Maintenance and cleaning</p>	<p>5.1 Production buildings shall be maintained clean at all times.</p> <p>5.2 Tools, machinery and production equipment shall be inspected and maintained for efficient use at all times.</p> <p>5.3 Chemical agents for washing and/or chemicals for production shall be stored and used under safe conditions and be isolated from production areas. Additionally, they must all have clear and correctly labeled.</p>
<p>6. Personnel and personnel hygiene</p>	<p>6.1 Workers and personnel in production areas shall not be infected with any communicable or contagious disease.</p> <p>6.2 During the production processing, all workers and personnel who may have direct contact with food shall follow the below practices:</p> <ul style="list-style-type: none">6.2.1 Workers' clothes must be clean and proper for undertake their duties.6.2.2 Workers' shoes must be managed appropriately, e.g. workers are required to change shoes and walk pass the cleaning solution before entering to the production area.6.2.3 Workers are not allowed to wear jewelry while performing their duties and their hands and nails must be clean at all times.6.2.4 Workers are required to wash their hands before performing their duties, after contacting any potential sources of contamination, and after use toilets.6.2.5 Workers are required to wear hats or hair nets while working.

Remark: (M) stands for major defect, meaning that if the premise fails in any aspects marked as (M), the premise will fail in that audit.

- Embassy Translation -

Notification of Food and Drug Administration

Re: Clarification for MOPH Notification No. 386 B.E. 2560 (2017)

**Re: The Requirements for Production Processes, Production Equipment,
Storage and Labelling of Some Fresh Fruits or Vegetables"**

Fresh fruits and vegetables are widely consumed in every household and the World Health Organisation (WHO) recommended the daily intake for consumer's good health; however, there have been incidents of pesticide residue detection exceeding the standards. It is therefore deemed appropriate to improve the regulations to upgrade the quality and safety of fresh fruits and vegetables and to reduce the problem on pesticide residue.

Ministry of Public Health (MOPH), through Food and Drug Administration (FDA), announces MOPH Notification No. 386 B.E. 2560 (2017) Re: The Requirements for Production Processes, Production Equipment, Storage and Labelling of Some Fresh Fruits or Vegetables, which will initially be implemented on some pilot fruits and vegetables that pose risk on consumer health and are driven by the market. Under this notification, the packinghouses shall put in place the measures to ensure that products are sourced from the production sources that apply pesticides safely. The key essence of MOPH notification No. 386 are as follows:

1. Scope of enforcement

This MOPH notification is applicable to producers, importers and distributors of some fresh fruits and vegetables, covered by the Annex 1 of the notification, as detailed below:

- 1.1 Producers mean those who arrange the sorting and packing process of some fresh fruits and vegetables. (See the diagram 1)
- 1.2 Importers mean those who import some fresh fruits and vegetables from other premises that arrange sorting and packing of the products.
- 1.3 Distributors mean those who sell some fresh fruits and vegetables from the producers under 1.1; or from importers under 1.2

2. Enforcement measures

2.1 The food production premise or food importer premise must be approved in accordance with the requirements.

2.1.1 Production standards

- (1) For local products, premise must comply with the Good Manufacturing Practice (GMP) stipulated in the Annex 2 of this MOPH notification.

(2) For imported products, importers shall source products from the packinghouses that operate the sorting and packing process which is equivalent or higher than the food production standards in Annex 2 of this MOPH notification.

(3) Example of food production standards that are equivalent or higher than Annex 2 of this MOPH notification, as below:

- (3.1) Code of Hygienic Practice for Fresh Fruits and Vegetables: CAC/RCP 53-2003 under Codex Alimentarius Commission, Joint FAO/WHO Food Standard Programme
- (3.2) Hazard Analysis and Critical Control Point System under Codex Alimentarius Commission, Joint FAO/WHO Food Standard Programme
- (3.3) BRC Global Standard for Food Safety : British Retail Consortium, Issue 7 January 2015
- (3.4) Food Safety Management Systems – Requirements for any Organisation in the Food Chain, ISO 22000:2005
- (3.5) International Food Standard; IFS, Version 6 (current version)
- (3.6) Agricultural Standard no.9035-2553 re: Good Manufacturing Practices for Packing houses for Fresh Fruits and Vegetables; or, Good Manufacturing Practices for Ready-to-Eat Fresh Fruit and Vegetables announced by Thailand's National Bureau of Agricultural Commodity and Food Standards (ACFS)
- (3.7) New Zealand Food Regulations 2015 under New Zealand Food Act 2014

(4) The production must be audited by an organisation or agency that is responsible for auditing the production premises and issuing the certification for packinghouses, which include the following organisations:

- (4.1) Competent authority in the producing country
- (4.2) Other organisation accredited by the government authority of the producing country
- (4.3) A certification body, which is assessed and accredited by Accreditation Body recognized by International Accreditation Forum (IAF),

2.1.2 Labelling requirement

(1) Prior to sale, producers or importers of fresh fruits and vegetables covered by Annex 1 shall arrange a label which contains the following information:

- (1.1) Name and location of the producer or importer (where applicable); for imported fresh fruits and vegetables, country of origin must be displayed as well.

(1.2) Registration number of food production premise or food importer premise (where applicable); Font of this number shall not be smaller than 2 mm, and be displayed in clearly defined white box, with a clear message 'registration number of food production premise' or 'registration number of food importer premise'.

(1.3) Any code or any form of information which indicates production lot, e.g. production date, barcode, QR code, etc.

(2) Distributors shall disclose the label from the producers or importers; or arrange the display of information or put in place a traceability system of the information to be provided to consumers or officials.

3. Effective date

3.1 For the existing operators who have obtained the registration numbers of the food production premise or food importer premise shall comply with this MOPH notification from 25 August 2019 onwards.

3.2 For new operators who have never requested a registration number before shall comply with this MOPH notification from 25 August 2018 onwards.

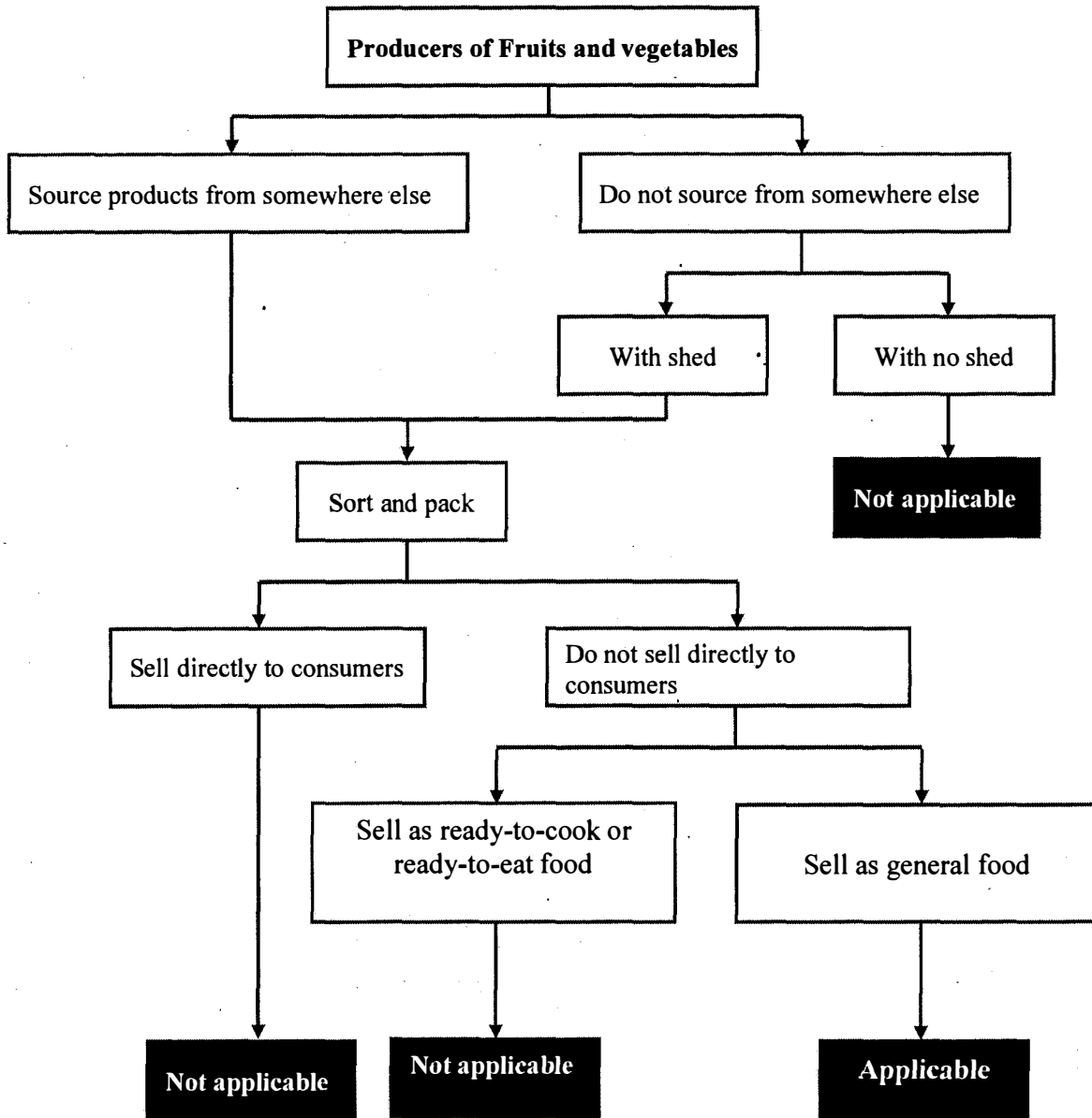
4. Those who fail to comply with this MOPH notification are considered to be violating to two sections; Section 6(7) which commit the offence under Section 49 of Food Act B.E.2522 shall be subject to the financial penalty of maximum 10,000 baht, and Section 6 (10) which commit the offence under Section 51 of the Food Act B.E. 2522 shall be subject to the financial penalty of maximum 30,000 baht.

Food and Drug Administration would like seek cooperation from producers and importers of fresh fruits and vegetables to comply with this MOPH notification. Any question, please contact Food Bureau of FDA, MOPH Tel. 02-590-7178 and 02-590-7406 (public government working hours).

Announced on 12 September 2017

Poonlarp Chantawichitwong
Deputy Secretary General
Acting for Secretary General
Food and Drug Administration

Diagram 1: Scope of enforcement of the MOPH Notification No. 386 B.E. 2560 (2017) Re: The Requirements for Production Processes, Production Equipment, Storage and Labelling of Some Fresh Fruits or Vegetables



*Sorting and packing means sorting and packing fresh fruits and vegetables into any packaging types such as plastic bag, foam container with plastic cover, mesh bag, basket, etc. to the transportation of products. The process may include cleaning, cutting, waxing or other processes which preserve quality of fruits or vegetables.