Guidance for Industry

Frequently Asked Questions about

ASEAN Guiding Principles for the Use of Additives and Excipients in Traditional Medicines and ASEAN Guiding Principles for the Use of Additives and Excipients in Health Supplements; Version 3.0

Introduction

This document is a collation of Questions and Answers (Q&A) which provide clarification and references that may be referred by the industry in order to have a better understanding of the ASEAN guidelines. It is developed by HSA based on discussions between HSA and the industry experts.

The industry may refer to this Q&A for products intended for the Singapore market. For products to be marketed in other ASEAN Member States, industry is advised to refer to regulatory guidelines provided by the regulatory authorities of the respective ASEAN Member State where your product would be exported to.

This document may be revised from time to time, to include new Q&As or to update the information if there are changes made to the ASEAN guidelines.

Questions & Answers

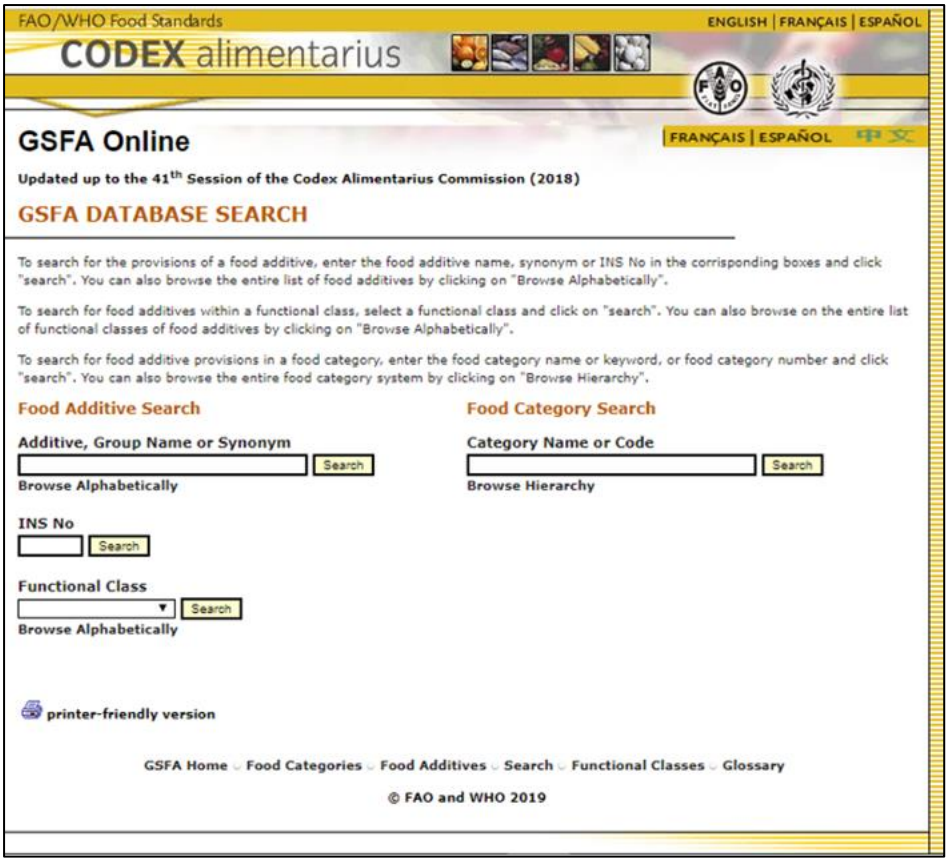
1. What does the term 'Good Manufacturing Practice' (GMP) mean in the guidelines?

The term GMP mentioned in the guidelines (Section 4) makes reference to the principles stipulated by the Codex Alimentarius. When applying this in the context of Traditional Medicines (TM) and Health Supplements (HS), it means:

a. the quantity of the additive added to the product shall be limited to the lowest possible level necessary to accomplish its desired effect;
b. the quantity of the additive that becomes a component of the product as a result of its use in the manufacturing, processing or packaging of a product and which is not intended to accomplish any physical, or other technical effect in the product itself, is reduced to the extent reasonably possible; and,
c. the additive is prepared and handled in the same way as a TM or HS ingredient.

2. How can I ascertain if a specific additive or excipient can be used in TM or HS?

You may perform a check using the Codex Alimentarius General Standard for Food Additives (GSFA) online database provided at http://www.fao.org/gsfaonline/additives/search.html. To search for information on a specific additive, key in the name of the additive under the field of "Additive, Group Name or Synonym" and click the "Search" button. Below is a screenshot of the search page.



From the search results listed under the header of “GFSA Table 3 Provisions”, you can check if the food category of “Food Supplement” is in the search results (The “Food Supplement” category is numbered as 13.6). If the “Food Supplement” category is reflected there, it means that the additive or excipient may be used under the conditions of Good Manufacturing Practice.

3. How can I ensure that the additives or excipients I use are in accordance with the required identity and purity?

You can request for the suppliers of the additives or excipients to provide you with a company statement attesting that the additives or excipients are in compliance with the specification requirements of any one of the following references:

- Joint FAO/WHO Expert Committee on Food Additives (JECFA)
- Food Chemical Codex (FCC)
- Handbook of Pharmaceutical Excipients
- All official international/national pharmacopoeias or national food additive standards

However, you are reminded of your responsibility to take due diligence to establish that the certificates and statements provided by your supplier are truthful and the supplier that you are dealing with is credible.
