Role of science in legal procedures

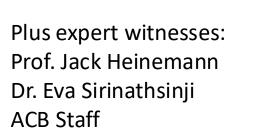
Case example: Court ruling demands the South African government to apply the precautionary principle in GMO approval requests

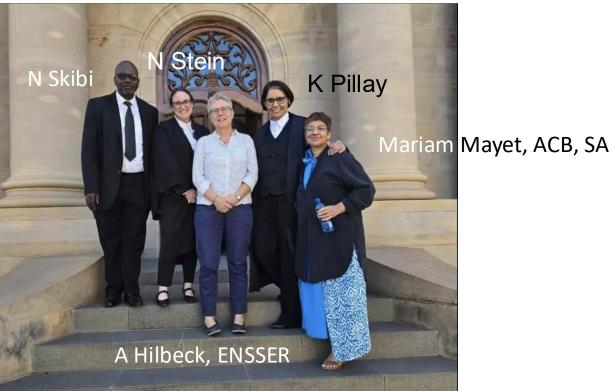
Angelika Hilbeck, ETH Zurich (ret.), Switzerland Mariam Mayet, ACB, South Africa

Groundbreaking judgment of the Supreme Court of Appeal in ACB vs Monsanto/Bayer and the State

Commercial approval of GM drought-tolerant maize set aside

Johannesburg, 22nd October 2024





David against Goliath...

In the matter between:

AFRICAN CENTRE FOR BIODIVERSITY NPC APPELLANT

and

MINISTER OF AGRICULTURE, FORESTRY

AND FISHERIES

FIRST RESPONDENT

DIRECTOR-GENERAL: DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES

SECOND RESPONDENT

EXECUTIVE COUNCIL FOR GENETICALLY

THIRD RESPONDENT

APPEAL BOARD, GENETICALLY MODIFIED

FOURTH RESPONDENT

MONSANTO SOUTH AFRICA (PTY) LTD

FIFTH RESPONDENT

BAYER (PTY) LTD

ORGANISMS

MODIFIED ORGANISMS

SIXTH RESPONDENT

The Case – 'Drought-tolerant' (DT) maize (MON 87460) of Monsanto / Bayer application for general release in South Africa

DT trait was introduced in different GM crops:

- a) MON87460 single DT gene maize (approval 2015, ACB lodged appeal)
- b) MON 89034 DT trait together with two different insecticidal Bt toxins (ACB launched objection against approval request by Monsanto)
- c) In addition, Monsanto has made an application to the South African authorities for approval of the commercial release of MON 87460 x NK 603 x MON 89034 (called the triple stack), which adds glyphosate resistance on top of the others (objection to field trials 2016 and to further release 2017). In 2019, the Ministry of Agriculture rejected the triple stack!



agriculture, forestry & fisheries Department: Agriculture, Forestry and Fisheries REPUBLIC OF SOUTH AFRICA

PUBLIC NOTICE:

03 October 2019

MINISTER'S FINAL DECISION ON THE APPEAL LODGED BY MONSANTO SOUTH AFRICA (PTY) LIMITED UNDER THE GMO ACT, 1997

On 28 August 2019 the Minister made the final decision and upheld the Appeal Board's decision and as such the refusal of a general release application for the MON87460 x MON89034 x NK603 maize event is sustained.

The reasons for the appeal board decision included the following:

- Kernel data cannot be used as the main criterion for efficacy of the drought tolerance trait; it can however be used as supporting evidence.
- The drought tolerance gene in the MON87460 x MON89034 x NK603 maize event did not provide yield protection in water-limited conditions.

Claims of drought tolerance have always been dubious

ISAAA claimed that Monsanto has indicated that MON 87460 had "about 7%" yield advantage under drought conditions, but that "early hopes of a 15% boost in yields under stress from this transgene have been replaced with a more modest expectation of 10%".*

"... On average, under water-limited conditions (?), MON 87460 hybrids are expected (!) to provide a <u>6% or greater (?)</u> yield advantage (?) compared to commercial hybrids (any?)."

Petition for the determination of Non-regulated status for MON 87460. Monsanto Petition Number: 07-CR-191U 2009, 561.

The ARC, in its trials of MON 87460, claims 8–14% yield advantage under moderate drought stress.**

*Edmeades GO (2013) Progress in achieving and delivering drought tolerance in maize – An update. ISAAA: Ithaca, NY.

** Mashingaidze K (2015) Cited in: African Centre for Biodiversity (ACB) (2017) The Water Efficient Maize for Africa (WEMA) Project – Profiteering not philanthropy! Johannesburg: African Centre for Biodiversity



United States Department of Agriculture

Economic Research Service

Economic Information Bulletin Number 204

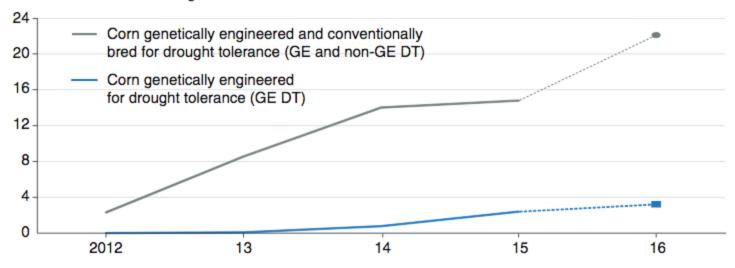
January 2019

Development, Adoption, and Management of Drought-Tolerant Corn in the United States

Jonathan McFadden, David Smith, Seth Wechsler, and Steven Wallander



Diffusion of drought-tolerant (DT) corn during first 5 years of commercialization



Percent of U.S. corn acreage

https://www.ers.usda.gov/webdocs/publications/91103/eib-204.pdf?v=5455.2

Groundbreaking judgment of the Supreme Court of Appeal in ACB vs Monsanto/Bayer and the State

Commercial approval of GM drought-tolerant maize set aside

"After nine long years of arduous litigation by the African Centre for Biodiversity (ACB), a full bench consisting of five judges of the Supreme Court of Appeal (SCA), sitting in Bloemfontein, South Africa, has today set aside several layers of decision-making regarding the approval of the application by Monsanto, now Bayer, for commercial release of its drought-tolerant genetically modified (GM) maize, MON87460."

https://acbio.org.za/gm-biosafety/groundbreaking-judgment-of-the-supreme-court-of-appeal-in-acb-vs-monsanto-bayer/

In the final analysis:

•The judgment of Judge Tolmay has been set aside.

•The approval by the EC during or around June 2015 of Monsanto's application is reviewed and set aside.

•The Appeal Board's decision of 1st September 2016 dismissing the ACB's appeal is reviewed and set aside.

•The Minister of Agriculture, Forestry and Fisheries decision of 2nd December 2016 confirming the dismissal of the appeal and the EC's approval is reviewed and set aside.

•Monsanto now Bayer's application for commercial release of its GM drought-tolerant maize MON87460 is sent back to the EC for reconsideration.

Unanimously, the SCA found that there was an abject <u>failure by the EC (Executive</u> <u>Council) to comply with a mandatory prescript contained in section 5(1)(a) of the GMO</u> <u>Act¹ to determine whether Monsanto was required to submit an environmental impact</u> <u>assessment</u> by the National Environmental Management Act (NEMA). The SCA, in its judgment, noted that it was a relatively straightforward matter for the state to have adduced evidence that a determination was made one way or the other, but it had failed to do so.

The ACB has consistently maintained that the **Executive Council: GMO Act (EC) merely rubber-stamped Monsanto's application for authorisation, uncritically accepting** its paucity of evidence **that the genetically modified organism (GMO) poses no threat to human health or the environment and ignoring the contrary expert evidence tendered by ACB's experts.** The expert opinions (affidavits) made by three experts (2 ENSSER members) concerned these scientific issues listed in the unanimous verdict of the five SCA judges[2], which triggered the application of the precautionary principle:

"[20] The experts, who provided opinions in support of the appellant, highlighted several fundamental concerns, all of which were articulated in the appeal document that served before the Appeal Board. Those concerns include:

(a) When regard is had to the Cartagena Protocol, which requires that claims of scientific certainty be substantiated with evidence to prove a lack of potential for scientific hazards; Monsanto's risk assessment was inadequate in identifying plausible hazards;

(b) Monsanto's claims of lack of allergenicity are unsubstantiated;

(c) Monsanto itself identified a fragment of the protein used in MON87460 (cspB) that was resistant to pepsin digestion, meaning that it is not fully digestible by gastric juices, further experimentation (such as serum analysis or animal testing) was thus required to assess potential allergenicity;

(d) The data Monsanto had included in its application showed <u>high expression of cspB in</u> <u>pollen</u>, but Monsanto has not conducted any studies on the potential and likelihood of allergenic responses to pollen;

https://www.saflii.org/za/cases/ZASCA/2024/143.html

(e) There is no history of the safe use of MON87460 in the form in which it is expressed since the data submitted by Monsanto in support of its safety claims were based on fermented and digested forms of the product.

(f) There was no evidence in the record before the Executive Council, the Appeal Board, and the Minister on the effects of food processing and the safety of human exposure via cooked MON87460 in South African diets, the only data included was <u>summaries</u> of the following –

(i) A chicken feeding study in which raw maize was fed to chickens;

(ii) An acute toxicity study on the effects on mice of the bacterially derived isolated protein, which has limited application to human exposure and is in any event not a study of all proteins associated with MON87460

(iii) A rat feeding study;

(iv) A broiler chicken study, which was concerned with food quality standards and not with any adverse impacts on health; and

(v) Aggregated field trial summaries, which contain insufficient information to interpret and apply the findings to the application for approval for the general release of MON87460."

https://www.saflii.org/za/cases/ZASCA/2024/143.html

Fun Fact & Conclusions

GM industries submit near-identical applications to ALL regulators in the world, including the EU (and the US).

Almost all regulators act like the SA regulator and accept at face value what the applicant industry says, including the EU (following the US).

Again, the highest South African court sets precedent not only for South Africa or Africa but also for Europe, alas non-binding. In South Africa, the courts gave the precautionary principle teeth while in Europe it is mostly window dressing. In South Africa, the court acted independently from the government and, in fact, scolded the government to side with the industry rather than with the courts and the law. Update May 2025 ...

The South African government submitted an application to the Constitutional Court for leave to appeal the Supreme Court judgement.

Bayer/Monsanto is a respondent. As of yet, unclear if they have submitted anything in this role.

ACB has submitted arguments against granting leave to appeal

Decision of Constitutional Court to grant leave to appeal (accept the case to be submitted before them) in the next weeks.

Thank you!