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The questions raised by the Maggi crisis

The real story is of a regulator that has lacked the resources and know-how to safeguard public health



Whether or not a product should be approved for sale and consumption is based almost entirely on scientific analysis provided by the manufacturers themselves. Photo: Bloomberg

There's a crisis in the packaged food market after Hindustan Unilever Ltd followed Nestle India Ltd in pulling its instant noodles off the shelves. Tata Starbucks Ltd, too, has withdrawn some of its products.

The crisis has raised several questions.

Are we consuming food that is not safe? How can companies launch food products without requisite approvals? And, at a larger level, who is responsible for food quality in India?

Apart from the manufacturers, until 2006, a myriad laws and regulatory bodies were responsible for determining and enforcing quality and health standards.

Those were replaced by the Food Safety and Standards Authority of India (FSSAI) which, since becoming operational in 2011, became the central regulatory authority responsible for food safety in India, under the Food Safety and Standards Act, 2006, that consolidated all the existing laws.

FSSAI's job, in its own words, is to lay down "science-based standards" for the manufacturing, processing, distribution, sale and

import of food in India.

But a big problem is that there might not be enough science to go around.

Gatekeeper

FSSAI is responsible for approving all new food products coming into the Indian market, but since it has only been operating for a few years now, the procedure also applies to those products which were already in the market before that time and to imported products.

FSSAI has laid down an online process for applications by companies seeking approval for their products. The application requires the manufacture to give detailed information, such as the ingredients used, the manufacturing process, place of manufacture and source of raw materials, including water. FSSAI has also released detailed regulations laying down permissible levels of toxins or additives such as lead and MSG (monosodium glutamate) in different kinds of food products.

However, the practical process of obtaining approval for a food product can be a bit of a nightmare.

According to Gowree Gokhale, a partner at Nishith Desai Associates, delayed approvals are a frequent feature with FSSAI and a major cause of frustration for companies. In fact, the entire procedure of approval is a subject of great confusion, and FSSAI itself gives the impression that it is a work in progress, with frequent announcements of changes and alterations in procedure on its website.

Despite all the detailed guidelines, the law does not make testing of food products before approval mandatory.

How the system works is that a person seeking approval fills in a detailed application form, including a variety of undertakings and affidavits regarding all the ingredients used, processes employed and other relevant information. This application is then either approved straightaway, or, depending on the product and the details furnished by the manufacturer, sent for scrutiny before one of the "scientific panels" of FSSAI.

These panels are supposed to conduct a "risk assessment" of the product. In this assessment, the panel may call for a laboratory test, but that is neither mandatory nor the usual practice.

"What I keep hearing from the industry is that at the government-identified labs or regulators' labs, there is no equipment available and even if equipment is available, people are not trained (in their use)," adds Gokhale.

Whether or not a product should be approved for sale and consumption is based almost entirely on scientific analysis provided by the manufacturers themselves, and not on that done by FSSAI.

Gokhale adds that the problem does not end with testing (or the lack of it). For instance, even if a product is tested at the time of approval, that itself is no guarantee that the next batch of the same product will be of the same quality.

She notes that in the case of drugs and cosmetics, the law mandates that each batch of pharmaceutical product be tested before coming into the market. One needs to examine what could be the best method of ensuring consistent quality of food products. "And if a batch is found to be in non-compliance with FSSAI standards, a robust recall mechanism needs to be established, given the vastness of our country," she says.

Other licences, such as domestic manufacturing licences that need to be renewed and reviewed every one to five years also impose certain requirements on food makers, focusing on manufacturing processes, machinery, manuals and procedures. Companies that want to export food ingredients to other countries may also have to comply with global regulations, and require certification by independent standards bodies.

Even the "peeling of paint on the walls" was considered non-compliant during one such audit, explains Gokhale, but all those tests are also often insufficient to pinpoint every possible problem of adulteration because they focus on manufacturing processes and procedures.

Lab rats

The law does provide for random inspections and raids where samples can be seized (or acquired), and sent for lab testing (as was done with Maggi noodles in more than 20 states recently).

"Often the government regulators work on tips," explains Gokhale, noting that often disgruntled employees or competitors are suspected as the source.

If any irregularities are found, the penalties (mostly in the form of fines and recalls) can be steep. The idea is that the fear of being caught automatically ensures compliance with food safety regulations, but the system is not foolproof. And even where testing is done, there is no way to be completely sure.

According to Vivek Kathpalia, a Singapore-based partner with Nishith Desai Associates, who has researched food laws, the real question is not about the frequency of lab tests, but the standards themselves. "We need to take a look at the standards laid down by the Food Safety and Standards Act regarding quality of food in India and see whether they are up to international standards or not," he says.

Enforcement issues

Another major issue is that FSSAI virtually has no enforcement mechanism to speak of. Not only does it have no way of ensuring that projects rejected by it are properly recalled, it also doesn't have any way of ensuring that products never approved by it do not get to the market in the first place.

For instance, on 8 June, FSSAI sent a notice to the commissioners of food safety of all states, with a list of 33 food products under the category of "noodles, pastas and macaroni with tastemaker" which had been approved by it.

It asked the commissioners to take samples of all these products for lab testing in view of the contaminants allegedly found in Maggi noodles. As for any products which were not on the list, the notice said such products are "unauthorized and illegal and cannot be intended for human consumption..." and the state regulators were "advised to ensure that such products are recalled, removed from the market and destroyed".

That's easier said than done, and while it has prompted Hindustan Unilever to recall its **Knorr** noodles—which have never been approved by FSSAI—from the market, it highlights the fact that companies were not only openly selling unapproved food products, but were also carrying out massive advertising campaigns for them without the food regulator taking any action.

While delayed product approvals are a major issue in the industry, as discussed above, this does not seem to be the case here as Hindustan Unilever had applied for approval of Knorr instant noodles only in February 2015, according to its official press release.

Indeed, it would appear to be common practice to apply (for approval) and simultaneously launch the product. Or maybe even launch the product ahead of applying for approval.

A product recall in a market as large as India is almost impossible in practice. "If you'd ask me to recall (a brand of) biscuits tomorrow, how would you be able to? Can you even reach some parts of India to even recall those items?" asks Gokhale, doubting that an effective machinery and system exists.

Food regulation is not completely novel—milk adulteration probes by FSSAI have been common for years now—but the rise in regulatory activity in the food sector is novel. "If you just see the last couple of years, the Maharashtra FDA on the drugs and cosmetics side has been extremely active," recounts Gokhale. "That was more on the drugs and cosmetics side—now is the time of food."

One concern regarding FSSAI's new-found enthusiasm in the food space is the risk of over-regulation, she fears. "The crisis happens one time but the regulation happens thereafter—we need to figure out (how) to strike the right balance."

Once a brand is found to have violated food safety procedures by FSSAI, there's not much recourse available.

The FSSAI appeal procedure is entirely internal and departmental and not very effective, Gokhale says, and even a legal challenge via a writ petition, such as that attempted by Nestle in the Bombay high court, is usually too slow to be effective except in rare cases, because courts are often extra-cautious in questions affecting public health and safety.

But such instances of brands being pulled up are still (despite the increased activism on the regulator's part) few and far between. The real

story is of a market that has mostly escaped heavy regulation from a regulator that has traditionally lacked the resources and know-how to effectively safeguard public health and standards.

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