

Our objections against GM mustard DMH-11 & its parental lines: very need, benefit claims, safety claims and testing

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This application in front of GEAC is for:

...Approval of environmental release of transgenic mustard lines and hybrid DMH-11:

- Growing and multiplication of mustard (*B. juncea*) parental lines containing event bn 3.6 (bar-barnase genes) and event modbs 2.99 (bar-barstar genes) for hybrid seed production
- Production seed of mustard hybrid DMH-11 using the parental lines Varuna bn 3.6 and EH-2 modbs 2.99 for cultivation by the farmers
- Use of the two events for introgressing the bar-barnase and bar-barstar genes into new set of parental lines to develop next generation of hybrids with higher yields, disease resistance and quality traits.

ONE DOSSIER & ONE APPLICATION FOR 3 GMOs!

We contend that each of these requires independent risk assessment and separate dossiers for any scientific, considered decision-making – not enough that all of them are used in a set of tests undertaken (in fact, some tests not done on parental lines). Today's presentations focus mainly on DMH-11, that too agronomic and environmental safety studies, apart from raising many other issues related to GMOs in general and impacts of DMH-11 in particular

GM Mustard R&D and Testing brings shame to the scientific establishment

- **GMO changed midway** : Dossier continues to be the same!
- **GMO went into BRL stage trials straightaway** – no apparent discussions in GEAC when moved from agronomic trials back to a new GMO & straight to BRL!
- Trial protocols rigged for favorable results – **GEAC decisions on protocols willfully violated** – ample scope given to crop developer to fix own protocols – Regulators rubber-stamped
- Trials against poor performing old comparators not used in ICAR system of cultivar evaluation – when 100s of public sector scientists put themselves through the AICRPRM protocols, ***why a lesser standard for a risky GMO??***
- *THE one year when ICAR MLRT takes place (2006-07), hybrid check is used, and DMH-11 does not perform better than DMH-1. Only 18.5%/16.5% increase reported over Checks in that year. Did regulators ask why so low only that year?*
- **Data tweaked and miscalculated** at least by 7.5% (higher yield projection with DMH-11) **within the already compromised protocols!**
- **“Derived yield” from raw data of trials completely at variance** with the good projections being made for DMH-11 yields
- DMH-11 testing completely inadequate – **DRMR’s RTI reply reveals that they were only forwarding reports. They also show that DMH-11 is not high yielding.**
- Regulators have no business entertaining an application for “environmental release” or commercial cultivation
- **IMPORTANTLY, NO SCIENTIFIC EVIDENCE THAT DMH-11 OUTYIELDS EXISTING BEST PERFORMING VARIETIES AND HYBRIDS IN INDIA**

ANY BENEFIT ASSESSMENT AT ALL?

- Risk Assessment frameworks are all about assessing comprehensively both Risks and Benefits, for intelligent decision making. Such a framework should begin with Needs & Alternatives Assessment for any application.
- Yield claim, and import reduction claim of DMH-11 are both disproven with our evidence : Production and Yield data of Rapeseed Mustard in India has no evidence to show that entry of hybrids has increased yields and reduced imports
- There is also evidence from Regulatory CCC field visits and from data from field trials that Male Sterility trait is breaking down (the technical basis for the hybrid creation in transgenic GM mustard): again, the very technological basis of the benefit claims has been unverified in a thorough fashion – in fact, there are outright lies in the crop developer responses on this front, belying field data in tables of BRL reports and CCC field visit reports – if GEAC does not believe its own CCCs, who will it believe? Unless it is a matter of pre-decided functioning!
- No import bill decline or yield increases from other hybrids...Was this claim assessed?
- We also present evidence on successful alternatives that are safer, affordable (to farmer and government) and ecological – alternatives like System of Mustard Intensification are showing fantastic results in farmers' fields, leave alone from rigged trials!

SO, WHY SHOULD DMH-11 OPTION BE CONSIDERED AT ALL, WITH ITS FRAUDULENT CLAIMS? MORE SO WHEN IT IS USING A HERBICIDE TOLERANT TRAIT, IN A CROP FOR WHICH WE ARE A CENTRE OF DIVERSITY WITH GURT TO BOOT!

DMH-11 testing woefully inadequate

In the absence of the biosafety dossier in public domain, within the limited information we were able to get, it is clear that:

- No chronic health safety testing (only 1 sub-chronic)
- No feeding trials
- No assessment of impacts on Ayurveda/ISM
- No assessment of impact on honey (bees &) production
- No proteomics, transcriptomics & metabolomics
- No assessment of impact on organic sector

WHEN YOU SAY INDIA HAS A CASE-BY-CASE APPROACH, HOW CAN YOU HAVE UNIFORM GUIDELINES WHICH FURTHER HAVE WAIVERS OF SOME STUDIES?

HAVE YOU ASSESSED GM MUSTARD MORE SPECIFICALLY IN THIS CASE BY CASE APPROACH GIVEN THAT IT IS A HT GURT CROP?

Even data provided is inadequate (allelic arrangement and crop genetics & gene flow, for eg. is not provided):

Do the regulators care?

DMH-11 TESTING PROTOCOLS & DATA UNSCIENTIFIC & EVEN LAUGHABLE

- * YIELDS
- * Beneficial Insects
- * Pests
- * Pollen Flow
- * Diseases
- * Pollination Behaviour
- * Aggressiveness & Weediness etc. etc.

Test protocols unscientific

Observations unbelievable and untenable

Interpretation also consisting of outright lies!

(Since biosafety dossier is not in public domain, we are able to make only limited comments here with limited access to information).

WE CAN'T IMAGINE WHAT IS HIDDEN INSIDE THE FULL DOSSIER AND CAN ONLY
IMAGINE WHY IT IS BEING HIDDEN.

**Regulators have to prove to the nation why they think
authentic testing has been done and data reflects authentic
scientific test results**

DMH-11 IS A HT CROP NOT BEING CALLED OR ASSESSED AS ONE....

- Herbicide Tolerance trait will be used by farmers – Glufosinate will have its own UNASSESSED implications for health and environment (numerous studies exist to show its adverse impacts already)
- THIS IS A HERBICIDE TOLERANT CROP TRYING TO COME IN THROUGH THE BACK DOOR, BUT NOT APPLIED FOR, OR ASSESSED AS A HT GMO!
- Indian regulators don't have any risk assessment regimes for HT crops
- Male Sterility trait will also spread in Indian mustard – this has implications for yield losses

DMH-11 will jeopardise farm livelihoods...

**INDIA BEING MADE A DUMPING GROUND FOR TOXIC REJECTED
TECHNOLOGIES BY OUR OWN “PUBLIC SECTOR” SCIENTISTS &
BY USAGE OF TAXPAYERS' FUNDS!**

PARENTAL LINES ALSO FULLY HERBICIDE TOLERANT!

Farmers will incur losses & lose sovereignty

- With possibility of F2 seeds being kept for sowing (no point in using national Seed Replacement Rates here when in many important mustard growing states, SRRs range from 20% to 50%), herbicide tolerance trait sought to be exploited by farmers (& chemical companies??) and male sterility increasing, **farmers lose on 3 fronts, even as yield claims are false.**
- Neighboring non-GM farmers will not be able to save seed – upto 25% of their crop will be male sterile when outcrossing occurs; further damage with any accidental glufosinate sprays.
- MUSTARD FARMERS WILL LOSE THEIR SOVEREIGNTY

INFRINGEMENT ON RIGHTS OF CHOICE

- Farmers who want to remain GM-free cannot do so – their mustard crop will get contaminated
- Organic farmers will be particularly affected – their organic status will be jeopardised (No organic canola possible in Canada/USA now)
- Consumers will have no choices either : right to know what is in their food and right to make informed choices will be violated

NO LIABILITY REGIME IN PLACE

- WHO IS RESPONSIBLE FOR FAILURES & RISKS?
CROP DEVELOPERS? NDDDB & DBT?
GOVERNMENT OF INDIA? REGULATORS?
- UNDER WHICH LAW, AND CLAUSES?
- WHAT IS THE REDRESSAL MECHANISM LEFT
FOR CITIZENS WHO ARE AFFECTED?
- AND WHO IS STANDING GUARANTEE FOR THE
BENEFIT & SAFETY CLAIMS BEING MADE??

CONFLICT OF INTEREST ALL OVER DMH-11

- DBT: SITS IN MEETINGS WHERE IT IS PROPOSED TO ASK FOR FUNDING, ACCEPTS PROPOSALS, FUNDS, APPROVES TESTING AS PER CONVENIENT PROTOCOLS EVOLVED BY CROP DEVELOPER AND ALSO JUDGES THE SAFETY: **INCIDENTALLY IS ALREADY PROCLAIMING IN SOCIAL MEDIA THAT EVERYTHING IS SAFE WITH GM MUSTARD! REALLY??**
- DR AKSHAY PRADHAN, TEAM MEMBER OF UDSC DMH-11 TEAM IS A GEAC MEMBER
- DR SESIKERAN WHO HEADS RCGM IS ILSI BOARD MEMBER, GEAC MEMBER AND ALSO GOT TO TAKE UP TESTING AFTER PRESCRIBING PROTOCOLS FOR HIMSELF AS THE THEN NIN-DIRECTOR – WILL NOW ENDORSE HIS OWN PROTOCOLS AND RESULTS, WE GUESS!
- DR DEEPAK PENTAL IS HEAD OF DRMR DECISION-MAKING BODIES ON RESEARCH – GOT TO DECIDE ON HIS OWN TEST PROTOCOLS
- A PUBLIC PRIVATE CONSORTIUM CALLED BCIL GETS DBT FUNDS TO PREPARE BIOSAFETY DOSSIER – THESE ARE TAX PAYERS' FUNDS WORTH CRORES OF RUPEES.....

Why should the nation trust decision-making with such rampant conflict of interest?

INCIDENTALLY, REGULATION IS MOSTLY ABOUT BIOSAFETY SCIENCE, NOT FOR CROP DEVELOPERS AND PROMOTERS TO GIVE GREEN SIGNALS TO THEMSELVES

Regulators fail the nation badly

- Why have ONE biosafety dossier that is of 6 GMOs? Can decision-making happen soundly in this manner?
- Why should a sub-committee finish its job in 15 days that too AFTER planting season was over? What was the hurry?
- Why did GEAC not ask for raw data?
- Why did GEAC allow DMH-11 to reach this stage when before BRL II trials they are supposed to have appraised biosafety – there are so many protocols that needed to have been verified at least at that stage??
- Why did regulators ignore biosafety violations related complaints by civil society as well as their own CCC reports??
- Why did regulators not insist on sharing data in the public domain so that their mandate as regulators is supplemented by independent scientific scrutiny?
- Why do regulators not attend meetings in the first instance and GEAC is allowed to take decisions with just 11-12 members out of a 30+member body?
- Where is representation and participation of Health Ministry and AYUSH Ministry in GEAC (other than invitation to one meeting)?

DATA ON DMH-11 CONTINUES TO BE SHROUDED IN SECRECY

- DESPITE CIC ORDERS, GEAC HAS NOT PUT OUT BIOSAFETY DOSSIER IN PUBLIC DOMAIN
- THIS, INSPITE OF THE FACT THAT GEAC ITSELF TOOK A DECISION ON THIS PRIOR TO THE CIC HEARING & ORDERS!
- **CIC ORDERS EXPRESSLY SAY THAT PUBLIC SCRUTINY NEED NOT AWAIT REGULATORS' REVIEW OF DATA.**
- HIGH TIME THAT ALL DOCUMENTS AND CORRESPONDENCE WITH REGARD TO DMH-11 ARE PUT IN THE PUBLIC DOMAIN – THIS IS AFTER ALL TAXPAYERS' MONEY BEING USED

DMH-11 is about promoting BAD SCIENCE

- Inadequate Risk Assessment
- Lack of assessment of benefit claims
- Unscientific Risk Assessment protocols
- Conflict of Interest
- Ignoring post-modern science and practice of agro-ecology
- Secrecy
- Rigging and Regulatory violations
- Ignoring of negative fallouts of GM canola

GEAC FAILING TO APPRAISE, & KEEN ON APPROVING

GENTLE REMINDER

- THE MATTER OF HT CROPS IS SUB-JUDICE
- THE MATTER OF RISK ASSESSMENT REGIME FOR TRANSGENIC CROPS IS SUB-JUDICE

**THERE IS HUGE RESISTANCE FROM SCIENTISTS,
STATE GOVTS, FARMER UNIONS, CONSUMER
GROUPS & ORDINARY CITIZENS**

**REGULATORS SHOULD NOT HAVE PROCEEDED THIS
FAR IN THE FIRST INSTANCE!**

WE REITERATE ONCE AGAIN WHAT WE HAVE ALWAYS SAID:

TRANSGENIC TECHNOLOGY FOR MAKING GMOs IS A LIVING TECHNOLOGY.

GMOs ARE CREATED BASED ON IMPRECISE SCIENCE AND TECHNOLOGY WITH IRREVERSIBLE, UNCONTROLLABLE & UNPREDICTABLE RESULTS.

GMOs IN GENERAL & THIS GM MUSTARD IN PARTICULAR ARE UNNEEDED, UNWANTED AND UNSAFE.

OUR DEMANDS TO REGULATORS

- Reject DMH-11 application *in toto* and immediately (incl. parental lines): YOU SHOULD NOT HAVE PROCESSED THE APPLICATION THIS FAR AT ALL
- Fix liability on crop developers for false and incorrect information provided – blacklist such applicants
- Share all information in the public domain
- Accept responsibility for failure to discharge duty