Global Product Approval Overview

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* Data and knowledge here is from Public domain and experience that's spans across industries

Introduction

FSSAI CEO recently shared his views on future product approval process

Dated 13 April 2016

"In case of proprietary food products, if ingredients are the same, there should not be any requirement for product approvals every time. The fixation about product approval has to go. Our responsibility regarding product approval has to shrink. And then this authority will have greater resources to devote to some of these issues."

- We have to change the very culture of food manufacturing, the way food is served and that culture change can be brought about by working with the food businesses… You guide food businesses on what is right for them to do and see that they implement it. They do it because it is the right thing for them. And that's precisely the way the developed countries work.So a lot of our focus will be on training, dissemination of what are ideal manufacturing practices, hygienic practices, hazard analysis and control and critical control points in a food processing unit. Ensuring that food is produced and processed safely and served hygienically are the focus areas of the work of FSSAI.

"We want citizens to be our inspectors. They give us feedback and we align our enforcement based on that. This is how we would like to move forward as we work in this authority and try to ensure food safety, get confidence of the public and the government."

Source: http://www.livemint.com/Politics/IpeNSnVB56hzxgRWTXb8PJ/Fixation-on-product-approval-has-to-go-FSSAI-chief.html

Global Landscape-indicative figures

Consolidation starts mid 1990's in developed nation

Europe
- No product approval system
- Compliance lies on manufacturers/ importers' responsibility

USA
- No product approval system
- Compliance lies on manufacturers/ importers' responsibility

Greater China
- China/ Hong Kong require product registration **8 months**
- Taiwan – no product registration requirement

LATAM
- Caribbean/ Argentina - Complex product approval registration process

Middle East
- Simple product approval process 3 months
- GSO Menat progress towards harmonization with codex

India
- Complex product approval registration process on hold.
- Review new approval scheme

South East Asia
- All except Singapore and Malaysia have product registration
- Complex registration in Indonesia- may take **22 months**
- Thailand –**need 8 months**

Countries closer in the Region ---a look at Product registration

SINGAPORE

- No product registration
- Turnover time 1 month
- Product specification as needed

MALAYSIA

- Product registration on GMO
- Required documents –Packaging Keyline, Halal, micro ,IEC no, COA ,Factory license

CODEX ALIMENTARIUS

The **CODEX** ALIMENTARIUS international food standards, guidelines and codes of practice contribute to the safety, quality and fairness of this international food trade. Consumers can trust the safety and quality of the food products they buy and importers can trust that the food they ordered will be in accordance with their specifications

While being recommendations for voluntary application by members, Codex standards serve in many cases as a basis for national legislation. Codex has far reaching implications for resolving trade disputes. WTO members that wish to apply stricter food safety measures than those set by Codex may be required to justify these measures scientifically.

Source -http://www.fao.org/fao-who-codexalimentarius/about-codex/en/

Codex food additive standard---a quick look

- Annex A is a guideline for considering maximum use levels for additives with numerical JECFA ADIs.
- ii. Annex B is a listing of the food category system used to develop and organize Tables 1, 2, and 3 of the standard. Descriptors for each food category and sub-category are also provided.
- iii. Annex C is a cross-reference of the food category system and Codex commodity standards.

Clear definitions and guidelines provided-
- **Food Additives Included in this Standard**
- **Foods in Which Additives May Be Used**
- **Foods in Which Additives May Not Be Used**
- **Maximum Use Levels for Food Additives**
- **Definitions of food categories**
- **Key principles and GMP/ carryovers**
- **Independent review on key additives by CCFA and JEFCA**

Typical Snapshot of documents in a registration / approval process that countries follow

- Packaging Keyline
- Certificate of origin
- Actual sample
- Raw mat spec
- Product spec
- Non Gmo letter
- Melamine
- Halal status
- Radiation free
- Health certificate on egg and ilk products
- COA
- Packaging test certificate etc
- Dilution rate
- Serving size per day
- Support documents related to claims
- **Micro testing with clear compliance levels across**
- **China, Vietnam and Thailand.**

Key Markets for benchmarking

South East Asia

Indonesia/ Thailand

Each product has different ML no. to be printed on label

Multi (est.15) document required

Local lab testing needed

Long lead time for Indonesia (22months)

GCC

UAE/ KSA

Online product registration process

2 document required: COA and Actual Artwork

Actual Sample required

Europe

No product approval/ registration

Products/ Ingredients that meet EU **regulations will be able to distribute freely**

Relies on CODEX and JEFCA standards on commodity and additives

USA

No product approval/ registration

Products/ Ingredient that meet FDA regulations will be able to distribute freely

Current state in India

Food Regulations
Lack of standards for all food
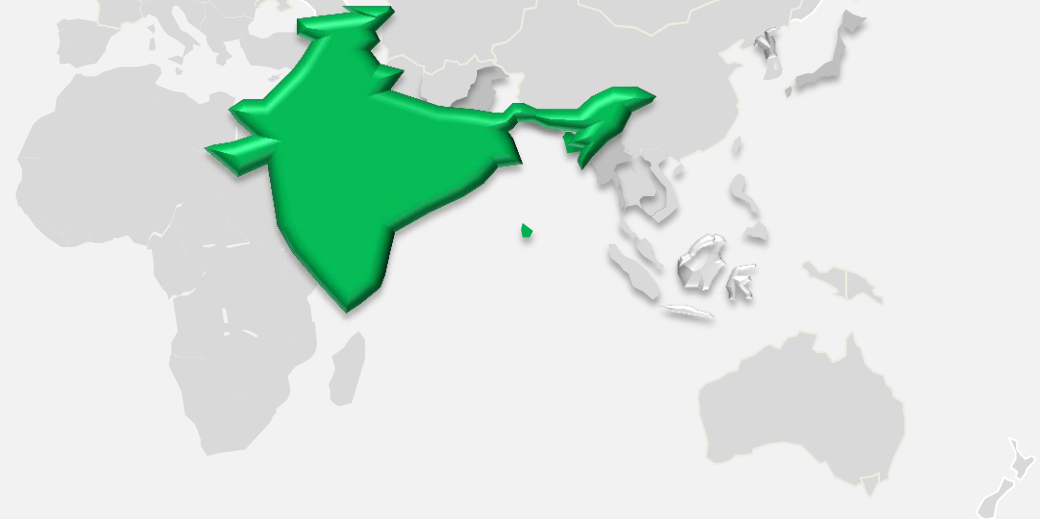Require proprietary food approval

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Current Proprietary Product Approval System put on hold by High Court till regulations are revised and meet international standards to enable trade

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- The system require a long list of 27 document to be submitted for review and approval.
- More than XX millions products in India not possible for all to be approved with the current system
- Resource is a challenge

Industry can now continue to submit new product registration to manufacture until the revised regulations are ready
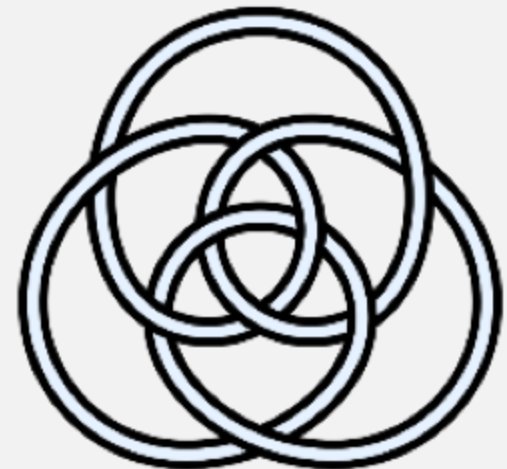
Industry working together to understand Global system and brainstorm on the way forward

Local implications and challenges

1. **Lack of food standards for all categories**

2. **Legacy Approval system require lots of resource to manage, lack of clarity on manufacturing license and registration (different ministries handle)**

3. **Ingredient Declaration and Labelling requirement not aligned to codex**
4. **Two separate bodies on license and approval**

The draft Proposal

- Recommend to follow EU / Codex A. regulations over long term
- Industry to take ownership of product regulatory compliance
- To have a simple new product registration system for all products with key document submission i.e COA, Product specification, label and health certification (depending on categories)
- Single online portal to apply in that will cover fssai registration and Mfg License

- Harmonization of FSSAI & Mfg. Licensing Authority

- All proprietary category shall be included in manufacturing license categories

- FBOs shall make online application for new product

- If the product fits into any of the product categories defined by FSSAI, manufacturing license shall be grated in 30 days. This approval will include both product and Mfg.

- Responsibility of adherence to standards lies with FBO

- No online approval system required

- FBOs are solely responsible for safety and compliance of product and manufacturing processes

- FBOs need to only intimate governing bodies about the product and manufacturing (Like US)

2-3 yrs

5-6 yrs

Source

- http://www.livemint.com/Politics/lpeNSnVB56hzxgRWTXb8PJ/Fixation-on-product-approval-has-to-go-FSSAI-chief.html