SUBMISSION TO THE DEPARTMENT OF AGRICULTURE

IN RESPECT OF

THE APPEAL BY ARC-IIC AGAINST THE DOA REFUSAL FOR A TRIAL RELEASE OF GENETICALLY MODIFIED CASSAVA

5 OCTOBER 2007

INTRODUCTION AND BACKGROUND

The Agricultural Research Council (ARC) Institute for Industrial Crops (IIC) submitted an application to the Directorate of Genetic Resources (DGR) within the Department of Agriculture (DOA) in 2006 for a trial release of genetically modified cassava. The African Centre for Biosafety (ACB) submitted its objections to the proposed trial release. On the 19th March 2007 the Executive Council (EC) of the DGR denied the application by the ARC-IIC for a trial release and granted permission instead for the proposed activities to be conducted within the confines of a containment level 2 greenhouse.

The ground for refusal was the EC's concern that the applicant had not provided sufficient information to enable an informed risk assessment. The EC requested that the recommended greenhouse trial be used to collect additional data on the stability of the traits as well as the potential for gene flow. Further the EC made specific requests of the ARC-IIC to include in all further applications information on:

1. The influence of the environment on the quality and expression of the amylase-free starch
2. Details of the trial undertaken in the Virgin Islands
3. Confirm if statements in the original application referring to further field trials referred to the trial in the Virgin Islands

On the 18 April 2007 the ARC-IIC submitted a written appeal against the decision citing its belief in the completeness of the information originally submitted as being adequate for making an informed and comprehensive risk assessment. Further, the ARC-IIC emphasized that the proposed field trial is a "proof of concept" trial to enable investigation of the potential and stability of the cassava under local field conditions as well as monitor for any potential gene flow.

The ACB has been invited by the EC to make a submission at the appeal hearing to be held on the 8-9 October 2007 at the offices of the DOA in Pretoria. This paper details our response to the ACI-IIC appeal application.

ACB CONCERNS IN RESPECT OF THE APPLIED FOR FIELD TRIAL OF GENETICALLY MODIFIED CASSAVA

The appeal application comprises a cover letter and paper on the reproductive biology and practices for confinement of experimental field trials. This paper is written on the assumption that we have been provided with the complete appeal dossier.

THE RISK ASSESSMENT

Any risk assessment of genetically modified plants has to take into account:

- Characteristics of the donor and recipient organisms;
- The genes inserted and expressed;
- Potential consequences of the genetic modification;
- Potential environmental impacts following a deliberate release;
- The potential toxicity and allergenicity of gene products and metabolites;
- Compositional, nutritional, safety and agronomic characteristics;
- The influence of food processing on the properties of the food or feed;
- The potential for changes in dietary intake;

- The potential for long-term nutritional impact.
- Potential impact of horizontal DNA transfer between plant or plant components and micro-organisms in relevant environments. Genes integrated in the GM plant should also be subjected to risk assessment with respect to the possible effects of ingestion of the protein expressed in plant parts.[i]

No new information in respect of the risk assessment has been provided by ARC-IIC. In respect of the molecular characterisation of the modified food, all the experiments were conducted by the developer of the organism and there is no indication anywhere in the document that any independent audit of the scientific experiments were carried out as would be done to comply with international standards of good laboratory practice.

GENE FLOW

Crop-to-wild gene flow is not uncommon, so transgenic plants should not be expected to behave any differently.ii Transgenic crops have been shown to hybridize spontaneously with wild relatives and their hybrids are somewhat or fully fertile.ii The consequences, both ecological and evolutionary of crop-to-crop gene flow are only now beginning to be investigated in any meaningful way and the possible exposure of non-target organisms, including humans to novel proteins cannot be discounted.[iii]

The proposed deflowering and observational approaches to measuring gene flow, whilst being economical are not the most effective. This approach often overlooks rare events or events which occur over long distances. The supporting documentation submitted by ARC-IIC[iv] states clearly that "there is little direct experimental data on gene flow in cassava that is useful in constructing standards for reproductive isolation. Existing information is experiential and often qualitative, rather than experimental and quantitative" (page 9 of 24 of the appeal application). Given that this is the case, perhaps alternative approaches to measuring gene flow need to be considered and developed before going out to field trial. The ACB recommends that pattern-based methods, such as the use of molecular markers[v], be considered on unmodified plants to get a more complete picture of gene flow in cassava before conducting field trials with transgenic plants.

VIRGIN ISLANDS FIELD TRIALS

According to ARC-IIC, genotypes of the GM products are stable – the three years of Virgin Island field trials is one of the main pieces of evidence cited in support of this claim. Contrary to the EC request for detail on the Virgin Islands field trials, the supplied information on the trial details is scanty at best and includes information on containment, signage and general planting conditions and strategies. The data in support of the gene stability claim has not been provided.

CONCLUSIONS AND RECOMMENDATIONS

The ARC-IIC appeal documentation fails to introduce any new or additional supporting information in respect of the field trial application. The applicant is of the opinion that the originally introduced information was adequate for assessment. In light of this, our original objections remain. The ACB would like to reiterate its concerns as stated in the original objection which are the same concerns as that of the EC.

1. The original ARC-IIC application appealed to an EFSA Panel ruling on similarly genetically modified potato (event EH92-527-1) that there was no threat to human health. Lack of adverse effects in one event cannot be used to suggest a similar lack in a totally new event. Potential harmful unintended effects are specific to the gene, crop and site of growth of any transformation event. Even in the USA where regulation of the movement and release into the environment of GE crops has been widely criticized as inadequate,[vi] such extrapolations are not considered acceptable. Each event must be evaluated on its own merits in every respect both in laboratory experiments as well as in the field.
2. In point 2.7 (page 30) of the risk assessment (original application), it is conceded that there could be movement of material from the site through "flooding, animal feeding or unlawful harvest".[vii] As stated in the application, the purpose of this field trial is for "research purposes to establish the efficacy of the modification under field conditions" (point 23, page 28 of the risk assessment). No formal safety assessment has been conducted on this particular event, in particular no data is given on environmental assessments relevant to cassava and this particular modified cassava. The risk management practices that are proposed by the applicant do not go far enough. Typically, field trials are conducted to assess agronomic properties like yield, fruit/grain quality and pest susceptibility and are not typically designed for safety assessments. Although the agronomic data may reveal some potential environmental harm, informal observations are likely to miss many potential environmental impacts.[viii] There is a lack in the application of any mention of protocols for collecting environmental impact data from the field trials.

In the absence of any new substantive information from ARC-IIC in response to very specific queries, most importantly relating to gene stability and gene flow, to the EC, the ACB is of the opinion that ARC-IIC have not adequately responded to the EC comments and questions. We therefore request that the EC uphold the initial decision to refuse the ARC-IIC to conduct field trials of genetically modified cassava.

REFERENCES

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