



## **FSSAI working on draft standards for foods related to IEM for infants**

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FSSAI is working on draft standards for food related to inborn errors of metabolism for infants. It would be put out for comments and suggestion shortly. The country's apex food regulator has also identified the food products that would be named in a list and shall be allowed to be imported in the country, once approved.

Pawan Kumar Agarwal, chief executive officer, FSSAI, said that under the initiative of diet4life, the apex food regulator has allowed the import of certain foods that are required to be given to kids suffering from IEM.

"These are specialised food. It is not about lactose intolerance. In such cases, there are specialised foods that are to be imported. Some companies in India have also started manufacturing the same, which we could only import earlier," he added.

In an estimate, close to 35,000 children die due to IEM every year, and FSSAI has come up with an interim arrangement before finalising the draft standards for that.

Agarwal said, "Now we have identified the items which are related to IEM and only they will be allowed to be imported. A positive list was prepared as an interim arrangement till the standards are finalised. The standards are also being finalised."

"So once the standards are finalised, there would be certain conditions where breast feeding is just not possible. The Infant Milk Substitutes (IMS) Act, 1992, will be applicable in every case, except where there is a special need for such children," he added.

He, however, said that if comments were received with reasoning that the draft should be changed/modified, FSSAI will examine it.

Foods related to IEM and the IMS Act, 1992, has become a matter of debate with many experts raising the concern that behind the permission of IEM foods, the companies may introduce their baby foods, which are banned under the IMS Act, 1992.

Dr Shweta Khandelwal, associate professor, Public Health Foundation of India, cautioned, "There is enough evidence that big food or big pharma would leave no

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opportunity to maximise profits. In this case, these specialised foods are a necessity for children born with IEM.”

“Thus, the industry must be strongly regulated at all stages, so that no needy person is catastrophically affected. There should be schemes or strategies which allow people from low-income families to access these products for their children/families,” she added.

“Import duties can be reduced or waived off on these products as requested by several bodies working in this space,” Dr Khandelwal said.

She added that there were allegations that the industry was trying to get these exempted from the IMS Act, 1992, so that they can make better profits and be less regulated.

However, to address the challenges faced by IEM patients, FSSAI, ministry of health and family welfare, Government of India, launched the Diet4life initiative in partnership with various stakeholders comprising the Indian Dietetic Association (IDA), the Indian Society for Inborn Errors of Metabolism (ISIEM), the Metabolic Errors and Rare Diseases Organisation of India (MERD), the Indian Academy of Paediatrics (IAP), the National Neonatology Forum (NNF), the Indian Council of Medical Research (ICMR), the Indian Society of Paediatric Gastroenterology, Hepatology and Nutrition (ISPGHAN) and the Infant and Young Child Nutrition Council of India (IYNCI).

The Diet4Life initiative is a collaborating effort that aims to provide a holistic service for IEM patients, with facilities of diagnosis, treatment and management of IEM.

So what is IEM and IMS Act, 1992? Dr Khandelwal said, “IEM are genetic disorders in which the body cannot properly turn food into energy. In India, the prevalence of IEM is about 1/2,500 newborns.”

“IEM is estimated to affect over 30,000-40,000 children in India currently. The disorders result because of defects in specific proteins (enzymes) that help metabolise or break down parts of food in our body,” she added.

“IEM is life-threatening. Thus, for their treatment, specialised diets which fall under the category of food for special medical purposes (FSMPs) are prescribed,” Dr Khandelwal said.

These FSMPs are life-saving, as without these diets/foods, the children may not survive. Some examples of IEM include congenital hypothyroidism, congenital adrenal hyperplasia (CAH), Glucose 6 Phosphate Dehydrogenase Deficiency (G6PD), biotinidase deficiency, galactosemia (GAL), phenylketonuria (PKU), maple syrup urine disease (MSUD), etc.

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The IMS Act, 1992, provides for the regulation of production, supply and distribution of infant milk substitutes, feeding bottles and infant foods with a view to the protection and promotion of breastfeeding and ensuring the proper use of infant foods and for matters connected therewith or incidental thereto.

Dr Khandelwal stated that the confusion or controversy starts because of infant foods being included under them.

FSSAI clarified, saying that placing FSMPs in the category of IMS foods may have been problematic and begged exemption from the IMS Act, 1992.

Some concerns FSSAI has highlighted are as follows:

- All infant milk substitutes and infant food labels have to carry a statement, reading, "Mother's milk is best for your baby" in capital letters. In cases of some IEM conditions, an infant cannot digest mother's milk, hence such a label is medically contraindicated and cannot be affixed
- Products under the IMS Act, 1992, can be taken under advice of health workers, but this cannot be done for IEM diets, which need to be taken only under medical supervision, etc. Hence it would not be feasible to apply the IMS Act, 1992, into infant FSMPs