Draft Notification regarding Food Safety and Standards (Labelling & Display) Amendment Regulations, 2022 related to Front of Pack Nutritional Labelling (FOPNL) and High fat, sugar, salt (HFSS) etc.

Sr. No.	Name and Address of the organisation/ person, contact number and E-mail	Relevant section in the draft notification on which comments are being provided	Comments/ suggestion	Rationale	Remarks
1.	Nutrition Advocacy in Public Interest – India (NAPi)/ 011-42683059 napiindia.in@g mail.com	Food Safety and Standards (Labelling & Display) Amendment Regulations, 2022. Section 2 and 14(1)	Keeping public health at the center stage , FSSAI may like to reconsider the decision taken on 15.02.2022. Warning labels as an option for FoPNL may be considered.	The issue concerns people's health at large. All persons living in India will be affected by the regulation. We should, therefore, move towards an objective that the regulation helps in curtailing consumption of unhealthy food products and make use of the front-of-pack labelling to reduce the obesogenic environment and promote healthy diets. This should be based on scientific evidence. List of <b>substantiating evidence/studies</b> in favour of 'Warning Label' is available on this link https://www.bpni.org/wp- content/uploads/2022/03/EVIDENCE-OF-FOPL.pdf <b>In addition to the global evidence</b> , here is a peer reviewed randomised control trial published in July 2022. The study is titled "Front-of-Package Labels on Unhealthy Packaged Foods in India: Evidence from a Randomized Field Experiment" https://www.mdpi.com/2072- <u>6643/14/15/3128</u> Nutrients <b>2022</b> , <i>14</i> (15), 3128; <u>https://doi.org/10.3390/nu14153128</u> ). Findings of this study make a compelling case for Warning Labels. 1. Relative to the control group, each FOPL led to an	FSSAI, Government of India has already identified the definition of HFSS –foods high in fat, sugar and salt in <b>Section 2.(ib)</b> and the "food risk factors" in the Table-1 of the draft regulation. <b>This is the</b> <b>opportunity</b> to inform all the persons likely to be affected, know which food products are "high in" and what is the risk factor via Warning labels on the products, which carry any of the 4 food risk factors. May call it 'warning' or 'Alert' or by whatever name.

## FORMAT FOR SENDING THE COMMENTS AND SUGGESTIONS

Annex-2

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				<ul> <li>increase in the percentage of participants who correctly identified all products with high levels of nutrient(s) of concern, which are total sugar, salt or saturated fats. The biggest differences observed were for the warning label (60.8%) followed by the traffic light label (54.8%), GDA label (55.0%) and HSR label (45.0%).(Fig. 1-Annex-2a)</li> <li>2. Relative to the control, warning labels led to a small but statistically significant reduction in participants' intentions to purchase unhealthy products.</li> <li>3. Other outcomes: Warning labels performed best on perceived message effectiveness, a scale that reflects both message perceptions (judgments about how well the message will lead to persuasion) and is predictive of behavioral change.</li> <li>4. Other outcomes: Warning labels also performed best identifying products as unhealthy, making participants concerned about health consequences and being true. The HSR performed worse than all other FOPL types tested. The authors concluded, <i>"This randomized field experiment found that, relative to a control label, all FOPLs helped consumers to identify unhealthy packaged products high in sugar, sodium, and saturated fat. The pattern of results suggested that the warning label is the optimal FOPL to achieve the goal of informing consumers about packaged foods and drinks high in nutrients of concern"</i></li> </ul>	

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2.		Secion 1.(2) (2) They shall come into force on the date of their final publication in the Official Gazette. Compliance shall be voluntary until a period of 48 months from the date of final notification of these regulations and mandatory thereafter.	Replace 48 months by "12 months".	Most countries have taken shorter durations to bring a change in Labels. Those who took longer it was mandatory to reduce the nutrient from high to low. This issue has been in discussion for almost a decade, giving 4 more years is not acceptable. It does not need a change in manufacturing process , only the labels.	If the food industry wants it can change in a few days. It is not a chance that the product label in ((Annex-2b) was done within 2 weeks of draft regulation. It contains "20% Protein" implying to be healthy , which it is not. That makes it another reason for FOPL to be mandatory and inform about food risk factors under the Def. of HFSS.
3.		Section 2.(1) (ib) Definition of HFSS: "High fat, sugar, salt (HFSS) food means a processed food product which has high levels of saturated Fat or total sugar or sodium. The declared values of these ingredients are such that the product; does notsatisfy the value of energy (kcal) from total	Follow this definition all over.	It currently says, "high levels of saturated fat or total sugar or sodium" but fails to make use of the definition anywhere	It would be simple and true way to communicate to people.

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		sugar less than 10 percent of total energy, or from saturated fat 10 percent of total energy, and sodium less than 1 mg/1 k cal."			
4.		Section 2(2) (2) in regulation 5 relating to "Labelling Requirements", - (a) in sub-regulation (2), after clause (b), the following proviso shall be inserted, namely, - "provided that the percentage of Fruits, Vegetable, Nuts, Legumes & Millets, if present in the food product, shall be declared" . (b) in sub-regulation (3), in sub-clause (ii) of clause (b), after item (D) relating to "Sodium (mg)", the following shall be inserted, namely, - "(E) Dietary Fibre (g);"	Delete this section.	Refer to Section 2 (ib) and Chapter 6. Schedule III Table 1. FSSAI has already identified the definition of the "HFSS" and "Food Risk Factors". It does not leave the need to go to another step. Such a declaration of positive factors in FoPNL, to be used to calculate star value is in fact misleading. There is NO scientific evidence that presence of positive factors reduces the risk of disease from other nutrients e.g. high sugar or salt/sodium.	Regulations needed to be clear for people to follow and reduce their risk of disease. Therefore, FSSAI may inform people about food risk factors in order to reduce obesogenic environment.

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5.		Section 14(1) Indian Nutrition Rating (INR) (1) Baseline Reference values and Categories Para-1 For the purpose of Front of Pack Nutritional Labelling (FOPNL), the baseline reference values for four health risk increasing factors i.e., energy, total sugars, saturated fat and sodium per 100 g or 100 ml of the product; and, the minimum percentage of positive nutrients viz., fruit & vegetable (FV); nuts, legumes & millets (NLM); fibre and protein for consideration in the calculation for rating of a specific solid foods or liquid foods, is provided in Table-1 of Schedule – III.	In this para delete the words "and, the minimum percentage of positive nutrients viz. , Fruit& vegetable (FV); nuts, legumes &millets (NLM); fibre and protein"	The definition of HFSS andbaseline reference values for <b>fourhealth risk increasing factors i</b> .e., energy, total sugars, saturated fat and sodium per 100 g or 100 ml of the product; has been identified	Since there is no evidence that presence of 'positive factors' reduces the harm caused by the 'risk increasing factors' it may well be left to the food industry to mention these within the ingredient list not on FoPNL. It is likely to lead to bold claims of positive factors in the advertisements (See Annex-2c) and on product labels that would mask the harmful impact of food risk factors. Refer to Annex-2b for how the product is advertised and its Front of Pack label as on September 29.

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6.		Section 14(1) Para 2 , 4 <sup>th</sup> line onwards: The baseline reference values for food risk factors and minimum percentage of positive factors; INR baseline points for Category-I; INR baseline points for Category – II; capping of positive points; formula to calculate star rating and associated interpretation are provided in Table 1, 2, 3, 4, 5 & 6 of Schedule- III, respectively. The list of solid foods/liquid foods under Category- III (exempted from FOPNL) are provided in Schedule-IV."	<b>Replace the Para 2</b> as "The baseline reference values for food risk factors can be used for INR and FoPNL for Category-I and for Category – II, respectively. The list of solid foods/liquid foods under Category- III (exempted from FOPNL) are provided in Schedule-IV."	As above in point 4,5,	As above
7.		Section 14(1) Para 3 Provided that any beverage/carbonated beverage without energy and/or sugar shall not be eligible for	Add after (INR), "unless these contain artificial sweeteners, stabilisers, emulsifiers or taste/flavour enhancers or the likes"	Evidence shows that artificial sweeteners and other additives are linked to NCDs and make the food products as ultra-processed. Most updated evidence is: <b>1. The trouble with ultra-processed foods</b> <i>BMJ</i> 2022; 378 doi: <u>https://doi.org/10.1136/bmj.o1972</u> (P ublished 31 August 2022)Cite this as: BMJ 2022;378:o1972	Scientific evidence should guidedevelopment of a food policy in the interest of people's health-all are going to be affected. It helps

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		declaring Star Rating (INR).		2. Consumption of ultra-processed foods and health outcomes: a systematic review of epidemiological studies Chen et al. Nutrition Journal (2020) 19:86 https://doi.org/10.1186/s12937-020-00604-1 3. Ultra-processed foods and human health: from epidemiological evidence to mechanistic insights Bernard Srour*, Melissa C Kordahi*, Erica Bonazzi*, Mélanie Deschasaux-Tanguy, Mathilde Touvier†, Benoit Chassaing† DOI: https://doi.org/10.1016/S2468-1253(22)00169-8 https://www.napiindia.in/docs/Annex-4.pdf 4. Artificial sweeteners and cancer risk in a network of case-control studies S.Gallus <sup>1</sup> L.Scotti <sup>1</sup> E.Negri <sup>1</sup> R.Talamini <sup>2</sup> S.Franceschi <sup>3</sup> M.Monte lla <sup>4</sup> A.Giacosa <sup>5</sup> L.Dal Maso <sup>2</sup> C.La Vecchia <sup>16</sup> https://doi.org/10.1093/annonc/mdl346	ensure their human rights to health as per the Consititution of India. India cannot take a chance with it as the rapidly growing consumtion especially in urban India according to a new study in BMJ https://pubmed.ncbi.nl m.nih.gov/36207045/
8.		14.(2) (a) Pictorial Display Format (a) Every packaged food except those exempted from nutritional information under these regulations, shall display the prescribed format (INR) on front of pack calculated on the basis of contribution of	Replace the text of this para as: "Every packaged food except those exempted from nutritional information under these regulations, shall display the prescribed format (INR) on front of pack calculated on the basis of contribution of	As above, the <b>risk factors are critically important to</b> <b>inform people. The</b> 'Stars' do not convey the real risk to health. rather in the regulation it says all processed foods are least healthy to healthiest. Stars are calculated using a hypothetical formula not based on any scientific evidence. <b>Stars can be manipulated.</b> https://www.smh.com.au/healthcare/nestle-wipes-4-5- health-star-rating-off-flagship-milo-product-20180301- p4z295.html	If the Food Authaurity has identified risk factors , simply need to inform people about it. Scientific evidence should guide development of policy in the interest of people's health. It helps ensure their <b>human</b>

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		energy (in kilo calories; kcal), saturated fat (g), total sugar (g) and sodium (mg) and the positive nutrients per 100 g of solid food or 100 ml of liquid food on a "as sold" basis, using the formula mentioned in Table- 5 of Schedule –III.	energy (in kilocalories; kcal), saturated fat (g), total sugar (g) and sodium (mg) 100 g of solid food or 100 ml of liquid food on a 'as sold' basis; and indicate whichever of these is HIGH IN /EXCESSIVE as per the HFSS definition."	Stars don't work well : Experience from Australia can be viewed as spoken on 9 <sup>th</sup> March 2022- https://youtu.be/HdMgh8gmGac https://www.bpni.org/wp- content/uploads/2022/03/HSR-India-talk-Mark- Lawrence.pdf Australian Experience of using HSR: Prof Mark Lawrence https://www.bpni.org/wp- content/uploads/2022/03/HSR-India-talk-Mark- Lawrence.pdf	<b>rights to health</b> as per the Consititution of India. Further, there is no logic/basis in labelling a unhealthy food product with "stars"
9.		14.(2).(b) (b) The INR system rates the overall nutritional profile for packaged food by assigning it a rating from ó star (least healthy) to 5 stars (healthiest). More stars indicate that the food product is better positioned to provide for daily human need of nutrients. The format of logo for INR is as indicated below:	Replace the text by "The INR system rates the overall nutritional profile for packaged food by assigning "food risk factors" as indicated in Table.1 As per the format of the Logo these will be displayed on FoPNL." Delete the designs of INR depicting Stars and replace them with new designs to indicate	This is not a true representation of the unhealthy food products based on which the regulation is being made.It is important to identify unhealthy products ( through food risk factors) and it is easier for consumers to focus on traditional diets based on fresh or minimally processed foods. Evidence shows that if people are alerted it can work to reduce the consumption of unhealthy food products. ( See Above in Point 1.)	As above 4,5,6.

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			food risk factors. e.g. High in Sugar, Energy , Sodium and or Saturated Fats.		
10		14.(2) b. Para 3 Provided that food business operators may give optionally additional interpretive information as per serve percentage contribution to RDA of energy, total sugars, saturated fats and sodium expressed as salt equivalent, along with the INR logo as illustrated below:	<b>Delete</b> this para	Once the consumer can identify food risk factors on FoPNL, there is no need to provide such information along . It can be kept at back panel .	This step may avoid the confusion caused by too much information and no clarity of understanding.
11.		14.(3) Generation of INR logo The FBO shall submit their products relevant nutrient profile in the FoSCoS system for generating the respective INR score and the logo with or without the optional interpretive information	<b>Replace the text by</b> : "The FBO shall submit their product relevant nutrient profile for 4 risk factors in the FoSCoS system for assigning food risk factors on the FoPNL based on the HFSS definition"	This will help to simply and truly identify health risk increasing factors	Evidence supports this.

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12.		15. Food products with milk logo as specified under Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011 shall be exempted from the purview of HFSS definition."	FSSAI may consider this section to be revised. It may reflect additives to avoid specifically. <b>See</b> <b>above</b> on additives.	Because the risk of sweeteners and food additives are increasingly known, it is critical to address this.	Evidence supports this.
13.		"Schedule-III Table 1. Baseline reference values for Food risk factors and minimum percentage of positive factor per 100 gm or 100 ml o n 'as sold' basis.	Replacethetextas:"Table1.BaselinereferencevaluesforFoodriskfactorsper100 growthmonitoringor 100 ml on 'as sold'basis."DeletetheColumn 4and 5	the communication to be consumed by the population as	Evidence supports this.
14.		Schedule III Table -1	Revise the Food risk factors as per FSSAI Guidelines 2019/WHO SEARO Cut off limits or WHO.PAHO Reference values for Energy- 400 Kcal, Total sugar- 10 g, Saturated Fat-6.6 g, Sodium- 250 mg, per 100 gram of solid food. For liquid foods ( non dairy)	It is important to harmonize the food risk factors with definition of HFSS. There is enough evidence to say that high sugar, salt/sodium and saturated fat in the packaged processed food products and drinks is associated with over - consumption, obesity and non -communicable diseases such as type-2 diabetes, cancers and cardiovascular disease and all cause deaths and other poor health indicators. Pan American Health Organization (PAHO) and WHO SEARO have developed models for developing policies to reduce the consumption of unhealthy food products. In order to encourage healthy eating it is critical	Evidence: Review The association of ultra-processed food consumption with adult mental health disorders: a systematic review and dose-response meta- analysis of 260,385 participants https://www.tandfonli

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			reference values are Energy- 30 Kcal, Total sugar- 3g, Saturated Fat-3 g, Sodium- 100 mg, per 100 ML on 'as sold' basis.	<ul> <li>to change the environment that pushes people to eat harmful products.</li> <li>The WHO Population Nutrition Intake guidance is updated continuously with evidence and recommends the above for Sodium, saturated fats and total sugars.</li> <li>The thresholds in the WHO SEARO model are that considering 2000 Kcal energy consumption/per person/per day; there should be less than: Sodium: 1 mg sodium: 1 kcal energy or lower,</li> <li>Total/Free Sugar: 10% of the total energy for foods and 5% for sugar-sweetened beverages, Saturated fats: 10% of total energy.</li> <li>The WHO PAHO Nutrient profile Model https://www.paho.org/en/nutrient-profile-model suggests Excessive in sodium, if the ratio between the amount of sodium (mg) in any given quantity of the product and the energy (kcal) is equal to or higher than 1:1, • Excessive in free sugars, if in any given quantity of the total energy (kcal); and</li> <li>Excessive in saturated fats, if in any given quantity of the product the amount of energy (kcal) from saturated fats (g of saturated fats x 9 kcal) is equal to or higher than 10% of the total energy (kcal).</li> </ul>	ne.com/doi/abs/10.108 0/1028415X.2022.2110 188?journalCode=ynns 20 Consumption of ultra- processed foods and growth outcomes in early childhood: 2015 Pelotas Birth Cohort https://pubmed.ncbi.nl m.nih.gov/36093936/

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15.		Schedule III	In the Table 1 or otherwise: Add a Risk Factor : Ultra –processed food product(UPF). UPF may also be included in Schedule II of the Food Safety and Standards Regulations (Labelling and Display) 2020 FSSAI may consider a logo for UPF products such as "U" the way it is done for Fortified or Ayurveda foods. or processed by radiation.	If the food product is UPF, it is clearly a health risk and evidence is mounting by the day to show the association of UPF increased consumption with NCDs <b>and this is</b> <b>independent of the nutrient content.</b> FSSAI asked for a concept note and the Scientific Committee presentation was made upon request. It requires consideration <u>https://www.napiindia.in/docs/Concept- Note-for-regulating-UPF.pdf</u> UPFs have not been defined by FSSAI as part of any regulation so far. The definition, which is most acceptable in the scientific circles is <i>"Ultra-processed foods are not 'real food'. As stated, they are formulations of food substances often modified by chemical processes and then assembled into ready-to-consume hyper- palatable food and drink products using flavours, colours, emulsifiers and a myriad of other cosmetic additives. Most are made and promoted by transnational and other giant corporations. Their ultra processing makes them highly profitable, intensely appealing and intrinsically unhealthy." FAO has also defined it too. THE NIN dietary guidelines ,too recommend avoiding such foods. The American Heart Association has recommended reducing the consumption of UPFs in diet. <u>Dietary Guidelines in Brazil</u> by MOH have recommended cutting down consumption of UPFs. Similarly, the Government of Canada has also recommended The World Health Organisation and</i>	Supporting Evidence: Ultra-processed foods: what they are and how to identify them https://www.cambridg e.org/core/journals/pu blic-health- nutrition/article/ultrap rocessed-foods-what- they-are-and-how-to- identify- them/E6D744D714B1F F09D5BCA3E74D53A1 85 And the FAO Document. Ultra-processed foods, diet quality, and health using the NOVA classification system https://www.fao.org/3 /ca5644en/ca5644en.p df One can listen to experts here. https://www.youtube.c om/watch?v=yBYRGpgc VVY Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain:

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				<ul> <li>UNICEF recognise the importance of UPF consumption for ending childhood obesity. The Pan American Health Organisation recognizes UPFs as important for reducing health risk, as part of their nutrient-profiling model. Some other national dietary guidelines that promote limiting UPF intake are Uruguay and Israel. France is also planning to reduce UPF consumption by 20% from 2018 to 2021.</li> <li>It is important that regulations are in harmony with dietary guidelines. The National Institute for Nutrition Dietary Guidelines for Indians states as:</li> <li>"The shift from traditional to 'modern' foods, changing cooking practices, increased intake of processed and ready-to-eat foods, intensive marketing of junk foods and 'health' beverages have affected people's perception of foods as well as their dietary behavior." (Page ii) "Since people consume food, it is essential to advocate nutrition in terms of foods, rather than nutrients." (Page 1) https://www.nin.res.in/downloads/DietaryGuidelinesfor NINwebsite.pdf</li> </ul>	An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake https://pubmed.ncbi.nl m.nih.gov/31105044/ Elizabeth, L., Machado, P., Zinöcker, M., Baker, P., & Lawrence, M. (2020). Ultra-processed foods and health outcomes: a narrative review. <i>Nutrients</i> , <i>12</i> (7), 1955. https://www.ncbi.nlm. nih.gov/pmc/articles/P MC7399967/ Pagliai, G., Dinu, M., Madarena, M. P., Bonaccio, M., Iacoviello, L., & Sofi, F. (2021). Consumption of ultra- processed foods and health status: a systematic review and meta-analysis. <i>British</i> <i>Journal of</i> <i>Nutrition</i> , <i>125</i> (3), 308- 318.https://www.camb ridge.org/core/journals

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					/british-journal-of- nutrition/article/consu mption-of- ultraprocessed-foods- and-health-status-a- systematic-review-and metanalysis/FDCA00C0 C747AA36E1860BBF69 A62704 Chen, X., Zhang, Z., Yang, H., Qiu, P., Wang, T., Wang, F., &Nie, J. (2020). Consumption of ultra-processed foods and health outcomes: a systematic review of epidemiological studies. <i>Nutrition</i> <i>journal</i> , <i>19</i> (1), 1-10. https://nutritionj.biom edcentral.com/articles/ 10.1186/s12937-020- 00604-1 An excellent review on 37 cohort studies
					published on Dec 22, 2021; "The Role of Diet Quality in Mediating the Association between Ultra-Processed Food

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					Intake, Obesity and Health-Related Outcomes: A Review of Prospective Cohort Studies" suggests that the adverse consequences of UPFs are independent of dietary nutrient content 'questioning the utility of reformulation to mitigate against the obesity pandemic and wider negative health outcomes of UPFs'. https://www.mdpi.com /2072-6643/14/1/23
16.		Schedule III	<b>Delete the columns</b> 4 and 5 of Positive Factors	<b>As above</b> these factors carry no scientific backing for reducing risk of disease due the identified food risk factors.	
17.		Schedule III Table 2, 3, 4, 5, 6	Delete the Table 2 and 3, 4, 5 and 6	<b>As above</b> these factors carry no scientific backing for reducing risk of disease due the identified food risk factors	
18.		Schedule IV Category-III Solid Foods/Liquid Foods exempted from FOPNL under INR. The category numbers refer to food categories as provided under FSS (FPS & FA)	Provide a criteria for exemption. FSSAI may think of giving a Green Label to the exempted food items to send a strong signal about a healthy	If we have a criteria to identify healthy food it would be easy to exempt and help in objectively identifying such foods and remove any bias that may happen. For example Israel has done a criteria that can be adapted to Indian needs. Gillon-Keren M, Kaufman-Shriqui V, Goldsmith R, Safra C, Shai I, Fayman G, Berry E, Tirosh A, Dicker D, Froy O, Gordon E, Chavia Ben-Yosef AC, Nitsan L, Altman H,	There is something valuable to learn from Israel on the development and its process to develop the criteria.

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		Regulations, 2011.	diet.	Blaychfeld-Magnazi M, Endevelt R. Development of Criteria for a Positive Front-of-Package Food Labeling: The Israeli Case. Nutrients. 2020 Jun 23;12(6):1875. doi: 10.3390/nu12061875. PMID: 32585990; PMCID: PMC7353345. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC735334</u> <u>5/</u> Table in the Annex-2d.	
19.		Schedule-IV Category-III Solid Foods/Liquid Foods exempted from FOPNL under INR. The category numbers refer to food categories as provided under FSS (FPS & FA) Regulations, 2011.	Delete the 13.4, 13.5 and 13.6	Food supplements are widely advertised in a mislaeding way, make health claims, and conatin high sugar contents. These need to be included in the category of FoPNL. Reasons are presence of food risk factors and these products asre mostly UPFs.	Both adults and children are using these supplements . We checked four common products and these were all high in Total Sugar and all are UPFs.
20.		General point on the process	The decision of 15.02.2022 needed to be re -looked at because of conflicts of interest. ( Joseph Stiglitz, the Noble laureate economist defined governance- How the policy is being developed and in whose interest )	The decision is based on a "stakeholder meeting" in which there were 16 representatives of the food industry, which suggests a bias and presents a situation of conflicts of Interest. It has been reported that some members of the Sc. Panel also had conflicts of Interest and the due process was not followed to arrive at the decision. <u>https://www.policycircle.org/opinion/fssai- backs-health-star-rating/</u>	In the principles of FSSA 2006 it must operate without conflicts of interest. The Hon'ble Supreme Court has observed that FSSAI panels should remain independent. Section 13 of the FSS Act "13. Scientific Panels. (1) The Food Authority shall establish scientific panels, which shall

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					consist of independent scientific experts. (2) The Scientific Panel shall invite the relevant industry and consumer representatives in its deliberations." It means the process required a consultative approach but not for decision- making.