Effectiveness of product approval system

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Sept.11, 2015

Product Approval & Food Safety

Product Approval

Purpose - to ensure the **food articles are safe** for human consumption.

Methodology - by prescribing Standards; or by an approval mechanism.

"Food Safety" has been defined in Sec.3(q) as " **an assurance that the food is acceptable for human consumption according to its intended use"**.

- The Act itself has used the words "acceptable" and "intended use".
- Act has not used the words "safe" or "of high quality" etc...
- Indirectly the law has put the onus on the consumers too - with the words **intended** use so he exercises moderation in consumption.

Responsibility of the FBO

- **Shall not** by himself or by any person on his behalf mfg., store, distribute, sell any article of food that is **unsafe**……." for the reason that **..**
- Misbranded, substandard or contains extraneous matters..
- Where such a food requires a license, except in accordance with the conditions of the license;
- In contravention of any provisions of this Act, Rules or Regulations made there under;

Food safety….

Unsafe food means-

An article of food whose nature, substance or quality is so affected as to render it **injurious** to health –

The article of food or the package thereof , contains poisonous or deleterious substance;

Any filthy, putrid, diseased, decomposed animal or vegetable substance;

Unhygienic processing or presence of harmful substance;

By the substitution of substandard or cheaper substance

By addition of a substance directly or as an ingredient.. ….

product not being “tampered” with so as to make it better or greater value than it actually is..

Presence of any coloring matter or preservatives other than that specified;

Misbranded, substandard or contains extraneous matter.

We need to find out how many PA application were rejected on the above grounds.

Product Approval

Objective

- Approval required for products specified under Section 22 (Novel, GM, FSDU, Food supplement, **Proprietary food** etc.)
- Where standards (vertical) have not yet been set by the Act.
- To ensure product safety / safety of the consumer;

Methodology & Outcome

- Close to a dozen adisories were issued; advisory dated May11, 2013 superseded all earlier ones.
- Last advisory made it mandatory for all Proprietary Foods / Products (irrespective of they are existing as on date / previously licensed / new products to be launched) to get approval;
- Detailed information such as ingredients list, additives list, recipe, source of origin, labels, agreement with the supplier/ vendor/ test certificates/ shelf life etc… were required to be furnished to FSSAI.
- Any changes in its composition or % thereof in the product needed fresh approval – **"combinatorial effect" vs bio availability and country specific**
- **Except the product itself companies were made to submit everything including mfg. process etc.**
- **Result**- delay, mechanical rejection with insufficient reasoning / same information were repeatedly sought; rejection was made on even label claim related issues.

Bombay High Court Order- Vital Nutraceuticals

- Ruled that the advisories issued were without legal sanction and hence void. **(now what happens to the fees paid??)**
- Mandated that what needs to be done thru' regulations have to be done only by regulations.
- If FSSAI has to issue any advisories / directions need like other bodies like RBI etc., then the Act has to provide such power.
- Definition of "Standards" and "Notification" further mandates publication of Standards in official gazette...

What's next? Possible scenarios

Scenario-1

- Likelihood of amendment to Act itself whereby powers are given to FSSAI or its designated officials to issue advisories and directions that include product Approval as well.
- Based on such amendment, FSSAI might reissue advisories

Scenario-2

- Issue regulations as mandated by the court / the current Act, inter alia covering product approval process.

What do we need to do for an effective and workable system?

Food Scientists / Industry bodies to help FSSAI in drafting the Regulation– our recommendation may cover…

- Option-1 – follow what majority of the advanced countries do..
- Option-2 – follow a hybrid model – prescribe list of permitted ingredients and the upper limit (like it was done for additives);
- For any product claim based on ingredient, prescribe a minimum limit thereof as well.
- Option-3 – specify only negative list of ingredients with respective upper limit;
- **Bio availability vs Combinatorial effect& country specific factors…**

What is important to note is Product Approval per se doesn't ensure safe food. Rigor in mfg. process, enforcement, robust testing standards and analysis process too are imperative;

RBI Act, 1934

- 58. **Power of the Central Board to make regulations.—**
- (1) The Central Board may, with the previous sanction of the 1[Central Government], 2[by notification in the Official Gazette,] make regulations consistent with this Act to provide for all matters for which provision is necessary or convenient for the purpose of giving effect to the provisions of this Act.
- (2) In particular without prejudice to the generality of the foregoing provision, such regulations
- may provide for all or any of the following matters, namely:— 3[***]
- (l) the provision of an official seal of the Bank and the manner and effect of its use;
- (m) the manner and form in which the balance sheet

- note may be refunded; and
- (r) generally, for the efficient conduct of the (4)
- **Every regulation shall, as soon as may be after it is made by the Central Board, be, forwarded to the Central Government and that Government shall cause a copy of the same to be laid before each House of Parliament, while it is in session, for a total period of thirty days** which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the regulation, or both Houses agree that the regulation should not be made, the regulation shall, thereafter, have effect only in such modified form or be of no effect as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that regulation.] 8[(5)]

1[45JA. Power of Bank to determine policy and issue directions.—

(1) If the Bank is satisfied that, in the public interest or to regulate the financial system of the country to its advantage or to prevent the affairs of any non-banking financial company being conducted in manner detrimental to the interest of the depositors or in a manner prejudicial to the interest of the non-banking financial company, it is necessary or expedient so to do, it may determine the policy and give directions to all or any of the non-banking financial companies relating to income recognition, accounting standards, making of proper provision for bad and doubtful debts, capital adequacy based on risk weights for assets and credit conversion factors for off balance-sheet items and also relating to deployment of funds by a non-banking financial company or a class of non-banking financial companies or non-banking financial companies generally, as the case may be, and such non-banking financial companies shall be bound to follow the policy so determined and the direction so issued.

(2) Without prejudice to the generality of the powers vested under sub-section (1), the Bank may give directions to non-banking financial companies generally or to a class of non banking financial companies or to any non-banking financial company in particular as to—

(a) the purpose for which advances or other fund based or non-fund based accommodation may not be made; and

(b) the maximum amount of advances of other financial accommodation or investment in shares and other securities which, having regard to the paid-up capital, reserves and deposits of the non-banking financial company and other relevant considerations, may be made by that non-banking financial company to any person or a company or to a group of companies.]

person from whom the non-banking institution holds, as on the last day of the year to which the accounts relate, deposits higher than such sum as may be specified by the Bank.

*45L. Power of Bank to call for information from financial institutions and to give directions.—

(1) If the Bank is satisfied for the purpose of enabling it to regulate the credit system of the country to its advantage it is necessary so to do, it may—

(a) require financial institutions either generally or any group of financial institutions or financial institution in particular, to furnish to the Bank in such form, at such intervals and within such time, such statements, information or particulars relating to the business of such financial institutions or institution, as may be specified by the Bank by general or special order;

(b) give to such institutions either generally or to any such institution in particular, directions relating to the conduct of business by them or by it as financial institutions or institution.

Thank You