

April 15, 2006
The Secretary
Ministry of Health and Family Welfare
Government of India
Nirman Bhavan, New Delhi – 110 011

Dear Madam/Sir,

**SUB: RESPONSE TO THE LABELLING OF GMOS
[DRAFT RULES TO AMEND PREVENTION OF FOOD ADULTERATION Rules
1955: (COPY OF NOTIFICATION DATED 10TH MARCH '06)]**

We, the undersigned, have gone through the draft rules notified to amend the Prevention of Food Adulteration Act, 1955 which seek to make the labelling of GM foods mandatory in the country.

We cannot accept your Ministry's draft rules which have been devised to accommodate a GM policy for India based on an 'approval' agenda for Genetic Engineering [GE], including LMOs [Living Modified Organisms] by the regulatory bodies of Genetic Engineering Approval Committee [GEAC] and the Department of Biotechnology [DBT]. You have come up with these rules without independent assessment of GM technology and products, of the hazards of this risky technology, which include serious health-safety concerns of GM foods and animal feed. This, despite the fact that your Ministry has independent responsibility and commensurate with this, the authority to oversee and ensure food safety and public health.

It is an established fact that there can be no co-existence between GM and Non-GM crops. Contamination is a biological and physical certainty. Our well-founded fears, with regard to the proposed draft rules for labelling GM crops and foods, are based on the fact that plans for a full-scale launch of GM/LMO products both within India and through imports are part of the GEAC/DBT 'approval agenda'. Labelling, then, instead of being a restrictive and safety mechanism for the Indian people, to safeguard the countryside and wildernesses and the food chains from transgenic contamination, becomes the means for legalising contamination by employing a regulatory system that is deeply flawed, from the viewpoint of both logic and science.

The proposed draft rules for the compulsory labelling of GM products, without exception, will essentially serve to provide the legal face to GEAC approvals for GM imports and locally produced GM crops and foods. They will not promote food safety, food security and health. They will also negate consumer choice, because of the certainty of transgenic contamination. India's public policy to guard the country's significant comparative and competitive advantage in an exploding world demand for 'organic' and non-GMO/LMO products dictates that India must ensure a No-GMO/LMO policy.

The points below clarify the dangers of the proposed labelling of GM. They also clearly showcase the faulty and dangerous assumptions behind India's draft rules on GMO

labelling. These rules seek to come up with some misplaced and erroneous "end-of-the-pipe" solutions rather than talk about "clean production" technologies to use an analogy from other sectors.

On the issue of imports:

1. The current draft proposals do not address widespread contamination in a GM producing nation like the US or Canada, where no labelling rules exist. Up to 85% of the soy, corn and rape in foods/feed including processed foods is GM or contaminated with GM content. This is well known to the regulators too in India, who have chosen to turn a blind eye to the illegal imports of such products into India. Given the 'approval' agenda of the GEAC and DBT, such imports will no doubt be approved; heading a long line of approvals, to give various violations of EPA rules the garb of legality. Is the Ministry of Health & Family Welfare proposing to fall in line with such contamination in such countries through the use of a mere GM label?

2. Further, no GM crop has been formally approved as safe for human consumption in countries like the US. The FDA merely acknowledges the crop developer's assurance that "foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements". By the most lax yardstick for bias and 'conflict of interest', this is unacceptable. Is India therefore planning to accept the crop developer's assurance of safety, through the inclusion of the words as required by the draft rules: "cleared for marketing and use in the country of origin"?

On the issue of production of GMOs/LMOs in the country:

3. The Draft Rules do not acknowledge that there is a lot of food & feed contamination already present with the Bt Cotton approvals as well as the illegal Bt Cotton plantings that have happened in the country. In the case of Bt Cotton, the complete laxity of the regulatory process and the resultant non-compliance of even the basic biosafety safeguards have resulted in the certain contamination of the food/feed chain through derivatives of Bt Cotton. The GEAC continues to maintain that no GM food has been approved for production and release in India. This is of course disingenuous and should not be accepted on grounds of health safety by your Ministry. While accepting the approval of Bt Cotton, the Ministry of Health & Family Welfare chose to go by the GEAC's definition of calling the Bt Cotton crop as a non-food/feed crop. However this is not the case and the Ministry now has to acknowledge that it has utterly failed in not independently asking for/doing any tests on the food and feed chain contamination with Bt Cotton.

Cottonseed cake is the 2nd highest source of animal feed in the world and in India, cottonseed is traditionally valued as feed for milch cattle to increase the fat content of milk. The Bt Cotton seed oil and cake find their way into cattle feed, thus contaminating much of the milk production and supply chain in the country. Further, such oil finds its way into the food chain and ends up in the vanaspati in the country. Bt Cotton has also contaminated the clothing/apparel chain in the country. On grounds of allergenicity, the

cotton textile and clothing industry is affected. The most serious cases of contamination involve medical bandages, sanitary towels amongst other things. What labelling and testing is the Ministry proposing in this context?

4. The amendment pre-supposes that co-existence through segregation of GM and non-GM is possible in India and that based on such segregation, labelling would offer benefits to consumers. However, such segregation is simply impossible given that right from the seed used for planting crops, physical and genetic contamination is unavoidable. Since co-existence between GM and Non GM is impossible, the draft rules burden non-GM producers with the cost of testing and labelling. This is true both for India based producers and exporting countries. Thus all the non-GM producers will lose either way – if they cannot bear the cost of testing for and maintaining a non-GM label, then their products must necessarily be labelled as GM!

5. The "May Contain" option is untenable. There is every danger of all produce from India getting labelled as "MAY CONTAIN" because co-existence of GM and non-GM is impossible and it may well suit producers and traders at various levels of the distribution chain to mark in this manner almost all packaged food/feed products as such [given the huge cost burdens involved in maintaining segregation, even if we assume that it might be possible to an extent]. In such a situation, consumer choice is negated and the only option may well be an imported non-GM product.

Have issues related to trade losses to Indian producers and exporters been worked out in such a case?

What options will actually be available for consumers in such a situation, other than imported non-GM labelled food?

What about the losses in premium for non-GM producers?

6. The draft rules in any case, are incomplete as they stand as they do not for example, address trade losses, liability, including loss of premium organic markets and tort laws, which require time and discussion with civil society in an inclusive way, in order to arrive at fair and comprehensive legislation whose aim must be the serious discouragement of GM contamination of India and of non-GM farmers' fields, through punitive measures.

On the issue of consumer rights and consumer choices:

The objective of labelling is to provide and secure consumer choice about GM foods. Thus a food that carries no label should mean that it is free of GM content and there must be such a choice. However, given the complete breakdown in the regulatory mechanism in India, and the lax approach to GM safety in other countries particularly the US, this clearly is and will not be the case.

7. As mentioned above, there is every danger of all produce from the exporting country and India getting labelled as "MAY CONTAIN" because of the certainty of transgenic contamination. This certain fall out would deny consumer choice with regard to ethical

and healthy food considerations. It would also lead to the rapid contamination of the food chain without the possibility of redressing the situation. So, in the end, where is consumer choice and the health safety of our food chain?

8. The amendment pre-supposes a particular level of knowledge, information and awareness amongst both consumers and producers on the issue of GM foods; however, this is manifestly not so.

9. More importantly, much of the consumption in this country would be outside the ambit of labelling. How does the Ministry of Health and Family Welfare propose to protect the health and welfare of consumers and producers in such a case, leave alone protect their right towards choice?

Other issues related to regulation, its enforcement etc.:

10. The amendment pre-supposes that other regulatory mechanisms are functioning well and therefore, as the next logical step, to protect the right of consumers as end-users, proposes labelling of GM foods. However, right from the field trials' stage, there are blatant violations of biosafety and other environment protection norms and guidelines. Therefore, labelling is a meaningless affair in this context of complete failure of regulation at all levels.

11. The amendment assumes that India has already decided through a coherent, broad-based, well-debated policy that GM foods should be allowed into the country. However, this is not the case and the biotechnology policy drafted by the Department of Biotechnology has met with serious objections from farmers' as well as consumers' unions.

12. Such end-of-the-pipe solutions as labelling do not ensure that the "precautionary principle" and the "polluter pays" principles are actually upheld in the production and supply processes.

Amendments Sought

The draft rules for the labelling of GM foods/feed/LMOs imported and locally produced, pre-suppose in essence, that GM crops are a foregone conclusion. It is acknowledged by us that this 'foregone conclusion' is clearly the objective of a regulatory body that has paid no heed to the evidence placed before it by farmer and civil society groups, of serious concerns with genetic engineering.

On the other hand, your Ministry must safeguard public health and food safety as a first order of priority, because this is your Ministry's clear responsibility and 'raison d'etre'. There is well-established evidence of serious health and biosafety concerns including well-documented evidence for the toxicity of GM crops, particularly Bt crops.

It is a truism that the goal of health safety-assessment is that a "food should not cause

harm when prepared, used or eaten according to its intended use" (Codex Alimentarius guideline 2003). We are sure that this is also the objective of India's food laws and particularly the 'Prevention of Food Adulteration Rules'.

Thus, if GMOs cause cancer in rats, as has been firmly demonstrated along with other significant health risks, then, eminent world scientists are absolutely right to call for stringent, independent and peer-reviewed long-term animal feeding studies to determine the health safety of GM crops. Until then, they have called for a global moratorium. It is impeccable logic, which we fully endorse for India. Therefore, it is the 'Precautionary Principle' that is the superior scientific principle that must be followed most urgently for GMOs/LMOs. Even if eventually, for the sake of argument, the evidence against GM were proved wrong on all dimensions of health and biosafety, it would still prove to be 'right action' based on prudence for India to apply the precautionary principle in the SHORT TERM in order to be reasonably sure of the safety of GMOs/LMOs.

Therefore, our national laws and rules, including labelling rules for GM products, must reflect the unique risks of genetic engineering. This is the secure ground for our insistence that the draft rules for labelling products derived from genetic modification should therefore serve to safeguard a moratorium and underpin the precautionary path. Therefore, we demand:

On all agricultural imports (food, feed and seeds/planting material) into the country:

- a. A ban on the import of any product (whether obtained as part of trade or aid and whether it is primary or processed or any ingredient of food, feed, food/feed additives or food product that contains, composes of or is derived from modern biotechnology)), unless it is certified and labelled to be GM-free and LMO-free by the exporting country/agency. Such a ban is particularly critical to be applied to infant and baby food.
- b. A blanket ban on the import of a listed range of products, like corn, soy and rape and other products (whether it is primary or processed or any ingredient of food, feed, food/feed additives or food product that contains, composes of or is derived from modern biotechnology) from countries that are growing them and have no GM labelling laws in place for GM content. Due diligence on a continuous basis of a country-wise update with regard to new releases of GMOs/LMOs is imperative to secure the ban on such imports.
- c. There must be zero tolerance for transgenic contamination particularly from GM pharm products and primary products' imports [seed and planting material], which would put at risk, the country's seed stock and genetic diversity. Such products must carry additional certification that they have been tested for "Zero GM Content" by the exporting country/agency. Such imports must be subjected to independent sample testing in India where our labs must be upgraded as necessary to be routinely capable of testing to 0.01% of GM/LMO content, matching the current performance of the best international laboratories.

On all products derived from Bt Cotton:

Immediate cleaning up of the contamination from Bt Cotton seed cake and oil of the food and feed chain; pending such clean-up, there should be clear stamping, "CONTAMINATED WITH GM UNFIT FOR CONSUMPTION" and disposed off appropriately as a biohazardous substance.

On any new releases of GMOs/LMOs in India:

d. A ban on the release of any GMO/LMO into the Indian Environment and into the food/feed chain

Therefore, we demand that the Ministry of Health and Family Welfare takes an approach to labelling for GMO/LMOs that secures a GM/LMO-free policy for India. There can be no wishful thinking that the notified Draft Rules for Labelling would protect India's sovereign interests of public health safety, farmer and consumer rights and the choice to grow, produce and consume non-GM food/feed.

The only guarantee towards providing a choice of Non-GM to Indians is to have no GM production or imports or sale at all and any labelling regime that reinforces this approach.

Signed

- 1 Dr G V Ramanjaneyulu & Kavitha Kuruganti - Centre for Sustainable Agriculture, Secunderabad
- 2 Devinder Sharma & Bhaskar Goswami - Forum for Biotechnology and Food Security, New Delhi
- 3 Vijay Jawandhia Shetkari Sanghatan, Wardha
- 4 Chukki Nanjundaswamy - Karnataka Rajya Rytha Sangha [KRRS], Karnataka
- 5 Dr Narasimha Reddy - Centre for Handloom Information & Policy, Andhra Pradesh
- 6 Uzamma Dastkaar, Hyderabad
- 7 Dr P Duraisingam, Chairman & Chief Functionary of Federation of Consumer Organisations -Tamil Nadu & Pondicherry, FEDCOT, Paramakudi and Chairman of Consumer Co-ordination Councils [CCC], New Delhi
- 8 Mohan & Devika Advocates, Chennai
- 9 S A Shameer - Speak India
- 10 Kanchi Kohli Kalpavriksh, New Delhi
- 11 Wilfred D'Costa - INSAF, Delhi
- 12 Shripad Dharmadhikary, Manthan Adhyayan Kendra, Badwani
- 13 Shalini Bhutani - Concerned citizen, Delhi
- 14 P Damoder Sarvodaya - Youth Organisation, Warangal
- 15 Dr Usha Dharmangadhan - Professor, All Saints' College, Trivandrum
- 16 Dr Anand P K V - Lecturer, Vaidyaratnam Ayurveda College, Thrissur
- 17 Nelwin, C Joy - AVARD, Chalakudy, Thrissur
- 18 Dr S Sankar - Scientist, Kerala Forest Research Institute, Thrissur
- 19 K C Santhosh Kumar - Film maker, Trivandrum
- 20 Dr Abey George - Asst Professor, Kerala Institute for Local Administration, Thrissur

- 21 Sujith Kumar, C K - Writer, CEDAR, Thrissur
- 22 Uma Devi K - Teacher, Malappuram
- 23 Vishnu - RASTA, Wayanad
- 24 Dr A Latha Chalakudy, Puzha Samrakshana Samithy, Thrissur
- 25 Shaji, K V - Society for Environmental Education in Kerala, Kannur
- 26 A S Ahimohan - President, Greenview, Vellayani, Trivandrum
- 27 Vinodkumar P - Engineer & Development activist, 'Maithri', Palakkad
- 28 C Rajendran - Teacher, Palakkad
- 29 M Gangadharan - Convenor, Paddy Protection Forum, Wayanad
- 30 Dr S Shanti - Biologist, Trivandrum
- 31 Satish Satyavardhanan - Organic Farmer, Thrissur
- 32 Sujatha - Zero Waste Centre, Kovalam, Trivandrum
- 33 Babychan - Coordinator, Organic Bazaar, Trivandrum
- 34 Jacob Lazar - People's Union for Civil Liberties, Kochi
- 35 Purushan Eloor - Periyar Anti Pollution Samithy, Kochi
- 36 R Satish - Paddy Farmer, Palakkad
- 37 Harish D - Management expert
- 38 Ajith Venniyoor Fellow, Lead India, Trivandrum
- 39 Philip Mathew & Sonia George - SEWA, Trivandrum
- 40 Robin C - Journalist, Thrissur
- 41 Sudheerkumar P V - Kasargod District Environmental Protection Samithy, Kasaragod
- 42 Rajasree V V - Coordinator, CLEAN Trivandrum
- 43 Dr E R Balagopal - Ayurveda doctor, Kottakkal Arya Vaidyasala, Kannur
- 44 C Jayakumar - Member, Task Force on Pesticides, Pesticide Action Network-Asia Pacific
- 45 R Sridhar - Coordinator, Thanal, Trivandrum
- 46 S Usha - Member, Women & Environment Task Force, Asia Pacific Forum for Women, Law & Environment [APWLD]
- 47 R Ajayan- Convenor, Plachimada Support group, Trivandrum
- 48 C R Neelakantan - Environmental Activist and writer, Kochi
- 49 Geo Jose - NAPM, Kochi
- 50 Aliyamma Vijayan - SAKHI, Women's Resource Group, Trivandrum
- 51 Lawrence Surendra - Environmental Economist, Mysore
- 52 Dr V Rukmini Rao - Gramya Resource Centre for Women, Hyderabad
- 53 Goldy George - Dalit Mukti Morcha, Kerala
- 54 Oswald Quintal - LEISA Network
- 55 Arundhati Muthu - Concerned consumer, Bangalore
- 56 Uma Shankari & Narendranath - Rashtriya Rythu Seva Samithi
- 57 Manoharan - ACCORD, Gudalur, Nilgiris
- 58 R Selvam - Secretary, Organic Farmers' Federation, Erode
- 59 Thatchinamoorthy - Aranya Pudukottai
- 60 Narayanan Tamilaga - Velan Neervalu Niruvanam, Erode
- 61 S Poongodi Vithu, Arachalur, Erode district
- 62 A Gunasekaran - Organic Farmers' Association of Arachalur region, Erode district
- 63 A Kuppusamy - Organic Farmers' Association of Mettur, Kolathur, Salem district

- 64 R Selvam - Trust Nature, Arachalur, Erode district
 65 Kannan - Organic Erode, Erode district
 66 S Poongodi - Manonmani vermin farm and organic cultivation training centre, Erode
 67 Selvam - Thulir, Erode district
 68 Boopathy - Ananthan Ammaippu, Coimbatore
 69 M Shiva Shanmugam - Eco People, Coimbatore
 70 Sharchchandra Lele - Senior Fellow & Coordinator, CISED, Bangalore, as a concerned citizen of India
 71 Gijs Spoor & Jessamijn Miedema - Concerned consumers
 72 Nitya Menon - Concerned consumer of India, Mumbai
 73 Virginia Saldanha - Satyashodak Women's Group, Mumbai, concerned citizen of India
 74 Arun Ambatipudi - Chetna Organic, Hyderabad
 75 Dr Shambu Prasad - Concerned Citizen of India
 76 Afsar Jafri - Concerned consumer of India, Mumbai
 77 Ashish Kothari - Co-Chair, IUCN Theme on Indigenous/Local Communities, Equity and Protected Areas
 78 E S Jayachandran - Researcher, National Institute of Technology, Kozhikode
 79 Shantha BhushanKalpavriksh, Pune
 80 Dr D Narasimha Reddy - Prof of Economics [Retd], University of Hyderabad
 81 Dr Prajit K Basu - Dept of Philosophy, University of Hyderabad
 82 Somanath Nayak - Nagarika Seva Trust
 83 Sharanya Naik - ActionAid, Orissa
 84 Dr Thomas Varghese - Retired Agriculture Scientist, Trivandrum

ANNEXURE: INFORMATION ON THE DRAFT AMENDED RULES

DRAFT RULES TO AMEND PREVENTION OF FOOD ADULTERATION RULES, 1955

Copy of NOTIFICATION dated 10th March 2006

The following draft of certain rules further to amend the Prevention of Food Adulteration Rules, 1955, which the Central Government, after consultation with the Central Committee for Food Standards, proposes to make, in exercise of the powers conferred by sub-section (1) of section 23 of the Prevention of Food Adulteration Act, 1954 (37 of 1954), is hereby published, as required by the said sub-section, for the information of all persons likely to be affected thereby, and notice is hereby given that the said draft rules will be taken into consideration after the expiry of a period of sixty days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public.

2. (1) Objections or suggestions, if any, in respect of the draft rules, may be addressed to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhavan, New Delhi – 110 011.

(2) The objections and suggestions, which may be received from any person with respect to the said draft rules before the expiry of the period so specified, will be considered by the Central Government.

DRAFT RULES

1. (1) These rules may be called the Prevention of Food Adulteration (Amendment) Rules, 2006.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Prevention of Food Adulteration Rules, 1955 (hereinafter referred to as the said rules,) after rule 37D, the following shall be inserted, namely, -

(i) "37- E Labelling of Genetically Modified Food – Genetically engineered or modified Foods means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not contained genetically modified or engineered organisms obtained through modern biotechnology;

In addition to the labelling provisions as prescribed under these rules, the Genetically Modified Food shall also conform to the following labelling requirements:-

(a) a GM Food, derived there from, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall be compulsorily labelled, without any exceptions;

(b) the label of all package(s) of GM Food(s) or foods containing ingredients, derived from Biotechnology or Bioengineering or food additives or any food product that may contain GM material shall indicate that they have been subject to genetic modification. These provisions will be applicable to all such products both imported or domestically produced; and

(c) the label of imported GM Food or derived there from, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall also indicate that the product has been cleared for marketing and use in the country of origin so that the verification, if needed can be taken up with that country without having to resort to testing."

(ii) After rule 48-E of the said rules, the following shall be inserted, namely, -

"48-F Restriction on Sale of Genetically Modified Food: - No person shall except with approval of and subject to the conditions that may be imposed by the Genetic Engineering Approval Committee (GEAC) constituted under the Environment Protection Act, 1986, manufacture, import, transport, store, distribute or sell raw or processed food

or any ingredient of food, food additives or any food product that may contain GM material in the country:

Provided that in case of imported genetically modified foods, the importer shall submit documents supporting the purported clearance at the time of import."

Signed

(Rita Teaotia)

Jt. Secretary

G.S.R.152(E)

F.No.P.15014/14/2005-P.H. (Food)

Issued by: Ministry of Health and Family Welfare

(Department of Health) New Delhi.