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**Date:** 1/30/2013

**GAIN Report Number:** IN3004

## India

**Post:** New Delhi

### **FSSAI issues new guidelines on Indian import clearance procedures**

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

Exporter Guide

Product Brief

**Approved By:**

David Leishman

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**Report Highlights:**

On January 24, 2013, the Food Safety and Standards Authority of India (FSSAI) published new “guidelines related to food import clearance process by FSSAI’s Authorized Officers.” The document provides operational details on (i) labeling requirements for wholesale packaging; (ii) testing of proprietary food; (iii) import procedures for dietary supplements; (iv) laboratory reports; and (v) wholesale package labeling for flavors.

## **General Information:**

**DISCLAIMER:** The information contained in this report was retrieved from the following Government of India website <http://www.fssai.gov.in/>. The U.S. Government makes no claim of accuracy or authenticity.

On January 24, 2013, the Food Safety and Standards Authority of India (FSSAI) published new “guidelines related to food import clearance process by FSSAI’s Authorized Officers.” The document provides operational details on (i) labeling requirements for wholesale packaging; (ii) testing of proprietary food; (iii) import procedures for dietary supplements; (iv) laboratory reports; and (v) wholesale package labeling for flavors.

Following the previously published guidelines, the new FSSAI document specifies:

- a) (i) If the labels attached by the manufacturer are from the country of origin on the container of wholesale packages, which fulfill the labeling requirements of the FSSAI regulations, then the same may be allowed. However, tampering of label and pasting of one label over the other will not be permitted. (ii) A wholesale package can have either best before date/expiry date/use by date. In the case of wholesale packages, if both best before date and expiry date are given, then the two should be different and clearly specified.
- b) Every ‘proprietary food’ for which FSSAI has no standards should be tested on the safety parameters, micro-biological parameters and for heavy metals, wherever applicable depending upon the nature of the product. The Certificate of Analysis (COA) submitted by the importer may also be sent with the sample. The COA may or may not have information on the list of ingredients but it will carry information on quality control parameters like microbiological parameters, specific gravity, pH, etc. that can be referenced while undertaking the requisite tests.
- c) With regard to the use of certain food additives in food supplements, currently there are no Food Safety and Standards (FSS) for food/dietary supplements. It has therefore been decided that the Food Authority in accordance with Codex GSFA for food supplements may clear the consignments. The list of food additives that allowed in food/dietary supplements are given under Category 13.6 of the Codex General Standard for Food Additive (GSFA). Table 3 of GSFA also provides the list of additives that can be used in general at the level of GMP even in food supplements.
- d) All the laboratories will have to follow the standard format of report as given in FSS (Laboratory and Sample Analysis) Regulations, 2011.
- e) In the case of mixtures of flavorings, the name of each flavoring present in the mixture need not be

given. The generic express “flavor” or “flavoring” may be used together with a true indication of the nature of the flavor. The expression “flavor” or “flavoring” may be qualified by the words “natural”, “nature-identical”, “artificial”, or a combination of these words, as appropriate. This provision does not apply to flavor modifiers, but does apply to “herbs” and “spices” which generic expressions may be used where appropriate.

For details on the previously published (March 23, 2012) guidelines, please refer to USDA GAIN Report [IN2055](#).

**Details on guidelines:**

- **Published on:** January 24, 2013
- **Effective from:** with immediate effect
- **Effective until:** until further orders of final notification of regulations in this regard whichever is earlier

The full text of the guidelines as mentioned on the FSSAI website is given below. It can also be accessed at [FSSAI](#) website.

**No. 1-96/FSSAI/T/2012**  
**Food Safety and Standards Authority of India**  
**Ministry of Health and Family Welfare**  
**Government of India**

**FDA Bhawan, Kotla Road**  
**New Delhi – 110002.**

**Dated: 24<sup>th</sup> January, 2013**

**Subject: Guidelines related to Food Import Clearance Process by FSSAI's Authorized Officers.**

In continuation to the guidelines issued vide letter No 1-17/FSSAI/T/2012 (Part J) dated 23<sup>rd</sup> March, 2012, Food Safety and Standards Authority of India (FSSAI) after due consideration of various operational issues raised by the stakeholders and to facilitate genuine trade while ensuring the mandate of safe food imports in India is issuing the following guidelines/clarifications with immediate effect till further orders or final notification of regulations in this regard, whichever is earlier:

**I. Guidelines/Clarifications related to Labeling Requirements for Wholesale Packages:**

- a) If the labels attached by the manufacturer are from the country of origin on the container of wholesale packages, which fulfil the labelling requirements of the FSSAI Regulations then the same may be allowed. However, tampering of label and pasting of one label over the other label will not be permitted.
- b) A wholesale package can have either best before date/ expiry date/ use by date. In the case of wholesale packages, if both best before date and expiry date are given, then the two should be different and clearly specified.

**II. Guidelines/Clarifications related to testing of 'proprietary food':**

Every "proprietary food" for which FSSAI has no standards should be tested on the safety parameters, micro-biological parameters and for heavy metals, wherever applicable depending upon the nature of the product. The Certificate of Analysis (COA) submitted by the importer may also be sent with the sample. The COA may or may not have information on the list of ingredients but it will carry information on quality control parameters viz. microbiological parameters, specific gravity, pHi etc. that can be referenced while undertaking the requisite tests.

**III. Guidelines/Clarifications related to Import of Dietary Supplements:**

This is regarding the use of certain food additives in food supplements. Currently, there are no FSS Standards for food/dietary supplements. It has therefore been decided that the Food Authority in accordance with Codex GSFA for food supplements may clear the consignments. The list of food additives that are allowed in food/dietary supplements are given under Category 13.6 of the Codex General Standard for Food Additive (GSFA) (copy enclosed). Table 3 of GSFA also provides the list of additives that can be used in general at the level of GMP even in food supplements (copy enclosed).

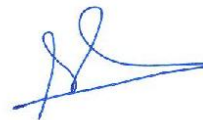
#### **IV. Guidelines/Clarifications related to Laboratory reports:**

All the laboratories will have to follow the standard format of report as given in FSS (Laboratory and Sample Analysis) Regulations, 2011.

#### **V. Guidelines/Clarifications related to Import of flavours for wholesale packages:**

In the case of mixtures of flavourings, the name of each flavouring present in the mixture need not be given. The generic expression "flavour" or "flavouring" may be used together with a true indication of the nature of the flavour. The expression "flavour" or "flavouring" may be qualified by the words "natural", "nature-identical", "artificial", or a combination of these words, as appropriate. This provision does not apply to flavour modifiers, but does apply to "herbs" and "spices" which generic expressions may be used where appropriate.

These issues with the approval of Chairperson, FSSAI.

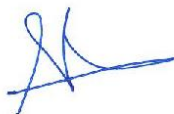


(Manish Kumar Singh)  
Assistant Director (Imports)

To,

#### **Authorized Officers**

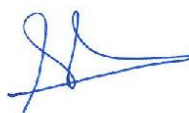
1. Sh. Sanjay Gupta, AO Delhi  
Food Safety and Standards Authority of India,  
Ministry of Health & Family Welfare,  
1<sup>st</sup> Floor, East Tower, NBCC Place,  
Bhisampitamah Marg,  
Pragati Vihar, New Delhi- 110003.
2. Dr. B. G. Pandian, AO Chennai  
Food Safety and Standards Authority of India,  
Ministry of Health & Family Welfare, Govt. of India,  
C/o Directorate of Marketing & Inspection,  
4<sup>th</sup> Floor, 6<sup>th</sup> Block, C-Wing, Shastri Bhawan,  
26, Haddows Road, Chennai-600006,  
Tamil Nadu.



3. Sh. Krishan Murari, SIO Mumbai  
JNPT-Nhava Sheva, Sea & Air Port  
Food Safety and Standards Authority of India,  
Ministry of Health & Family Welfare, Govt. of India,  
902, Hall Mark Business Plaza, Sant Dyaneshwar Marg,  
Opposite Guru Nanak Hospital Road, Bandra (East),  
Mumbai- 400 051.
4. Sh. D. P. Guha, AO  
(Kolkata Seaport, Kolkata International Airport and Haldia Seaport)  
Food Safety and Standards Authority of India,  
Ministry of Health & Family Welfare,  
Government of India,  
4th Floor, Mayukh Bhawan, Salt Lake,  
Kolkata-91.

**Laboratories:-**

5. Geochem labs Pvt. Ltd  
Geo Chem House,  
294, Shahid Bhagat Singh Road,  
Fort, Mumbai 400001.  
Tel: +91 22 66383838  
Fax: + 91 22 66383800  
E-mail: [mumbai@geochem.net.in](mailto:mumbai@geochem.net.in)
6. Export Inspection Agency Mumbai pilot Test House  
E/3, Pilot Test House, Andheri Midc, Chakala M.i.d.c., Near Marol Depot, Mumbai,  
MH 400093  
022 28363396
7. Envirocare labs Pvt. Ltd  
Enviro House, A7, MIDC, Wagle Industrial Estate, Main Road,  
Thane, 400 604.  
Tel: +91 22 2583 8286  
Fax: +91 22 2583 8289
8. Reliable Analytical laboratory,  
Reliable Analytical Laboratories, Indian Corporation, Bldg No. 125/139, Dapode,  
Gundavli, Bhiwandi, Thane- 421 302.  
Phone / Fax : 02522 398100.
9. Board of Radiation & Isotope Technology (BRIT)  
BRIT/BARC Vashi Complex , Sec-20 Vashi, Navi Mumbai - 400 705.





10. Microchem Labs Pvt. Ltd  
MicroChem House, A-513, TTC Ind Area  
MIDC, Mahape, Navi Mumbai- 400 701.  
Tel.: 022 - 2778 7800.  
[customercare@microchem.co.in](mailto:customercare@microchem.co.in)

**Referral Laboratories:-**

11. Food Research & Standarization Laboratory  
Food Research & Standarization Laboratory (Ministry of Health & Family Welfare)  
Indrapuram, Ahinsa Khand-II, Near CISF Camp, Ghaziabad - 201014 (UP) Tele /  
Fax: 0120-2650950  
E Mail : [frslfssai@yahoo.com](mailto:frslfssai@yahoo.com)
12. Central Food Laboratory Mysore  
Dr. Lalitha Gowda  
Director,  
Referral Food Laboratory  
CSIR-Central Food Technological Research Institute, Mysore  
Tele / Fax : 0821-2412064
13. Central Food Laboratory Pune  
Referral Food Laboratory  
Central Food Laboratory  
Stavelly Road,  
Cantonment Water Works Compound,  
Near Pulgate, Pune - 411001  
E Mail: [cflpune123@yahoo.in](mailto:cflpune123@yahoo.in)  
Phone : 020-26330509  
Fax: 020-26330223
14. Referral Food Laboratory  
Dr. A K Adhikari,  
Director  
Referral Food Laboratory,  
3, KYD Street, Kolkata - 700016  
Phone: 033-22291309, 22278127  
Fax: 033-22498897  
E Mail: [cflcal@gmail.com](mailto:cflcal@gmail.com)
15. Dr. Arun K. Panda, Joint Secretary, Ministry of Health and Family Welfare, Room  
No. 254-A, Nirman Bhawan, New Delhi: 011-23063156.

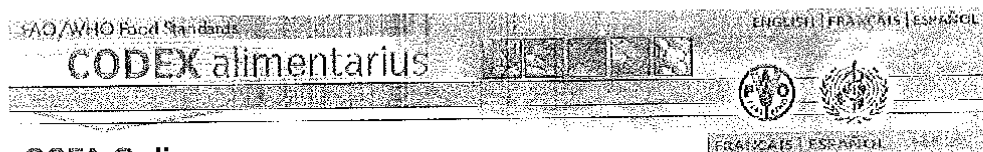
16. Mr. Sandeep M. Bhatnagar, Joint Secretary (Customs), Room No. 156B, North Block, Central Board of Excise and Customs, Department of Revenue, Ministry of Finance, New Delhi – for information please and with the request to kindly get it circulated to Custom Authorities at various ports of entries.

Copy to: -

1. PPS to Chairperson, FSSAI
2. Director (Enforcement), FSSAI
3. Director (Surveillance), FSSAI
4. Director (Q & A), FSSAI
5. Director (Product Approval), FSSAI
6. FSSAI's Website.







## GSFA Online

Updated up to the 35<sup>th</sup> Session of the Codex Alimentarius Commission (2012)

### FOOD CATEGORY DETAILS

#### Food supplements (13.6)

##### Description:

Includes vitamin and mineral supplements in unit dose forms such as capsules, tablets, powders, solutions etc., where national jurisdictions regulate these products as food.<sup>1</sup>

This page provides information on the food additive provisions that are acceptable for use in foods conforming to the food category.

#### GSFA Provisions for Food Category 13.6

INS No.	Food Additive or Group	Max Level	Notes	Defined In
	ASCORBYL ESTERS	500 mg/kg	Note 10	13.6
950	Acesulfame potassium	2,000 mg/kg	Note 188	13.6
129	Allura red AC	300 mg/kg		13.6
951	Aspartame	5,500 mg/kg	Note 191	13.6
962	Aspartame-acesulfame salt	2,000 mg/kg	Note 113	13.6
	BENZOATES	2,000 mg/kg	Note 13	13.6
901	Beeswax	GMP	Note 3	13.6
133	Brilliant blue FCF	300 mg/kg		13.6
320	Butylated hydroxyanisole (BHA)	400 mg/kg	Note 15 Note 196	13.6
321	Butylated hydroxytoluene (BHT)	400 mg/kg	Note 15 Note 196	13.6
	CAROTENOIDS	300 mg/kg		13.6
	CHLOROPHYLLS AND CHLOROPHYLLINS, COPPER COMPLEXES	500 mg/kg	Note 3	13.6
	CYCLAMATES	1,250 mg/kg	Note 17	13.6
902	Candelilla wax	GMP	Note 3	13.6
150c	Caramel III - ammonia caramel	20,000 mg/kg		13.6
150d	Caramel IV - sulfite ammonia caramel	20,000 mg/kg		13.6
120	Carmines	300 mg/kg		13.6
903	Carnauba wax	5,000 mg/kg	Note 3	13.6
160a(ii)	beta-Carotenes, vegetable	600 mg/kg		13.6
1503	Castor oil	1,000 mg/kg		13.6
472e	Diacetyltartaric and fatty acid esters of glycerol	5,000 mg/kg		13.6
	ETHYLENE DIAMINE TETRA ACETATES	150 mg/kg	Note 21	13.6
143	Fast green FCF	600 mg/kg		13.6
163(ii)	Grape skin extract	500 mg/kg	Note 181	13.6
	IRON OXIDES	7,500 mg/kg	Note 3	13.6
132	Indigotine (Indigo carmine)	300 mg/kg		13.6
961	Neotame	90 mg/kg		13.6
	PHOSPHATES	2,200 mg/kg	Note 33	13.6
	POLYSORBATES	25,000 mg/kg		13.6
900a	Polydimethylsiloxane	50 mg/kg		13.6
1521	Polyethylene glycol	70,000 mg/kg		13.6
1203	Polyvinyl alcohol	45,000 mg/kg		13.6
1201	Polyvinylpyrrolidone	GMP		13.6
124	Ponceau 4R (Cochineal red A)	300 mg/kg		13.6
310	Propyl gallate	400 mg/kg	Note 15 Note 196	13.6
	RIBOFLAVINS	300 mg/kg		13.6
	SACCHARINS	1,200 mg/kg		13.6
	SORBATES	2,000 mg/kg	Note 42	13.6
904	Shellac, bleached	GMP	Note 3	13.6
960	Steviol glycosides	2,500 mg/kg	Note 26 Note 203	13.6

INS No.	Food Additive or Group	Max Level	Notes	Defined in
955	Sucralose (Trichlorogalactosucrose)		2,400 mg/kg	13.6
474	Sucroglycerides		2,500 mg/kg	13.6
110	Sunset yellow FCF		300 mg/kg	13.6

Items in uppercase (e.g. PHOSPHATES) refer to food additive groups.

### GSFA Table 3 Provisions

The following additives, as indicated by Table 3, may be used in this food category under the conditions of good manufacturing practice (GMP) as outlined in the Preamble of the Codex GSFA.

INS No.	Food Additive or Group
260	Acetic acid, glacial
472a	Acetic and fatty acid esters of glycerol
1422	Acetylated distarch adipate
1414	Acetylated distarch phosphate
1451	Acetylated oxidized starch
1401	Acid treated starch
406	Agar
400	Alginate acid
1402	Alkaline treated starch
264	Ammonium acetate
403	Ammonium alginate
503(i)	Ammonium carbonate
510	Ammonium chloride
503(ii)	Ammonium hydrogen carbonate
527	Ammonium hydroxide
328	Ammonium lactate
1100	alpha-Amylase from <i>Aspergillus oryzae</i> var.
1100	alpha-Amylase from <i>Bacillus licheniformis</i> (Carbohydrase)
1100	alpha-Amylase from <i>Bacillus megaterium</i> expressed in <i>Bacillus subtilis</i>
1100	alpha-Amylase from <i>Bacillus stearothermophilus</i> expressed in <i>Bacillus subtilis</i>
1100	alpha-Amylase from <i>Bacillus stearothermophilus</i>
1100	alpha-Amylase from <i>Bacillus subtilis</i>
300	Ascorbic acid, L-
162	Beet red
1403	Bleached starch
1101(iii)	Bromelain
629	Calcium 5'-guanylate
633	Calcium 5'-inosinate
634	Calcium 5'-ribonucleotides
263	Calcium acetate
404	Calcium alginate
302	Calcium ascorbate
170(i)	Calcium carbonate
509	Calcium chloride
623	Calcium di-L-glutamate
578	Calcium gluconate
526	Calcium hydroxide
327	Calcium lactate
352(ii)	Calcium malate, DL-
529	Calcium oxide
282	Calcium propionate
552	Calcium silicate
516	Calcium sulfate
150a	Caramel I - plain caramel
290	Carbon dioxide
410	Carob bean gum
407	Carrageenan
427	Cassia gum
140	Chlorophylls
1001	Choline salts and esters
330	Citric acid
472c	Citric and fatty acid esters of glycerol

INS No.	Food Additive or Group
468	Cross-linked sodium carboxymethyl cellulose (Cross-linked cellulose gum)
424	Curdian
457	Cyclodextrin, alpha-
458	Cyclodextrin, gamma-
1400	Dextrins, roasted starch
628	Dipotassium 5'-guanylate
627	Disodium 5'-guanylate
631	Disodium 5'-inosinate
635	Disodium 5'-ribonucleotides
1412	Distarch phosphate
315	Erythorbic Acid (Isoascorbic acid)
968	Erythritol
462	Ethyl cellulose
467	Ethyl hydroxyethyl cellulose
297	Fumaric acid
418	Gellan gum
575	Glucono delta-lactone
1102	Glucose oxidase
620	Glutamic acid, L-(+)-
422	Glycerol
626	Guanylic acid, 5'-
412	Guar gum
414	Gum arabic (Acacia gum)
507	Hydrochloric acid
463	Hydroxypropyl cellulose
1442	Hydroxypropyl distarch phosphate
464	Hydroxypropyl methyl cellulose
1440	Hydroxypropyl starch
630	Inosinic acid, 5'-
953	Isomalt (Hydrogenated Isomaltulose)
416	Karaya gum
425	Konjac flour
270	Lactic acid, L-, D- and DL-
472b	Lactic and fatty acid esters of glycerol
966	Lactitol
322(i)	Lecithin
1104	Lipases
160d(iii)	Lycopene, Blakeslea trispora
160d(i)	Lycopene, synthetic
160d(ii)	Lycopene, tomato
504(i)	Magnesium carbonate
511	Magnesium chloride
625	Magnesium di-L-glutamate
580	Magnesium gluconate
528	Magnesium hydroxide
504(ii)	Magnesium hydroxide carbonate
329	Magnesium lactate, DL-
530	Magnesium oxide
553(i)	Magnesium silicate, synthetic
518	Magnesium sulfate
296	Malic acid, DL-
965(i)	Maltitol
965(ii)	Maltitol syrup
421	Mannitol
461	Methyl cellulose
465	Methyl ethyl cellulose
460(i)	Microcrystalline cellulose (Cellulose gel)
471	Mono- and di-glycerides of fatty acids
624	Monoammonium L-glutamate
622	Monopotassium L-glutamate
621	Monosodium L-glutamate
1410	Monostarch phosphate

INS No.	Food Additive or Group
941	Nitrogen
942	Nitrous oxide
1404	Oxidized starch
1101(ii)	Papain
440	Pectins
1413	Phosphated distarch phosphate
1200	Polydextroses
964	Polyglycol syrup
1202	Polyvinylpyrrolidone, insoluble
632	Potassium 5'-inosinate
261	Potassium acetates
402	Potassium alginate
303	Potassium ascorbate
501(i)	Potassium carbonate
508	Potassium chloride
332(i)	Potassium dihydrogen citrate
577	Potassium gluconate
501(ii)	Potassium hydrogen carbonate
351(i)	Potassium hydrogen malate
515(ii)	Potassium hydrogen sulfate
525	Potassium hydroxide
326	Potassium lactate
351(ii)	Potassium malate
283	Potassium propionate
515(i)	Potassium sulfate
460(ii)	Powdered cellulose
407a	Processed eucheuma seaweed (PES)
944	Propane
280	Propionic acid
1204	Pullulan
470(i)	Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium
470(ii)	Salts of oleic acid with calcium, potassium and sodium
551	Silicon dioxide, amorphous
350(ii)	Sodium DL-malate
262(i)	Sodium acetate
401	Sodium alginate
301	Sodium ascorbate
500(i)	Sodium carbonate
466	Sodium carboxymethyl cellulose (Cellulose gum)
469	Sodium carboxymethyl cellulose, enzymatically hydrolyzed (Cellulose gum, enzymatically hydrolyzed)
331(i)	Sodium dihydrogen citrate
316	Sodium erythorbate (Sodium isoascorbate)
365	Sodium fumarates
576	Sodium gluconate
350(i)	Sodium hydrogen DL-malate
500(ii)	Sodium hydrogen carbonate
514(ii)	Sodium hydrogen sulfate
524	Sodium hydroxide
325	Sodium lactate
281	Sodium propionate
500(iii)	Sodium sesquicarbonate
514(i)	Sodium sulfate
420(i)	Sorbitol
420(ii)	Sorbitol syrup
1420	Starch acetate
1450	Starch sodium octenyl succinate
1405	Starches, enzyme treated
473a	Sucrose Oligoesters, Type I and Type II
553(iii)	Talc
417	Tara gum
957	Thaumatococin
171	Titanium dioxide

INS No.	Food Additive or Group
413	Yragacanth gum
1518	Yriacetin
380	Triammonium citrate
333(iii)	Tricalcium citrate
332(ii)	Tripotassium citrate
331(iii)	Trisodium citrate
415	Xanthan gum
967	Xylitol

1. Codex Standard for Formula Foods for Use in Weight Control Diets (CODEX STAN 181-1991) and Codex Standard for Formula Foods for use in Very Low Energy Diets for Weight Reduction (CODEX STAN 203-1995).

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