

# PROCESSING AIDS

# What are the regulations in various countries?



At the international platform, the Codex Alimentarius Commission has put in place guidelines on the use of processing aids. According to the *Guidelines on Substances Used as Processing Aids*, processing aids are defined as "any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product".

Within the region, most countries' definition of processing aids matches the definition of processing aids under the Codex framework. However, a comparison of existing regulatory frameworks shows that processing aids are regulated to varying extents among the countries in Asia. For instance, processing aids are still regulated as food additives in some market while the rest regulates it under the processing aids regulations. This report aims to help companies understand the regulatory framework of processing aids in markets in the region.



# **ASIA AT A GLANCE**

# **Definition Countries Defined** as **Processing Aids Defined as Food Additives**

# Regulatory

#### **Countries**

Framework	
Regulated as Processing Aids	
Regulated as Food Additives	
Processing Aids Regulations in Draft Phase	
Others (Regulated under Biological and Chemical Pollution in Food)	

**Provision for List of Countries Permitted Processing Aids** 



Disclaimer: You may use this report at your own discretion. Every effort has been made to ensure that the information contained in this review is reliable. However, as global regulations often involve legal uncertainties and differences in interpretation, we are therefore not liable whatsoever for any loss or damage resulting from the use of the information contained herein.



#### INTRODUCTION

Processing aids are usually defined as substances completely independent from the actual food product, used in the lowest possible amount during food processing to fulfil a technological function and may leave behind residues in the final product. The substance used would preferably be completely removed from the food before the final product is obtained. Otherwise, it is ensured that the trace amounts left behind are not harmful to the consumer.

Codex draws the differentiation by specifying that processing aids perform a technological function in the food processing stage whereas food additives are used in the manufacturing, processing, preparing, treating, packing, transport, or packaging of food which results, or may be reasonably expected to result, in the additive or its byproducts becoming a component of, or affecting the characteristics of such food. The report examines the existing regulatory frameworks of processing aids, including how processing aids are defined and their conditions for use.

# **CODEX**

Processing aid refers to any substance, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing, which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product<sup>1</sup>.

The principles of use of processing aids are as follows:

- When the processing aid performs one or more technological functions during treatment or processing of raw materials, foods or ingredients
- Residues of processing aids remaining in food after processing should be reduced to the extent reasonably achievable and should not perform a technological function or pose any health risk
- Quantity of processing aid shall be limited to the lowest achievable level necessary to accomplish its desired technological function
- Processing aids are prepared and handled in the same way as a food ingredient
- Processing aids are of food grade quality
- Processing aids shall comply with microbiological criteria in CAC/GL 21-1997 and be prepared and handled in accordance with CAC/RCP 1-1969

The Inventory of Substances used as Processing Aids (IPA) database<sup>2</sup> contains the list of substances that have met the definition of processing aid as established by Codex under the Guidelines on Substances Used as Processing Aids. Having said that, entry into the IPA database does not indicate any approval status granted by Codex<sup>3</sup>.

The IPA database provides information on **18 types** of processing aids — antifoaming agents; boiler water additives; catalysts; clarifying agents/filtration aids; contact freezing and cooling agents; desiccating agents/anticaking agents; detergents (wetting agents); enzyme immobilisation agents and supports; flocculating agents; ion-exchange resins, membranes and molecular sieves; lubricants, release and anti-stick agents, moulding aids;

<sup>&</sup>lt;sup>1</sup> CAC/GL 75-2010 Guidelines on Substances used as Processing Aids. (2010). Retrieved from: https://ipa.cfsa.net.cn/download/CXG\_075e.pdf

<sup>&</sup>lt;sup>2</sup> IPA Database by CCFA. (n.d). Retrieved from: <a href="https://ipa.cfsa.net.cn/login?task=index">https://ipa.cfsa.net.cn/login?task=index</a> pro

<sup>&</sup>lt;sup>3</sup> Inventory of Substances used as Processing Aids, Updated List. (2012). Retrieved from: http://www.fao.org/tempref/codex/Meetings/CCFA/ccfa44/fa44\_inf3e.pdf



micro-organism control agents; microbial nutrients and microbial nutrient adjuncts; propellants and packaging gases; solvents for extraction and processing; washing and peeling agents; other processing aids; food enzymes.

#### CHINA

Processing aid refers to any substance, not related to the food itself, which enhances food processing. Examples of functions performed by processing aids include filtration, clarification, adsorption, demoulding, bleaching, peeling, solvent extraction and nutrients for fermentation<sup>4</sup>.

The principles of use of processing aids are as follows:

- Amount of processing aid shall be limited to the lowest achievable level necessary to accomplish its desired technological function
- Processing aids shall be removed before preparation of the final product. Residues of processing aids remaining in food should be reduced as much as possible and should not perform a technological function or pose any health risk
- Processing aids should comply with the relevant quality specifications

Permitted processing aids are categorised into **3 groups** – processing aids which can be used for all food products without restriction on the residual amount (excluding enzymes), processing aids that can be used according to the stipulated functions and scope of applications (excluding enzymes), and enzymes from permitted sources that can be used in food.

#### HONG KONG

Processing aids are classified as food additives, which refer to substances, not commonly regarded or used as food, which are added to food to serve technological functions<sup>5</sup>. There is no specific provision for the use of processing aids in food.

#### **INDIA**

On 15 October 2020, the Food Safety and Standards Authority of India (FSSAI) released the Food Safety and Standards (Food Product Standards and Food Additives) Ninth Amendment Regulations<sup>6</sup>, 2020 relating to the inclusion of provisions for the use of processing aids in food. The amendments come into force with immediate effect and food business operator shall comply with all the provisions of these regulations by 1 July 2021.

Under the regulation, processing aids categories have been stated in Appendix C, whereby 12 categories of processing aids have been stipulated with the definitions, residual level in different product category. The permitted processing aids include antifoaming agents; catalyst; clarifying agents and filtration agents; lubricants,

<sup>&</sup>lt;sup>4</sup> GB 2760-2014 Standards of Use of Food Additives. (2014). Retrieved from: <a href="https://sppt.cfsa.net.cn:8086/staticPages/E13798C0-F243-4ACB-B541-C4E543349BE5.html">https://sppt.cfsa.net.cn:8086/staticPages/E13798C0-F243-4ACB-B541-C4E543349BE5.html</a>

<sup>&</sup>lt;sup>5</sup> Food and Drugs (Composition and Labelling) Regulations (Cap. 132W). (2016). Retrieved from: https://www.elegislation.gov.hk/hk/cap132W?xpid=ID 1438402695864 001

<sup>&</sup>lt;sup>6</sup> Food Safety and Standards (Food Product Standards and Food Additives) Ninth Amendment Regulations (2020). Available: https://fssai.gov.in/upload/notifications/2020/10/5f8d5a959fdedGazette Notification Processing Aids 15 10 2020.pdf



release and antistick agents; microbial control agents, microbial nutrients and microbial nutrient adjuncts; solvent for extraction and processing; bleaching, washing, peeling and denuding agents; flocculating agents; contact freezing and cooling agents; desiccating agent; enzymes and generally permitted processing aids.

#### **INDONESIA**

In October 2019, Indonesia enforced the regulations for processing aids<sup>7</sup>. The definition and conditions of use of processing aids are similar to the Codex guidelines.

The regulations state **11 categories** of processing aids - bleaching agents, washing and/or peeling agents; purifying agents, filtration aids, adsorbents and/or colour removers; boiler water additives; enzymes; flocculating agents; catalysts; microbial nutrients; micro-organism control agents; enzyme adsorbents; ion-exchange resins; other processing aids. Each category specifies the level of residual that is permitted.

In September 2020, Indonesia revised the regulations for processing aids<sup>8</sup>. **5 new categories** of processing aids have been introduced, including antifoaming agent, contact freezing & cooling agent, desiccating and anticaking agent, lubricants and anti-stick agent and solvents for extraction.

### **JAPAN**

Processing aids are classified as food additives under Japan's regulations<sup>9</sup>. The scope of definition follows Codex but does not include provision for the principles or rules of use as stated in Codex Guidelines. Permitted processing aids may be used within the approved application scope and shall not exceed the maximum use levels.

## MALAYSIA

The Food (Amendment) (No. 3) Regulations 2019, gazetted on 27 June 2019 specifies the use of processing aids which should be in accordance with the Codex Guidelines on Substances used as Processing Aids (CAC/GL 75)<sup>10</sup>. The scope of definition follows Codex Guidelines and there is no list of permitted processing aids.

In August 2020, the Malaysia Ministry of Health (MOH) released Guidelines on the Safe Used of Processing Aids<sup>11</sup> which aim to provide information for the safe used of processing aids in the preparation of foods and food ingredients as stipulated under Regulation 19A, Malaysia Food Regulations 1985.

<sup>&</sup>lt;sup>7</sup> BPOM Regulation No. 28 of 2019. Available: <a href="http://standarpangan.pom.go.id/dokumen/peraturan/2019/PBPOM-No-28-Tahun-2019-tentang-Bahan-Penolong-dalam-Pangan-Olahan.pdf">http://standarpangan.pom.go.id/dokumen/peraturan/2019/PBPOM-No-28-Tahun-2019-tentang-Bahan-Penolong-dalam-Pangan-Olahan.pdf</a>

<sup>&</sup>lt;sup>8</sup> BPOM Regulation No.20 of 2020. Available:

https://jdih.pom.go.id/showpdf.php?u=MdbTXHUpJFScli6aGH%2FUBJPOww9Aw70HpCuSWVgs2%2BE%3D

<sup>&</sup>lt;sup>9</sup> Food Additives. (n.d.). Retrieved from: https://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html

<sup>&</sup>lt;sup>10</sup> Food (Amendment) (No. 3) Regulations 2019. (2019). Retrieved from: http://fsq.moh.gov.my/v6/xs/dl.php?filename=8b24eac22305f21bb6fd7f3fc23cb210.zip

<sup>&</sup>lt;sup>11</sup> Guidelines on the Safe Used of Processing Aids (2020). Retrieved from: http://fsq.moh.gov.my/v6/xs/page.php?id=441000631



Under the guidelines, the following contexts have been provided

- Definition of processing aid
- Principles for the safe use of substances used as processing aids
  - The principles conform with the principles stated in the Codex Guidelines of Substances Used as Processing Aids (CAC/GL75-2010)
- Labelling of processing aids
- List of substances that may be used as processing aids. The list of substances are not exhaustive list and the list does not serve as a positive list for regulatory purposes.

#### **PHILIPPINES**

Processing aids are additives that are used in the processing of food to achieve a specified technological purpose and may or may not result in the presence of residues or derivatives in the final product<sup>12</sup>.

Bureau Circular No. 2006-016 includes the list permitted additives with the function as processing aids, along with the permitted use level in selected food categories<sup>13</sup>.

However, these regulations on processing aids are expected to be revised under the draft amendment of the regulations on food additives and processing aids<sup>14</sup>. In the draft, it is stipulated that the use of processing aids shall be guided by the latest revision of at least any one of the references – Food Chemical Codex; US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21; and the latest issuance of Codex Standard on Inventory of Processing Aids (CXA003e or CAC/MISC 3)<sup>15</sup>.

#### **SINGAPORE**

Processing aids are classified as general purpose food additives, which refer to substances which serve a useful and specific purpose during processing or packing of a food 16. There is no separate definition provided for processing aids.

The general purpose food additives are further categorised into permitted general purpose food additives and permitted enzymes (derived from animal, plant and microbial sources).

Only permitted general purpose food additives may be used in food and there is no restriction for general purpose food additives in general, with the exception for acetone, methanol and triethyl citrate where these substances can only be used as processing aids in specific food categories and shall not exceed the specified maximum use levels.

https://ww2.fda.gov.ph/attachments/article/183669/ao%2088a%20s.%201984.pdf

<sup>&</sup>lt;sup>12</sup> Administrative Order No. 88-A s.1984. (1984). Retrieved from:

<sup>&</sup>lt;sup>13</sup> FDA Circular No. 2006-016 Updated List of Food Ad<mark>ditives</mark>. (2006). Retrieved from: https://ww2.fda.gov.ph/attachments/article/19772/BC%202006-016.pdf

<sup>&</sup>lt;sup>14</sup> Draft Revised Regulatory Guidelines Concerning Food Additives and Processing Aids. (2017). Retrieved from: https://members.wto.org/crnattachments/2017/TBT/PHL/17 3520 00 e.pdf

<sup>&</sup>lt;sup>15</sup> The phrase is a direct transcription from the Administrative Order. However, based on CCFA discussion, IPA is now maintained in a separate web page and is not under Codex and hence, is not considered as a Codex Standards

<sup>&</sup>lt;sup>16</sup> Food Regulations. (2019). Retrieved from: <a href="https://www.sfa.gov.sg/docs/default-source/legislation/sale-of-food-act/food-regulations-(1-sep-2019).pdf">https://www.sfa.gov.sg/docs/default-source/legislation/sale-of-food-act/food-regulations-(1-sep-2019).pdf</a>



### **SOUTH KOREA**

Processing aids are substances intentionally used to fulfil a certain technological purpose during food manufacturing and are removed such that the substance does not remain in the final product. However, processing aids may result in the unavoidable presence of residues or derivatives in the final product<sup>17</sup>.

Processing aids are classified into **6 categories** – filtration aids; release agents; cleaning agents; catalysts; solvents, extraction and processing; and enzyme.

# **TAIWAN**

Processing aid refers to any substance, not including apparatus or utensils that is intentionally used in the processing of food or raw materials to fulfil a certain technological purpose, which may result in the non-intentional but unavoidable presence of residues in the final product. The processing aid should not serve any technological purpose in the final product<sup>18</sup>.

The Sanitation Standard for Processing Aids covers 7 solvents, along with the application restrictions, residual limits and solvent specifications. Separately, the Standards for Specification, Scope, Application and Limitation of Food Additives specifies the other permitted processing aids<sup>19</sup>. Enzymes is also included but there is no provision on the specific enzymes that can be used.

#### **THAILAND**

Processing aid refers to any substance, not including food ingredients, intentionally used in the processing of food or raw materials to fulfil a certain technological purpose, which may result in the non-intentional but unavoidable presence of residues in the final product<sup>20</sup>. The provision for processing aids is limited where the Notification of the Ministry of Public Health (No. 259) B.E. 2545 (2002) is specifically directed to the use of methyl alcohol as a processing aid.

In November 2019, the Thailand Food and Drug Administration (FDA) issued Notification 409 B.E. 2562 on Enzymes for Use in Food Production<sup>21</sup>.

https://www.mfds.go.kr/eng/brd/m 15/view.do?seq=72242&srchFr=&srchTo=&srchWord=&srchTp=&itm seq 1=0&itm seq 2=0&multi \_itm seq=0&company cd=&company nm=&page=1

https://www.fda.gov.tw/TC/lawContent.aspx?cid=62&key=%E5%8A%A0%E5%B7%A5%E5%8A%A9%E5%8A%A991&id=2792

<sup>&</sup>lt;sup>17</sup> Food Additives Code. (2019). Retrieved from:

<sup>&</sup>lt;sup>18</sup> Sanitation Standard for Processing Aids. (2016). Retrieved from:

<sup>&</sup>lt;sup>19</sup> Standards for Specification, Scope, Application and Limitation of Food Additives. (2018). Retrieved from: https://www.fda.gov.tw/EN/lawContent.aspx?cid=16&id=308

<sup>&</sup>lt;sup>20</sup> MOPH Notification No 259 B.E. 2545 Application of Methyl Alcohol as Processing Aid in Some Foods. (2002). Retrieved from: http://food.fda.moph.go.th/law/data/announ\_moph/V.English/No.259-

 $<sup>\</sup>underline{45\%20Application\%20of\%20Methyl\%20Alcohol\%20as\%20Processing\%20Aid\%20in\%20Some\%20Foods.pdf}$ 

<sup>&</sup>lt;sup>21</sup> Notification of MOPH (No. 409) B.E. 2562 on Enzymes for Use in Food Production http://food.fda.moph.go.th/law/data/announ\_fda/62\_409\_Enzyme.pdf



# **VIETNAM**

Processing aid is a substance used in the processing of food materials or ingredients to fulfil a technological purpose in food processing and handling<sup>22</sup>.

Processing aids are classified into **16 categories** – antifoaming agents; catalysts; clarifying agents/filtration aids; contact freezing and cooling aids; desiccating agents/anticaking agents; detergents (wetting agents); enzyme immobilisation agents and supports; enzyme preparations (including immobilised enzymes); flocculating agents; ion-exchange resins, membranes and molecular sieves; lubricants, release and anti-stick agents, moulding aids; micro-organism control agents; propellant an packaging gases; solvents, extraction and processing; washing and peeling agents; other processing aids. The application scope and maximum use levels of processing aids are indicated. The permitted processing aids also include those that are listed in the IPA database.

This report is prepared by the FIA Regulatory team. Should you have any questions, please contact:

Jiang YiFan

Head of Science and Regulatory Affairs

yifan.jiang@foodindustry.asia

33 Mohamed Sultan Road, #03-02 Singapore 238977 T. +65 6235 3854

<sup>&</sup>lt;sup>22</sup> Decision No. 46/2007/QD-BYT on Promulgation of "Regulation on Maximum Levels of Biological and Chemical Pollution in Food". (2007). Retrieved from: <a href="https://vanbanphapluat.co/decision-no-46-2007-qd-byt-on-promulgation-regulation-of-maximum-level-of-biology">https://vanbanphapluat.co/decision-no-46-2007-qd-byt-on-promulgation-regulation-of-maximum-level-of-biology</a>