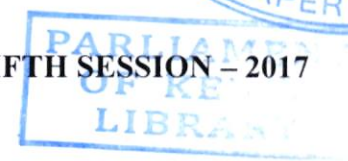
Approved for tabling
15/6/17

REPUBLIC OF KENYA

Paper laid
By the Hon. Karoki Mbiuki, MP V/Chair, Dept. Committee on Agriculture, Livestock & Cooperative L on Thursday, June 15, 2017

NATIONAL ASSEMBLY



ELEVENTH PARLIAMENT – FIFTH SESSION – 2017

DEPARTMENTAL COMMITTEE ON AGRICULTURE, LIVESTOCK AND COOPERATIVES

REPORT ON THE PETITION BY THE KENYA UNIVERSITY BIOTECHNOLOGY CONSORTIUM (KUBICO) ON LIFTING OF THE BAN IMPOSED ON CONSUMPTION OF GMO FOODS, AND FOR THE ISSUANCE OF A PERMIT TO CONDUCT FIELD TRIALS OF BT MAIZE

DIRECTORATE OF COMMITTEE SERVICES,
CLERK'S CHAMBERS
PARLIAMENT BUILDINGS
NAIROBI

JUNE , 2017

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NA: Report on a petition by Mr. Joel Winya Ochieng on behalf of Kenya University Biotechnology Consortium KUBICO on the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize.

CHAIRMAN'S FOREWORD

The petition by Mr. Joel Winya Ochieng on behalf of Kenya University Biotechnology Consortium KUBICO on the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize. The report was tabled before the House pursuant to Standing Order No. 225 (2) (a) by Hon. Daniel Maanzo, M.P on behalf of Mr Joel Winya Ochieng and other petitioners.

The Committee held meetings with the Mr. Joel Winya Ochieng on behalf of the petitioners. The meetings were aimed at responding to the issues raised in the petition.

The Committee wishes to thank the Speaker and the Clerk of the National Assembly for the logistical and technical support they accorded the committee during the inquiry.

On behalf of the Committee, and pursuant to Standing Order, 227 it is my pleasant duty to table in the House the Report of the Departmental Committee on Agriculture, Livestock and Fisheries on its consideration of a by Mr. Joel Winya Ochieng on behalf of Kenya University Biotechnology Consortium KUBICO on the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize.

HON. KAREKE MBIUKI, MP

EXECUTIVE SUMMARY

This report has considered and responded to the prayers sought Mr. Joel Winyo Ochieng on behalf of the Kenya University Biotechnology Consortium (KUBICO) for the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize. The Committee found out that The ban imposed covered importation only. As such the petitioners' key prayer is already granted. For the avoidance of doubt, the ban on consumption is lifted, whereas that of importation is sustained.

The report entails presentations by the Petitioner, Mr. Joel Winyo Ochieng. After deliberations, the Committee took cognizant of the fact a report on the Lift of Ban on Genetically Modified Products is before the House awaiting adoption. The Committee is of the view that the petitioner and any other interested party awaits the adoption of the said report by the House and move amendments should it be necessary.

The Committee also notes that conducting test trials for research purpose is not banned hence the consortium can continue with their test trials without any undue hindrance under the regulations by the Kenya Biosafety Authority

1.0 PREFACE

1.1 On Tuesday 20th December, 2016, a Petition was tabled before the House pursuant to Article 119 (1) of the Constitution of Kenya 2010 and Standing Order No. 225 (2) (a) by the Hon. Daniel Maanzo, MP on behalf of the Kenya University Biotechnology Consortium (KUBICO) for the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize.

1.2 The House pursuant to Standing Order 227 referred the Petition to the Departmental Committee on Agriculture Livestock and Cooperatives for preparation of the Report;

1.3 The Committee received the Petition on Thursday 22nd December ,2016 and set out a procedure for consideration of the petition and to report to the House within 60 days as set out in Standing order no 227(2);

1.2 MANDATE OF THE COMMITTEE

The Committee under Standing Order 227 is mandated to respond to the petitioner by way of a report addressed to the petitioner or petitioners and laid on the floor of the House

The Committee is established in accordance with the provisions of Standing Order No. 216, with the following terms of reference: -

i. To investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration, operations and estimates of the assigned Ministries and departments;

ii. To study the programme and policy objectives of Ministries and departments and the effectiveness of the implementation;

iii. To study and review all legislation referred to it;

iv. To study, access and analyze the relative success of the Ministries and departments as measured by the results obtained as compared with their stated objectives;

v. To investigate and inquire into all matters relating to the assigned Ministries and departments as they may deem necessary, and as may be referred to them by the House or a Minister;

vi. To vet and report on all appointments where the Constitution or any law requires the National Assembly to approve, except those under Standing Order 204 (Committee on Appointments); and

vii. To make reports and recommendations to the House as often as possible, including recommendation of proposed legislation.

1.2.1 Committee Subjects

The Committee is mandated to consider the following subjects:-

i. Agricultural services
ii. Livestock services
iii. Fisheries
iv. Cooperatives

1.2.2 Oversight

In executing its mandate, the Committee oversees the following Government Departments and agencies, namely:-

i. The State department of Agriculture
ii. The State Department of livestock
iii. The State Department for fisheries
iv. The State Department of Cooperatives

1.3 MEMBERS OF THE COMMITTEE

Chairperson	The Hon. Adan M. Nooru, MBS, CBS, MP
Vice Chairperson	The Hon. Kareke Mbiuki, M.P
Members	The Hon. Daniel Maanzo, MBS,
	The Hon. Silas Tiren, M.P
	The Hon. Maison Leshoomo, M.P
	The Hon. Mary Wambui, M.P
	The Hon. (Dr.) Victor Munyaka, M.P
	The Hon. Korei Ole Lemein, M.P
	The Hon. John B. Serut, M.P

The Hon. Peter N. Gitau, M.P

The Hon. Florence Mutua, M.P

The Hon. John Kobado, M.P

The Hon. Benjamin Washiali, M.P

The Hon. Patrick Wangamati, M.P

The Hon. Andrew AnyangaToboso, M.P

The Hon. Raphael Letimalo, M.P

The Hon. Ayub Savula Angatia, M.P.

The Hon. Waititu Munyua, M.P

The Hon. Kimani Ichung'wah, M.P

The Hon. Ferdinand Wanyonyi, M.P

The Hon. Kabando Wa Kabando, M.P

The Hon. Justice Kemei, M.P

The Hon. Benjamin Andayi, M.P

The Hon. Millie Odhiambo - Mabona, M.P

The Hon. Jude Njomo, M.P

The Hon. Fredrick Outa, M.P

The Hon. Aisha Jumwa, M.P

The Hon. Alfred Kiptoo Keter, M.P

The Hon. Paul Simba Arati, M.

1.4 COMMITTEE SECRETARIAT

First Clerk Assistant	Mr. Benjamin Magut
Clerk Assistant	Ms. Naserian Lotuai
Clerk Assistant	Mr. Ahmad Guliye
Legal Counsel	Ms. Brigita Mati
Research & Policy Analyst	Ms. David Ngeno
Fiscal Analyst	Mr. Abdinassir Mogare

NA: Report on a petition by Mr. Joel Winya Ochieng on behalf of Kenya University Biotechnology Consortium KUBICO on the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize.

1.5 FINDINGS & OBSERVATIONS

The Committee made the following observations from evidence adduced in the meetings: -

I. Despite the surveillance at entry and exit points by NBA and other bodies, GMO foods are still finding their way into the country. There is a gap in enforcing the ban on GMO foods.

II. The ban imposed covered only importation and consumption of Genetically Modified Food and not research. As such the petitioners' key prayer is already granted. For the avoidance of doubt, the ban on consumption and importation of GM Food is still in place.

III. There was need to review the National Biosafety Act No. 2 of 2009 to give it more teeth;

IV. Kenya has the potential of applying biotechnology with proper safety measures in place to be able to increase its food basket to be food secure;

V. It was not sufficient for the precautionary ban to only affect food products and leave out non-food products;

VI. By-products of the non-food GM products may be used in food industries e.g the Bt-Cotton thus making it difficult to manage roll out of non-food GMO products.

VII. Despite the ban, there are foods and foods flavours circulating in our supermarket stores e.g the aromat seasoning.

VIII. Local researchers be allowed to conduct field trials of *Bt* maize through KEPHIS to ascertain drought tolerance and insect resistance, as well as collecting compositional data for safety analysis, but not for cultivation or commercialization.

IX. Local biotechnology researchers in public universities be funded to perform safety assessment of foods derived from genetic engineering (appendix). These should include

a. Assess the level of risk associated with GM foods using a two year feeding experiment on GM maize and Roundup ready herbicide using rats, to inform public health mgmt.

b. Quantifying the impact of Roundup Ready herbicide and pesticides on human, fish and environmental health

c. Estimate the level of gene flow occurring between Bt maize and indigenous maize under local conditions.

NA: Report on a petition by Mr. Joel Winya Ochieng on behalf of Kenya University Biotechnology Consortium KUBICO on the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize.

1.6 LIST OF RECOMMENDATIONS

In response to the prayers by the petitioners, the Committee recommends that: -

1. The National Biosafety Authority to facilitate the Local researchers to conduct field trials of *Bt* maize to ascertain drought tolerance and insect resistance, as well as collecting compositional data for safety analysis, but not for cultivation or commercialization.

2. The ban imposed on GM food covered only Importation and Consumption. As such the petitioners' key prayer to undertake research has never been curtailed. For the avoidance of doubt, the ban on consumption and importation remains in place until such a time when the National Government put in place proper regulatory and surveillance framework to manage the production and use of GM foods and GM derived foods.

3. The Public Universities to consider funding their Local biotechnology researchers to perform safety assessment of foods derived from genetic engineering. These should include and not limited to:
    a. Assessing the level of risk associated with GM foods using a two year feeding experiment on GM maize and Roundup ready herbicide using rats, to inform public health management.
    b. Quantifying the impact of Roundup Ready herbicide and pesticides on human, fish and environmental health
    c. Estimate the level of gene flow occurring between Bt maize and indigenous maize under local conditions.

4. The Committee takes cognizant of the fact that a report on the Lift of Ban on Genetically Modified Products is before the House awaiting adoption.

The petitioner and any other interested party should await the adoption of the said report by the House.

5. There is need to kick start Commercialization of Bt-Cotton, however the government should put in place safety nets to ensure the byproducts of non-food GMOs do not find way into the food chain.

6. National Biosafety Authority should have a structured working relationship with other bodies to harmonize the process of developing, testing and regulating GMO products.

7. The country to review the existing policy on regulation of GMO products.

2.0 INTRODUCTION

2.1 The petition by Mr. Joel Winyo Ochieng on behalf of the Kenya University Biotechnology Consortium (KUBICO) for the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize was tabled in the House by pursuant to Standing Order 225 (2) (a) by the Hon. Daniel Maanzo, MP on Tuesday 20th December, 2016.

2.2 Pursuant to the House rules, the petition was referred to the Committee 22nd December, 2016 for consideration and preparation of a report within 60 days. The Committee considered the petition pursuant to the provisions of Standing Order 227.

2.3 The Petitioners prayed for the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize.

3.0 EVIDENCE

3.1 Presentation by Mr. Joel Winyo Ochieng on behalf of the Kenya University Biotechnology Consortium (KUBICO)

Appearing before the Committee, Mr. Joel Winyo Ochieng presented the following;

1. The petitioners are praying for lifting of ban on consumption of GMO foods

II. The petitioners are involved in Biotechnology research including genetic engineering at public universities, and develop GM products locally

III. Locally developed GM crops in Kenya so far are insect resistant (Bt-based), not Roundup tolerant varieties

IV. The ban on foods derived from genetically modified organisms (GMOs) was specific to importation only

V. Consumption and Research into GM safety was not banned

VI. Provisions of Part V, No 38 (3) of the Biosafety Act No 2, 2009 provides the National Biosafety Authority (NBA) as the only regulatory body authorized by law to impose such a ban

VII. The ban was not implemented in the manner prescribed in law, i.e., Not placed by the National Biosafety Authority; Not gazette. The Biosafety Act 2009, Part 33 and 38 (3) outlines what must be done when a new risk is suspected

VIII. Several products indicated as being carcinogenic (causing cancer) are still freely sold in the market in Kenya, including Roundup Ready herbicide, Mouthwash, Meat, Smoked fish, and Johnson's baby powder.

IX. Safety concerns regarding GM foods are centered on the Glyphosate herbicide (Roundup), and not *Bacillus thuringiensis* (*Bt*), a bacterium occurring naturally in our environment and soil, and often ingested.

X. Bt insecticides are currently used by farmers in Kenya, such as Thuricide®, Xenthari® and Dipel®. These are not genetically modified but they use the same bacterium and do not persist in the environment (degradable), and are very specific in their target pests and thus do not kill unintended insects.

XI. Food security in Kenya is fragile, and the *Bt* maize was intended to improve food production by reducing insect damage and reducing afflatoxins in maize.

XII. Lack of local research on safety of GM foods justified ban GM foods in 2012

NA: Report on a petition by Mr. Joel Winya Ochieng on behalf of Kenya University Biotechnology Consortium KUBICO on the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize.

3.2 SUBMISSION BY THE NATIONAL BIOSAFETY AUTHORITY (NBA) ON GMO

Appearing before the Committee the National Biosafety Authority made the following submissions:

i. The NBA has established a transparent science-based and predictable risk assessment process to guide decision making on applications for approval of research and commercial activities involving GMOs;

ii. The safety assessment process on GM foods is on a case by case basis. As such, approvals or rejections are for each GMO, based on data generated on their safety;

iii. In the decision making process, the Department of Public Health, among others are involved as they are part of the NBA Board, the organ that makes decisions on all GMO applications;

iv. NBA has attained a critical mass of best talents for regulating and testing of GMOs and their products.

v. In terms of capacity to carry out surveillance, the Authority has opened 4 offices at major entry and exit points namely Mombasa, Busia, Namanga and Jomo Kenyatta International Airport (JKIA);

vi. The Biosafety Inspectors manning the entry points are mandated to scrutinize shipping documents to ensure they are complete and have declared GMO status, monitor and take official samples from consignments entering the country and send them to our collaborating GMO testing laboratories;

vii. Infrastructural capacity to detect GMOs in the country is available in various public institutions and regulatory agencies (KEPHIS and KEBS) research institutes, including KARI's Biotechnology Centre and Public Universities;

viii. NBA works closely with other regulatory agencies, including Kenya Bureau of Standards (KEBS), Pest Control Products Board (PCPB), Kenya Plant Health Inspectorate Service (KEPHIS), National Environmental Management Authority (NEMA), Kenya Wildlife Service (KWS), the Kenya Industrial Property Institute (KIPI) and Department of Public Health;

ix. Within Sub-Saharan Region, NBA has the lead in supporting regional regulatory harmonization at COMESA and East African Community, and number of countries have since benchmarked with NBA as they continue to establish their regulatory framework.

x. It is also important to note that the Authority has adequate mechanisms to assess safety of all GM products before they can be imported and/ or released to the market and that there exists international standards that have been used over the years by regulatory agencies which provide sufficient data and information that have found no adverse effects of GM foods on human health over the last two decades of their use;

xi. Note that Kenya is a signatory of the International law on application of GM Technology the Cartagena Protocol and also the World Trade Organization (WTO). Under the Cartagena Protocol and WTO, Kenya cannot restrict trans-boundary movement of GM foods without any scientific or socio economic consideration that demonstrates the need for such action;

xii. To recommend and support adequate allocation of resources to enhance GMO detection and testing capacity for the National Biosafety Authority to adequately perform her mandate considering the dynamic nature of modern biotechnology;

4.0 FINDINGS AND OBSERVATIONS

The Committee made the following observations from evidence adduced in the meetings: -

I. Despite the surveillance at entry and exit points by NBA and other bodies, GMO foods are still finding their way into the country. There is a gap in enforcing the ban on GMO foods.

II. The ban imposed covered only importation and consumption of Genetically Modified Food and not research. As such the petitioners' key prayer is already granted. For the avoidance of doubt, the ban on consumption and importation of GM Food is still in place.

III. There was need to review the National Biosafety Act No. 2 of 2009 to give it more teeth;

IV. Kenya has the potential of applying biotechnology with proper safety measures in place to be able to increase its food basket to be food secure;

V. It was not sufficient for the precautionary ban to only affect food products and leave out non-food products;

VI. By-products of the non-food GM products may be used in food industries e.g the Bt-Cotton thus making it difficult to manage roll out of non-food GMO products.

VII. Despite the ban, there are foods and foods flavours circulating in our supermarket stores e.g the aromat seasoning.

VIII. Local researchers be allowed to conduct field trials of *Bt* maize through KEPHIS to ascertain drought tolerance and insect resistance, as well as collecting compositional data for safety analysis, but not for cultivation or commercialization.

IX. Local biotechnology researchers in public universities be funded to perform safety assessment of foods derived from genetic engineering (appendix). These should include

a. Assess the level of risk associated with GM foods using a two year feeding experiment on GM maize and Roundup ready herbicide using rats, to inform public health mgmt.

b. Quantifying the impact of Roundup Ready herbicide and pesticides on human, fish and environmental health

c. Estimate the level of gene flow occurring between Bt maize and indigenous maize under local conditions.

NA: Report on a petition by Mr. Joel Winya Ochieng on behalf of Kenya University Biotechnology Consortium KUBICO on the removal of a ban imposed on consumption of GMO foods, and for the issuance of a permit to conduct field trials of Bt maize.

5.0 RECOMMENDATIONS

In response to the prayers by the petitioners, the Committee recommends that: -

1. The National Biosafety Authority to facilitate the Local researchers to conduct field trials of *Bt* maize to ascertain drought tolerance and insect resistance, as well as collecting compositional data for safety analysis, but not for cultivation or commercialization.

2. The ban imposed on GM food covered only Importation and Consumption. As such the petitioners' key prayer to undertake research has never been curtailed. For the avoidance of doubt, the ban on consumption and importation remains in place until such a time when the National Government put in place proper regulatory and surveillance framework to manage the production and use of GM foods and GM derived foods.

3. The Public Universities to consider funding their Local biotechnology researchers to perform safety assessment of foods derived from genetic engineering. These should include and not limited to:
    a. Assessing the level of risk associated with GM foods using a two year feeding experiment on GM maize and Roundup ready herbicide using rats, to inform public health management.
    b. Quantifying the impact of Roundup Ready herbicide and pesticides on human, fish and environmental health
    c. Estimate the level of gene flow occurring between Bt maize and indigenous maize under local conditions.

4. The Committee takes cognizant of the fact that a report on the Lift of Ban on Genetically Modified Products is before the House awaiting adoption.

The petitioner and any other interested party should await the adoption of the said report by the House.

5. There is need to kick start Commercialization of Bt-Cotton, however the government should put in place safety nets to ensure the byproducts of non-food GMOs do not find way into the food chain.

6. National Biosafety Authority should have a structured working relationship with other bodies to harmonize the process of developing, testing and regulating GMO products.

7. The country to review the existing policy on regulation of GMO products.

Signed.....Date.....15-06-2017

HON. JAPHET KAREKE MBIUKI, MP

VICE CHAIRMAN DEPARTMENTAL COMMITTEE ON AGRICULTURE, LIVESTOCK AND COOPERATIVES.

REPUBLIC OF KENYA

NATIONAL ASSEMBLY

CLERK'S CHAMBERS

DEPARTMENTAL COMMITTEE ON AGRICULTURE, LIVESTOCK AND COOPERATIVES.

ADOPTION LIST

REPORT ON A PETITION BY THE KENYA UNIVERSITY CONSORTIUM ON THE LIFTING OF BAN IMPOSED ON CONSUMPTION OF GMO FOODS AND FOR THE ISSUANCE OF PERMIT TO CONDUCT FIELD TRIALS OF BT MAIZE.

NO	NAME	SIGNATURE
1	The Hon. Adan Mohamed Nooru, MBS,MP	
2	The Hon. Japhet M. Kareke Mbiuki, M.P.	
3	The Hon. Benjamin Jomo Washiali, M.P	
4	The Hon. John Bomett Serut, M.P.	
5	The Hon. Benjamin Andayi, M.P.	
6	The Hon. KabandoWa Kabando, M.P.	
7	The Hon. (Dr.) Victor K Munyaka, M.P.	
8	The Hon. Fredrick Outa, M.P.	
9	The Hon. Millie Odhiambo, M.P.	
10	The Hon. Raphael Letimalo, M.P.	
11	The Hon. Mary Wambui Munene, M.P.	
12	The Hon. Francis Munyua Waititu, M.P.	
13	The Hon. Peter Njuguna Gitau, M.P.	

14	The Hon. Maison Leshoomo, M.P.	
15	The Hon. Anthony K. Ichung'wah, M.P.	
16	The Hon. Aisha Jumwa, M.P.	
17	The Hon. Patrick Wangamati, M.P.	
18	The Hon. Maanzo, Daniel Kitonga, M.P.	
19	The Hon. Justice Kemei, M.P.	
20	The Hon. Korei Ole Lemein, M.P.	
21	The Hon. Ferdinand K. Wanyonyi, M.P.	
22	The Hon. Alfred Kiptoo Keter, M.P.	
23	The Hon. Ayub Savula Angatia, M.P.	
24	The Hon. Silas Tiren, M.P.	
25	The Hon. Florence Mwikali Mutua, M.P	
26	The Hon. James Wandayi, M.P.	
27	The Hon. John Kobado, MP	
28	The Hon. Paul Simba Arati, MP	
29	The Hon. Jude Njomo,M.P	

Directorate of Legislative and Procedural Services

MEMO

TO : DIRECTOR, COMMITTEE SERVICES

FROM : PRINCIPAL CLERK ASSISTANT

DATE : 20 DECEMBER, 2016

SUBJECT : PUBLIC PETITIONS

The above-mentioned matter refers.

On Tuesday, 20th December, 2016, the following Petitions were conveyed/presented to the House: -

(i) By the Hon. Speaker on lifting of ban on consumption of food derived from GMOs; and DC- AGRICULTURE

(ii) By the Hon. Isaac Mwaura, MP on enactment of legislation on prevention, control and management of sickle cell anaemia. DC- HEALTH

Enclosed herewith, please find the Petitions for your action.

Lucy Wanjohi

Encl.

Copy to: Clerk of the National Assembly
Director, Legislative and Procedural Services
Chair DC, Agriculture, Livestock and Fisheries
Chair DC, Health

1. MARUT
2. GSITHER

Pls deal
FA
22/12

REPUBLIC OF KENYA
ELEVENTH PARLIAMENT- (FOURTH SESSION)
THE NATIONAL ASSEMBLY
PETITIONS

(No.28 of 2016)

CONVEYANCE OF A PETITION REGARDING LIFTING OF BAN ON CONSUMPTION OF GOODS DERIVED FROM GENETICALLY MODIFIED ORGANISMS AND ISSUANCE OF PERMIT FOR NATIONAL PERFORMANCE TRIAL OF LOCALLY DEVELOPED Bt MAIZE

Honourable Members,

Pursuant to the provisions of Standing Order 225(2) (b), I hereby convey to the House that my office is in receipt of a Petition signed by one Joel Winyo Ochieng on behalf of Kenya University Biotechnology Consortium (KUBICO). The petitioners are praying for lifting of ban on consumption of foods derived from Genetically Modified Organisms commonly referred as GMOs and issuance of permit to conduct field trials of Bt maize, a maize crop developed locally using genetic engineering for resistance to a common stalk borer.

Honourable Members, The Petitioners contend that:-

(i) The government in banning of consumption of all food derived from genetically modified organisms violates the Chapter VI of the Constitution on Bill of Rights and provisions of Biosafety Act of 2009 which provides that the National Biosafety Authority is the only regulatory body authorized to impose such ban;

(ii) To-date the ban on GMO foods has not been gazetted and that no legal notice has been issued to that effect hence the Ministry of Health may be irregularly implementing the order to ban GMOs in Kenya;

(iii) Sufficient evidence demonstrates that the ban was imposed in a discriminatory manner and does not suggest any safety measure or an act of precautionary nature; and

(iv) The ban on GMOs undermines the authority of Parliament, which enacted the Biosafety Act No.2 of 2009.

Honourable Members, In this regard, the Petitioners pray that the National Assembly examines the prayers contained in this Petition with a view of causing lift of ban on consumption of foods derived from Genetically Modified Organisms commonly referred as GMOs and issuance of permit to conduct field trials of Bt maize crop.

Honourable Members, This Petition therefore stands committed to the Departmental Committee on Agriculture, Livestock and Cooperatives for consideration. The Committee is required to consider the Petition and report its findings in accordance with the provision of Standing Order 227 (2).

I, Thank you!

THE HON. JUSTIN B.N. MUTURI, E.G.H, MP

SPEAKER OF THE NATIONAL ASSEMBLY

Tuesday, 20th December, 2016

THE CONSTITUTION OF KENYA

(Article 119)

NATIONAL ASSEMBLY STANDING ORDERS

(Standing Order 220)

PETITION FOR REMOVAL OF BAN ON CONSUMPTION OF FOODS DERIVED FROM GENETICALLY MODIFIED ORGANISMS, AND FOR ISSUANCE OF PERMIT FOR NATIONAL PERFORMANCE TRIAL OF LOCALLY DEVELOPED *Bt* MAIZE.

TO: THE NATIONAL ASSEMBLY,
PARLIAMENT BUILDINGS,
NAIROBI.

We, KENYA UNIVERSITY BIOTECHNOLOGY CONSORTIUM (KUBICO), a society of biotechnology experts in public universities, do hereby petition for the removal of a ban imposed on consumption of foods derived from genetically modified organisms, and for the issuance of a permit to conduct field trials of *Bt* maize, a maize crop developed locally using genetic engineering for resistance to a common stalk borer on the following grounds-

1. Serious violation of the law;
2. Serious violation of the Constitution;
3. Gross misconduct in the performance of functions;

The facts constituting the grounds are as follows-

1. **THAT** the government, in banning CONSUMPTION of all foods derived from genetically modified organisms in October 2012, seriously violated the Constitution by breaching-

   (a) the doctrine of legitimate expectation which is at the root of the constitutional principle of rule of law embodied in Article 10 of the Constitution, and requires '*regularity*', '*predictability*' and '*certainty*' in government's dealings with the public. When research on *Bt* maize began in 2010, local scientists applied to the National Biosafety Authority (NBA), the body set up by an Act of Parliament to regulate all matters relating to genetically modified organisms (Biosafety Act No 2, 2009), and were granted authority. The NBA has subsequently monitored the process through and gave another approval for Confined Field Trials (CFT) conducted at KALRO Kiboko. In June 2015, local scientists applied and following rigorous review, risk assessments and public participation, were in February 2016 granted approval by NBA to conduct National Performance Trial (NPT) in order to collect compositional data (NBA approval letter; **Appendix 001**). However, the Cabinet Secretary for health has written to the National Environmental Management Authority (NEMA) instructing the authority that a ban on GM foods is in place and hence the field trial (a research phase) cannot continue (**Appendix 002**). Although the government banned only IMPORTATION and CONSUMPTION, the Cabinet Secretary for Health has stopped research and technology development into GM crops. Our efforts to resolve this with the Cabinet Secretary has failed (**Appendix 003 A and B**).

   (b) Provisions of Part V, No 38 (3) of the Biosafety Act No 2, 2009, that provides The National Biosafety Authority (NBA) as the only regulatory body authorized by law to impose such a ban. This section provides that: "Where a regulatory agency, in carrying out its mandate, becomes aware of any significant new scientific

information indicating that approved activities with genetically modified organisms may pose potential biosafety risks not previously known, the regulatory agency shall immediately inform the Authority of the new information and of the measures proposed to be put in place to ensure the continued safe use of the genetically modified organism". Development of *Bt* maize by local scientists is approved activity since 2011. Further, the Biosafety Authority granted approval for National Performance Trials (NPT) of the *Bt* maize in February 2016 (**Appendix 001**). Further, Part V No 38 (3) demands there to be "significant new scientific information indicating that an approved genetically modified organisms pose potential biosafety risks not previously known". The ban was instead premised on there being "no sufficient evidence to show that GM foods were safe". Further, the Fifth Schedule of the Biosafety Act No 2, 2009 (s. 27) on Risk Assessment provides the general principles guiding risk assessment to include that a lack of scientific knowledge or scientific consensus shall not necessarily be interpreted to indicate a particular level of risk.

(c) Provisions of Part VI, No 42 (1) of the Biosafety Act No 2, 2009, that provides that a cessation order issued under the Act may be withdrawn once the Authority determines that sufficient information exists to permit the activity concerned to resume, or to resume in the presence of additional risk management measures, without posing a significant risk to human health and the environment. The Biosafety Authority granted approval for National Performance Trials (NPT) of the *Bt* maize in February 2016 (**Appendix 001**), however, the government has not lifted the ban imposed on CONSUMPTION of the locally developed Bt maize.

(d) Provisions of Chapter VI 33 (1) of the Bill of Rights which provides every person the right to freedom of expression, including academic freedom and freedom of scientific research. The Cabinet Secretary for Health has breached this provision by extending the ban to cover research (**Appendix 002**). The National performance trial (NPT) is a research phase meant to collect compositional data

on a GM crop event, and has been approved by the National Biosafety Authority in February 2016 to allow scientists to collect compositional data.

2. **THAT** the Ministry of Health is implementing a ban that has no backing of the law. The ban on GM foods, which was never gazetted, is devoid of a legal basis and provisions of written law, and is in contravention of the provisions of the Biosafety Act, 2009 as the only authoritative legal framework enacted to regulate activities involving GMOs. The Biosafety Act, 2009 (with its implementing regulations) outlines steps to be taken when a new risk is identified, and when a GMO or its product is to be withdrawn from the market. Of specific mention is that a ban on GMO must be contained in a legal notice. A 'ban' such as the one imposed in Kenya, is a mere public pronouncement by the Minister, devoid of any legal basis and authority and the same cannot establish legitimate rights or expectations.

3. **THAT** sufficient evidence shows that the ban was imposed in a discriminatory manner, and does not suggest a safety fear or an act of precautionary nature:

   (a) The cornerstone publication informing the ban, Seralini et al., 2012, claimed that Roundup Ready herbicide caused more tumors than GMO maize, and that Roundup was more toxic at the lowest dilutions (**Appendix 004**). Roundup ready is a major formulated glyphosate -based herbicide used in agriculture worldwide, including Kenya, where the herbicide is used both before and after planting in non-GM crop fields to control weeds. Unavoidably, the residues are washed from farms into major water sources. Mammals and humans may be exposed to herbicide residues by agricultural practices, or when they enter the food chain. As such, those who genuinely believed Seralini et al, should also believe that Roundup is a higher public health concern than GMO foods. Roundup Ready herbicide is still on sale in Kenya, and is even subsidized by the government.

(b) Several non-GM products have since been shown to cause cancer, even by the World Health Organization (WHO), but the Ministry does not find any reason to ban them. These include the following:

- Johnsons baby powder; whence in February 24, 2016, a jury in Missouri awarded $72 million to the family of a woman who died of ovarian cancer after using baby powder for decades as a hygiene product. It contains talcium powder. Talc is a mineral that is structurally similar to asbestos, a known carcinogen.
- Salted or smoked fish – prostate, stomach and colorectal cancers (Torfadottir et al. 2013, PLoS ONE 8(4): e59799). Smoked foods contain higher levels of nitrates, nitrites, and salts.
- Processed meats or unprocessed red meat carcinogenic to humans – colorectal and prostate cancer (WHO IARC, 2015; Lancet Oncology, 2015).
- Mouthwash (such as Colgate) – Overuse may lead to oral cancer: Alcohol content raises risk of carcinogens in mouth lining according to major publications: Aqudo et al. Oral Oncology, 2014; Farah & McCullough, Australian Dental Journal, 2008.
- All these reports replicated in local dailies for wider access

All these products, together with the Roundup herbicide that confers safety fears in GM crops are allowed for sale in Kenya, showing the ban on CONSUMPTION to be selective and instigated by interests other than the need to protect the health of the people.

4. **THAT** Safety concerns so far raised anywhere in the world regarding GM foods are centered on the active compound making up the Glyphosate herbicide (Roundup), and not *Bacillus thuringiensis* (*Bt*), a bacterium occurring naturally in our environment and soil, and often ingested with foods from gardens. Multiple studies have shown *Bt* to be safe for human, animal and the environment, and there has never been a concern regarding *Bt*, available naturally in soils. The GM trait recently

developed in Kenya, and which is awaiting national performance trial (NPT) is the insect resistant *Bt* maize. Further, *Bt* insecticides are currently safely used by farmers in Kenya, including commercially available products such as Thuricide®, Xenthari® and Dipel® among others. These are used in the country as organic pesticides and are found in our agrovets. These are not genetically modified but they use the same bacterium and do not persist in the environment (degradable), and are very specific in their target pests and thus do not kill unintended insects.

5. **THAT** new pieces of evidence have since emerged after the Taskforce set up by the Ministry of Health to review literature and advise on whether the ban should be lifted:

   (a) The cornerstone publication that catalyzed the ban (Seralini *et al.* 2012), has since been retracted for misinterpretation of results and conclusions (Food and Chemical Toxicology (2014) 63: 244; **Appendix 005**), and only republished by another Journal to archive mistakes in scientific methodology and interpretation (Environmental Sciences Europe, 2014; **Appendix 006**).

   (b) The Senior Author to the controversial paper (Seralini GE) recently published another work in a more prestigious Journal, clarifying that tumors observed in his earlier publication (Seralini *et al.*, 2012) resulted from environmental contaminants in the feeds used, and not from genetic modification (Mesnage *et al.*, 2015; **Appendix 007**).

6. **THAT** ban undermines the authority of Parliament, which enacted the Biosafety Act No 2 of 2009. This Act defines how GMO are handled, and set up the National Biosafety Authority (NBA) to manage issues regarding GMO in the Country. If GM foods remain banned, then it is illogical to continue straining scarce government resources to sustain NBA. If GM foods are banned, then they become contraband, and the duty of ensuring none is found within our borders become the function of the

Police, not NBA. Contraband products are dealt with by the Police, not a regulatory agency.

7. **THAT** the ban threatens the already fragile food security in Kenya, especially because *Bt* maize was intended to improve food production (by reducing insect damage) and food safety (by reducing afflatoxins in maize), consistent with the constitution, and Chapter VI (46. (1)) of the Bill of rights, which affords a consumer, the right (a) to goods and services of reasonable quality; (c) to the protection of their health, safety, and economic interests.

8. **THAT** this petition arises from our inability to resolve the subject matter with the Cabinet Secretary for Health. The Consortium wrote to the Minister, seeking clarification and reasons why NPT, a research phase in GM crop development, was stopped by his Ministry yet the ban was imposed on IMPORTATION AND CONSUMPTION, but not research (**Appendix 003A**). However, the said Cabinet Secretary evaded and never addressed any of the issues raised in our letter. Instead, he reminded us that the ban was still in force (**Appendix 003B**). We find this response unsatisfactory.

NOW THEREFORE your humble petitioner prays that the National Assembly finds-

1. **THAT** this Petition is committed to the Departmental Committee of Agriculture, Livestock and Cooperatives for consideration.

2. **THAT** the above ban on <u>CONSUMPTION</u> of GM foods as having contravened and violated the Constitution and be annulled.

3. **THAT** the Cabinet Secretary for Health and the National Environmental Management Authority, have jointly and severally contravened the aforementioned provisions of the Constitution and of the law;

4. **THAT** in contravening the Constitution and the Law, the Cabinet Secretary for Health and the Director General of the National Environmental Management Authority have jointly and severally, committed acts of gross misconduct in the performance of their functions;

5. **THAT** the said Cabinet Secretary for Health and the Director General of the National Environmental Management Authority be compelled to issue the required permits, which is already approved by said Authority, for the conduct of National Performance Trials (NPT) on the aforesaid grounds.

6. **THAT** the said Cabinet Secretary for Health be restrained from further interference with the independence of NEMA and NBA with regards to safety assessments of GM foods.

7. The ban on *importation* and *consumption* was imposed in 2012. The petitioner (KUBICO) supports local development and deployment of GM crops, as such, pray that the ban on CONSUMPTION be lifted to allow local development of GM crops under the laid down biosafety procedures and regulations. The object of this petition is not before any court within the jurisdiction of Kenya.

Dated the 5th Day of December 2016

KENYA UNIVERSITY BIOTECHNOLOGY CONSORTIUM
05 DEC 2016

JOEL WINYO OCHIENG, PhD
Secretary General,
Kenya University Biotechnology Consortium (KUBICO)
National ID number 13550245; Tel: 0738888817; email: secretarygeneral@kubico.ac.ke

Petition for removal of ban on CONSUMPTION of GM foods and research field trials

(001)

NATIONAL BIOSAFETY AUTHORITY

DECISION ON GM MAIZE APPLICATION

Following an application submitted by Kenya Agricultural Research Organization (KALRO) and African Agricultural Technology Foundation (AATF) in June 2015 seeking NBA approval for ***"environmental release, cultivation and placing on the market"*** of a genetically modified maize [commonly referred to as Bt Maize (MON 810)] the Authority has granted a conditional approval only for environmental release for the purpose of conducting National Performance Trials (NPTs) and collecting compositional analysis data but ***not for cultivation, importation or placing on the market*** of the Bt Maize .

This approval is granted subject to the applicants meeting the following conditions:

1. Prior to establishment of NPT sites, conduct an Environmental Impact Assessment (EIA) and submit an Environmental and Social Impact Assessment (ESIA) Project Report to NEMA for review and approval;
2. Comply with other existing national laws and policies relevant to this approval; and
3. Provide a detailed Biosafety Stewardship Program and Monitoring Roadmap to NBA for approval;

Once these conditions are met, NBA will allow NPTs to be conducted by Kenya Plant Health Inspectorate Service (KEPHIS) in collaboration with other relevant government regulatory agencies.

Willy K. Tonui, PhD, RBP, EBS
CHIEF EXECUTIVE OFFICER

BUSINESS DAILY

A NATION MEDIA GROUP PUBLICATION NO. 2457 | TUESDAY, OCTOBER 11, 2016 | WWW.BDAFRICA.COM

Minister Mailu blocks planned testing of GMO maize in Kenya

CS argues genetically modified crops remain banned, citing a 2012 Cabinet decision that said further tests are needed on their effects

Dr Cleopa Mailu, Health secretary.

BY GERALD ANDAE

Health secretary Cleopa Mailu has rejected the planned trial of genetically modified (GM) maize in Kenya, dealing a big blow to scientists and global seed companies, who have been pushing for policy change on the controversial crop science.

Dr Mailu says in a letter to the Ministry of Environment that introduction of genetically modified organisms (GMOs) in Kenya remains bound by a decision of the 16th Cabinet meeting that banned imports of biotech foods.

He says the ban remains in force until a review and evaluation of scientific information on safety of GM foods on human health is undertaken.

Dr Mailu was responding to news that local scientists have sought permits from the National Environmental Authority (Nema) to carry out GM maize trials in selected sites. "It should be not[illegible] [illegible] tal Impact Assessment

GMO, Page 10

BRIEFS

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Page 5n

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Telephone: +254 738888817

Biotech Consortium
Championing Agricultural & Health advancement through biotechnology

Email:
secretarygeneral@kubico.ac.ke

KENYA UNIVERSITY BIOTECHNOLOGY CONSORTIUM

NAIROBI, 14 OCTOBER 2016

Dr. CLEOPHA MAILU, EBS
CABINET SECRETARY FOR HEALTH
REPUBLIC OF KENYA

Dear Dr. Mailu,

RE: BAN ON GENETICALLY MODIFIED FOODS

Against a background of media reports citing the Ministry of Health as 'blocking' national performance field trial for genetically modified (GM) maize, we seek your interpretation of the Cabinet ban on GM foods in 2012. The possibility of media misrepresentation of your actions or intentions strengthens the basis of this enquiry. We are of the understanding that the ban was specific to importation and consumption of GM foods in Kenya, and that research was exempted. We appreciate that the ban was precautionary and temporary, aimed at protecting the health of citizens to whom the government owes a duty.

Early this year, local scientists coalescing around KALRO submitted an Environmental and Social Impact Assessment (ESIA) report to the National Environment Management Authority (NEMA) as a condition by the National Biosafety Authority (NBA) to allow conduct of National Performance Trials (NPTs) by KEPHIS, one of the last steps of research on the maize genetically modified for insect protection (Bt maize). As you already know, Sir, the conditional approval by NBA in February this year (subject to sending an ESIA to NEMA) is not for cultivation by farmers, but a research stage (NPT) to be conducted by KEPHIS. We have made our claim that the introduced traits protect the plant from insects, and the plant is nutritionally and agronomical equivalent to the ordinary type. This now needs to be verified by independents scientists (KEPHIS) in an NTP (to collection of compositional data). Once demonstrated, the applicants will get back to NBA to now apply for open cultivation (by farmers) and commercialization.

We request that your Ministry kindly considers allowing this research phase (NPT) to continue, but agree that issues of safety may need to be widely discussed before eventual release to farmers and placing on the market. The Kenya University Biotechnology Consortium (KUBICO) is a consortium of leading biotechnology research and policy experts in public universities in Kenya. We conduct research, public education and promote responsible and safe use of biotechnology. We are available at your convenience to discuss this or related matter(s) to maximize agricultural benefits to the people of Kenya, while assuring safety.

Sincerely yours,

Joel W. Ochieng, PhD
Secretary General

MINISTRY OF HEALTH
OFFICE OF THE CABINET SECRETARY

Telephone Nairobi 0202715677
Email:cabsecretary@health.go.ke
When replying please quote

AFYA HOUSE
CATHEDRAL ROAD
P O Box 30016
NAIROBI

Ref. No.MOH/EVH/10/20

18th October 2016

Joel W. Ochieng, PhD
Secretary General
Kenya University Biotechnology Consortium
NAIROBI

Dear Dr. Ochieng,

RE: BAN ON GENETICALLY MODIFIED FOODS (GMO)

This is to acknowledge receipt of your letter dated 14th October, 2016 and the contents therein.

As you are aware, the ban on Genetically Modified Foods on 8th November 2012 has not been lifted hence still in force. However, we are open to discussions with any stakeholder to share any scientific information which may inform future discussions on this matter

Thank you

Yours Sincerely,

Cleopa Mailu

Dr. Cleopa Mailu, EBS
CABINET SECRETARY

Table 3
Percentage variation of parameters indicating kidney failures of female animals.

Discriminant variables		GMO 11% + R	GMO 22% + R	GMO 33% + R	GMO 11%	GMO 22%	GMO 33%	R (A)	R (B)	R (C)
Urinary decrease	Clairance	−4	−11	−20	−20	−20	−19	−20	−24	−40
	Creatinine	−5	−32	−37	−19	−37	−36	−43	−23	−1
	Creatinine ex	−5	−11	−19	−18	−17	−21	−21	−22	−39
Urinary increase	Urea	12	18	15	15	12	−1	0	13	32
	Na	25	33	30	52	−2	95	62	65	91
	Na ex	24	50	68	50	24	125	108	51	7
	Cl	14	35	28	46	5	101	67	56	94
	Cl ex	20	63	70	51	31	138	121	48	13
Serum decrease	Na	2	1	1	−1	−4	−6	−7	0	−3
	Cl	−1	−2	−2	−5	−7	−6	−8	−1	−4
	P	−6	−11	−13	−17	−18	−20	−32	−9	−13
	K	4	5	10	2	−4	0	−4	8	−5
	Ca	4	3	3	2	−2	[illegible]	[illegible]	3	−6
Gonads	Estradiol	8	−1	2	5	−2	[illegible]	[illegible]	−73	39
	Testosterone	5	−9	27	56	17	[illegible]	9	−72	10

OPLS-DA was performed on 48 variables at month 15. Here we showed mean differences (%) of variables (discriminant at 95% confidence level, in bold character) indicating kidney parameters of female animals, together with sex hormones. Male kidney pathologies are already illustrated in Table 2.

parison to our controls but also for the number of mammary tumors in comparison to the same Harlan Sprague Dawley strain (Brix et al., 2005), and overall around 3-fold in comparison to the largest study with 1329 Sprague Dawley female rats (Chandra et al., 1992). In our study the tumors also developed considerably faster than the controls, even though the majority of tumors were observed after 18 months. The first large detectable tumors occurred at 4 and 7 months into the study in males and females respectively, underlining the inadequacy of the standard 90-day feeding trials for evaluating GM crop and food toxicity (Séralini et al., 2011).

Suffering inducing euthanasia and deaths corresponded mostly in females to the development of large mammary tumors. These appeared to be clearly related to the various treatments when compared to the control groups. These tumors are generally known to be mostly estrogen-dependent (Harvell et al., 2000). We observed a strikingly marked induction of mammary tumors by R alone, a major formulated pesticide even at the very lowest dose administered. R has been shown to disrupt aromatase which synthesizes estrogens (Richard et al., 2005), but can also interfere with estrogen and androgen receptors in cells (Gasnier et al., 2009). In addition, R appears to be a sex endocrine disruptor *in vivo*, also in males (Romano et al., 2010). Sex steroids are also modified in treated rats. These hormone dependent phenomena are confirmed by enhanced pituitary dysfunction in treated females. An estrogen modified feedback mechanism may exist at this level (Popovics et al., 2011; Walf and Frye, 2010). The similar pathological profiles provoked by the GM maize containing R residues may thus be explained at least by R residues themselves, knowing that the medium dose of the R treatment corresponds to acceptable levels of this pesticide residues in GMOs.

Interestingly, in the groups of animals fed with the NK603 without R application, similar effects with respect to enhanced tumor incidence and mortality rates were observed. A possible explanation for this finding is the production of specific compound(s) in the GM feed that are either directly toxic and/or cause the inhibition of pathways that in turn generate chronic toxic effects. This is despite the fact that the variety of GM maize used is this study was judged by industry and regulators as being substantially equivalent to the corresponding non-GM closest isogenic line. As the total chemical composition of the GM maize cannot be measured in details, the use of substantial equivalence is insufficient to highlight potential unknown toxins and therefore cannot replace long-term animal feeding trials for GMOs. A cause of the effects of the effects could be that the NK603 GM maize used in this study is engineered to overexpress a modified version of the *Agrobacterium tumefaciens* 5-enolpyruvyl-shikimate-3-phosphate synthase (EPSPS) (Hammond et al., 2004) allowing the R tolerance. The modified EPSPS is not inhibited by glyphosate by contrast to the wild enzyme. This enzyme is known to direct the first step of aromatic amino acid biosynthesis in the plant shikimate pathway; in addition estrogenic isoflavones and their glycosides are also products of this pathway (Duke et al., 2003). They were not disturbed in our study. By contrast, the levels of caffeic and ferulic acids in the GM diets, which are also secondary metabolites from this pathway, but not always measured in regulatory tests, are significantly reduced. This may lower their protective effects against carcinogenesis and even mammalian tumors (Kuenzig et al., 1984; Baskaran et al., 2010). Moreover, these phenolic acids and in particular ferulic acid may modulate estrogen receptors or the estrogenic pathway in mammalian cells (Chang et al., 2006). This does not exclude the action of other unknown metabolites. This explanation also corresponds to the fact that the observed effects of NK603 and R are not additive and reached a threshold. This implies that both the NK603 maize and R may cause hormonal disturbances in the same biochemical and physiological pathway.

As expected, mammary tumors in males occurred far less frequently than in females. Death in male rats was mostly due to the development of severe hepatorenal insufficiencies, confirming the first signs of toxicity observed in 90 day feeding trials with NK603 maize (Spiroux de Vendômois et al., 2009). In females, kidney ion leakages were evidenced at the biochemical levels at month 15, when severe nephropathies were evidenced in dead male animals afterwards, at the anatomopathological level. Early signs of toxicity at month 3 in kidney and liver were also observed for 19 edible GM crops containing pesticide residues (Séralini et al., 2011). As a matter of fact, only elderly male rats are sensitive to chronic progressive nephropathies (Hard and Khan, 2004). The disturbed kidney parameters may have been induced by the reduction of phenolic acids in our study, since caffeic and ferulic acids are beneficial in the kidney as they prevent oxidative stress (Srinivasan et al., 2005; U Rehman and Sultana, 2011). Accordingly, we previously demonstrated that plant extracts containing ferulic and caffeic acids were able to promote detoxification of embryonic kidney cells after R contamination (Gasnier et al., 2011). It is thus possible that NK603 consumption by reducing these compounds may well provoke an early aging of kidney physiology in this study, like R by oxidative stress.

Disturbances that we found to occur in the male liver are characteristic of a chronic intoxication, confirmed by alterations

Contents lists available at

Food and Chemical Toxicology

journal homepage: www.elsevier.com/locate/foodchemtox

Retraction notice

Retraction notice to "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" [Food Chem. Toxicol. 50 (2012) 4221–4231]

Gilles-Eric Séralini [a,*], Emilie Clair [a], Robin Mesnage [a], Steeve Gress [a], Nicolas Defarge [a], Manuela Malatesta [b], Didier Hennequin [c], Joël Spiroux de Vendômois [a]

[a] University of Caen, Institute of Biology, CNRIGEN and Risk Pole, MRSH-CNRS, EA 2608, Esplanade de la Paix, Caen Cedex 14032, France
[b] University of Verona, Department of Neurological, Neuropsychological, Morphological and Motor Sciences, Verona 37134, Italy
[c] University of Caen, UR ABTE, EA 4651, Bd Maréchal Juin, Caen Cedex 14032, France

This article has been retracted: please see Elsevier Policy on Article Withdrawal ( ).

The journal Food and Chemical Toxicology retracts the article "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize," which was published in this journal in November 2012. This retraction comes after a thorough and time-consuming analysis of the published article and the data it reports, along with an investigation into the peer-review behind the article. The Editor in-Chief deferred making any public statements regarding this article until this investigation was complete, and the authors were notified of the findings.

Very shortly after the publication of this article, the journal received Letters to the Editor expressing concerns about the validity of the findings it described, the proper use of animals, and even allegations of fraud. Many of these letters called upon the editors of the journal to retract the paper. According to the journal's standard practice, these letters, as well as the letters in support of the findings, were published along with a response from the authors.[1] Due to the nature of the concerns raised about this paper, the Editor-in-Chief examined all aspects of the peer review process and requested permission from the corresponding author to review the raw data. The request to view raw data is not often made; however, it is in accordance with the journal's policy that authors of submitted manuscripts must be willing to provide the original data if so requested.[2] The corresponding author agreed and supplied all material that was requested by the Editor-in-Chief. The Editor-in-Chief wishes to acknowledge the co-operation of the corresponding author in this matter, and commends him for his commitment to the scientific process.

Unequivocally, the Editor-in-Chief found no evidence of fraud or intentional misrepresentation of the data. However, there is a legitimate cause for concern regarding both the number of animals in each study group and the particular strain selected. The low number of animals had been identified as a cause for concern during the initial review process, but the peer review decision ultimately weighed that the work still had merit despite this limitation. A more in-depth look at the raw data revealed that no definitive conclusions can be reached with this small sample size regarding the role of either NK603 or glyphosate in regards to overall mortality or tumor incidence. Given the known high incidence of tumors in the Sprague–Dawley rat, normal variability cannot be excluded as the cause of the higher mortality and incidence observed in the treated groups.

Ultimately, the results presented (while not incorrect) are inconclusive, and therefore do not reach the threshold of publication for Food and Chemical Toxicology. The peer review process is not perfect, but it does work. The journal is committed to getting the peer-review process right, and at times, expediency might be sacrificed for being as thorough as possible. The time-consuming nature is, at times, required in fairness to both the authors and readers. Likewise, the Letters to the Editor, both pro and con, serve as a post-publication peer-review. The back and forth between the readers and the author has a useful and valuable place in our scientific dialog.

The Editor-in-Chief again commends the corresponding author for his willingness and openness in participating in this dialog. The retraction is only on the inconclusiveness of this one paper. The journal's editorial policy will continue to review all manuscripts no matter how controversial they may be. The editorial board will continue to use this case as a reminder to be as diligent as possible in the peer review process.

DOI of original article:
* Corresponding author.
[1] Please see Food and Chemical Toxicology 53 (1), pp. 440–483, for all Letters to the Editor and the response.
[2]

0278-6915/$ - see front matter

Empirical natural and social sciences produce knowledge (in German: Wissenschaften schaffen Wissen) which should describe and explain past and present phenomena and estimate their future development. To this end quantitative methods are used. Progress in science needs controversial debates aiming at the best methods as basis for objective, reliable and valid results approximating what could be the truth. Such methodological competition is the energy needed for scientific progress. In this sense, ESEU aims to enable rational discussions dealing with the article from G.-E. Séralini et al. (Food Chem. Toxicol. 2012, 50:4221–4231) by re-publishing it. By doing so, any kind of appraisal of the paper's content should not be connoted. The only aim is to enable scientific transparency and, based on this, a discussion which does not hide but aims to focus methodological controversies. -Winfried Schröder, Editor of the Thematic Series "Implications for GMO-cultivation and monitoring" in Environmental Sciences Europe.

Background

There is an ongoing international debate as to the necessary length of mammalian toxicity studies, including metabolic analyses, in relation to the consumption of genetically modified (GM) plants [1]. Currently, no regulatory authority requires mandatory chronic animal feeding studies to be performed for edible genetically modified organisms (GMOs), or even short-term studies with blood analyses for the full commercial formulations of pesticides as sold and used, but only for the declared active principle alone. However, several 90-day rat feeding trials have been conducted by the agricultural biotechnology industry. These investigations mostly concern GM soy and maize that are engineered either to be herbicide-tolerant (to Roundup (R) in 80% of cases), or to produce a modified Bt toxin insecticide, or both. As a result, these GM crops contain new pesticide residues for which new maximum residue levels (MRL) have been established in some countries.

Though the petitioners conclude in general that no major physiological changes is attributable to the consumption of the GMO in subchronic toxicity studies [2-5], significant disturbances have been found and may be interpreted differently [6,7]. A detailed analysis of the data in the subchronic toxicity studies [2-5] has revealed statistically significant alterations in kidney and liver function that may constitute signs of the early onset of chronic toxicity. This may be explained at least in part by pesticide residues in the GM feed [6,7]. Indeed, it has been demonstrated that R concentrations in the range of 10^3 times below the MRL can induce endocrine disturbances in human cells [8] and toxic effects thereafter [9]. This may explain toxic effects seen in experiments in rats *in vivo* [10] as well as in farm animals [11]. After several months of consumption of an R-tolerant soy, the liver and pancreas of mice were affected, as highlighted by disturbances in sub-nuclear structure [12-14]. Furthermore, this toxic effect was reproduced by the application of R herbicide directly to hepatocytes in culture [15].

More recently, long-term and multi-generational animal feeding trials have been performed, with some possibly providing evidence of safety, while others conclude on the necessity of further investigation because of metabolic modifications [16]. However, in contrast with the study we report here, none of these previous investigations have included a detailed follow-up of the animals, including multiple (up to 11) blood and urine sampling over 2 years, and none has investigated either the GM NK603 R-tolerant maize or Roundup.

Furthermore, evaluation of long-term toxicity of herbicides is generally performed on mammalian physiology employing only their active principle, rather than the complete formulations as used in agriculture. This was the case for glyphosate (G) [17], the declared active chemical constituent of R. It is important to note that G is only able to efficiently penetrate target plant organisms with the help of adjuvants present in the various commercially used R formulations [18]. Even if G has shown to interact directly with the active site of aromatase at high levels [19], at low contaminating levels, adjuvants may be better candidates than G to explain the toxicity or endocrine disruptive side effects of R on human cells [8,20] and also *in vivo* for acute toxicity [21]. In this regard, it is noteworthy that the far greater toxicity of full agricultural formulations compared to declared supposed active principles alone has recently been demonstrated also for six other major pesticides tested *in vitro* [22]. When G residues are found in tap water, food, or feed, they arise from the total herbicide formulation although little data is available as to the levels of the R adjuvants in either the environment or food chain. Indeed, adjuvants are rarely monitored in the environment, but some widely used adjuvants (surfactants) such as nonylphenol ethoxylates, another ethoxylated surfactant like POEA present in R, are widely found in rivers in England and are linked with disruption of wildlife sexual reproduction [23]. Adjuvants are found in groundwater [24]. The half-life of POEA (21 to 42 days) is even longer than for G (7 to 14 days) in aquatic environments [25]. As a result, the necessity of studying the potential toxic effects of total chemical mixtures rather than single components has been strongly emphasized [26-28]. On this basis, the regular measurement of only G or other supposed active ingredients of pesticides in the environment constitute at best markers of full formulation residues. Thus, in the study of health effects, exposure to the diluted whole formulation may be more representative of environmental pollution than exposure to G alone.

participated in and received payment for a lecture organized by Sevene Pharma.

Competing Interests: The authors have declared that no competing interests exist.

contamination has never been described. We have thus measured residues of 262 pesticides, 22 genetically modified organisms (GMOs), 4 heavy metals, 18 polychlorinated biphenyls (PCBs) and 17 polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/Fs) in 13 rodent diets. These samples derived from 13 suppliers from 9 countries on 5 continents (North and South America, Europe, Asia, Africa and Oceania), representative of diets used in academic research and regulatory assessment.

These contaminations could participate to explain why populations of laboratory rodents across the world develop high rates of so-called "spontaneous" diseases. For instance in Sprague-Dawley rats from Harlan after 2 years, the mean incidences of mammary fibroadenomas and pituitary adenomas among control populations were 71 and 42% respectively [2]. The same strain from Charles River had means of 38% (13 to 62%) mammary fibroadenomas and 71% (26 to 93%) pituitary adenomas [3]. Moreover, these incidences were not stable, but increased or diminished over time [4]. It indicates that differences among rat populations cannot only be explained by genetic drift and may arise from different environmental conditions, including feed or water contamination. This work was conducted to test the extent of the feed contamination from 5 continents, and to deduce chemical exposures and hazards from regulatory official calculations (EPA guidelines). In fact, it is known that the mortality of laboratory rats has an extremely unexplained wide range, from 38 to 83% after 2 years [3], it is in general less for some Wistar rat strains [5].

These statistics are used as external controls for regulatory chronic tests. Treated rats are not only compared with the internal control of the experiment, but are subsequently compared with this whole population, represented by the compilation of all control groups formed by the past experiments of the laboratory, or on the rat strain, called "historical control data". Historical controls are assumed to be of importance in the interpretation of regulatory chronic tests, and they are thus used to determine the biological significance of a statistical difference between the experimental animals and the concurrent controls. This does not usually apply to academic research, in which treated groups are only compared to concurrent matched controls, raised in the same conditions, fed with the same diet, except for one studied parameter.

Rat pellets are mostly constituted of cereals (wheat, maize or barley) and other legumes (such as soybean). These are sprayed with different pesticides according to the methods of cultivation, but also according to the year or location, resulting in different contaminants [6,7]. Pesticides are formulated toxics (Fig 1A), supposed to be specific for plants (herbicides), insects (insecticides) or fungi (fungicides). However, non-target effects of their residues are increasingly being identified at chronic dietary levels [8,9]. Some pesticides are strongly associated with agricultural GMOs, such as Roundup, a glyphosate-based formulation, or mutated Bt toxins (Fig 1B). These GMOs are essentially modified to tolerate and/or produce pesticide residues [10]; they are generally not labelled nor monitored in their countries of production, in particular North and South America for GM soybean or maize. Their general use in rodent diet is not documented. Known dietary toxicants such as heavy metals [11] and dioxins [12] are also important to measure, because these are ubiquitous contaminants.

We collected rodent feed samples from 5 continents, because agricultural practices in various locations may generate different contaminants. Although several batches of the same diets may not be exactly equal in contaminations [13, 14], the multiple sampling performed in this study allows approaching the variability and omnipresence of pollutants in rat diets. We included both rat feed used in regulatory toxicity trials (such as Purina 5002) and in university laboratories, but also by breeding companies, to raise and reproduce laboratory rodents (such as Mucedola TD.2016). In the latter case, rodents are exposed during their whole life cycle and across generations. To estimate the hazards due to chronic exposures to these contaminants in diets, we calculated the chronic non cancer hazard indexes (to take into account general

RESEARCH ARTICLE

Laboratory Rodent Diets Contain Toxic Levels of Environmental Contaminants: Implications for Regulatory Tests

Robin Mesnage[1,2☯¤], Nicolas Defarge[1,2☯], Louis-Marie Rocque[2], Joël Spiroux de Vendômois[2], Gilles-Eric Séralini[1,2*]

1 University of Caen, Institute of Biology, EA2608 and Network on Risks, Quality and Sustainable Environment MRSH, Esplanade de la Paix, 14032 Caen Cedex, France, 2 CRIIGEN, 40 rue Monceau, 75008, Paris, France

☯ These authors contributed equally to this work.
¤ Current address: Gene Expression and Therapy Group, King's College London, Faculty of Life Sciences & Medicine, Department of Medical and Molecular Genetics, 8th Floor, Tower Wing, Guy's Hospital, Great Maze Pond, London, SE1 9RT, United Kingdom
* [redacted]

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Abstract

The quality of diets in rodent feeding trials is crucial. We describe the contamination with environmental pollutants of 13 laboratory rodent diets from 5 continents. Measurements were performed using accredited methodologies. All diets were contaminated with pesticides (1-6 out of 262 measured), heavy metals (2-3 out of 4, mostly lead and cadmium), PCDD/Fs (1-13 out of 17) and PCBs (5-15 out of 18). Out of 22 GMOs tested for, Roundup-tolerant GMOs were the most frequently detected, constituting up to 48% of the diet. The main pesticide detected was Roundup, with residues of glyphosate and AMPA in 9 of the 13 diets, up to 370 ppb. The levels correlated with the amount of Roundup-tolerant GMOs. Toxic effects of these pollutants on liver, neurodevelopment, and reproduction are documented. The sum of the hazard quotients of the pollutants in the diets (an estimator of risk with a threshold of 1) varied from 15.8 to 40.5. Thus the chronic consumption of these diets can be considered at risk. Efforts toward safer diets will improve the reliability of toxicity tests in biomedical research and regulatory toxicology.

Introduction

Rodent feeding trials are the most widely used experiments in biomedical research and are particularly used to study the potential side effects of commercial products in mammals. They do not only constitute a test for human health but also for the environment. The rat may also be considered as a toxicological model for small mammals, either wild or kept as farm animals or pets. The quality of the rodent diet is thus crucial. Rodent diets are mostly formulated with agricultural products and by-products, and are susceptible to contamination with toxic environmental contaminants [_]. However, the extent and worldwide variability of this