



Review Article

Global policy changes on homologous substances of food and medicine

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Abstract: Homologous substances of food and medicine (HSFM) are substances that are both food and traditional Chinese medicine (TCM), implementing the TCM concept of “food and medicine homology”. Due to the improvement of people’s standard of living and the high demand for improving the quality of life, the usage of HSFM is becoming more and more common, and the legislative issue of HSFM is becoming more and more urgent. HSFM now have a clearer definition and related management policies, which are constantly being improved and updated. However, there is little research to sort out and analysis the current status of management in each country. Therefore, this paper aims to collect the relevant policies that are publicly available in several country and, in particular, elucidates explicitly the historical traceability of HSFM in China, the evolution of the relevant policies, and the catalogue of HSFM that has been updated to date. The data show that the management of HSFM is similar but not identical among different countries, and that there are areas that can be learnt from each other as well as areas that need to be improved. By analysing the policies of different countries, this paper finds that South Korea, Singapore and China have adopted a catalogue for the management of HSFM, which has avoided the current situation of market scrutiny through a clearer catalogue management. It also points out that there is no country that makes health claims on HSFM in terms of policy, which also limits the development of the HSFM industry to a certain extent. A comparison of policies in different countries shows that policymakers can optimise policies to meet consumer demand and stimulate product development in the market by accelerating the addition of substances to the catalogue of HSFM and attempting to make health claims, among other measures.

Keywords: homologous substances of food and medicine; policy and regulation; international comparison

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1 Introduction

The world is facing a major health challenge of chronic non-communicable diseases (NCD) globally^[1], such as hypertension, hyperlipidemia, type 2 diabetes and etc., and there is a growing demand for people to improve their quality of life^[2]. In addition to improving the quality of life through the use of medicines to treat diseases and slow down their progression, prevention of diseases and protection of health through daily physical exercise, rationalization of the dietary pattern and application of health preserving substances are also important ways of preventing diseases and promoting health^[3,4].

At present, the use of dietary therapy and medicinal diets to prevent and treat diseases has become a popular trend in self-care in modern society^[5,6]. Traditional Chinese medicine (TCM) has begun to pay attention to the dialectical relationship between dietary regimens and longevity at a very early stage^[7-9]. According to TCM, food can not only replenish nutrients but also play a role

in the treatment of disease due to the different components it contains. Food therapy is the daily consumption of substances under the guidance of TCM to regulate the function of the body^[10]. The medicinal diet is a combination of medicine and food, in which the food is imbued with the effect of the medicine and is prepared using unique cooking techniques^[11]. A randomized controlled trial demonstrated that TCM food therapy was effective in helping individuals with hypertension manage their blood pressure, reduce the need for antihypertensive medication, and improve health-related quality of life^[12]. Food therapy and medicinal diet were guided by the four principles—light eating, balancing “hot” and “cold” foods, harmonizing the five flavors, and aligning diet with individual health conditions^[13]. These principles emphasize personalized and balanced dietary approaches, suggesting that food therapy offer holistic benefits for managing chronic health conditions like hypertension.

Food and medicine homology (FAMH), i.e., medicine and food have the same origin^[14]. Certain foods can treat disease, while certain medicines can also be used to nourish the body. In recent years, under the guidance of FAMH, the concept of homologous substances of food and medicine (HSFM) has gradually been derived and continuously improved all over the world. HSFM are broadly defined as herbs that are both edible and medicinal in TCM. The Regulation on the Management of the Catalogue of HSFM, issued by National Health Commission in 2021, has confirmed that HSFM are traditionally used as food and are listed in *Chinese Pharmacopoeia*^[15]. From the current status of research and application of HSFM, there is still a chaotic situation of cognitive bias towards the standards and specifications. Therefore, this paper provides in-depth analyses of the development of HSFM from the perspective of the policy change so as to provide references for the standardized use and development of HSFM by food enterprises and related industries.

2 Origin of HSFM

In ancient China, there was a legend called *The Holy Farmer Tasting Plants*. However, it was not until the Zhou Dynasty, when the division of medicine was formally formed, that there were ancient records about the application of the concept of FAMH. According to “*Zhou li*”, food medicine (*Shi yi*) and other three types were in charge by a certain kind of court officials. The “six foods, six drinks, six meals, a hundred shyness, a hundred sauces, and the eight treasures of the food are subject to its control” statement are recorded in this book, which reflects that they are responsible for the royal family’s full-time meal and nutrition, and are actually equivalent to the role of nutritionists^[16]. Along with the setting up of this official positions, the basic concept of FAMH have sprouted up. Thus, dating back to the Western Zhou period, the boundary between food and medicine was blurred, and the doctors of this period were also adept at using substances that were both edible and medical effects to nourish the body and achieve the purpose of disease prevention or recovery after illness. “*The Huangdi Emperor’s Internal Classic*”, written during the Warring States period, also points out that “medicine is used to dispel illness and food is used to follow it”. It expressed that food plays a good complementary role to medication while medicines are used to treat the illness^[17]. It also further elaborates that attention should be paid to the adjustment of diet once the stages of illness change. Moreover, in the later stages of recovery, the structure of dietary also need to be varied rather than choosing to ignore the role of the diet^[18].

“*Shennong’s Herbal Classic*” was compiled during the Eastern Han Dynasty. As the first systematic summary of TCM, it uses a three-point classification method to classify substances that are beneficial to the human body into three classes. For example, ginseng, liquorice, coix seed, cassia seed and other edible substances belong to the upper class; *Pueraria lobata*, lily, ginger, red bean and other edible substances belong to the middle class; and the Chinese tangerine stalks, almonds and other edible substances belong to the lower class^[19]. “*Thousand-Golden-Prescriptions*”, written by Sun Simiao in the Tang Dynasty, has a separate chapter on food remedies, featuring 155 types of food^[20]. Its content deeply reflects that food and medicine are homologous. At the same time, “*Taiping Holy Prescriptions for Universal Relief*” is a more systematic and comprehensive therapeutic monograph, the book for the first time, both edible and medicinal substances are separated from TCM, indicating the efficacy of the substances

and contraindications. Some of the substances are also described in its form and origin so that later generations of researchers can further trace accordingly^[21].

Until the Yuan Dynasty, the first Chinese book specializing in food nutrition, “*Principles for Correct Diet*” written by Hu Sihui came out. The book not only introduces the dietary taboos and recommended guidelines for special populations, but also expounds how to nourish the body through therapeutic feeding when the body is in a pathological state, as well as food poisoning. In addition, substances are classified and organized in more detail than previous books, documenting its traits, medicinal properties, efficacy and contraindications^[22]. This book is the first in the history of TCM to emphasize, from a nutritional point of view, that normal people should enhance their dietary hygiene in order to prevent disease.

Therefore, from the point of view of the history of TCM, the concept of homology completes its transformation from germination to maturity. HSFM in its budding stage, there is the theory of FAMH. As ancient scholars continued to sort out and prepare Chinese herbal medicines, HSFM were gradually selected from Chinese medicine monographs and organized into separate book. This shift causes an influence that HSFM have been served the daily dietary and healthcare needs of the population in a clearer and more effective way.

3 Policy on HSFM in China

3.1 Chinese policy development and change

With the introduction of modern medicine into China, there is an increasing amount of modern medical and nutritional research on HSFM, and more and more food products are developed using HSFM as raw materials in the market. Therefore, in order to keep up with the development of HSFM in terms of traceability, application and development, the process of identifying related regulations and policies has been advancing over time (Fig. 1).

“Food Hygiene Law of the People’s Republic of China”, which was introduced on a trial basis in 1982^[23], states that ‘no medicines can be added to food except those that are traditionally used as HSFM and those that are added as seasoning or food fortification’. In 1987, the former Ministry of Health, in formulating the Measures for the Hygienic Administration of Prohibiting the Addition of Drugs to Food, published the first list of HSFM, which included a total of 33 species^[24]. The regulation stipulated that if TCM were used as new food resources, test information should be provided on the special target indicators of their pharmacological effects^[24]. In 1995, in “Food Hygiene Law of the People’s Republic of China”, the regulation was amended that ‘No medicines can be added to food, except those which are HSFM in accordance with the tradition and which are added as raw materials, seasonings or nutrient-fortifying agents’^[25]. In 2002, the list of HSFM was updated from 33 to 87 items in the “Circular of the Ministry of Health on Further Standardizing the Management of Health Food Ingredients”^[26]. “Food Safety Law of the People’s Republic of China”^[27], amended in 2015, redefined the scope of the addition of HSFM to food: “No drugs can be added to food in production and operation, but HSFM in accordance with tradition may be added”. The HSFM catalogue is developed and published by the health administrative department of the State Council in conjunction with the China Food and Drug Administration. In 2019, including Chinese Angelica, six substances were included in the catalogue of HSFM^[28]. And in 2020, nine substances, including

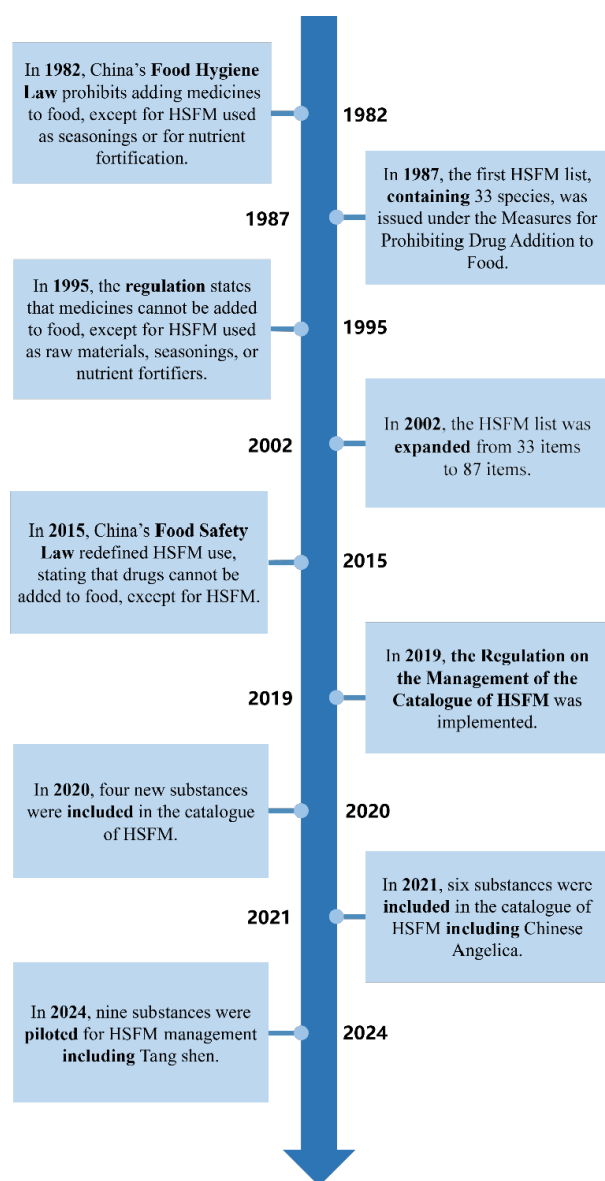


Figure 1 Development of HSFM's policy.

Tang shen, were piloted for HSFM management^[29,30]. Four substances, including Rehmannia, Dwarf Lilyturf Root Tuber, Cochinchinese Asparagus Root Tuber and Tomentose Pummelo Peel, were included in the catalogue in 2024^[31]. To date, 106 substances have been included in the catalogue of HSFM, accompanied by the development of policies of the relevant regulatory authorities.

"The Regulation on the Management of the Catalogue of HSFM"^[15], as the first regulation specifically on the management of HSFM, replaced the "Measures for the Hygienic Management of Prohibition of the Addition of Drugs to Food" to regulate the management of the catalogue of HSFM. The regulation specifies the conditions that substances included in the catalogue of HSFM should be: firstly, the substance has the habit of being consumed as food traditionally, which means that the substance has a history of more than 30 years of production and operation of a certain kind of food as a stereotyped or non-stereotyped packaged food within the area under the jurisdiction of the province; secondly, the substance has been included in the main body of *Chinese Pharmacopoeia*, merely appearing in local standards does not fulfil the condition of being HSFM; and thirdly, no food safety

problems are found after the safety assessment; lastly, the substance should also comply with relevant laws and regulations such as the protection of resources of TCM, the protection of wild animals and plants, and the protection of ecology. The materials for updating the catalogue of HSFM and the information for safety assessment are clearly required in this regulation. Moreover, the regulations require the dynamic management of the catalogue of HSFM. If there is new scientific evidence indicating that HSFM in the catalogue have food safety problems, the catalogue should be revised in time to complete the update. These provisions are based on actual practice and provide a clearer definition of the scope of HSFM to enhance food safety.

3.2 Comparison of HSFM with other types of food ingredients

Local specialty foods (LSF) are foods that have been traditionally consumed in some geographical areas for more than 30 years, including foods with locally specific materials and foods produced using traditional processes that involve food safety indicators or requirements that existing national standards cannot cover for food safety^[32]. New food ingredient (NFI) refer to animals, plants, microorganisms and their isolated components or structurally altered food ingredients that have no traditional consumption habits in China and are subject to safety assessment and approval before they can be used in the production and operation of common foods^[33]. Health food raw materials (HFRM) refer to all kinds of substances, including raw materials from natural sources and synthetic sources, which are processed or extracted for the purpose of manufacturing food with specific health functions or supplementation of vitamins, minerals and other purposes^[34]. The definitions of different food ingredients mean that the management authorities will also adopt a corresponding management approach. Due to the uniqueness of their local natural conditions, customs and habits, LSF use local food safety standards to provide safety and hygiene for the production, processing and sale of LSF in areas not yet covered by national standards^[32]. Sichuan's hot pot base and Yunnan's flower cakes are LSF in China, each reflecting local culinary traditions. To ensure quality and safety, both Sichuan and Yunnan have established provincial food safety standards^[35]. The management of NFI mainly follows the "Administrative Measures for the Review of the Safety of New Food Ingredients", which are approved and announced by the former Ministry of Health. Applicants are required to submit detailed information, and will be granted a license only after passing the review^[33]. HFRM take special food management due to their strict requirements for safety and functionality^[34]. Whereas HSFM are managed through catalogues, giving priority to safety (Table 1).

Table 1 Comparison of management approaches for different food ingredients

Food ingredients	Management approach
HFRM	Special food management
LSF	Local food safety standards management
NFI	Approval management
HSFM	Catalogues management

3.3 Catalogue of HSFM

A total of 106 substances are included in the catalogue of HSFM implemented by the National Health Commission. The 87

substances in the first list of HSFM were released only by name, and the six substances published in the second batch were used only as spices and flavorings. Compared with the first batch, the names, Latin scientific names, the names of the families, and the parts of the body have been supplemented. The nine substances

published in the third batch had their restricted scope of use and safety limit values added. The fourth batch of four substances announced in the document also gave the safety limit values. The catalogue of HSFM based on the above policies was summarized in Table 2.

Table 2 Catalogue of 106 kinds of HSFM according to the Chinese government policy

No.	HSFM name (Chinese/English/Latin)	Source		
		Botanical or animal	Family	Parts to be consumed
1	Ding xiang/Clove/ <i>Caryophylli Flos</i>	<i>Eugenia caryophyllata</i> Thunb.	Myrtaceae	Bud
2	Ba jiao hui xiang/Chinese star anise/ <i>Anisi stellati fructus</i>	<i>Illicium verum</i>	Magnoliaceae	Mature fruit
3	Dao dou/Sword jackbean/ <i>Canavaliae Semen</i>	<i>Canavalia</i>	Fabaceae	Mature seed
4 ^a	Xiao hui xiang/Fennel fruit/ <i>Foeniculi fructus</i>	<i>Foeniculum vulgare</i> Mill.	Umbelliferae	Mature fruit
5	Xiao ji/Common thistle field thistle/ <i>Cirsii herba</i>	<i>Cirsium setosum</i> (Willd.) MB.	Asteraceae	Aboveground part
6	Shan yao/Common yam rhizome/ <i>Dioscoreae Rhizoma</i>	<i>Dioscorea opposita</i> Thunb.	Dioscoreaceae	Rhizome
7	Shan zha/Chinese hawthorn fruit/ <i>Crataegi Fructus</i>	<i>Crataegus pinnatifida</i> Bge.	Rosaceae	Mature fruit
8	Ma chi xian/Purslane herb/ <i>Portulaca oleracea</i> L.	<i>Portulaca pilosa</i>	Portulacaceae	Aboveground part
9 ^b	Wu shao she/Black soake/ <i>Zaocys</i>	<i>Zaocys dhumnades</i> (Cantor)	Colubridae	Whole body
10	Wu mei/Smoked plum/ <i>Mume Fructus</i>	<i>Prunus mume</i>	Rosaceae	Nearly mature fruit
11	Mu gua/Common flowering quince fruit/ <i>Chaenomeles Fructus</i>	<i>Chaenomeles speciosa</i> (Sweet) Nakai	Rosaceae	Nearly mature fruit
12	Huo ma ren/Hemp fruit/ <i>Cannabis Fructus</i>	<i>Cannabis</i>	Cannabaceae	Mature fruit
13 ^c	Dai dai hua/Daidaihua/ <i>Citrus aurantium</i>	<i>Citrus × aurantium</i>	Rutaceae	Bud
14	Yu zhu/Fragrant solomonseal rhizome/ <i>Polygonatum odoratum</i> (Mill.) Druce	<i>P. odoratum</i> (Mill.) Druce	Liliaceae	Rhizome
15	Gan cao/Liquorice root/ <i>Glycyrrhizae Radix et Rhizoma</i>	<i>Glycyrrhiza uralensis</i> Fisch.	Fabaceae	Roots and rhizomes
16	Bai zhi/ <i>Angelica dahurica</i> / <i>Angelicae Dahuricae Radix</i>	<i>A. dahurica</i> (Fisch. ex Hoffm.) Benth. et Hook. f., <i>A. dahurica</i> (Fisch. ex Hoffm.) Benth. et Hook. f. var. <i>Formosana</i> (Boiss.) Shan et Yuan	Umbelliferae	Roots
17	Baiguo/Ginkgo seed/ <i>Ginkgo Semen</i>	<i>Ginkgo biloba</i>	Ginkgoaceae	Mature seed
18	Bai bian dou/White hyacinth bean/ <i>Lablab Semen Album</i>	<i>Dolichos lablab</i> L.	Leguminosae	Mature seed
19	Bai bian dou hua/Flower of white hyacinth bean/ <i>Lablab Semen Album</i>	<i>D. lablab</i> L.	Leguminosae	Flower
20	Long yan rou/Dried longan pulp/ <i>Longan Arillus</i>	<i>Dimocarpus longan</i> Lour.	Sapindaceae	Aril
21 ^d	Jue ming zi/Sickle senna seed/ <i>Cassiae Semen</i>	<i>Cassia obtusifolia</i> L., <i>Cassia tora</i> L.	Leguminosae	Mature seed
22	Bai he/Greenish lily/ <i>Lilii Bulbus</i>	<i>Lilium lancifolium</i> Thunb., <i>Lilium brownii</i> F. E. Brown var. <i>viridulum</i> Baker, <i>Lilium pumilum</i> DC.	Liliaceae	Fleshy scaly leaf
23 ^e	Rou dou kou/Nutmeg/ <i>Myristicae Semen</i>	<i>Myristica fragrans</i> Houtt.	Leguminosae	Ripe kernel, testa
24	Rou gui/Cassia bark/ <i>Cinnamomi Cortex</i>	<i>Cinnamomum cassia</i> Presl	Lauraceae	Cortex
25	Yu gan zi/Emblic leaf flower fruit/ <i>Phyllanthi Fructus</i>	<i>Phyllanthus emblica</i> L.	Euphorbiaceae	Mature fruit
26	Fo shou/Finger citron fruit/ <i>Citri Sarcodactylis Fructus</i>	<i>Citrus medica</i> L. var. <i>sarcodactylis</i> Swingle.	Rutaceae	Mature fruit
27 ^d	Xing ren/Apricot seed/ <i>Armeniaca Semen Amarum</i>	<i>Prunus armeniaca</i> L. var. <i>ansu</i> Masim., <i>Prunus sibirica</i> L., <i>Prunus mandshurica</i> (Maxim.) Koehne, <i>P. armeniaca</i> L.	Rosaceae	Mature seed
28	Sha ji/Seabuckthorn fruit/ <i>Hippophae rhamnoides</i> L. subsp. <i>Sinensis</i> Rousi	<i>Hippophae rhamnoides</i> L. var. <i>sinensis</i>	Elaeagnaceae	Mature fruit
29	Mu li/Common oyster shell/ <i>Ostreae Concha</i>	<i>Ostrea gigas</i> Thunberg, <i>Ostrea talienwhanensis</i> Crosse, <i>Ostrea rivularis</i> Gould	Ostreidae	Shell
30	Qian shi/Gordon euryale seed/ <i>Euryales Semen</i>	<i>Euryale ferox</i> Salisb.	Nymphaeaceae	Kernel
31	Hua jiao/Bunge pricklyath pericarp/ <i>Zanthoxyli Pericarpium</i>	<i>Zanthoxylum bungeanum</i> Maxim.	Rutaceae	Mature pericarp
32	Chi xiao dou/rice bean/ <i>Vignae Semen</i>	<i>Phaseolus calcaratus</i> Roxb.	Fabaceae	Mature seed
33	E jiao/Ass-hide gelatin/ <i>Asini Corii Colla</i>	<i>Equus asinus</i> L.	Equidae	Boiled glue after unhairing
34	Ji nei jin/Chicken's gizzard-membrane/ <i>Galli Gigeria Endothelium Corneum</i>	<i>Gallus gallus domesticus</i> Brisson	Phasianidae	Sandbag intimae of chicken
35 ^f	Mai ya/Barley sprout/ <i>Hordei Fructus Germinatus</i>	<i>Hordeum vulgare</i> L.	Poaceae	Ripe fruit
36	Kun bu/Kelp/ <i>Laminariae Thallus</i>	<i>Laminaria japonica</i> Aresch., <i>Ecklonia kurome</i> Okam.	Laminariaceae, Alariaceae	Follicle
37	Zao/Chinese date/ <i>Ziziphus zizyphus</i>	<i>Ziziphus jujuba</i> Mill.	Rhamnaceae	Mature fruit

(Continued)

No.	HSFM name (Chinese/English/Latin)	Source		
		Botanical or animal	Family	Parts to be consumed
38	Luo han guo/Grosvenor momordica/ <i>Siraitiae Fructus</i>	<i>Siraitia grosvenorii</i> (Swingle) C. Jeffrey ex Lu et Z. Y. Zhang	Cucurbitaceae	Mature fruit
39	Yu li ren/Dwarf flowering cherry seed/ <i>Pruni Semen</i>	<i>Prunus humilis</i> Bge., <i>Prunus japonica</i> Thunb., <i>Prunus pedunculata</i> Maxim.	Rosaceae	Mature seed
40	Jin yin hua/Wild honeysuckle flower/ <i>Lonicerae Japonicae Flos</i>	<i>Lonicera japonica</i> Thunb.	Caprifoliaceae	Bud or flowers with first bloom
41	Qing guo/White canarytree fruit/ <i>Canarii Fructus</i>	<i>Canarium album</i> Raeusch.	Burseraceae	Mature fruit
42	Yu xing cao/Heartleaf houttuynia herb/ <i>Houttuyniae herba</i>	<i>Houttuynia cordata</i> Thunb.	Saururaceae	Fresh whole grass or dried above-ground parts
43	Jiang/Ginger, dried ginger/ <i>Zingiberis Rhizoma</i>	<i>Zingiber officinale</i> Rosc.	Zingiberaceae	Rhizome
44 ^g	Zhi ju zi/Raisin tree seed/ <i>Hovenia acerba</i> Lindl.	<i>Hovenia dulcis</i> Thunb.	Rhamnaceae	Fruit or seeds
45	Gou qi zi/Babury wolfberry fruit/ <i>Lycii Fructus</i>	<i>Lycium barbarum</i> L.	Solanaceae	Mature fruit
46	Zhi zi/Common gardenia fruit/ <i>Gardeniae Fructus</i>	<i>Gardenia jasminoides</i> Ellis	Rubiaceae	Mature fruit
47	Sha ren/Villous amomum fruit/ <i>Amomi Fructus</i>	<i>Amomum villosum</i> Lour., <i>A. villosum</i> Lour. var. <i>xanthioides</i> T. L. Wu et Senjen, <i>Amomum longiligulare</i> T. L. Wu	Zingiberaceae	Mature fruit
48	Pang da hai/Boat-fruited sterculia seed/ <i>Sterculiae Lychnophorae Semen</i>	<i>Sterculia lychnophora</i> Hance	Sterculiaceae	Mature seed
49	Fu ling/Indian buead/ <i>Poria</i>	<i>Poria cocos</i> (Schw.) Wolf	Polyporaceae	Dried Sclerotium
50	Xiang yuan/Medical citron fruit/ <i>Citri Fructus</i>	<i>C. medica</i> L., <i>Citrus wilsonii</i> Tanaka	Rutaceae	Mature fruit
51	Xiang ru/Chinese mosla herb/ <i>Moslae Herba</i>	<i>Mosla chinensis</i> Maxim., <i>M. chinensis</i> 'Jiangxiangru'	Labiatae	Aboveground part
52	Tao ren/Peach seed/ <i>Persicae Semen</i>	<i>Prunus persica</i> (L.) Batsch, <i>Prunus davidiana</i> (Carr.) Franch.	Rosaceae	Mature seed
53	Sang ye/Mulberry leave/ <i>Mori Folium</i>	<i>Morus alba</i> L.	Moraceae	Leaf
54	Sang shen/Mullberry fruit/ <i>Mori Fructus</i>	<i>M. alba</i> L.	Moraceae	Drying grain
55	Ju hong/Orange/ <i>Exocarpium citri</i> Rubrum	<i>E. citri</i> Rubrum	Rutaceae	Outer pericarp
56	Jie geng/ <i>Platycodon grandiflorum</i> / <i>Platycodonis Radix</i>	<i>P. grandiflorum</i> (Jacq.) A. DC.	Campanulaceae	Roots
57	Yi zhi ren/Sharpleaf galangal fruit/ <i>Alpiniae Oxyphyllae Fructus</i>	<i>Alpinia oxyphylla</i> Miq.	Zingiberaceae	Mature fruit
58	He ye/Hindu lotus leaf/ <i>Nelumbinis Folium</i>	<i>Nelumbo nucifera</i> Gaertn.	Nymphaeaceae	Leaf
59	Lai fu zi/Garden radish seed/ <i>Raphani Semen</i>	<i>Raphanus sativus</i> L.	Brassicaceae	Mature seed
60	Lian zi/Lotus seed/ <i>Nelumbinis Semen</i>	<i>N. nucifera</i> Gaertn.	Nymphaeaceae	Mature seed
61	Gao liang jiang/Galangal/ <i>Alpiniae officinarum</i> Rhizoma	<i>A. officinarum</i> Hance	Zingiberaceae	Rhizome
62	Dan zhu ye/Common lophatherum herb/ <i>Lophatheri Herba</i>	<i>Lophatherum gracile</i> Brongn.	Poaceae	Stem leaf
63	Dan dou chi/Fermented soybean/ <i>Sojae Semen Praeparatum</i>	<i>Glycine max</i> (L.) Merr.	Fabaceae	Fermented processed products from mature seeds
64	Ju hua/Chrysanthemum flower/ <i>Chrysanthemi Flos</i>	<i>Chrysanthemum morifolium</i> Ramat.	Asteraceae	Capitulum
65	Ju ju/Chicory/ <i>Cichorium intybus</i> L.	<i>C. intybus</i> L.	Asteraceae	Aboveground part or roots
66	Huang jie zi/Mustard seed/ <i>Sinapis Semen</i>	<i>Brassica juncea</i> (L.) Czern. et Coss.	Brassicaceae	Mature seed
67	Huang jing/Siberian solomonseal rhizom/ <i>Polygonati Rhizoma</i>	<i>Polygonatum kingianum</i> Coll. et Hemsl, <i>Polygonatum sibiricum</i> Red., <i>Polygonatum cyrtoneura</i> Hua	Liliaceae	Rhizome
68	Zi su/Common perilla/ <i>Perilla frutescens</i> (L.) Britt.	<i>P. frutescens</i> (L.) Britt.	Lamiaceae	Leaf
69	Zi su zi/Cultivated purple perilla fruit/ <i>Perillae Fructus</i>	<i>P. frutescens</i> (L.) Britt.	Lamiaceae	Mature fruit
70	Ge gen/Lobed kudzu vine root/ <i>Puerariae Lobatae Radix</i>	<i>P. lobata</i> (Willd.) Ohwi	Leguminosae	Roots
71	Hei zhi ma/Black sesame/ <i>Sesami semen nigrum</i>	<i>Sesamum indicum</i>	Pedaliaceae	Mature seed
72	Hei hu jiao/ <i>Piper nigrum</i> / <i>Piperis Fructus</i>	<i>P. nigrum</i> L.	Piperaceae	Mature fruit
73	Huai mi/Sophora flower-bud/ <i>Flos Sophorae Immaturus</i>	<i>Sophora japonica</i> L.	Fabaceae	Bud
74	Huai hua/Sophora flower/ <i>Sophorae Flos</i>	<i>S. japonica</i> L.	Fabaceae	Flower, bud
75	Pu gong ying/Mongolian dandelion herb/ <i>Taraxaci Herba</i>	<i>Taraxacum mongolicum</i> Hand.-Mazz., <i>Taraxacum borealisinense</i> Kitam.	Asteraceae	Flower, leaf, steam, root
76	Feng mi/Honey/-	<i>Apis mellifera</i> L.	Apidae	Honey sugar
77	Feizi/Grand torreyia/ <i>Torreya Semen</i>	<i>Torreya grandis</i> Fort.	Taxaceae	Mature seed
78	Suan zao ren/Spine date seed/ <i>Ziziphi Spinosae Semen</i>	<i>Z. jujuba</i> Mill. var. <i>spinosa</i> (Bunge) Hu ex H. F. Chou	Rhamnaceae	Mature seed

(Continued)

No.	HSFM name (Chinese/English/Latin)	Source		
		Botanical or animal	Family	Parts to be consumed
79	Xian bai mao gen/Lalang grass rhizome/ <i>Imperatae Rhizoma</i>	<i>Imperata cylindrica</i> Beauv. var. <i>major</i> (Nees) C.E.Hubb.	Poaceae	Rhizome
80	Xian lu gen/Reed rhizome/ <i>Phragmitis Rhizoma</i>	<i>Phragmites communis</i> Trin.	Poaceae	Rhizome
81 ^b	Fu she/Viper/ <i>Agkistrodon</i>	<i>Agkistrodon halys</i>	Viperidae	Whole body
82	Ju pi/Dried orange peel/ <i>Citri Reticulatae Pericarpium</i>	<i>Citrus reticulata</i> Blanco	Rutaceae	Mature pericarp
83	Bo he/Wild mint herb/ <i>Menthae Haplocalycis Herba</i>	<i>Mentha haplocalyx</i> Briq.	Lamiaceae	Aboveground part
84	Yi yi ren/Ma-yuen jobsteers seed/ <i>Coicis Semen</i>	<i>Coix lacryma-jobi</i> L. var. <i>ma-yuen</i> (Roman.) Stapf	Poaceae	Kernel
85	Xie bai/Longstamen onion bulb/ <i>Allii Macrostemonis Bulbus</i>	<i>Allium macrostemon</i> Bge., <i>Allium chinense</i> G. Don	Liliaceae	Bulb
86	Fu pen zi/Palmleaf raspberry fruit/ <i>Rubi Fructus</i>	<i>Rubus chingii</i> Hu	Rosaceae	Fruit
87	Huo xiang/Cablin potchouli herb/ <i>Pogostemonis Herba</i>	<i>Pogostemon cablin</i> (Blanco) Benth.	Labiatae	Aboveground part
88 ^h	Dang gui/Chinese angelica/ <i>Angelicae Sinensis Radix</i>	<i>Angelica sinensis</i> (Oliv.) Diels	Umbelliferae	Roots
89 ^h	Shan nai/Galanga resurrectionlily rhizome/ <i>Kaempferiae Rhizoma</i>	<i>Kaempferia galanga</i> L.	Zingiberaceae	Rhizome
90 ^h	Xi hong hua/ <i>Crocus Sativus</i>	<i>C. sativus</i> L.	Iridaceae	Stigma
91 ^h	Cao guo/Tsaoko amomum fruit/ <i>Tsaoko Fructus</i>	<i>Amomum tsao-ko</i> Crevost et Lemaire	Zingiberaceae	Mature seed
92 ^h	Jiang huang/Turmeric/ <i>Curcuma Longae Rhizoma</i>	<i>Curcuma longa</i> L.	Zingiberaceae	Rhizome
93 ^h	Bi ba/Long pepper/ <i>Piperis Longi Fructus</i>	<i>Piper longum</i> L.	Piperaceae	Drying grain
94 ^h	Dang shen/Tang shen/ <i>Codonopsis Radix</i>	<i>Codonopsis pilosula</i> (Franch.) Nannf., <i>C. pilosula</i> Nannf. var. <i>modesta</i> (Nannf.) L. T. Shen, <i>Codonopsis tangshen</i> Oliv.	Campanulaceae	Roots
95 ⁱ	Rou cong rong/Desertliving cistanche herb/ <i>Cistanches Herba</i>	<i>Cistanche deserticola</i> Y. C. Ma	Orobanchaceae	Succulent stem
96 ⁱ	Tie pi Shi hu/Noble dendrobium stem herb/ <i>Dendrobii Caulis</i>	<i>Dendrobium officinale</i> Kimura et Migo	Orchidaceae	Stem
97 ^k	Xi yang shen/American ginseng/ <i>Panacis Quinquefolii Radix</i>	<i>Panax quinquefolium</i> L.	Araliaceae	Roots
98 ^j	Huang qi/Milkvetch root/ <i>Astragali Radix</i>	<i>Astragalus membranaceus</i> (Fisch.) Bge. var. <i>mongholicus</i> (Bge.) Hsiao, <i>A. membranaceus</i> (Fisch.) Bge.	Leguminosae	Roots
99 ^l	Ling zhi/Lucid ganoderma/ <i>Ganoderma</i>	<i>Ganoderma lucidum</i> (Leyss.ex Fr.) Karst., <i>Ganoderma sinense</i> Zhao, Xu et Zhang	Polyporaceae	Sporocarp
100 ^m	Shan zhu yu/Asiatic cornelian cherry fruit/ <i>Corni Fructus</i>	<i>Cornus officinalis</i> Sieb. et Zucc.	Cornaceae	Mature fruit
101 ⁿ	Tian ma/Tall gaxtraodia tuber/ <i>Gastrodiae Rhizoma</i>	<i>Gastrodia elata</i> Bl.	Orchidaceae	Tuber
102 ^o	Du zhong ye/Eucommia Leaf/ <i>Eucommiae Folium</i>	<i>Eucommia ulmoides</i> Oliv.	Eucommiaceae	Leaf
103 ^p	Di huang/Rehmannia/ <i>Rehmannia glutinosa</i> Libosch	<i>R. glutinosa</i> Libosch.	Scrophulariaceae	Root tuber
104 ^j	Mai dong/Dwarf lilyturf root tuber/ <i>Ophiopogonis Radix</i>	<i>Ophiopogon japonicus</i> (Thunb.) Ker-Gawl.	Liliaceae	Root tuber
105 ^q	Tian dong/Cochinchinese asparagus root tuber/ <i>Asparagi Radix</i>	<i>Asparagus cochinchinensis</i> (Lour.) Merr.	Liliaceae	Root tuber
106 ⁿ	Hua ju hong/Tomentose pummelo peel/ <i>Citri Grandis Exocarpium</i>	<i>Citrus grandis</i> 'Tomentosa', <i>C. grandis</i> (L.) Osbeck	Rutaceae	Outer pericarp

Note: a, leaves and stalks are also used for flavouring; b, removing internal organs; c, fruit for *H. dulcis*; d, requires preparation before use; e, use only as a condiment; f, processed by germination and drying of concocted products; g, used medicinally as mature seeds; eaten as fleshy expanded infructescence rachises, leaves and stem branches; h, as a spice and flavouring only; i, the content of Pb ≤ 1.0 mg/kg; Cd ≤ 0.5 mg/kg; As ≤ 0.5 mg/kg; Hg ≤ 0.1 mg/kg; SO₂ ≤ 400 mg/kg; j, the content of Pb ≤ 1.0 mg/kg; Cd ≤ 0.5 mg/kg; As ≤ 0.5 mg/kg; Hg ≤ 0.1 mg/kg; k, Pb ≤ 1.0 mg/kg; Cd ≤ 0.5 mg/kg; As ≤ 0.5 mg/kg; Hg ≤ 0.05 mg/kg; l, the content of Pb ≤ 1.0 mg/kg; Cd ≤ 1.0 mg/kg; As ≤ 1.0 mg/kg; Hg ≤ 0.3 mg/kg; m, the content of Pb ≤ 1.0 mg/kg; Cd ≤ 0.5 mg/kg; As ≤ 1.0 mg/kg; Hg ≤ 0.1 mg/kg; n, the content of Pb ≤ 1.0 mg/kg; Cd ≤ 0.1 mg/kg; As ≤ 0.5 mg/kg; Hg ≤ 0.1 mg/kg; o, the content of Pb ≤ 1.0 mg/kg; Cd ≤ 1.0 mg/kg; As ≤ 0.5 mg/kg; Hg ≤ 0.05 mg/kg; SO₂ ≤ 400 mg/kg; p, the content of Pb ≤ 2.0 mg/kg; Cd ≤ 0.5 mg/kg; As ≤ 1.0 mg/kg; Hg ≤ 0.1 mg/kg; q, the content of Pb ≤ 1.0 mg/kg; Cd ≤ 0.5 mg/kg; As ≤ 1.0 mg/kg; Hg ≤ 0.2 mg/kg.

4 Other countries' policy on the similar concept of HSFM

4.1 Japan

Japan shares the same cultural cognition with China in terms of herbs, so the theory of HSFM also exists in Japan. In recent years, products centred on this philosophy have gained momentum in Japan, with HSFM such as jujube commonly found in the daily diet of Japanese people. Tea drinks such as Coix Seed are also extremely popular in the Japanese market due to the high level of aging in Japan. In addition, Japanese social organizations have set

up a public welfare foundation for research on medicinal food and medicinal herbs to fund research on agricultural and marine products that have been regarded as herbal medicines since ancient times. There are three types of functional foods in Japan^[36-38]: Food for Specified Health Uses (FOSHU), Foods with Nutrient Function Claims (FNFC), and Foods with Function Claims (FFC). FOSHU^[39] refers to foods which are officially permitted to make claims about the physiological effects of certain ingredients on the human body in terms of reducing disease risk. The rigorous review and approval process are required by the Consumer Affairs Agency (CAA) before it can carry a health claim on its label. Unlike FOSHU, FNFC refers to foods that can

display the health functions of specific nutrients, such as vitamins, for the human body. FNFC does not require strict approval from the Japanese government; it only needs to meet certain nutritional standards. These foods are mainly intended to help consumers supplement specific nutrients to promote everyday health. FFC^[40] offers a more flexible and accessible pathway for companies to promote the health benefits of their products without undergoing FOSHU's lengthy and costly approval process. It allows for a wider variety of products to enter the market with functional claims. FFC are required to submit an application 60 days prior to sale, and can be sold as long as they have systematic literature or clinical trial data, but they are still punished if they are subsequently falsely exaggerated or misleading^[38]. In the Japanese classification system, Most HFSM are included in the category of functional foods. However, the Japanese authorities have not established a list of HFSM or a policy for their management.

4.2 South Korea

The development of medicine in Korea has been heavily influenced by TCM^[41]. Korean scholars studied Shennong Ben Cao Jing in-depth, enriching the theory and practice related to Korean herbalism. Donguibokam (Precious Mirror of Oriental Medicine) by Heo Joon of Korea systematized the results of Korean medicine that relied on the Chinese medicine of the Ming Dynasty^[42]. Korea defines HFSM as both Korean medicinal herbs included in the Korean Pharmacopoeia and substances in the list of ingredients that can be used for food in Korea^[43]. There are a total of 601 herbs listed in the Korean Pharmacopoeia, of which 187 can be used in food according to the regulations of the Korea Food and Drug Administration (KFDA)^[44]. The meeting of the Food and Drug General Korean Herbal Medicine Management Program has identified 117 varieties of Chinese herbal medicines as the centralized management varieties. According to the Korean food standard norms, HFSM can be used as functional food ingredients for health functional foods, and a total of 59 food and drug substances have already been used in functional food ingredients. The management of HFSM in Korea is also in the form of catalogue management, with similar principles of inclusion as in China, but with different numbers included in the catalogue. The main reason for this is the difference between the pharmacopoeias of the two countries and the different approval processes.

4.3 Singapore

Singapore is relatively lenient on the similar concept of HFSM. Health Science Authority (HSA) and Singapore Food Agency (SFA) have jointly established the List of Chinese Medicinal materials commonly used in food in order to better guide the food industry in the application of HFSM^[45]. A total of 149 substances are included in the list, and the HSA and SFA have stated in the guidelines that the substances in the list are not intended for the prevention, treatment or mitigation of disease. There are three noteworthy points in Singapore's regulations on medicinal substances. Firstly, the dose of a medicinal substance added to food must be less than 100 times the therapeutic dose. This regulation ensures that food products containing medicinal ingredients are safe for consumption and avoids the risk of harmful effects from an ingredient that might otherwise be considered safe only at a therapeutic dosage under medical supervision. This limitation also could reduce the availability of some health products in the market, particularly those that claim

to offer medicinal benefits. Secondly, when only one medicinal substance is processed into a product on its own, it is classified as a proprietary Chinese medicine rather than a food product. At the same time, if a medicinal substance is made into a capsule through purification and other processes, such a form of preparation is classified as a drug in Singapore, while it can be recognized as food if it is made into a beverage. When HFSM are introduced into the Singapore market in the form of health supplements or traditional medicines, they do not need to be approved by the HSA^[45]. If a food business tests and reports on the safety and stability of their product for quality control and safety assurance purposes, their product will be entered into the HSA system and available on the website, which provides proof of the company's presence in the market.

4.4 USA

The United States is the world's largest market for dietary supplements, and herbal medicines have a sizeable presence in it. Botanicals are included in its pharmacopoeia in the early 20th century, allowing for "safe, effective, controlled mixtures". There are similarities between the US 'food is medicine' theory and FAMH^[46]. In order to achieve the goal of "eliminating hunger and reducing the prevalence of chronic disease in the United States by 2030", the US Department of Health and Human Services (HHS) has developed a 'food is medicine' program. In addition, The Rockefeller Foundation has committed \$100 million to further advance the Food as Medicine program, including support for important research such as the American Heart Association's Food for Health program^[47]. It is worth noting that although this concept also points to improving health and reducing the risk of disease through the nutrition of food, it has no direct relationship to HFSM.

5 Discussion

As seen above, the regulatory framework for HFSM in China has evolved significantly, reflecting both the expansion of the catalogue of approved substance and the refinement of regulatory guidelines. Initially, HFSM were restricted to use solely as ingredients or seasonings within food products. Now, diverse applications of these substances are permitted in various food forms, thereby broadening their use. This regulatory evolution includes the establishment of an official catalogue of approved HFSM and a structured process for the inclusion of new items. Due to their pharmacological properties, newly proposed substances must undergo a comprehensive evaluation process, which requires the submission of ingredient composition analyses, hygienic testing reports, toxicological evaluations, and pharmacological assessment data. These rigorous requirements are designed to ensure both safety and efficacy. Furthermore, the National Health Commission entrusts technical departments with the task of carefully reviewing all submitted data, reinforcing oversight mechanisms. This systematic approach not only supports the safe and effective use of HFSM in the marketplace but also highlights China's commitment to advancing both consumer safety and regulatory standards in this growing field.

From the international perspective, the policies of each country on the management of HFSM are both similar and not identical (Table 3). China, South Korea and Singapore have clearly defined and compiled regulated lists of HFSM, but the number of substances included varies. Most HFSM products in Japan are registered as functionally labelled foods as long as there is

Table 3 Comparison of HSFM's policies among different countries

Comparison	China	Japan	South Korea	Singapore	USA
Whether there is a clear concept of HSFM?	Yes	No	Yes	No	No
Whether a catalogue for the management of HSFM has been published?	Yes	No	Yes	Yes	No

systematic data that shows that the substances in the products have specific functions. When HSFM enter the market in the form of functional foods in countries such as Japan and Singapore, the approval procedures and processes are simpler and clearer, which shortens the time it takes for the products to enter the market and means that the industry can have different types of functional foods flowing in the market within a shorter cycle, providing consumers with more opportunities to choose. Especially, Singapore as a country that also has a list of HSFM, its regulatory approach is noteworthy for its balance between market accessibility and consumer safety. Companies voluntarily provide assessments of HSFM products, and if they do, there is a searchable whitelist for consumers to review. This approach streamlines market entry for businesses while empowering consumers to make informed decisions about product safety.

However, in China, health claims are not permitted for HSFM, which can only appear in the market as ordinary foods. According to the Food Safety Law of the People's Republic of China, only health foods can claim health functions, and most of the HSFM products belong to ordinary foods and are not allowed to claim any efficacy. Dating back to the history of the development of HSFM, this specific food makes use of the efficacy to achieve the purpose of human health care, health regulation and disease prevention. Existing general food regulations are not adequately tailored to the development of HSFM within the food industry. This regulatory gap may result in insufficient practical guidance for product development, potentially hindering innovation and delaying progress in the industry. Furthermore, the absence of defined nutritional claims for HSFM could diminish consumer awareness, limiting market demand. Consumers may struggle to find products that address their specific health needs, leading to suboptimal market performance and unmet public health objectives. For example, products like Poria cakes have been commercialized as ordinary foods but lack authorized health claims. This absence weakens their market performance, as they fail to fully convey their health benefits to consumers.

Thus, in China, obtaining a health claim for HSFM is only possible through registration as dietary supplements or functional health foods^[48]. These two food types are both regarded as health foods. Dietary supplement, regulated at the provincial level, undergo a streamlined notification process. Conversely, functional health foods, which assert particular health advantages, must navigate a rigorous registration regime administered. This involves comprehensive animal and human functional trials to substantiate their efficacy and safety, which greatly ensures the safety and stability of healthy food products.

Consequently, on the one hand, health-claim foods produced in Japan and Singapore may enter the international market sooner and establish brand credibility more quickly due to their faster certification. These products could gain consumer trust in China, making them more appealing and enhancing the competitiveness of imported products in the market. Given the more complex and lengthy certification process in China, domestic companies may face greater competitive pressure, especially when it comes to quickly responding to market demand. This could impact their market share as international brands move faster, thereby

negatively affecting product development and industrial innovation.

On the other hand, there is a greater risk of products with unsubstantiated or exaggerated health claims entering the market. Firstly, this could lead to misleading information for consumers, who might place unwarranted trust in the health benefits of certain products. Secondly, simplifying the authorisation process could reduce the thoroughness of quality and safety checks, increasing the risk of potentially harmful products reaching consumers, especially those who rely heavily on health claims when making purchasing decisions. As an example, Japan's Kobayashi Pharmaceutical Company, whose red yeast rice supplements are FFC products, has recently experienced food safety issues that have been detrimental to the health of consumers who trusted and purchased the product^[49]. This illustrates how an overly simplified process, while facilitating the launch of the company's products, also carries food safety risks due to a lack of strict regulation. Thirdly, a overly lenient influx of health claim products could overwhelm relevant regulatory bodies and make it difficult for them to monitor and enforce standards, especially if these bodies are not adequately resourced to handle the volume.

Whether it is a stricter or simpler approval process, there are both favourable and potentially risky implications for the industry as well as consumers. To solve these problems, the process of identifying HSFM and functional foods made from HSFM should be accelerated. At present, there is still a variety of substances that meet the requirements of both food and TCM not included in the list of HSFM, and the expansion of the catalogue of HSFM is of great significance to the development of new products. Besides, there is a lack of specific certification labelling and efficacy claims for HSFM and foods made from HSFM, which should take into account the dual attributes of food and TCM. Consumers are allowed to recognize the nutritional and efficacy value by adding health claims for HSFM, and differentiate between the functional claims of products added with a single HSFM and food products compounded with a variety of HSFM. Thirdly, on the basis of ensuring food safety, the National Health Commission are supposed to continue to standardize the procedures for the identification of HSFM and optimize the identification process in order to shorten the period to the greatest extent possible, so as to mobilize the enthusiasm of enterprises in researching and developing new products.

6 Conclusions and future prospects perspectives

Comparative analysis of regulatory approaches to HSFM across China, Japan, South Korea, and Singapore reveals that current frameworks are incomplete. There is a pressing need to streamline and expand inclusion procedures to establish a more robust and inclusive regulatory foundation. Accelerated expansion and formalization of the catalogue of HSFM are essential to develop a more thorough regulatory landscape. A viable regulatory improvement would be to introduce a new policy category, distinct from health foods, specifically designed to address products derived from HSFM. This policy framework would allow for scientifically supported health claims while balancing food

safety with industry innovation and development. Moreover, the development and refinement of such policies should incorporate the historical and scientific insights offered by TCM. Utilizing TCM's extensive historical documentation, combined with modern biomedical research, could provide a robust scientific foundation for these regulatory frameworks. This integration would not only support consumer confidence and enhance food safety but also establish a credible and culturally-informed approach to the regulation of HSFM both national and international stages.

Conflicts of interest

The authors declare that there are no conflicts of interest in this work.

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