

Food Safety and Standards Authority of India

Proposes

Regulation of Trans Fatty Acids (TFAs) in Partially Hydrogenated Vegetable Oils (PHVOs)

Background

1. Industrially produced trans fats are formed during partial hydrogenation, a process used by the vanaspati industry to harden and stabilize liquid vegetable oils. This process maintains the taste and smell characteristics of oils while enabling a longer shelf life for final food products. The majority of the trans fats in the food are industrially produced and are typically found in foods made with partially hydrogenated oil, baked and fried foods. Trans fats also occur naturally. They are found at low levels (generally 2-5% of fat content) in ruminant based foods, such as, dairy products and meat. TFAs level in vanaspati depends on multiple factors and could be as high as 50-60% of total fat content.
2. There are growing concerns about the potential health effects of TFAs particularly those derived from vanaspati. In India, vanaspati, margarine, desi ghee, butter etc. are sources of TFA. Commercially fried, processed, ready to eat, bakery foods are potential sources. There is a significant and growing body of evidence linking trans fats to coronary heart disease indicating that trans fats may do even more harm than saturated fats. Metabolic studies show that trans fats increase blood levels of LDL (bad) cholesterol and decrease blood levels of HDL (good) cholesterol. Both effects are strongly associated with increased coronary heart disease. Saturated fats are thought to be less damaging because they elevate both the "bad" and "good" types of cholesterol. Epidemiological data also point to greater risk of coronary heart disease from increases in dietary transfats than increases in saturated fats.
3. Studies carried out by National Institute of Nutrition(NIN) to evaluate the effects of TFA from Indian vanaspati in rats showed that both saturated fatty acids and TFA increased insulin resistance Since increasing dietary linoleic acid did not prevent TFA induced increase in insulin resistance, it is necessary to reduce the absolute intake of TFA. It has also been found that TFA intake by mothers may increase the susceptibility to biochemical/metabolic alterations known to be associated with increase in risk of diet related chronic diseases.

Risk Assessment Report on TFAs in Indian Diets submitted by National Institute of Nutrition, Hyderabad in October, 2009

4. On the request of FSSAI, NIN carried out a risk analysis of transfats in the Indian diet. A summary of the findings of the report is as under:-

(a) Not more than 10% (7% for those with cardiac problems) and 1% of total energy can be derived from saturated fat and TFA, respectively according to current scientific research and WHO recommendations, if risk of cardio- vascular disease has to be kept at safe levels. It is important for population and individual health that TFAs should be removed from the food supply and should be replaced by cis-unsaturated fats from vegetable oils rather than saturated fats from tropical oils and animal fats.

(b) In rural and urban India the fat consumption is around 20 and 30g /day, respectively, according to diet studies (National Consumption Survey data). If 10% TFA is permitted in vanaspati, a person consuming 2000Kcal derived from food which contains 20 and 30g vanaspati/day will derive 0.9 and 1.35 % energy from the TFA. (This shows that even at 10% TFA level there is health risk at 30g of vanaspati consumption per day (which exceeds the 1% energy, which is the limit for TFA recommended by WHO).

(c) Attempts to bring down the levels of TFAs in PHVOs by complete hydrogenation or higher levels of hydrogenation will result in elevated melting point and SFA content. This has to be viewed with caution as elevation of SFAs in vanaspati obtained from complete hydrogenation would result in increase in % of energy derived from SFAs (not more than 7% of total energy is to be derived from saturated fat as recommended by WHO). Increase in intake of SFAs will lead to increase in serum cholesterol levels and Low Density Lipoprotein (LDL) which are potential risk factors for CHD.

5. The World Health Assembly resolved in 2004 that elimination of TFA should be a key point for action by governments. WHO/FAO has recently completed an extensive review of latest research on the links of TFA to CVD and diabetes and recommended that all countries should take urgent regulatory steps to limit transfats in their diet so that clear danger to heart health in vulnerable groups is avoided. According to a report in New

England Journal of Medicine (Mozaffarian et al, 2006) consumption of transfats result in considerable potential harm with no benefit. National Academy of Sciences, USA has concluded that there is no safe level of TFA consumption, no recommended daily amount or tolerable upper limit as any incremental increase in TFA increases the risk of coronary heart disease.

6. The implications of replacing high TFA partially hydrogenated oil by substitutes were also considered by FSSAI. While the availability of alternative sources of fats is not likely to be a problem, test results of the fatty acids profile in the market indicate that technological solutions are available for reducing trans fats to acceptable limits. Industry may require a suitable time frame for adopting these practices and healthier alternatives. Support should be given to industry to communicate the healthier nature of its products to consumers and also help small and medium sized enterprises to prepare for compliance. The vegetable oil industry should take the lead in this area.

7. The experience of other countries who have introduced regulation to limit trans fats indicate that Polyunsaturated fatty acids including alpha-linolenic (Omega 3) and linoleic (Omega 6) acids are also important components of a cholesterol lowering and more healthful diet. However, the benefits depend to some degree on consuming an appropriate balance of these fatty acids. The goal, therefore, should be to replace, as much as possible, trans saturated fats with mono unsaturated fats and maintain adequate intake and appropriate balance of Omega 6 and Omega 3 polyunsaturated fatty acids.

8. It is also necessary to consider appropriate modifications in the edible oils regulations to encourage use of all available healthier alternatives. Further research on these possibilities need to be undertaken so that available options are considered and appropriate regulations are developed.

Current regulations for TFAs

9. The PFA Rules, 1955 require that:-

- (a) The foods in which hydrogenated vegetable fats or bakery shortening is used shall declare on the label that "**Hydrogenated vegetable fats or bakery shortening used-contains trans fats**".

(b) A health claim of '**trans fat free**' may be made where the trans fat is **less than 0.2g per serving of food.**

(c) A claim '**saturated fat free**' may be made only where the saturated fat does not exceed **0.1g per 100g or 100ml of food.**

Recommended dietary intake level of fats

10. WHO has recommended that TFA intake as a % of Energy should not exceed 1%. The total fat intake as a % of Energy should not be less than 15% and should not exceed 30%. The intake of Saturated Fat (SFA) as a % of Energy should not exceed 10% (7% for cardiac patients).

11. Countries such as Denmark, Canada, United States (New York City) and Australia & New Zealand have taken the lead in adopting initiatives to reduce TFA intake.

12. FSSAI adopted the following approach while finalising its recommendations regarding norms for trans fats :-

- (a) Review the current scientific evidence on health effects of trans fats and the fact that trans fats have no intrinsic health value above their calorie value, keeping in view the current dietary recommendations regarding trans fats including WHO's recommendations.
- (b) The likely presence of trans fats in typical Indian diet.
- (c) International experience in limiting trans fats and the possibility of substituting healthier alternatives.
- (d) Risk assessment of trans fats in Indian diet based on available data. It was felt that limited data need not prevent a preliminary decision in view of likely health effects.
- (e) Feasibility of substituting trans fats with healthier alternatives.
- (f) Technological options available to industry.
- (g) Amenability to easy implementation.

Proposed regulations under FSSAI

13. The need was felt to regulate the TFAs in partially hydrogenated vegetable oils and this issue was considered in the Third meeting of the Food Authority held on 26th November, 2009 where it was recommended to fix a limit of not more than 10 percent trans-fatty acids in partially hydrogenated vegetable oils. It was also recommended that a national consultation may also be organized to obtain feedback from consumers and industry and the scientific community for implementation of the regulation.

14. In view of above, National Institute of Nutrition, Hyderabad conducted a national consultation by inviting participants representing all stakeholders on 29.01.2010 which recommended the following with regard to TFA limits :-

- (a) The TFA level in PHVO should be below 10% and should not exceed 10%.
- (b) Existing melting point regulation which is 31 °C - 41 °C for partially hydrogenated vegetable oils, bakery shortening and margarines, interesterified vegetable fat and other fats made using vegetable oils should be removed in harmonization with Codex Standard.
- (c) Natural hard fractions like Palm Stearin should be included in list of edible oils and fats in line with Codex Standard.
- (d) Mandatory labelling of TFA and saturated fat content for all edible oils and fats should be implemented.
- (e) PFA regulation must allow both chemical and enzymatic inter esterification.

15. Thereafter the issue was considered in the meeting of Central Advisory Committee and Scientific Committee of Food Authority which endorsed the recommendation of a limit of 10 % TFA in vanaspati to be brought down to 5% within a period of three years.

16. An Expert Group constituted by FSSAI also deliberated on the need for fixing the TFA limit in vanaspati and recommended that level of TFA in Vanaspati / PHVO, be fixed at the level 10% maximum, to be brought down to 5% in 3 years. The Expert Group also suggested change in the regulations regarding melting point and enzymatic esterification for production of vanaspati for regulating trans fatty acids.

17. A large proportion of population in Indian sub continent is identified as genetically pre-disposed to CVD. Consumption of vanaspati and TFA compound the risk of CVD in Indian population. It seems appropriate, therefore, that steps are taken in our country to minimize the TFA intake through dietary fat.

18. Taking into account all the above mentioned inputs, the FSSAI proposes the following :-

- (a) **Level of TFA in Vanaspati / PHVO, be fixed at 10% maximum and brought down to 5% in 3 years. A phasing in period may be given to industry after the date of notification. A detailed review of the impact of the measure should be carried out by the end of 3 years to decide whether further reduction can be attempted.**
- (b) **There are no substantial studies on detrimental effects of raising the melting point of vanaspati from current level of 41° to 51° or to remove the melting point limit altogether. On the other hand, it has been argued that high melting point has no deleterious effect on health or digestion. Nor do Codex standards prescribe an upper limit on melting point. There is need to carry out studies for documenting the effects of raising / removing the melting point limit on digestion and overall health. It is, therefore, proposed that presently status quo may be maintained i.e. melting point of 41°C be retained or it be raised only to the extent that would facilitate bringing down the TFA level to the above limits.**
- (c) **There is also a need to look into the feasibility for laying down the limits of Saturated Fatty Acids (SFAs) in vanaspati and other fats. This is being thought of because if the melting point is raised, it will lead to increase in saturation of partially hydrogenated vegetable oils. WHO had recommended that not more than 1% and not more than 10% of energy in diet be derived from TFAs and SFAs, respectively.**
- (d) **Enzymatic esterification for production of vanaspati for regulating trans fatty acids can be considered. But it being a costly alternative, may take time for implementation.**

- (e) As regards permitting use of Palm Stearin in vanaspati, it also needs to be looked into whether to allow its use or not as in our country Palm Stearin is used in soap industry. However, there was no safety issue on its use and it is allowed in Codex standards with melting point of 44°C - 52°C. Palm Stearin after interesterification with another liquid oil like rice bran oil, mustard oil, sunflower oil or soybean oil in appropriate ratio is shown to produce shortening similar to vanaspati with comparable functional properties and the product is completely free from trans fatty acids. However, Palm Stearin content may be permitted only in partially hydrogenated / interesterified fat and not approved for blending of oils or to be used as such.
 - (f) There should be mandatory labelling of TFA & SFA content on vanaspati packs, edible oils or any other product containing TFA from vanaspati sources. This is necessary to enable informed choice by consumers.
 - (g) There is currently a limit on blending of more than two oils and a minimum requirement of 20% for each oil used for blending. These limits have been imposed to facilitate detection of adulteration. There is a demand for reviewing this restriction to facilitate greater use of other oils by industry and facilitate balance in SFA : MUFA : PUFA components.
19. The above recommendations are likely to:
- (a) Contribute to decreasing / removing one of the risk factors and significantly improve the heart health of Indian citizens and save lives.
 - (b) Reduce daily intake of transfats by Indian consumers of all age groups to between 1% and 2% of energy intake consistent with current dietary recommendations, over a period of 3 years.
 - (c) Those at the highest consumption level will benefit from the mandatory reduction of industrially produced trans fats. Even those with low consumption will benefit. Even if small amounts of fat is consumed, if it is devoid of TFA and contains unsaturated fatty acids, the population will stand to benefit.

- (d) Promote the development of alternative supplies of more healthful alternatives of trans fats.
- (e) Provide a level playing field to industry to compete on the basis of the safety and healthy features of their products.
20. Keeping in view the importance of the proposed measure in improving health and reducing the risk of cardiovascular disease to a large section of the population, Food Safety and Standards Authority believes that the proposed measure should be widely disseminated for feedback from all stakeholders. Those desirous of commenting on the proposed measure are invited to send their comments within 30 days from publishing of this note to Food Safety and Standards Authority. Thereafter, Food Safety and Standards Authority proposes to finalise the regulations for submission to the Government.

Please send your comments to :

Name : Dr. Dhir Singh, ADG(PFA)

E.mail : adgpfa@nb.nic.in

Contact No. : 23237418

Fax No. : 23220994