

Issues and Interpretations

Case laws dealing with labeling and
Nestle vs FSSAI

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COMPLIANCE

REGULATIONS

GUIDELINES

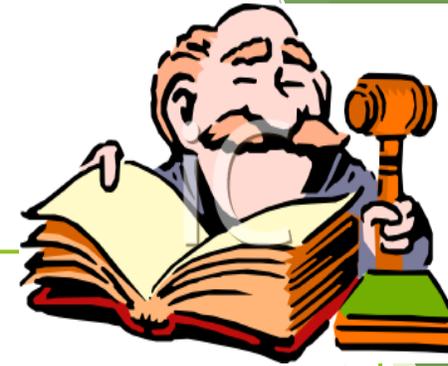


Process of Legislating



- Laws are framed for orderly conduct of the society, people and business
- Each of the three arms of the Government viz. Legislature, Judiciary and Executive have a role to play.
 - **Legislature-** Responsible for framing the Laws (Acts & Rules); to be passed by both houses of Parliament and approved by the president.
 - **Executive-** Responsible for framing Regulations and effective implementation.
 - **Judiciary-** interprets and decides on the applicability or otherwise of a legislation in a particular situation.

Process of enacting a legislation



- Parliament enacts the Act based on the societal needs

- Act- Lays down the broad frame work of the objective, constitution and responsibilities of the Authority to administer the Act and the scope of the Rules and Regulations through which the objective will be achieved.

- Rules and Regulations- lay down detailed compliance procedures and the do's and don'ts
- Act and Rules are drafted by the Government.
- Regulations are framed by the Authority set up for administering the Act

The Act, Rules and Regulations- all need to be placed before and approved by the Parliament.

Is “may” equivalent to “shall” or is it the other way?

In legal parlance “may” is a choice to act or not, or a promise of a possibility, as distinguished from “shall,” which makes it imperative. In statutes, and sometimes in contracts, the word “may” must be read in context to determine if it means an act is optional or mandatory, for it may be an imperative. Non-lawyers tend to see the word “may” and think they have a choice or are excused from complying with some statutory provision or regulation. .

- Whenever a statute directs the doing of a thing for the sake of justice or the public good, the word may is the same as shall. Shall means “an imperative command as in “you shall not kill.”
- The words shall and may in general acts of the legislature or in private constitutions, are to be construed imperatively; but the construction of those words in a deed depends on circumstances.

In some statutes, “shall” is a direction but does not mean mandatory, depending on the context.

Nearly every jurisdiction has held that the word “shall” is confusing because it can also mean “may, will or must.” Legal reference books like the *Federal Rules of Civil Procedure* no longer use the word “shall.” Even the Supreme Court (of USA) ruled that when the word “shall” appears in statutes, it means “may.” (from Federal Aviation Administration, USA).

Similarly we have provisions of sections starting with “ means”, “includes” etc.. While means is definitive ., includes is “not exhaustive”.



Construction of Provisions in the Act, Rules and Regulations

Section 22 of the Food Safety and Standards Act 2006

“Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf.”

So “only through the Act or regulation” can FSSAI permit manufacture / distribute / sale of above categories of foods;

.....

“**proprietary and novel food**” means an article of food for which standards have not not been specified but is not unsafe:

Provided that such food does not contain any of the foods and ingredients prohibited under this Act and regulations made thereunder”.

- if the food is not unsafe, then why should they require Govt. permission??
- ”does not contain”- should this has been worded as “shall not contain”



Construction of Act, Rules etc....

“2.12.1: For the purpose of these regulations, -

1) **Proprietary food means** an article of food that has not been standardized under these regulations, but does not include any novel food, food for special dietary use, functional food, nutraceutical, health supplement and such other articles of food which the Central Government may notify in this behalf;

2) Proprietary food shall contain only those ingredients other than additives which are either standardised in these Regulations or permitted for use in the preparation of other standardised food under these Regulations.

3) Proprietary food shall use only such additives as specified for the Category to which the food belongs and such category shall be clearly mentioned on the label along with its name, nature and composition.

4) Proprietary food product shall comply with the food additives provisions as prescribed in Appendix A and the microbiological specifications as prescribed in Appendix B of these Regulations and all other Regulations made under this Act.

5) The Food Business Operator shall be fully responsible for the safety of the proprietary food;

Questions-

- a. Cl.(1) Is there a proposal to further categorize (“junk food”)
- b. Cl.(2)- here the “combinatorial” argument has been dropped.
- c. Cl(33) Do we need to mention on the label the name, nature and composition of the Proprietary Food OR the name.... Of the Category (to which it belongs to)?
- d. Cl.5) Would anyone else be responsible? Who would be the FBO here- mfg./ brand owner / retailer?



Legal Metrology.. Legal construction



“Nominee “ responsible for complince of Legal Metrology

49. (1) Where an offence under this Act has been committed by a company,-- (a) (i) the person, if any, who has been nominated under sub-section (2) to be in charge of, and responsible to, the company for the conduct of the business of the company (hereinafter in this section referred to as a person responsible); or

.....

(2) Any company may, by order in writing, authorise any of its directors to exercise all such powers and take all such steps as may be necessary or expedient to prevent the commission by the company of any offence under this Act and may give notice to the Director* or the concerned Controller or any legal metrology officer authorised in this behalf by such Controller (hereinafter in this section referred to as the authorised officer) in such form and in such manner as may be prescribed, that it has nominated such director as the person responsible, alongwith the written consent of such director for being so nominated. ,

Explanation.-Where a company has different establishments or branches or different, units in any establishment or branch, different persons may be nominated under this subsection in relation to different establishments or branches or units and the person nominated in relation to any establishment, branch or unit shall be deemed to be the person responsible in respect of such establishment, branch 01: unit.

Who is the “Director” here? Who in a company having only a single location business, is responsible?

Delhi High Court, Divn. Bench) April 2015

Union of India - FSSAI vs Danisco India Pvt. Ltd & United Distributors Inc.

- Is “food additive” a food?
- Does the (Packaging and Labeling) Regulation issued under section 23 apply to Food additives?
- Who is the business operator in respect of imported food?
- Whose responsibility it is to label imported food? Can one make mfg. of imported food to label as per Indian laws?
- How much of Vegetable fat permitted in chocolate fillings instead of coca butter?
- Does the permission given earlier to M/s. Mars and M/s. Ferrero be a ground for similar relaxation?

"(j) "food" means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food, or.....food containing such ingredients,....., and includes any substance, including water used into the food during its manufacture, preparation or treatment but does not include

(k) "food additive" means any substance not normally consumed as a food by itself or used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing.....

Food additives a food or not?

So are food additives a food or not?

“Thus, a substance which is not normally consumed as a food by itself or used as a typical ingredient of a food and which may be a food additive, cannot be a food as only those substances which are intended for human consumption can be food. Merely because a food additive may fall within the expression "...and includes any substance.....used into the food during its manufacture, preparation or treatment" within the inclusive part of the definition of food will not make a food additive food because a food additive fails to satisfy the crucial part of the definition of food i.e. "intended for human consumption". Similarly, because a food additive is added for technological purpose in the manufacture, processing, packaging etc. of food and becomes a component of or affects the characteristics of such food would also not make it a food because a food additive by itself is normally not consumed as a food.

Is the labeling Regulations for Food applicable to food additives as well?

It is not as if the appellant authority is prohibited from making any other Regulations qua food additives as the one with which we are concerned, in the present case, if the need to provide any other restriction / limit, with respect to the same is felt. As aforesaid, Section 16 of the FSS Act vests wide powers in the appellant authority to make Regulations to ensure safe and wholesome food.

If the appellant authority feels that to ensure safe and wholesome food, any Regulations qua packaging and labeling of food additives are also required to be made, the appellant authority under [Section 16](#) read with [Section 92\(2\)\(e\)](#) would be entitled to do so. Not only so, [Section 19](#) read with [Section 92\(2\)\(h\)](#) also enables the appellant authority to make Regulations qua additives to be used in the manufacturing of food. However the appellant authority cannot be permitted to apply to food additives, Packaging and Labeling Regulations made under [Section 23](#)--for food, and application whereof to food additives would lead to ridiculous results.

Labeling a Food Product

(z) “label” means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, graphic, perforated, stamped or impressed on or attached to container, cover, lid or crown of any food package and includes a product insert; (as per FSS Act, 2006)

(j) "label" means any written, marked, stamped, printed or graphic matter affixed to, or appearing upon any pre-packaged commodity; (per Legal Metrology)

➤ Label shall be applied in such a manner that they will not become separated from the container;

➤ Contents on the label shall be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use;

➤ It shall not be permissible to affix individual stickers on the package for altering or making declaration required under these rules:

➤ Where a package is provided with an outside container or wrapper such container or wrapper shall also contain all the declarations which are required to appear on the package except where such container or wrapper itself is transparent and the declarations on the package itself are easily readable through such outside wrapper.

Provided that no such declarations on the inner package is required if the inner package does not contain any declaration on its outer cover.



Bickering over Labeling Vs “stickering”

- Large consignments Lindt chocolates were lying in government warehouses - reason not in conformity with labeling requirements of (FSSAI).
- In the case of **UNITED DISTRIBUTORS INCORPORATION VS UNION OF INDIA & ANR.**, FSSAI did not draw samples/ issue and NOC - reason not in compliance with (Packaging and Labeling) Regulations, 2011.
- Petitioner contended that not mentioning 'Date of Manufacture' on the label was curable in view of the instruction issued by FSSAI on 15.12.2011 and was ready before release of goods from the custom, to affix non-detachable stickers.
- It was submitted that stickers were not prohibited under the Labeling Regulations and stickers would fall within the meaning of 'label' as defined under [Section 3\(1\)\(z\)](#) of the Act.



The verdict

- Whether sticking a label is same as affixing a label directly on the container?
- As defined in [Section 3\(1\)\(z\)](#) of the Act, it is not necessary that a label be printed directly on the cover, wrapper of the container but can also be attached as a sticker, provided that the sticker conforms to Regulation 2.2.1:4 of the Labeling Regulations. In other words, the sticker should be “ applied in such a manner that they will not become separated from the container”.

The Court stated that -

“While, it is mandatory that the goods are labeled in a manner as specified by the Labeling Regulations, the purpose of providing labels should not be lost sight of. The object of labeling the packaged products is to ensure that relevant information regarding the product is available on the package for the benefit of the consumers.

Such information includes the name of the food item, the ingredients, the date of manufacture, expiry date, best before use date, the name of the manufacture, the name of the importer as well as the nature of the product i.e. whether it is a meat or a vegetable product. Since the idea is to ensure that the consumer is duly informed of the product being purchased/consumed by him, **a non-detachable sticker providing all information would sufficiently meet this object.**”



But the Calcutta and Madras High Courts have taken a different view

Division Bench of the Calcutta High Court in the case of **FSSAI vs., Heartland Trading Company Pvt Ltd.**, (supra), "the purpose of labelling is not to be ascertained by any one for diluting the rigours of the regulations and importing the concept of substantial compliance therewith and strict compliance principle seems to be the requirements of the regulations dictated by public interest that must prevail over any private interest of an importer. The rectification of the labelling deficiencies is not permissible under any law and cannot be ordered by the High Court in exercise of the power under Article 226 and illegal grant of NOC to any other importer for the same articles of food cannot entitle a subsequent importer to seek NOC, as an order for perpetuation of an illegality cannot be passed by the High Court under Article 226 of the Constitution of India.

- In **M/s. Gandour India Food Processing Pvt., Ltd., vs Union Of India** on 25 March, 2015 - Madras High Court

Accordingly in the matter of M/s Foodlever and another the importers were asked to reexport the goods after completing necessary customs formalities.

Per FSSAI stickers / rectification of deficiencies is permitted only for adding importers name and address, veg / non veg logo and the FSSAI logo.



Nestle vs FSSAI, FDA Maharashtra and CEO, FSSAI.

- Maggi, a Nestle product was inspected by the FSSAI, and faced legal consequences for high levels of monosodium glutamate (“MSG”) and lead in the noodles. Maharashtra FDA and FSSAI based on reports from various analytical lab on a complaint from a Food Safety Officer asked Nestle to stop selling different variants of Maggi noodles forth with and also stop producing oats noodles for which Product Approval was not yet granted. Nestle filed a writ petition before the Bombay High court
- The issues before the court were -
 - A. Should Nestle’s writ petition be admitted under Article 226?
 - B. Did Nestle suppressed any information on receipt of lab reports?
 - C. Did Nestle destroy Maggi noodles to suppress evidence?
 - E. what should be the permissible minimum of lead - one as prescribed by law or one as claimed by Nestle in its Product Approval application?
 - F. does the FSSAI have unfettered right to prescribe limits for additives / contaminants etc. irrespective of what is stated in the Regulations?
 - G. Does section 22 enforce a complete ban on proprietary foods without prior permission of FSSAI?
 - H. Under which exact section was the ban imposed by FSSAI and FDA Maharashtra?
 - “Emergency prohibition notice”),sec.34



What is Public Interest? What extent Transparency is relevant?

In this context it is important to emphasize that the absence of arbitrary power is the first essential of the rule of law upon which our whole constitutional system is based. In a system governed by rule of law, discretion, when conferred upon executive authorities, must be confined within clearly defined limits. The rule of law from this point of view means that decisions should be made by the application of known principles and rules and, in general, such decisions should be predictable and the citizen should know where he is. If a decision is taken without any principle or without any rule it is unpredictable and such a decision is the antithesis of a decision taken in accordance with the Rule of law. (Equality and arbitrariness were thus, declared "sworn enemies" and it was held that an arbitrary act would fall foul of the right to equality. Non-arbitrariness was equated with the rule of law about. Though Respondents have been shouting from roof top that their action was in public interest as they found that the food which was contaminated by lead beyond permissible limit was unsafe for human consumption, they promptly swung into action and banned the product. **The said tall claim has not been substantiated by them before us.**

Merely stating that the food was unsafe or that the action was in public interest is not sufficient as is observed by the Apex Court in Godawat Pan Masala Products I.P. Ltd vs. Union of India and Others¹. The Apex Court in the said case has observed in para 61, 68 and 77.5 as under:-

"61. We are unable to accept that the words "in the interest of public health" used in Clause (iv) of Section 7 of the Act can operate as an incantation or mantra to get over all the constitutional difficulties posited. In any event, the collocation of the words in the statutory scheme suggests not a matter of policy, but a matter of implementation of policy. For this reason also, we are of the view that the impugned notification must fail."

audi alteram partem (accused should be given opportunity of being heard) . From the conspectus of these cases, it can be seen that there is no straight-jacket formula which can be used in each and every case to decide a question as to whether the affected party has to be given hearing or not and that would depend upon facts and circumstances of each case.

Arbitrariness and for Extraneous reasons

In his written arguments, (counsel for the CEO, FSSAI) has given various links in which similar allegations have been made against the Petitioner. We do not wish to say anything about correctness or otherwise of the said allegations since no opportunity was given to the Petitioner to refute the same but the fact remains that from the said submissions which are made by the learned Counsel for Respondent No.2, it appears that Respondent No.2 is also influenced by extraneous considerations such as the material which has been placed before us which is not reflected in the reasons which are given in the impugned order. The order at Exhibit-A therefore will have to be quashed on this ground also.

106. For the same reasons the order passed by Respondent No.4 which is at Exhibit-B also will have to be held to be arbitrary and capricious and violative of [Article 14](#) and [19](#) of the Constitution of India.

107. What is most shocking is that though the samples of only three variants of the Maggi Noodles were taken all 9 variants of Maggi Noodles have been banned. Remaining six therefore have been banned only because lead was alleged to be found in excess of the permissible limit in other three and even without testing the said six Maggi variants, the order of ban has been imposed. This is one other incident of highhandedness and arbitrariness and there was no plausible explanation given in the impugned orders or even before us for such an action.



Section 22- prior approval for non-standardized products

We find that in number of cases which have come before us, this is a standard argument which has been advanced on behalf of the Food Authority, though we find that in support of the orders which are passed banning any food article or restraining the manufacturer from importing consignment after it has reached the customs warehouse, some other reason is given for not clearing the goods.

However, in the Court reliance is placed on [section 22](#) and this is the argument which is sought to be advanced in support of the action of the Food Authority. In our view, there is something fundamentally wrong in the approach of the Food Authority and in the interpretation which is sought to be given by it to several provisions of the Act, including [section 22](#) of the Act.

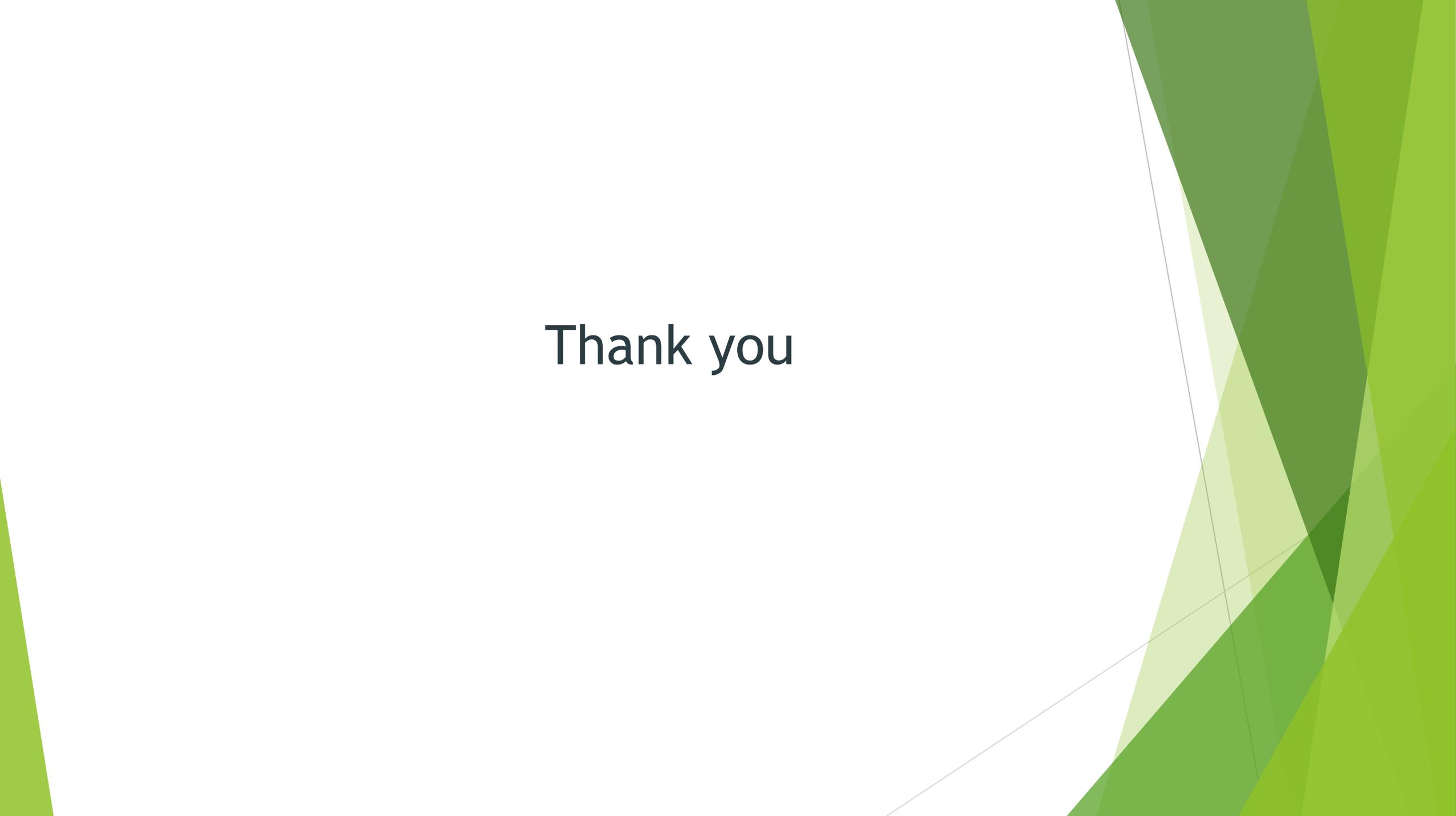


The verdict

- A. Since the ban preceded the show cause notice Nestle is well within its rights to file the writ.
- B. There was no suppression by Nestle. In fact the Counsel for FSSAI was misled by FSSAI
- C. Destruction of Noodles by nestle was not to suppress evidence. it was as agreed with FSSAI
- D. The court was astonished, surprised and found it fallacious with the argument of FSSAI counsel who contended that limits prescribed in Regulation for additives , contaminants etc. do not apply to Proprietary Food and that FSSAI has unfettered right to prescribe any limit;
- E. Prohibition of any food by virtue of the Act cannot be imposed by administrative advisories.
- The answer to Issue No(VII) is that the source of power under which the impugned orders were passed is traceable to either section 30 or section 34 of the Act and, in any case, the impugned orders could not have been passed under sections 10(5), 16(1), 16(5), 18, 22, 26, 28 and 29 of the Act. Issue No. (VII) therefore is answered accordingly.



Thank you

The background features abstract, overlapping geometric shapes in various shades of green, ranging from light lime to dark forest green. These shapes are primarily located on the right side of the frame, creating a modern, layered effect against the white background.