

**Dated, the 5<sup>th</sup> June, 2015**

## **Order**

**Subject: M/S Nestle India Limited's "Maggi Instant Noodles with Tastemaker" and any other food products covered under Section 22 which have not been examined for risk/safety assessment – regarding.**

M/S Nestle India Ltd. is aware of the currently on-going nation-wide concerns regarding the safety of its food products cited under the above subject. Pursuant to the sampling and testing of the said product by the establishment of the office of Commissioner of Food Safety, Uttar Pradesh and recognising the serious food safety concerns arising there from, the FSSAI had advised the Commissioners of Food Safety in various states to draw samples of the said Products and get the same tested from authorised laboratories.

2. Three major violations have been noted qua the subject cited products as of now, viz. (a) presence of Lead detected in the product in excess of the maximum permissible levels of 2.5 ppm, (b) misleading labelling information on the package reading "No added MSG", and (c) release of a non-standardised food product in the market, viz. **"Maggi Oats Masala Noodles with Tastemaker"** without risk assessment and grant of product approval.

3. The Company representatives were given a hearing at 1.00 pm on 04.06.2015 by the Chairman, FSSAI and the undersigned at the office of the Food Authority with a view to seek their response in the matter and also to know as to what steps the Company had taken in terms of compliance of its obligations under Section 26 of the FSS Act, 2006. Mr. Paul Bulcke, global CEO of the Company, Mr. Etienne Benet, MD & CEO, Nestle (India), Mr. Sanjay Khajuria were present along with two more company officials. The Company representatives stated that they were committed to providing safe food for the consumers and that the whole controversy had been created on account of confusions created and lack of proper understanding of the issue. The Company's response on each of the above issues was as follows:

(a) The Company asserted that the testing protocols had not been followed and interpreted correctly. According to them:

- (i) the Product contained two parts i.e. the Noodle and the Tastemaker. The samples had been tested for each of the two components separately whereas it should have been tested as a combined end product, i.e. the form in which it is finally consumed;
  - (ii) The CFL Kolkata had also tested the product as a combined product but the results showed a very high level of Lead because the samples remained open for a considerable period before being tested;
- (b) The “No added MSG” on the label was on account of lack of clarity in the regulation and that the Company had followed the practice generally followed by the industry in this behalf. However, they were quick to add that the Company would rectify the labels if it was interpreted as a case of mislabelling. They added that the Company had already ordered printing of new labels without mentioning “No added MSG” thereon and that their products would be packed in the re-printed packets after the current stock was exhausted. However, the Company also finally agreed to pack all freshly manufactured food in the new packaging.
- (c) As regards the issue of release of one of the variants, viz. **“Maggi Oats Masala Noodles with Tastemaker”** in the market without getting the product assessed for its risk/ safety and grant of product approval, the Company representative stated that this product had been launched at a time when the Advisory dated 11.05.2013 was under stay granted by the Court. The attention of the Company representatives was drawn to the provisions contained in Section 22 under which the food product as a ‘Proprietary Food’ was not at all allowed to be manufactured and placed in the market, the Company representatives stated they would comply with the directions of the Food Authority in this behalf.

4. Having heard the Company representatives on each of the issues, the observations of the Authority with regard to these issues are as under:

**A. Presence of Lead in excess of the permissible safety limits:**

A.1 The sample taken by the establishment of the Commissioner of Food Safety, UP and tested by the CFL, Kolkata found presence of lead at 17.2 ppm. The test results received from the GNCT, Delhi in respect of 13 samples drawn from different batches indicate the presence of Lead in excess of the maximum permissible level of 2.5 ppm in case of 10 out of the 13 samples tested (one of them being the product for which approval had not been taken). Similarly, a total of 40 samples are reported to have been drawn including the noodles of other brands. Having received the Test Reports in respect of 29 samples by last evening and found the presence of Lead in excess of the prescribed limits in 15 samples, the State of Gujarat has already issued a recall order. Further, the results of Test samples drawn and tested in

the state of Tamil Nadu also confirm the presence of Lead in excess of the permissible limits, including in the Noodles of some other manufacturing companies. It is clear from the reports received from various states that there is overwhelming evidence of the said food products being unsafe and hazardous for human consumption. The maximum permissible level of Lead is 2.5 ppm as stated by the Company in its application dated 04.12.2012 submitted for the Product Approval for '**Instant Noodles with Tastemaker**', of which Masala is one of the variants applied for. As per the Certificate of Analysis furnished by the Company with its application, the Lead was 0.0153 ppm vide report dated 17.10.2012.

A.2 The arguments advanced by the Company as recorded under para 3(a) above have not been found tenable on the following grounds:

- (i) The company manufactures the Noodles and the Tastemaker and markets the same in two separate packages (Tastemaker or Masala is always in a separate sachet placed inside the main packet). The prescribed Standards have to be applied in respect of each of these two components independently and have no linkage with the processing of the end product as it is consumed. Water is added to the preparation of the product before it is consumed and depending upon the source, water may also contain contaminants like lead, for which the Company may not be liable. Therefore, the final process of preparation has no linkage with the manufactured product as placed in the market and the compliance of standards has to be tested for each of two items;
- (ii) It has been ascertained from CFL Kolkata that the sample was tested separately for the Noodle and the Tastemaker and it is wrong to say that the sample remained in open condition for about two months.

A.3 Detection of Lead in a food product as a Heavy Metal contaminant beyond permissible levels renders the food product unsafe and hazardous. Reference is made to a document published by the Food Safety Authority of Ireland on "Mercury, Lead, Cadmium, Tin and Arsenic in Food" (Issue No.1, May 2009 in its Toxicology Factsheet Series) which succinctly brings out the adverse toxic effects of lead as under:

"Short-term exposure to high levels of lead can cause brain damage, paralysis, (lead palsy), anaemia and gastrointestinal symptoms. Long-term exposure can cause damage to the kidneys, reproductive and immune systems in addition to effects on the nervous system. The most critical effect of low-level lead exposure is on intellectual development in young children and like mercury, lead crosses the placental barrier and accumulates in the foetus. Infants and young children are more vulnerable than adults to the toxic effects of Lead, and they also absorb

lead more easily. Even short-term low-level exposure of young children to lead is considered to have an effect on neurobehavioural development. Consumption of food containing lead is the major source of exposure for the general population.”

- A.4 It is established from numerous scientific studies that presence of heavy metal (Lead in this case) as a contaminant beyond the permissible limits is a serious health hazard and cannot be allowed in any product in the market.

**B. Violation of labelling related Regulations:**

- B.1 It has been noted with concern that the label of the said product specifically mentions thereon “No Added MSG” whereas the product is found to be containing Mono Sodium Glutamate (MSG). The Company has stated vide its letter dated 2<sup>nd</sup> June, 2015 that its claim is regarding “Added MSG” which is a correct position since the Company has not added any MSG (E621). It has further stated that *“it is a known fact that it is not possible to distinguish between naturally occurring glutamate and added glutamate in foods”*. The Company’s aforesaid letter further reads *“We have been declaring “No Added MSG” on Maggie Noodle Packs as we do not add MSG (flavour enhancer- E621) as an additive in the product. This is a common practice across the industry in many food products viz. instant noodles, ready to eat foods, soups etc.”* Drawing support from the legal opinion taken from Mr. Justice V.N. Khare, former Chief Justice of India, it has been further stated that *“the declaration of “No Added MSG” on the labels of Maggie Noodles does not violate the Food Safety Standards Act, its rules and its regulations thereunder”*.

- B.2 The assertions made by the Company in its aforesaid letter dated 02.06.2015 have not been found acceptable. Attention in this behalf is invited to Regulation 2.2.1:1, which reads as under:

- “1. Every pre-packaged food shall carry a label containing information as required hereunder unless otherwise provided, namely, ---
3. Pre-packaged food shall not be described or presented on any label or in any labelling manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect;”

- B.3 It is amply clear that this sub-regulation prohibits any other information on the label other than what is otherwise provided for in the FSSR. It defies the common understanding as to why the Company has to make this assertion when it is not required to do so. The apparent reason for using such information on the label is driven by an undue commercial advantage/benefit to create an erroneous impression in the minds of consumers regarding the character of the product.

- B.4 As a matter of fact, the USFDA has placed a document titled '**Questions and Answers on Monosodium glutamate (MSG)**' on its website. The question framed in this behalf and the response thereto are reproduced below, being relevant and contextual:

**“How Can I know if there is MSG in my food?”**

FDA requires that foods containing added MSG listed in the ingredient panel on the packaging as monosodium glutamate. However, MSG occurs naturally in ingredients such as hydrolyzed vegetable protein, autolyzed yeast, hydrolysed yeast, yeast extract, soya extracts, and protein isolate, as well as in tomatoes and cheeses. While FDA requires that these products be listed on the ingredient panel, the agency does not require the label to also specify that they naturally contain MSG. **However, foods with any ingredient that naturally contains MSG cannot claim “No MSG” or “No Added MSG” on their packaging.** MSG also cannot be listed as “Spices and flavouring.”

- B.5 It is clearly established from the aforesaid that printing “No added MSG” on the label of the said Product is in violation of the FSS (Packaging & Labelling) Regulations, 2011.

**C. “Maggie Oats Masala Noodles with Tastemaker”:**

- C.1 M/s Nestle India Private Limited is aware that the said products, being proprietary food in nature, being non-standardised, are covered under Section 22 of the FSS Act, 2006 and require risk/ safety assessment and approval before these are manufactured and placed in the market. The Company has applied for ‘Product Approval’ in respect of product titled **“Maggie Oats Masala Noodles with Tastemaker”** vide its application dated 27.08.2014. Certain clarifications were sought from the Company for Safety/ Risk assessment in respect of the said product vide FSSAI communication dated 25.02.2015. The Company did not respond to the clarifications within the prescribed time, and as such the application already stands ordered to be closed being non-responsive.
- C.2 What is disturbing to note is that the Company had already released the said product in the market without completing the process of risk assessment and has been promoting its sales. The argument that this product was launched when the Advisory dated 11.05.2013 was under stay holds no ground in the face of legal provisions. This is illegal and a serious violation of the FSS Act, Rules and Regulations thereunder. In the absence of safety/risk assessment and grant of Product Approval of a food product covered under Section 22 of the FSS Act, the Company has acted in violation of law. As such, the product cannot be allowed to be intended for human consumption and has to be withdrawn from the market forthwith.

5. From the aforesaid, it is evident that the Company has also failed to comply with its obligations laid down under Section 26 of the Act (reproduced as Annex-1). Further, the Company has violated the FSS Act, Rules and Regulations thereunder and rendered itself liable to prosecution under Sections 20, 22, 23, Section 24 read with Section 53, Section 26, 27, 48, 50, 52, 58 and Section 59 of the FSS Act, 2006, read with the applicable Rules and Regulations thereunder.

6. In the meantime, the Commissioners of Food Safety of various states, viz. the U.P., GNCT of Delhi, Gujarat, Tamil Nadu, J&K, Assam and a few others are reported to have passed orders prohibiting the said products for varying periods within their respective jurisdictions.

7. Keeping the aforesaid in view, without prejudice to the rights of the respective Commissioners of Food Safety and the Food Safety establishments of various States and Union Territories and the consumers to file prosecutions against the Company for various violations, and in exercise of powers vested in the Food Authority under Section 16(1) of the FSS Act, read with the general principles enshrined under clauses (a), (b), (c) (f), and (g) of Sub-section (1) of Section 18, further read with the provisions contained in Sections 26 and 28 and the powers vested in me under Section 10(5) read with Section 29 of the FSS Act, 2006, the Company is hereby directed to:

- (i) Withdraw and recall all the 09 approved variants of its Maggi Instant Noodles from the market having been found unsafe and hazardous for human consumption, and stop further production, processing, import, distribution and sale of the said product with immediate effect;
- (ii) As already agreed by the Company during the hearing in respect of the rectification of label and removal of "No added MSG", the Company is directed to comply with the related labelling regulations in this behalf forthwith;
- (iii) Withdraw and recall the food product, "**Maggie Oats Masala Noodles with Tastemaker**" for which risk/ safety assessment has not been undertaken and Product Approval has not been granted.
- (iv) In case any other food product falling under Section 22 of the Act is being manufactured and marketed by the Company, for which risk assessment has not been undertaken by way of grant of Product Approval/ NoC by the FSSAI, the same be withdrawn from the market with immediate effect and the FSSAI be informed about such products within 24 hours of the receipt of this communication, and
- (v) Take appropriate action to re-ascertain the safety of its products in compliance of the obligations cast upon the Company in terms of provisions contained in Section 26 of the Act under intimation to the FSSAI.

8. M/s Nestle India Private Limited is further called upon to show cause within a period of 15 days from the date of issue of this communication as to why the Product Approval granted by FSSAI in respect of “**Instant Noodles with Tastemaker - (9 variants)**” vide its letter dated 04.07.2013 be not withdrawn.

9. The Company is further directed to submit a compliance report in this behalf within a period of three days and furnish progress reports on the recall process on a daily basis thereafter till the process is completed.

Sd/-  
Y.S. Malik  
Chief Executive Officer, FSSAI

To

M/s Nestle India Limited,  
Nestle House, Jacaranda Marg,  
M-Block, DLF City, Phase-II,  
Gurgaon -122002-05,  
Haryana

**Copies to:**

1. PS to Chairperson, FSSAI for the kind information of Chairperson, FSSAI;
2. All Commissioners of Food Safety of various States/ UTs for necessary action at their end;
3. Department of Consumer Affairs (Additional Secretary) for their kind information and necessary action at their end;
4. Dr. Sandhya Kabra, Director Q.A./P.A., FSSAI, for further necessary action;
5. IT Section of the FSSAI for publication on the website for general information of the consumers and all the FBOs involved in the marketing of the said products.

## Section 26 of the FSS Act, 2006

26. Responsibilities of the Food business operator.
- (1) Every food business operator shall ensure that the articles of food satisfy the requirements of this Act and the rules and regulations made thereunder at all stages of production, processing, import, distribution and sale within the businesses under his control.
- (2) No food business operator shall himself or by any person on his behalf manufacture, store, sell or distribute any article of food –
- (i) which is unsafe; or
  - (ii) which is misbranded or sub-standard or contains extraneous matter; or
  - (iii) for which a license is required, except in accordance with the conditions of the license; or
  - (iv) which is for the time being prohibited by the Food Authority or the Central Government or the State Government in the interest of public health; or
  - (v) in contravention of any other provision of this Act or of any rule or regulation made thereunder.
- (3) No food business operator shall employ any person who is suffering from infectious, contagious or loathsome disease.
- (4) No food business operator shall sell or offer for sale any article of food to any vendor unless he also gives a guarantee in writing in the form specified by regulations about the nature and quality of such article to the vendor:
- Provided that a bill, cash memo, or invoice in respect of the sale of any article of food given by a food business operator to the vendor shall be deemed to be a guarantee under this section, even if a guarantee in the specified form is not included in the bill, cash memo or invoice.
- (5) Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, **it shall be presumed that all the food in that batch, lot or consignment is also unsafe**, unless following a detailed assessment within a specified time, it is found that there is no evidence that the rest of the batch, lot or consignment is unsafe:
- Provided that any conformity of a food with specific provisions applicable to that food shall be without prejudice to the competent authorities taking appropriate measures to impose restrictions on that food being placed on the market or to require its withdrawal from the market for the reasons to be recorded in writing where such authorities suspect that, despite the conformity, the food is unsafe.

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