OBJECTIONS TO THE APPLICATIONS MADE BY THE SOUTH AFRICAN SUGAR RESEARCH INSTITUTE (SASRI) IN RESPECT OF PERMITS FOR ACTIVITES WITH GMO'S, SPECIFICALLY SUGARCANE, TO THE NATIONAL DEPARTMENT OF AGRICULTURE IN SOUTH AFRICA

PREPARED BY

THE AFRICAN CENTRE FOR BIOSAFETY

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INTRODUCTION

A legal and scientific assessment was made of the information obtained from the National Department of Agriculture in terms of the Public Access to Information Act (PAIA). The legal objections centre around concerns that that Bayer Cropscience is bankrolling the South African Association-Sugarcane Research Institute field trials and hopes to make inroads here because lax biosafety legislation and political climate that favours the interests of multinational corporations. The EC has a statutory duty to protect the environment and not promote the interests of gene giants. The information supplied by the applicant is very scant does not allow for a full and fair public participatory process. Further, we contend that EC has failed to comply with the provisions of PAJA and the ECA read together with the EIA regulations currently in force.

We are concerned that SASRI is carrying out transgene development utilising gene fragments for which it does not have complete sequence information. We believe that this compromises the ability to make informed and educated conclusions regarding the impacts of these transgenes. A full assessment of the scientific data could not be made because of the designation of sections of the application as Confidential Business Information. Genetic modification by the application of recombinant DNA technology is characterised by scientific uncertainty. This stems from several factors including the inherent imprecision of currently employed recombinant DNA techniques, the use of powerful promoter sequences in genetic constructs and the generation, as a result of genetic modification, of novel proteins to which humans and animals have never previously been exposed. The impression gained from the notifiers responses is that any possible impacts of the release of the transgene are negligible and that the transgenic line is equivalent to the conventional type – this is a view not supported by the published literature.

LEGAL OBJECTIONS

EC HAS STATUTORY DUTY TO PROTECT THE ENVIRONMENT AND NOT PROMOTE INTERESTS OF GENE GIANT, BAYER

It has come to out attention that Bayer Cropscience is bankrolling the South African Association-Sugarcane Research Institute's (SASRI) field trials. Bayer Agrosciences is well known for its acquisition of Aventis Cropscience, who was held legally accountable and responsible for food contamination scandal in the United States involving its 'Starlink' (Cry9c) maize.

We bring to the attention of the EC, that Bayer has withdrawn from the United Kingdom, has withdrawn its plans to commercialise GM canola in Australia and most recently, abandoned its research in India,[1] Bayer Cropscience has apparently turned to South Africa because of its lax biosafety legislation and political climate that favours the interests of multinational corporations over those of its citizens and the environment.

It is imperative that in exercising its decision-making powers, the EC bears in mind its constitutional obligations to protect the environment and not to allow the land of South Africa to be used as a haven for genetic engineering experimentation by the Gene Giants. In this regard, we remind the EC that the Constitution of the Republic of South Africa 108 of 1996 is the highest law in the country.

The centrality of the Bill of Rights to the Constitution, and its foundational values to South Africa's newly created democracy is expressed in section 7 of the Constitution, which provides:

"Rights

7 (1) This Bill of Rights is a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom.

(2) The State must respect, protect, promote and fulfil the rights in the Bill of Rights.

(3) The rights in the Bill of Rights are subject to the limitations contained or referred to in section 36, or elsewhere in the Bill."

Section 24 of the Constitution entrenches the rights of all South Africans to an environment that is not harmful to health or well-being and imposes and obligation on the state to protect the environment, for the benefit of present and future generations.

The guarantee contained in section 24 of the Constitution forms part of the cluster of socio-economic rights.

INADAQUACY OF INFORMATION SUPPLIED BY APPLICANT

ACB received an astonishing paucity of information, with the result that it has been severely hamstrung in conducting any meaningful assessment of the applications. This biased and grossly inequitable situation has arisen principally, because the NDA has failed to establish a proper formal process for the determination and characterisation of what constitutes confidential business information (CBI). Consequently, the ACB has been severely prejudiced in objecting to this application.

FAILURE BY EC TO COMPLY WITH PROVISIONS OF PAJA-NO AUTHORITY TO TAKE DECISIONS

Administrative action on the part of the EC, more particularly, decisions taken by it approving applications for the import, release and marketing of GMOs adversely affect the fundamental human rights of the public. These rights include inter alia, the right to nutritious, safe and culturally acceptable food, the right to informed choice, the right to fair administrative decision-making, the right to democratic participation, the right to save and exchange seeds, and the right to a safe and healthy environment. It also raises far-reaching ethical concerns for those that adhere to ethical and value systems underpinned by African communal spirituality concerning life and food.

It is our belief that administrative decision-making on the part of the EC established under the GMO Act concerning GMOs fall within the purview especially of section 4(1)(a) and (b) of Promotion of Administrative Justice Act No 3 of 2000 ("PAJA"). In terms of section 4(1) of PAJA, the EC must, in order to give effect to the right to procedurally fair administrative action, decide whether-

> " (a) to hold a public enquiry;
> (b) to follow a notice and comment procedure in terms of subsection (3);
> (c) to follow the procedures in both subsections (2) and (3);
> (d) where the administrator is empowered by an empowering provision to follow a procedure which is fair but different, to follow that procedure; or
> (e) to follow another appropriate procedure which gives effect to section 3."

We strenuously dispute the Registrar's contention contained in his letter to the ACB, of 16 August 2004, that regulation 6 of the Regulations dated 1 December 1999 made under the GMO Act, is a fair procedure, as contemplated by the objections and provisions of section 3(5) the PAJA. It is our view that regulation 6 of the Regulations made under the GMO Act is not in compliance with sections 3 and 4(1) of PAJA. We refer the EC to our numerous objections submitted to the EC over the last few months, to various applications for GM imports and releases, as well as to numerous correspondence wherein we have illustrated amply and clearly to the EC and the Registrar, that regulation 6 of the said GMO Regulations is inherently unfair, prejudicial and obstructs the administration of justice.

In this regard, we bring to your attention the judgement of Wills J, in an unreported judgment in the matter of Sasol Oil (Pty) Ltd and Bright Sun Developments CC v Mary Metcalfe NO Case No 17363/03, High Court of South Africa (Witwatersrand Local Division) when the learned Judge stated that:

" It is trite that in the interpretation of ordinary statutes, to the extent that there is inconsistency between earlier and subsequent legislation, the provisions of subsequent legislation will ordinarily prevail….The purpose of PAJA is plainly to give effect to the

rights, constitutionally enshrined in the Bill of Rights of the Constitution, to just administrative action. It is constitutional legislation. It is triumphal legislation…We have resolved, almost unanimously, that never again must such injustices as had been experienced under apartheid and in other parts of the world prevail in our own country…[PAJA] confers rights upon all who lives in South Africa in so far as their dealings with organs of State are concerned. To the extent that earlier legislation is inconsistent with PAJA, PAJA must prevail."

It is our contention that regulation 6 of the Regulations made under the GMO Act is inconsistent with the provisions of PAJA. In terms of the above judgment, PAJA triumphs the said Regulations made under the GMO Act; whereas the Regulations of the GMO Act came into effect on the 1 December 1999, PAJA came into effect on the 3 February 2000. The Regulations made under the GMO Act are in any event, subordinate legislation and can in no way be said to be equivalent to constitutional legislation such as PAJA.

In any event, we are of the belief that the said regulation 6 which deals with an invitation by an applicant to members of the public in the area where a release is intended to take place, is not within the contemplation of sections 3 and 4(1) of PAJA. Both section 3 and 4(1) of PAJA deal with administrative action. It is clearly the intention of the legislature that PAJA should apply to the duty on the part of the administrator regarding administrative actions vis-à-vis the public, in ensuring fair administrative justice.

Since regulation 6 of Regulations of the GMO Act deals with a notice and comment procedure (between an applicant and members of the public where the release is intended to take place), we illustrate below, for your convenience, the marked difference between regulation 6 and the Regulations promulgated in terms of PAJA (Government Gazette Vol. 446. No 23710, 31 July 2002.

In this regard, please take note special note that Chapter 2 of the latter Regulations (PAJA Regulations) deals with the Notice and Comment Procedure on the part of the administrator, regarding administrative action as is required by section 4(1) of PAJA and not, notices by the applicant, as is required by regulation 6 of the GMO Regulations, for comments by the public.

"18.

1. Information concerning the proposed administrative action must be published by way of notice-

(a) if the administrative action affects the rights of the public throughout the Republic, in the Government Gazette and a newspaper which is distributed, or in newspapers which collectively are distributed, throughout the Republic;

2. A notice published in terms of subregulation (1) must include-
   (a) an invitation to members of the public to submit comments in connection with the proposed administrative action to the administrator concerned on or before a date specified in the notice, which date may not be earlier than 30 days from the date of publication of the notice;
   (b) a caution that comments received after the closing date may be disregarded;
   (c) the name and official title of the person to whom any comments must be sent or delivered…."

3. A notice published in terms of subregulation (1) must-
   (a) contain, sufficient information about the proposed administrative action to enable members of the public to submit meaningful comments…"

19. 1. A notice published in terms of regulation 18(1) must be in at least two of the official languages.

20. .1 If any proposed administrative action may materially and adversely affect the rights of members of a specific community consisting of a significant proportion of people who cannot read or write or who otherwise need special assistance-
   (a) A notice must be published in the area of that community in a manner that will bring the proposed action to the attention of community at large; and
   (b) The Administrator must take special steps to solicit the views of the members of the community.

2. Special steps in terms of subregulation (1)(b) may include-
   (a) the holding of public or group meetings where the proposed action is explained, questions are answered and views from the audience is minuted;
   (b) a survey of public opinion in the community on the proposed action; or
   (c) provision of a secretarial facility in the community where members of the community can state their views on the proposed action."

In the light of there having been a failure on the part of the EC to comply with sections 3 and 4(1) of PAJA, read together with the said PAJA Regulations, we believe that decision-making on the part of the EC will be ultra vires and therefore null and void.

We therefore call upon the EC to desist from making any decision and comply with the said provisions of PAJA.

NON-COMPLIANCE WITH ENVIRONMENT CONSERVATION ACT AND THE ECA REGULATIONS

Section 21 (1) of the Environment Conservation Act 73 of 1989 ("ECA") provides as follows:

" The Minister may by notice in the Gazette identify those activities which in his opinion may have a substantial detrimental effect on the environment, whether in general or in respect of certain areas."

Acting pursuant to this power, and by Government Notice R1182, Government Gazette 18261 of 5 September 1997, the Minister identified certain activities, which may have a substantial detrimental effect on the environment. One of the activities listed in schedule 1 of Government Notice R1182 in item 6, is described as follows:

"the genetic modification of any organism with the purpose of fundamentally changing the inherent characteristics of that organism"

The effect of the identification of the activities listed in Government Notice R1182 is that it triggers the prohibition in section 22 of the ECA and requires written authorisation to carry on the activity in question by a competent authority designated by the Minister in the Gazette.

Regulations governing activities identified under section 21(1) of the ECA were promulgated in Government Notice R1183, Government Gazette of 5 September 1997 ("the ECA Regulations").

The ECA Regulations set out, inter alia, the requirements for an application for authorisation to pursue an identified activity. The ECA Regulations make provision for the submission of a Scoping Report together with the required contents of such a report (Regulation 6(1)).

In other words, the Applicant is obliged to submit a Scoping Report in terms of the ECA Regulations, and in compliance with its provisions and requirements. These include inter alia, the employment of an independent consultant; identification of environmental issues and full details regarding alternatives, in the said Scoping Report, as required by the ECA Regulations.

It is our contention that if the EC is satisfied that the applicants have been able to produce a Scoping Report, (which has not been furnished to the Centre) it is our contention that the Applicant has not fully complied with the requirements of the ECA Regulations.

In terms of section 3 (1) of the ECA Regulations an Applicant-

must appoint an independent consultant who must on behalf of the applicant comply with these regulations;

-

(c) must ensure that the consultant has no financial or other interests in the undertaking of the proposed activity, except with regard to the compliance of these Regulations.

It is our contention that the Applicant has failed to comply with section 3(1) of the ECA Regulations. We have thoroughly perused the information furnished to us, and have not found any evidence to show that the Applicant had complied with these provisions.

In terms of section 2(2) of the ECA Regulations, if any provision of sub-regulation (1) is not complied with by the applicant and not immediately attended to, after having been made aware of it by the relevant authority, the application is regarded to have been withdrawn.

The Applicant is obliged in terms of section 6(1) of the ECA Regulations to submit a scoping report to the EC, which must include:

a brief project description;

a brief description of how the environment may be affected;

a description of all alternatives; and

an appendix containing a description and public participation process followed, including a list of interested parties and their comments.

We have thoroughly perused the information furnished to us, and have not found any evidence to show that the Applicant had complied with these provisions. It is our contention that the Applicant has failed to comply with subsections (c) and (d) above

In the circumstances, the Applicant is obliged to withdraw its application.

SCIENTIFIC ASSESSMENT

BACKGROUND

Applications by SASRI and Available Information

Applications have been made by the South African Sugarcane Research Institute (SASRI) for continuation of a field trial of genetically modified sugarcane (Daily News 23.2.2004, The North Coast Courier 24.12.2004, The Witness 11.01.2005). Two independent modifications are being investigated. The first is to measure the levels and evaluate effects of pleurocidin, an antimicrobial peptide, produced in engineered sugarcane[2] (hereinafter designated as **T1**).

The second is to measure the extent to which Bt-modified varieties of sugarcane can withstand attacks by the lepidopteran stalk borer pest Eldana[2] (hereinafter designated as **T2**).

The information supplied after a request in terms of the Public Access to Information Act (PAIA) is copies of the applications (Non confidential information), Copies of the Public Notices, a journal article by Cole *et al* describing the isolation and characterization of pleurocidin, report of a previous trial, copies of permit authorizations and inspections by the National Department of Agriculture (NDA) and summary of a research proposal.

Bacillus thuringiensis: Mode of Insecticidal Action

Bacillus thuringiensis (Bt), a common soil bacterium produces insecticidal proteins during sporulation. Each of the several thousand strains of Bt that exist produces its own unique insecticidal crystal protein (delta endotoxin)[3], each of which displays differing insecticidal activity, but with a similar mode of action. Typically, ingested delta endotoxins are dissolved in the insect midgut liberating the protoxins of which they are comprised. These undergo proteolysis and one of the fragments binds to the cells of the insect midgut epithelium, disrupting the osmotic balance and forming pores in the cell membrane causing cell lysis, gut paralysis and death within a few hours of ingestion[3,4].

Horizontal Gene Transfer (HGT)

Horizontal gene transfer (HGT) is the transfer of genetic material between organisms, outside the context of parent to offspring reproduction[5]. It is most commonly recognized as infectious transfer[6]. HGT frequencies are now known to be much higher than originally thought. The evolution of antibiotic resistance, for example, is an indicator of the frequency of gene transfer, given that antibiotics have been used in medicine only for about 50 years[6]. The intentional modification of plants could through horizontal gene transfer result in the unintentional modification of other organisms. What the possible impacts of such gene transfer might be is not known.

Use of Antibiotic Resistance Markers

Antibiotic resistance marker genes are used often in the development of transgenic crops as selectable markers. Selectable markers allow the modified form to be selectively amplified while unmodified forms are eliminated. The use of antibiotic resistance markers has application in development of the transgenic line allowing for selection of modified plants in the laboratory. The transgenic crop line however, will retain the marker gene for its lifetime in each of its cells[7].

MOLECULAR CHARACTERIZATION

The Host Plant and Modified Sugarcane Varieties

Sugarcane, a perennial grass with no single genetic origin, consists of six species – two wild species, *S. spontaneum* L. and *S. robustum* and four cultivated species, *S.officinarum* L., *S. barberi* Jeswiet, *S. sinense* Roxb and *S. edule.* Hassk[8]. Sugarcane is vegetatively propagated and does not depend on seeds. What is sold to farmers and afterwards planted are sections of the cane with shoot buds. At the time of harvesting, the roots are left in the soil for regeneration of new canes. It is necessary the plant with new buds every four years[8].

T1 modifications involve the recipient *Saccharum ssp*. Cultivars N12, N19, N27 and N31. These have been subjected to co-bombardment with plasmid vectors pEmuKN and pUbi-pleuro-8. The Emu promoter has a truncated maize *Adh 1* promoter, multiple copies of the Anaerobic Responsive Element from the maize *Adh 1* gene and ocs-elements from the octapine synthase gene of *Agrobacterium tumefaciens*[9]. The gene contains an antibiotic selectable marker, *nptII,* from *Eschericihia coli* conferring resistance to the antibiotic geneticin and the terminator sequence contains the nopaline synthase (*nos*) gene derived from the Ti plasmid of *Agrobacterium tumefaciens*[9]. pUbi-pleuro-8 contains the *Zea mays* ubiquitin promoter and the 35S Cauliflower Mosaic Virus (CaMV) promoter, the pleurocidin gene from winter flounder (*Pleuronectes americanus*)[10], a maize ubiquitin enhancer and intron and a CaMV terminator.

T2 modifications involve the recipient *Saccharum ssp*. cultivars 88H0019, 93F0234 and N27. These have been subjected to co-bombardment with plasmid vectors pEmuKN and pMon15772. The Emu promoter has a truncated maize *Adh 1* promoter, multiple copies of the Anaerobic Responsive Element from the maize *Adh 1* gene and ocs-elements from the octapine synthase gene of *Agrobacterium tumefaciens*[9]. The gene contains an antibiotic selectable marker, *nptII,* from *Eschericihia coli* conferring resistance to the antibiotic genticin and the terminator sequence contains the nopaline synthase (*nos*) gene derived from the Ti plasmid of *Agrobacterium tumefaciens*[9]. The pMon15772 plasmid has the Cauliflower Mosaic Virus (CaMV) promoter, a *Bacillus thuringiensis* (Bt) gene coding for insecticidal protein, an enhancer of unknown identity and an *Agrobacterium tumefaciens nos* terminator. The delta endotoxin gene forming part of the transgene construct is identified in the application as Bt gene cry1Ac whilst the Risk Assessment identifies it as cry1Ab[9]. The bulk of the information in the application suggests that the latter is the correct gene the discussion that follows regarding T2 is based on this assumption.

Sequence Information

No sequence information has been provided for either T1 or T2 and the SASRI does not have complete information at hand for T2. The enhancer forming part of pMon15772 has been provided to SASRI by Monsanto and the "identity is unknown"[9]. Pleurocidin is an antimicrobial peptide which works by disrupting the membranes of a target cell, causing lysis

of the cell. The complete mechanism of action of antimicrobial peptides has not been fully elucidated and questions regarding what determines the activity and selectivity of these peptides, is currently only known approximately[11]. Some antimicrobial peptides are used in the bio-preservation of food. Despite this not much research has been carried out on the cytotoxicity of the peptides in mammalian systems[12].

GENETIC MODIFICATION

Degree of Certainty

In general, genetic modification by the application of recombinant DNA technology is characterised by scientific uncertainty. This stems from several factors including the inherent imprecision of currently employed recombinant DNA techniques, the use of powerful promoter sequences in genetic constructs and the generation, as a result of genetic modification, of novel proteins to which humans and animals have never previously been exposed[13]. Additionally, the gaps in the knowledge regarding composition and functioning of the genomes that are often subjected to genetic manipulation and ill-designed experiments compound such scientific uncertainty[13].

Uncertainty is a key element of the Biosafety Protocol (Cartagena Protocol on Biosafety to the Convention on Biological Diversity[14]. The lack of sufficient relevant scientific information and knowledge regarding the extent of potential adverse effects allows the Precautionary Principle referenced in the Biosafety Protocol to be triggered. The precautionary principle states "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

Possible unintended effects of the non-functional DNA fragments

Unintended effects that are not detected in the lab and that may only become apparent in the long term cannot be ruled out. Transformation by particle acceleration is associated with multiple fragments and gene rearrangements[15,16]. The European Commission Scientific Committee on Food[17] has stated that the lack of transcription or translation signals from Northern and Western blots, does not 'preclude absolutely the possibility that the truncated gene is expressed but the possibility that this is the case will be extremely remote'[17]. Inserted gene sequences may interrupt native gene sequences and/or their promoters and additional code fragments are not necessarily non-functional and may be transcribed. Extra gene fragments in Monsanto's Roundup Ready Soya were also claimed to be non-functional and not-transcribed[18], but were later found to be transcribed to produce RNA[19,20].

Further, it is not clear if the insert or fragments thereof lie on any transposons and what the impact of the DNA insert is on flanking sequences. The lack of sophisticated methods for

targeted insertion, especially in higher organisms[16] necessitates more rigorous research into possible position effects prior to the granting of any release of transgenic organisms into the environment. Further, if transgenes behave just like naturally occurring genes, then they have the potential to be inherited in the same way and persist indefinitely in cultivated or free-living populations. Any mixing of native and transgenic plants whether by dispersal, improper handling etc., can result in the spread of transgenes. 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[16].

Potential for HGT of Antibiotic Resistance Marker Genes (ARMG)

The significance of any potential gene transfer is dependent on the marker being transferred and what its existing or future therapeutic application is or might be. Where there are antibiotic resistant marker genes such as *nptII*, there is a potential for gene transfer of these markers to pathogenic organisms. Geneticin is toxic to bacteria, yeast, protozoa, helminths, and mammalian cells[21]. The possibility of transfer of the marker by HGT, and subsequent adverse effects on human and animal health, cannot be ruled out in those cases where these antibiotics are still being used. Several European countries including Austria, Luxembourg, France, Norway and the United Kingdom have expressed grave concerns about the presence of antibiotic genes in GM products and the EU has as a result, decided to prohibit GMOs with antibiotic resistance genes after the 31st December 2004 (directive 2001/18EC and Revising Directive 90/220/CEE)[22].

Stability of the CaMV Promoter

The genes in both T1 and T2 are under the control of the Cauliflower Mosaic Virus CaMV35S promoter and terminator[9]. The CaMV 35S promoter has been found to have a recombination hotspot where it tends to fragment and join with other double stranded DNA in very non-specific way[23]. These hotspots are flanked by multiple motifs involved in recombination and functions efficiently in all plants, green algae, yeast and *Escherichia coli*. The potential exists for the viral genes to recombine with other viruses to generate new infectious viruses[23], carcinogens and mutagens and reactivate dormant viruses. Detractors claimed that virus infected cabbages and cauliflower have been consumed for years with no ill effects and that similar pararetroviral sequences occur widely in plants causing no apparent harm[24]. That the intact virus causes no obvious harm in the natural host is related to the fact that its integrity is maintained and that it is adaptive to the host biology. This is unlike the fragments of naked DNA as in transformed plants where the natural regulatory mechanisms are not present[23]. A call has been made that the use of the CaMV promoter in transgenic plants be phased out due to the structural instability arising out of its use[25]. Information relating to "event specific" molecular analysis has not been provided for any of the transgenic events. We believe it to be necessary that such molecular characterization be

carried out and submitted or if it has been carried out be made available for independent scrutiny.

Bt Toxicity Effects on Non-target Organisms

Non-target organisms refer to those that are not the target of the pest control method, in this case the presence of a gene coding for Bt toxins. There are several possible categories of non-target organisms, including beneficial species, such as the natural enemies of the target pests, pollinators including insects and avian species, non-target herbivores, soil organisms, endangered species such as the monarch butterfly and species that contribute to local biodiversity[16]. For the most part toxicity studies completely disregard effects on non-target organisms. Results which show no toxicity effects on non-target pests are often taken as confirmation that these organisms are unaffected. Many studies often do not take into consideration any possible prey-mediated toxicity effects[26]. For example green lacewing larvae fed the Bt toxin directly exhibited no ill effects, but green lacewing larvae fed on prey that fed on Bt maize exhibited prolonged development times[27]. There is a concern that constant low level exposure of the target insects to the Bt toxins could result in these organisms themselves developing resistance to the toxin[28]. This could result in the use of higher toxicity pesticides[29].

Allergenicity

The nature of genetic modification of higher plants results in the production of novel proteins which might cause allergic reactions. One reason for the failure of identification of GM crops as allergenic is related to the fact that the testing and assessment thereof is left up to the developer of the transgenic organism and that no standardized agreed-upon protocols exist for such testing[7]. Cry1Ab, for example, has three characteristics of allergenic proteins, namely digestive stability, heat stability and structural similarity to vitellogenin, an egg yolk allergen[30].

CONCLUSIONS

The available scientific information, as provided by the notifier, does not allow for a full evaluation or determination of the associated risks of the use of the said transgenic line. The fact that the notifier does not have access to full and complete information regarding the insert calls into question the claims of low risk. At a minimum, the literature indicates that a great deal more investigation has to be carried out on the impacts of transgenes before their release into the environment. No indication is given of what the future intention of the transgenic development is and the purpose is stated as being for ‘proof of concept” only[9] . In several instances claims are made by the notifier of no adverse effects to human and animal health and the environment from release of the transgenic organism that no supporting literature is cited. Are we to assume that these conclusions are based on research

conducted by the notifier and if so, have any independent assessments been made of this research?

Any potential category of risk introduced by the genetic modification as compared to risks from conventional breeding is still unclear from the application. The ability of ecosystems to develop gradually, the ability to anticipate environmental health effects and very importantly, the establishment of regulatory mechanisms that can effectively, efficiently and credibly manage risks associated with the use of GMOs has not kept apace with the rapid introduction of GMOs. Traditional breeding practices have an established history of safe use dating back several years as opposed to the application of recombinant DNA technology for human use, which is as young as 22 years when genetically modified bacteria-produced insulin was first introduced and even younger for genetically modified plants at ten years[13].

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