PROTEST AGAINST THE STATED INTENT OF APHIS (USDA) TO DEREGULATE LLRICE601

http://www.regulations.gov/fdmspublic/component/main
We note that APHIS has made a preliminary decision to extend determination of nonregulated status to LLRICE601. We hereby protest in the strongest possible terms against your intent to deregulate this failed GM variety.

1. GENERAL OBSERVATIONS

1.1 We also protest strongly that APHIS / USDA has set itself upon a course of representing a very serious GM contamination incident as "a simple administrative oversight" -- and in so doing brings the whole regulatory process in the USA into disrepute. It has become involved in cover-up of the scale and seriousness of the contamination offence, and has allowed itself to be sucked into a damage limitation exercise on behalf of the US administration. In other words, it has placed political and economic considerations above health and safety considerations. It has treated the interests of the marketplace, and investors, above the interests of the consumer and the environment. It has thus strayed into territory that should properly be occupied by others.

1.2 We also protest strongly on the grounds that the preliminary decision to deregulate LLRICE601 is based upon bad science, with many assurances from the offending company (Bayer CropScience) accepted by the regulators but based upon "invisible evidence," and with key information hidden from scientific scrutiny by CBI classification. About 30 pages and other key diagrams have been deleted from the public access document APHIS-2006-0140-0003 without any justification. Assumptions and assurances seem to have been accepted by the regulators across the board, without regulatory examination of the hard data. Indeed, since this offence relates to a line discontinued in 2001, we suspect that in many instances the company has simply made extrapolations from other LL rice lines. Where is the evidence that LLRICE601 has maintained its molecular characteristics over the five years 2001 - 2006 without "gene scrambling"? Where is the evidence that something that might have been safe in 2001 is still safe today?

1.3 It almost beggars belief that a biotechnology corporation can commit a very serious offence by allowing a discontinued and redundant GM variety, which is acknowledged to be unfit for human consumption, to enter the food chain without being instantly penalized; that it can then communicate behind the scenes with the regulatory body which has responsibility for enforcing the law to achieve a measure of "damage limitation"; that it can ask the regulator for the status of the offending material (LL601 rice) to be changed following the commission of the offence; that it can ask the regulator to hide from the public all of the key information concerning the stability, uniformity, health and safety of the offending variety; and that the "impartial" regulator, which is supposed to protect the public and the environment, can accede to all of the offender's requests and in fact work with it to belittle the scale and seriousness of the offence and effectively to defend and promote the interests of the offender. This all reveals APHIS as a regulatory body which is failing to regulate; and as a body involved in a conspiracy to protect an offender and deceive the public.

2. SPECIFIC POINTS

2.1 On P 6 of the APHIS draft Environmental Assessment (1), there is mention of Purpose and Need. It is extraordinary that neither USDA, FDA, APHIS or Bayer have made even the feeblest attempt to argue that there is any PURPOSE or NEED for deregulation. This is highly significant.

There is no PURPOSE behind this application other than the evasion of liability by Bayer CropScience for the unauthorised release into the environment and the food chain of a product currently deemed unfit for human consumption. It is no part of APHIS's function to connive with this cynical and opportunistic petition for deregulation for a product which will never be commercialized and which is by any definition a "failed variety." It is clearly not Bayer's PURPOSE to use, market or develop this line any further; and to deregulate it under the present circumstances would bring the whole regulatory process into disrepute.

There is clearly no NEED for the variety either. The rice farming industry is not exactly clamouring for it, and there is no market niche which needs to be filled. It is not needed in foreign markets either for growing or for feed and food. Bayer has already effectively decided that its LL rice varieties (including LL06, LL62 and Ll601) have no place in the market-place. In spite of the deregulation that occurred in 1999, the only LL rice crop grown and intended for commercial release was that grown on Garrett Farms, Texas, in 2000, which was stored for one winter and then dumped into a landfill pit. If there was no market then, there is even less of a market now, and Bayer cannot possibly argue that LL601 NEEDS to be deregulated. We therefore protest strongly on these grounds.

If there is no purpose or need for LLRICE601 to be deregulated, it should continue to be a regulated article. We ask for the petition to be denied on these grounds.

2.2 According to p 5 of the Draft Environmental Assessment, LLRICE601 has never been intended for commercialization and has never been submitted to FDA for evaluation as human food. FDA says that Bayer has provided "information about the safety of the PAT protein, molecular characterization, and nutritional composition of grain from LLRICE601. Based on the available data and information, FDA has concluded that the presence of this bioengineered rice variety in the food and feed supply poses no food or feed safety concerns." This statement cannot possibly we well founded, since it is based upon unsupported assumptions of substantial equivalence and on mysterious evidence that is not available for anybody to examine. The "information" provided by Bayer could have been fanciful or fraudulent, and the complacency / connivance of FDA should be a source of shame to the regulators. In these circumstances, there are NO grounds for assuming that LLRICE 601 is safe either as animal feed or human food. It cannot even be assumed that LL62 is safe to eat. Indeed, it is clear from the fact that Bayer has effectively withdrawn all of its LL rice varieties that there may be serious problems relating to their stability and uniformity, and it would be wiser, in these circumstances, to assume that LLRICE601 is UNFIT FOR HUMAN CONSUMPTION until the company provides unequivocal evidence to the contrary.

2.3 Field testing of LLRICE601 continued into the year 2001. Its development was then discontinued. For five years the company showed no interest in the variety. Suddenly a Field Evaluation Report on the performance of LL601 (various lines) was submitted to APHIS on 4th August 2006. The research on which the Report was based was completed in 2001. There would have been absolutely no reason for the submission of this report last month except in preparation for an extremely belated petition for deregulation. Bayer officially notified USDA of the LL601 contamination incident on 31st July 2006. It is obvious that an immediate agreement was made between USDA and Bayer that deregulation would be requested and agreed to. No announcement was made to farmers, importers or the general public about the incident until 18th August 2006. No adequate explanation has been given for this delay. During the 18-day interval it is

obvious that both Bayer and APHIS were hard at work on the preparation of the "case for deregulation." In fact, the APHIS draft Environmental Statement reads more like a piece of advocacy than an impartial assessment of the facts laid before it. In our book this indicates a totally unacceptable level of cooperation and connivance between a regulator and a company guilty (by its own admission) of allowing a regulated and unfit article to enter the food chain. There is no doubt that it had committed a serious offence. In such circumstances USDA should have behaved with great circumspection; instead it participated in a deliberate attempt to cover up the incident, to protect the offender, to promote the offender's interests, and to mislead the public into a belief that all was well. To proceed to the deregulation of LLRICE601 now would be tantamount to conspiracy, and would compound an already corrupt situation.

2.4 There is other evidence of an improper and even corrupt relationship between the regulator (USDA) and the offender (Bayer). We note that the key author of the USDA / APHIS response to the Bayer petition (dated 17 August 2006) is Cindy Smith, Deputy Administrator, Biotechnology Regulatory Services. She was present alongside Agriculture Secretary Mike Johanns at the "press conference" on 18th August, and answered a number of questions from journalists. On the record, she told two lies (2), one relating to the regulatory status of LLRICE601 and the other relating to past episodes of GM rice contamination. It is clear from the tenor of the press conference, and from Ms Smith's remarks, that a strategy had already been agreed by 18 August for USDA and FDA to minimise the offence committed by Bayer CropScience and to represent that offence simply as an administrative oversight. The fact that Cindy Smith said that LL601 "was approved previously to be marketed" indicates either an inadequate knowledge of the regulatory status of LLRICE601 or an intent to deceive. In any event it is apparent that the APHIS response (APHIS-2006-0140-002) is tainted by the fact that the lead author has made a personal commitment to protect the interests of a biotechnology corporation which has committed a very serious offence. On this basis alone, the APHIS document should be withdrawn, and rewritten by an officer who is genuinely impartal.

3. NOTICE OF FURTHER SUBMISSIONS

3.1 We give notice that we intend to submit further protests of a more detailed nature during the consultation period which ends on October 10th.

4. NOTES

(1) APHIS-2006-0140-0002
USDA/APHIS, Draft Environmental Assessment, In response to Bayer CropScience Petition 06-234-01P seeking Extension of Determination of Non-regulated Status for Glufosinate Resistant rice, Oryza sativa, event LLRICE601

(2) Ms Smith said in relation to LLRICE601: "this was a crop that actually while it was approved previously to be marketed the company had not yet brought it to market." Wrong. LL601 has never been approved for release into the environment or for marketing. It was "discontinued" by Bayer and a request was never submitted for deregulation before the company cynically asked for "retrospective deregulation" on 22 August. She must have known that. She was also asked: ".... you've had other instances in the past where crops have been contaminated between biotech and traditional crops. Is this the first time this has happened as far as rice is concerned?" In reply, she said: "That's correct.....We've not had any other situations involving rice." Wrong. We have indeed had other

situations involving rice. It has been on the record since early in 2005 that illegal Bt rice has been contaminating rice crops in China. And Ms Smith must have known of the Heinz babyfood scandal in China in the spring of 2006, when Bt63 was found in rice. It is inconceivable that Ms Smith, as a specialist in this area, could have been unaware of these incidents.

We asked Cindy Smith on 29th August to correct these pieces of misinformation, but she has not responded.

Ref:
http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB/.cmd/ad/.ar/sa.retrievecontent/.c/6_2_1UH/.ce/7_2_5JM/.p/5_2_4TQ/.d/3/_th/J_2_9D/_s.7_0_A/7_0_1OB?PC_7_2_5JM_contentid=2006%2F08%2F0308.xml&PC_7_2_5JM_parentnav=TRANSCRIPTS_SPEECHES&PC_7_2_5JM_navid=TRANSCRIPT#7_2_5JM
Answering questions: Secretary of Agriculture Mike Johanns
Deputy Administrator for Biotechnology Regulatory Services, Cindy Smith
Dr. Robert Brackett from the U.S. Food and Drug Administration

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Please acknowledge the safe receipt of this objection to deregulation.

Yours sincerely,

Dr Brian John
GM Free Cymru
Trefelin, Cilgwyn
Newport
Wales SA42 0QN