MONITORING OF GENETICALLY MODIFIED FOOD PRODUCTS IN SOUTH AFRICA

By

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DECLARATION

I hereby certify that the thesis submitted by me for the PhD degree at the University of the Free State is my independent effort and has not previously been submitted for a degree at another university or faculty. I furthermore, waive copyright of the thesis in favour of the University of the Free State.

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Gertruida Martha Marx

CONTENTS

LIST OF SCIENTIFIC ABBREVIATIONS AND ACRONYMS

Bp	Base pairs
Bt	*Bacillus thuringiensis*
CaMV	Cauliflower mosaic virus
CRM	Certified reference material
Ct	Crossing time
CTAB	Cetryltrimethylammonium bromide
DALY	Disability-adjusted life years
DNA	Deoxyribonucleic acid
dNTP	Deoxyribonucleotide triphosphate
EDTA	Ethylenediamin tetra acetic acid
EFA	Essential fatty acids
ELISA	Enzyme-linked-immunosorbant assay
et al.	*Et alii* (and others)
FMV	Figwort mosaic virus
g	Gram
GM	Genetically modified
GMO	Genetically modified organism
GR	Golden Rice
GRII	Golden Rice II
Ha	Hectare
Hg	Hectogram

hr	Hour
hrs	Hours
HT	Herbicide tolerance
HCl	Hydrochloric acid
IgA	Immunoglobulin A
IP	Identity preservation
IR	Insect resistance
k	Kilo
KCl	Potassium chloride
Kg	Kilo gram
L	Liter
LDL	Low density lipoprotein
LMO	Living modified organism
LOD	Limit of detection
LOQ	Limit of qualification
m	Meter
M	Molar
mg	Milli-gram
$MgCl^2$	Magnesium chloride
M Has	Million hectares
M Acres	Million acres
min	Minute
ml	Milli-litre
mM	Milli-molar

mm^2	Millimetre square
NaCl	Sodium chloride
NEMA	National Environmental Management Act
NEMBA	National Environmental Management Biodiversity Act
ng	Nano-gram
PCR	Polymerase chain reaction
pH	Percentage hydrogen
RDA	Required daily allowance
rpm	Revolutions per minute
SDS	Sodium dodecyl suphate
sec	Seconds
TAE	Tris acetate EDTA
Taq	*Thermus aquaticus*
TE	Tris EDTA
TRIS	Tris hydroymethyl aminomethane
U	Unit
UV	Ultraviolet
V	Volts
VAD	Vitamin A deficiency
www	World wide web
˚C	Degree Celsius
%	Percentage
µg	Micro-gram
µl	Micro-litre

LIST OF ABBREVIATIONS AND ACRONYMS FOR ORGANIZATIONS, INSTITUTIONS AND/OR AUTHORITIES

ABS	African Biotechnology Sorghum
APHIS	Animal and Plant Health Inspection Services
BCH	Biosafety Clearing House
DAFF	National Department of Agriculture, Forestry and Fisheries
DEA	Department of Environmental Affairs
DOH	Department of Health
DTI	Department of Trade and Industry
EC	European Commission
EFSA	European Food Safety Authority
ELA	Earthlife Africa
ENGL	European Network of GMO Laboratories
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organisation
FDA	Food and Drug Administration
GRAIN	Genetic Resources Action International
HSRC	Human Science Research Council
ISO	International Organization for Standardization
KARI	Kenyan Agricultural Research Institute
NCF	National Consumer Forum Trust

NERA	National Economic Research Associates
NGO	Non-government organization
PUB	Public Understanding of Biotechnology
RASFF	Rapid Alert System of Food and Feed
SAFeAGE	South African Freeze Alliance on Genetic Engineering
SANGL	South African Network of GM Detection Laboratories
SCN	United Nations Standing Committee on Nutrition
UK	United Kingdom
UN	United Nations
USA	United States of America
USDA	United States Department of Agriculture
WHO	World Health Organisation

LIST OF GENES AND GENETIC ELEMENTS

amy797E	Alpha-amylase
als	Acetylated synthase
amp	Ampicillin
bar	Bialaphos resistance
barnase	Barnase ribonuclease
barstar	Barnase ribonuclease inhibitor
bla	Beta lactamase
bxn	Nitrilase
cordapA	Higher production of lysine
cspB	Cold shock protein B
cry	Insect resistance genes from *Bacillus thuringiensis*
cp4epsps	5-enolpyruvylshikimate-3-phosphate synthase of soil bacterium strain CP4
dam	DNA adenine methylase
epsps	5-Enolpyruvylshikimate-3-phosphate synthase
gat462	Glyphosate-N-acetyltransferase
gm-fad2-1	Oleic acid production
gm-hra	Acetolactate synthase
gox	Glyphosate oxidase
gus	Beta-D-glucuronidase
hmg	High Mobility Group
hpt	Hygromycin phosphotransferase

lectin	Soybean Lectin
NOS	Nopalin synthase gene terminator from *Agrobacterium tumefaciens*
nptII	Neomycin phoshotransferase II
pat	Phosphinotricin-N-acetyltransferase
pmi	Phosphomannose isomerase marker gene
TE	Thioesterase
vip3A	VIP3A vegetative insecticidal protein
35S	Cauliflower mosaic virus promoter

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PREFACE

Genetic engineering and genetic modification are terms that relate to the manipulation of an organism's genes through recombinant DNA technology. Genetically modified organisms (GMOs) are programmed to manufacture various substances such as enzymes, monoclonal antibodies, nutrients, hormones, or pharmaceutical products including drugs and vaccines. The production of GMOs is increasing considerably in the world in terms of the area planted, but notably in only a few countries. The societal issues regarding the use of genetic modification to improve food crops are complex and cannot be ignored.

South Africa is one of the few countries in the world commercially producing plant GMOs and the only country in Africa growing considerable amounts of GM crop. South Africa not only develops and produces GMOs, but also imports GM commodities. Despite the fact that GMOs has been produced in South Africa since 1996, there has been little discussion regarding consumer awareness, acceptance or choice. Although the South African government is admittedly "pro" GM technology, it does recognise the need to regulate GMO related activities. Thus, the purpose of this thesis is to provide scientific information to inform discussions in South Africa regarding the labelling of GM content in food, as well as the need for monitoring the food chain for unapproved GM events.

The first chapter in this thesis is a literature review that aims to contextualise the impact of genetic modification on society in terms of GM labelling systems and monitoring of

genetic modification in the food chain. This is followed by the first research chapter (Chapter 2), which determined the extent of the uptake of genetic modification into the food chain in South Africa. This study also included a preliminary investigation into the use of negative labelling to indicate the absence of genetic modification in food. Chapter 3 further investigates this with an in-depth study on the use of voluntary GM labelling in South Africa as well as batch effects on sampling for laboratory testing. After the introduction of mandatory GM labelling in the Consumer Protection Act of 2008, there was a general uncertainty in the food industry regarding the impact this would have. As a result, the study in Chapter 4 was initiated to investigate the impact of mandatory GM labelling in South Africa and its possible application. The final research chapter (Chapter 5) deals with the hitherto undiscussed topic of monitoring the food chain for unapproved GMOs. Currently, no monitoring is performed on local or imported commodities to ensure that illegal GM events that have not been shown to be safe for human consumption enter the food chain. The final chapter (Chapter 6), discusses and draws final conclusions over the implementation of GM labelling and monitoring in South Africa that are also applicable to other countries, especially in the developing world.

This PhD study was undertaken part time over six years, from 2005 until the end of 2010. As a result of developments to include mandatory GM labelling in the Consumer Protection Act, in part due to the information emanating from the studies presented in this thesis that contributed to inform discussions regarding these issues, some sections and arguments in Chapters 2 and 3 regarding the lack of mandatory GM labelling have become outdated in past publication. However, to maintain the context of developments during the duration of preparing this thesis, it was decided to maintain the outdated text

as it has been published in international journals. The reader's attention is specifically drawn to these chapters where necessary.

Care has been taken to present arguments in this thesis as scientifically as possible. While many of these considerations may be interpreted as "pro" or "anti" genetic modification, the intention has not been to motivate either for or against the use of GM technology. Instead, the focus of this thesis was on societal and regulatory issues, often ignored in terms of the impact of GM technology, such as GM labelling and monitoring. While there are divided views on these issues, the purpose of this research was to inform discussions (or lack thereof) on these topics, in the context of a country resembling South Africa that is considered to be "pro" GM technology. As a result, rather than posing a continual critique of the status quo, this thesis rather serves to provide suggestions for the implementation of GM labelling and monitoring of the food chain.

The chapters of this thesis are represented as separate articles (some of which are published under my maiden name, Botha). Notably, sections of the literature review also represent published papers. Thus, although care has been taken to avoid unnecessary duplication, some repetition due to the publication of various sections and/or chapters has become inevitable.

I would like to extend my sincere gratitude to the Department of Haematology and Cell Biology of the University of the Free State for financial support, as well as to my promoter, Professor C.D. Viljoen, for the opportunity to complete this degree and for his guidance. I owe a special thanks to my colleagues and friends in the Department of

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Gerda Marx

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CHAPTER 1

LITERATURE REVIEW

1.1 Introduction

The development of genetic engineering holds the promise to improve agronomic traits, resistance to diseases and nutritional properties of crops, which could not be achieved through conventional breeding because of species boundaries. However, new technologies often raise new concerns and the use of genetic modification to improve food crops is no exception. Thus, the potential benefits of genetically modified crops have to be balanced by concerns over the potential risks to human health and the environment as well as the sustainability of this technology.

It is argued that the management of GM crops is unnecessary, since they are considered to be equivalent to their conventional counterparts and there has been no documented evidence of risks to human health or the environment (Paarlberg, 2010). Compared to this, concerns have been raised on the potential adverse effects of genetic modification on human health and the environment (Cellini *et al*., 2004; Falck-Zepeda, 2009). In response to these concerns, many countries have taken steps to regulate the development, use and application of GM crops. Many countries also require the labelling of GM content in food to allow consumer choice (Botha and Viljoen, 2009). In addition to this, there is a concern that the trade in GM grain may result in the spread of genetically modified organisms (GMOs) to countries where they

have not been approved (Clapp, 2008). As a result of this it has become important to monitor the food chain for the presence of unapproved illegal GMOs as well as to ensure the application of GM labelling. The aim of this literature study is to review the current status, production, adoption and sustainability of current and future GM crops as well as to contextualise societal considerations regarding GM food, including food safety and consumer perceptions to highlight the need for monitoring genetic modification in the food chain. Furthermore the aim is to compare international and national agreements of regulatory approaches to GM food with particular reference to monitoring of genetic modification in the food chain in terms of labelling systems and unintended GM releases. Finally, the state of the art in GM detection and quantification methodology is also reviewed.

1.2 Application of GM technology in crops

Currently, GM crops are categorised as first, second or third generation, based on their intended benefit and use (Yonekura-Sakakibara and Saito, 2006). First generation GM crops are characterised as having improved agronomic traits for insect and weed management and were first commercialised in 1994. Second and third generation GM plants have been developed during the last 10 years, but have not been commercialised as extensively as first generation GM crops. Second generation GM crops are intended to benefit consumers by improving the nutritional content of food or feed as well as decreasing allergenicity or toxicity. Second generation GM crops also include other qualities such as improved shelf life (Jefferson-Moore and Traxler, 2005). Third generation GMOs are intended for industrial application, including the production of pharmaceuticals, industrial compounds or bio-fuels such as

increased amylase content in maize for alcohol production or a reduction of lignin in wood for paper (Steward and McLean, 2008). Thus, based on the extent of research and development currently underway, as evident by scientific publications, it appears that many new applications of GM crops may be commercialised in the near future.

1.2.1 Current status of commercial GM crop production

In 2009, GM crops made up approximately 9% (134 million hectares) of commercial agriculture worldwide with an 80-fold increase from the 1.7 million hectares planted in 1996 (Figure 1.1) (James, 2009). It is currently estimated that genetic modification accounts for 77% of soybean, 26% of maize, 49% of cotton and 21% of canola in terms of global production (Figure 1.2) (James, 2009). Of the 25 countries growing GM crops, the eight largest producers are the USA (48% or 64 million hectares), Brazil (16% or 21.4 million hectares), Argentina (15% or 21.3 million hectares), India (6.3% or 8.4 million hectares), Canada (6.1% or 8.2 million hectares), China (2.8% or 3.7 million hectares), Paraguay (1.6% or 2.2 million hectares) and South Africa (1.6% or 2.1 million hectares) (James, 2009).

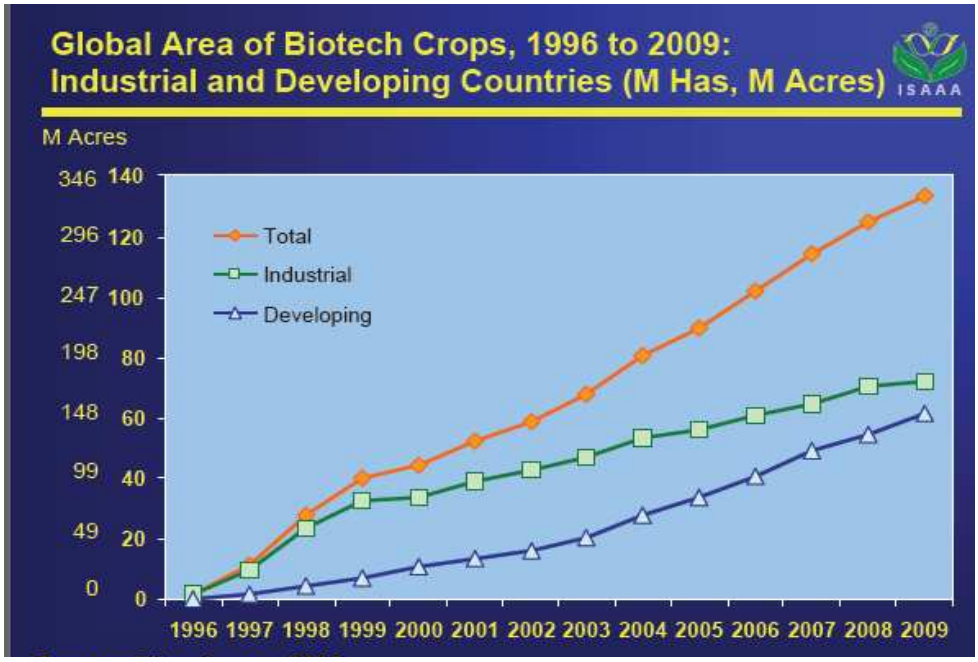

Figure 1.1 Adoption of GM crops since 1996 in millions of hectares (M Has) and millions of acres (M Acres) copied from James (2009).

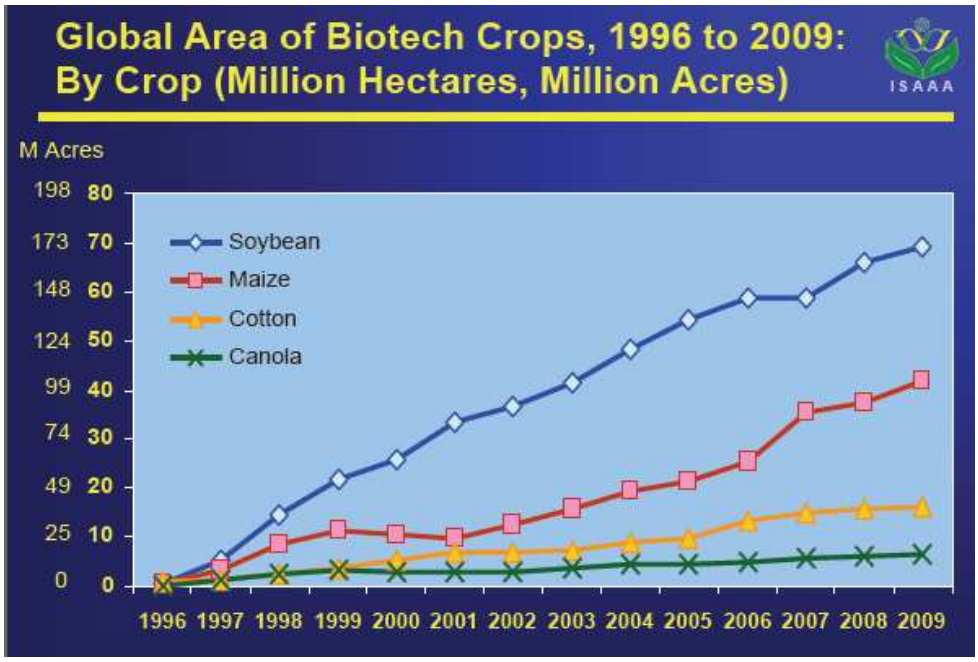

Figure 1.2 Adoption of GM in terms of crop type since 1996, copied from James (2009).

Herbicide tolerance (HT), insect resistance (IR) or stacked traits containing HT and IR are the most widely commercially grown GM crops (James, 2009). HT is the result of using a modified form of the *5-enolpyruvylshikimate-3-phosphate synthase* (*epsps*) gene from the soil bacterium *Agrobacterium tumefaciens* or *PPT-acetyltransferase* (*pat*) from *Streptomyces viridochromogenes* combined with a modification of *Acetolactate synthase* (*als*) that makes crops tolerant to herbicides (Table 1.1). HT offers farmers a management tool to control weeds by allowing crops to be sprayed with herbicides. IR plants are engineered to produce an insect toxin used to control target pests (Table 1.1). Insect resistant plants produce a toxin known as Bt, through the insertion of *cry* from the bacterium, *Bacillus thuringiensis*, an endotoxin to certain insect species. There are other first generation traits such as virus resistance but these are not considerable in terms of the area planted.

In terms of second generation genetic modification, three food crops and traits have been approved for commercial production, including maize with increased lysine, canola with higher levels of laurate, myristic acid and oleic acid and soybean with increased oleic and linolenic acid (Table 1.2). Currently, the only third generation GM crop being commercially produced is a maize event with increased starch amylase for industrial ethanol production (Table 1.2). Thus, although the production of second and third generation GM crops is currently limited, the application of these crops is expected to increase in the future.

Table 1.1 A summary of the current status of first generation GM crops, in terms of crop type, trait(s), gene(s), number of commercialised events and countries in which they are produced (www.cera-gmc.org).

Crops	**Trait(s)**	**Gene(s)**	**Number of commercialised events[1]**	**Producing countries[2]**
Canola	HT	*cp4epsps, pat*	8	Australia, Canada, USA
Cotton	HT and IR	*cp4epsps, pat*, *cry1Ac, cry2Ab,cry1F, vip3A*	16	Argentina, Australia, Brazil, Canada, China, India, Mexico, South Africa, USA
Maize	HT and IR	*cry1Ab, cry1AC, cry1F, cry3A, cry3Bb1, cry9C, cry34Ab1, cry35Ab1*, *cp4epsps*, *pat*	41	Argentina, Brazil, Canada, Philippines, South Africa, Spain, Uruguay, USA
Soybean	HT	*cp4epsps*, *pat*	6	Argentina, Bolivia, Brazil, Canada, Mexico, Paraguay, South Africa, Uruguay, USA
Rice	HT	*als*, *pat*	3	USA
Wheat	HT	*als*	4	Canada
Papaya	Virus resistance	Viral coat protein	1	China, USA
Squash	Virus resistance	Viral coat protein	2	USA
Sugar beet	HT	*cp4epsps, pat*	3	Canada, USA
Sweet pepper	Virus resistance	Viral coat protein	Unknown	China

[1] Events that are commercially grown.

[2] Countries growing more than 50,000 ha of the specific GM event.

Table 1.2 A summary of commercialised second generation GM crops for nutritional enhancement (James, 2009) (www.cera-gmc.org).

Crop	Event	Characteristic	Country and regulatory status	Intended use
Protein quality and essential amino acids				
Maize	LY038	Enhanced lysine	Australia[2], Canada[1], Japan[1], Mexico[3], Philippines[2,3], Taiwan[2], USA[1]	Livestock feed, primarily for poultry and swine
Oils and fatty acids				
Canola	23-18-17, 23-198	High levels of laurate and myristic acid	Canada[1], USA[1]	Human consumption (oil), livestock feed and industrial applications
Canola	45A37, 45A40 and 46A12, 46A16	High oleic acid and low linolenic acid	Canada[2]	Human food production (oil) and livestock feed
Soybean	G94-1, G94-19, G168	High oleic acid	Australia[2], Canada[1], Japan[1], USA[1]	Human consumption (oil, protein, and fibre)
Soybean	OT96-15	Low linolenic acid	Canada[2]	Human consumption (mostly oil, protein, and fibre)
Starch enzyme production				
Maize	3272	Increased starch amylase	Australia[2,3], Canada[1], Philippines[2,3], USA[2,3]	Modified amylase for industrial ethanol production

[1] Approved for environmental release (includes food and feed).

[2] Approved for use as food.

[3] Approved for use as feed.

1.2.2 Adoption of GM crops in Africa

For the most part, African countries have been sceptical about GM technology and only South Africa, Egypt and Burkina Faso have approved the commercial production of GM crops. Egypt produces insect resistant yellow maize for silage and Burkina Faso insect resistant GM cotton. South Africa is currently the only country in Africa growing more than 50,000 ha of GM crop. This includes six cotton events, of which two are herbicide tolerant, two are insect resistant and two are stacked events, three maize events that include two insect resistant, one herbicide tolerant and one stacked

event as well as a single HT soybean event (Table 1.3). White maize is an important staple consumed by the majority of people in South Africa and soybean, cotton oil and yellow maize are used in processed foods. Thus, South Africa as the leader in GM production on the African continent is a case study for the rest of Africa in terms of managing GMOs.

Table 1.3 GMOs approved for environmental release in South Africa since 1997 (DAFF, 2010a).

Event	Commercialized by	Crop	Trait	Year approved
Bollgard II x RR flex (MON15985 x MON88913)	Monsanto Company	Cotton	HT and IR	2007
MON88913 (RR flex)	Monsanto Company	Cotton	HT	2007
MON810 x NK603	Monsanto Company	Maize	HT and IR	2007
Bolgard RR	Monsanto Company	Cotton	HT and IR	2005
Bollgard II, line 15985	Monsanto Company	Cotton	IR	2003
Bt11	Syngenta Seeds	Maize	IR	2003
NK603	Monsanto Company	Maize	HT	2002
GTS40-3-2 (RR Soybean)	Monsanto Company	Soybean	HT	2001
RR lines 1445 and 1698	Monsanto Company	Cotton	HT	2000
Line 531 / Bollgard	Monsanto Company	Cotton	IR	1997
MON810 / Yieldgard	Monsanto Company	Maize	IR	1997

1.3 Future developments in genetic modification

The production and development of GM crops is increasing worldwide. Future GMOs will also bring about new and complex challenges in terms of regulation and food monitoring not only for Africa through imports but also for the major GMO producing countries. The next generation genetic modification is aimed at two main aspects,

firstly to improve the nutritional quality of food and secondly to make GM technology relevant to developing countries, especially Africa through the genetic modification of traditional crops. Thus, it is important to know what the future frontier in GM development is, since it will bring the next challenge for the management of this technology. The following sections of the literature review deal with the application of genetic modification to produce nutritionally enhanced food, and the application of genetic modification in African food crops.

A decade after the first introduction of GM crops, the new goal is to use this technology to improve food nutrition (Engel *et al*., 2002). First generation GM crops were developed with improved agronomic traits for insect and weed management. Second generation GM crops are aimed at food quality characteristics with consumer benefits including improved nutrition, while third generation GMOs are intended to produce industrial and pharmaceutical products (Yonekura-Sakakibara and Saito, 2006). The focus of genetic engineering for nutrition is the enhancement of macronutrients (proteins, carbohydrates, lipids or oils, fibre), micronutrients (vitamins, minerals) as well as the exclusion or decrease of anti-nutrients and allergens (Newell-McGloughlin, 2008). Second generation GMOs aim to provide solutions for malnutrition as well as overall human health and well-being (Engel *et al*., 2002; Yonekura-Sakakibara and Saito, 2006; Zhu *et al*., 2007; Newell-McGloughlin, 2008; Ufaz and Galili, 2008). The aim of the next generations of GMOs are to address the basic causes of malnutrition including a deficiency in vitamins, minerals, fatty acids and amino acids (Table 1.2). In addition, GMOs are also being developed to improve carbohydrate and protein composition for improved digestion or metabolism. These advances require major financial investment and it is thus important to consider the

impact of these proposed modifications to assess their potential efficacy (Fresco, 2001; Biosorghum, 2007).

1.3.1.1 The use of GM technology to improve vitamin and carotenoid content of food crops

Vitamin A deficiency (VAD) is estimated to result in 2 million people becoming blind each year and is considered to be a nutritional epidemic in the developing world resulting in 17,000 deaths annually (Potrykus, 2001; Qaim *et al.,* 2006). The cost of VAD as measured in Disability-adjusted life years (DALYs) in 2004 was 629,387, of which 276,908 were for children up to four years old (Table 1.4) (WHO DALY, 2004.).

To combat VAD in Asia, GM rice has been developed with increased beta-carotene (precursor of vitamin A) content and is known as Golden Rice (GR) because of its yellow colour and potential benefit (gold) to people in poor countries suffering from VAD (Potrykus, 2001). The first version of GR was criticised because it contained too little beta-carotene (a maximum of 1.6 µg/g) to be effective (Ye *et al*., 2000). Subsequently GRII was developed with improved carotene production ranging from 9 to 37 µg/g (Paine *et al*., 2005). Thus GRII can provide up to half of the required daily allowance (RDA) of 700 to 900 µg vitamin A (Nestle, 2001; IOM, 2002; Paine *et al*., 2005; Botha and Viljoen, 2008). However, to achieve this based on the different conversion ratios reported for beta-carotene to vitamin A, ranging from 1:6 (ILSI, 2008), 1:12 (Nestel *et al*., 2006; ILSI, 2008; Meenakshi *et al*., 2010), 1:14 or 1:28 (WHO VIT, 2004), an adult would have to consume at least 62 g to 292 g of uncooked GRII rice per day (Nestle, 2001; IOM, 2002; Nestel *et al*., 2006; ILSI, 2008; Newell-

McGloughlin, 2008). One potential problem with GRII is that of social acceptance due to its yellow colour, a similar problem with brown rice which, while more nutritious than white rice, is considered culturally unacceptable in Asia (Royals, 2000; Panap, 2009). Furthermore, a concern has been raised that GM rice will impact the biodiversity of wild rice in Asia as the centre of origin (Lu *et al*., 2003; Chen *et al*., 2004).

Strategies such as vitamin supplementation, health care education, home gardening, nutritional feeding programmes and bio-fortification using plant breeding are being applied to reduce VAD in developing countries (Ahmed, 1999; Bishai, 2005; Nestel *et al*., 2006). For example, in Africa, conventional plant breeding has been used to increase the beta-carotene content in sweet potato (between 100 to 200 µg/g). Another study in Mozambique, utilized vitamin A bio-fortified maize to reduce VAD (Stevens and Winter-Nelson, 2008). After being informed of the nutritional value of the orange maize (as a result of bio-fortification with vitamin A), participants in a survey to test consumer acceptance, indicated that they would be prepared to supplement their diet with the vitamin A maize, if it was sold at the same price as traditional varieties (Stevens and Winter-Nelson, 2008). Based on their results, Stevens and Winter-Nelson (2008) suggested that if consumers are made to understand the benefit of GRII rice, sweet potato or maize, they may be willing to accept it if the price was comparable to conventional products. GRII will most likely determine the acceptance of B-carotene enhancement in other food crops improved for nutritional value including crops including canola, maize, mustard, potato, soybean, strawberries and tomato (Shintani and DellaPenna, 1998; Shewmaker *et al*., 1999; Fraser *et al*., 2001; Rocheford *et al*., 2002; Agius *et al*., 2003; Chen *et al*., 2003; Ducreaux *et al*., 2005; Newell-McGloughlin, 2008).

1.3.1.2 The use of GM technology to improve mineral content of food crops

Iron, zinc, calcium, selenium and iodine play an important role in child development and maintaining overall health (WHO VIT, 2004). For example, it is estimated that iron deficiency affects one to two billion people annually and is considered to be the most frequently undersupplied micronutrient especially in diets lacking in meat, fish or poultry. Pregnant women and children are affected most and as a result, iron deficiency anaemia accounts for 153,000 deaths annually, of which 64% are women (WHO DALY, 2004). The cost of iron deficiency anaemia is 16,152,000 DALYs and represents 42% of DALYs lost from total nutritional deficiencies (Table 1.4). As a result, plants are being genetically engineered to increase ferritin content (an iron storage protein) or reduce phytase (an enzyme responsible to degrade phytic acid that reduces the bioavailability of iron) (Lucca *et al*., 2002; Drakakaki *et al*., 2005). The ferritin gene from soybean is being used to improve iron storage in lettuce, rice, maize, soybean and wheat (Denbow *et al*., 1998; Brinch-Pedersen *et al*., 2000; Goto *et al*., 2000; Drakakaki *et al*., 2005). However, there is no simple solution to combat iron deficiency through the use of GM technology since over exposure to iron is as detrimental as deficiency. Compared to genetic modification, conventional breeding has already been used to develop varieties of barley, bean, maize, rice and wheat with higher iron content (Raboy, 1996; Stein *et al*., 2008). In addition, popular aromatic rice varieties such as jasmine and basmati naturally contain higher levels of iron and zinc (Graham *et al*., 1997).

Table 1.4 The cost of leading nutritional deficiencies in terms of mortality and burden of disease (WHO DALY, 2004).

Category	Nutritional deficiency combined		Vitamin A deficiency	Iron deficiency
	Deaths	**% Total[1]**	**Deaths**	**Deaths**
Global both sexes	487,000	0.8	17,000	153,000
Global male	223,000	0.7	9,000	55,000
Global female	264,000	1.0	8,000	98,000
Africa	159,000	1.4	13,000	27,000
South East Asia	179,000	1.2	2,000	83,000
Americas	57,000	0.9	0	15,000
Eastern Mediterranean	50,000	1.1	2,000	12,000
Europe	13,000	0.1	0	7,000
Western Pacific	27,000	1.5	0	9,000
	DALYs	**% Total[1]**	**DALYs**	**DALYs**
Global both sexes	38,703,000	2.5	629,000	16,152,000
Global male	18,436,000	2.3	339,000	6,918,000
Global female	20,268,000	2.8	291,000	9,234,000
Africa	11,753,000	3.1	478,000	2,850,000
South East Asia	13,503,000	3.0	82,000	6,821,000
Americas	2,294,000	1.6	1,000	980,000
Eastern Mediterranean	4,289,000	3.0	64,000	1,280,000
Europe	1,893,000	1.2	1,000	933,000
Western Pacific	4,920,000	1.9	4,000	3,266,000

[1] Percentage calculated from all causes of death or burden of disease per gender or country.

1.3.1.3 The use of GM technology to improve carbohydrates in food crops

The focus of GM technology in terms of carbohydrates is directed towards optimising the content of 'good' or nutritionally beneficial carbohydrates (Newell-McGloughlin,

2008). Beneficial carbohydrates are metabolised more slowly and thus not absorbed in the small intestine, but broken down by intestinal microflora to produce short-chain saturated fatty acids that enhance the absorption of micronutrients, reduce low density lipoprotein (LDL) cholesterol and act against colon cancer by inducing apoptosis (Watkins *et al*., 1999; German *et al*., 2005). 'Good' carbohydrates include fructans, inulins and raffinose (Newell-McGloughlin, 2008). Fructan content has been genetically modified in chicory, maize and sugar beet and fructan and inulin content modified in potato (Caimi *et al*., 1996; Sénevier *et al*., 1998; Hellwege *et al*., 1997; Hellwege *et al*., 2000). A pure form of either amylose or amylopectin is digested more slowly and is considered to be healthier. As a result, the ratio of amylose to amylopectin in potato, cassava and banana are being genetically altered (Visser *et al*., 1997; Schwall *et al*., 2000). Currently the only commercialised GM crop in terms of carbohydrates is maize event 3272 that has modified amylase content for the production of industrial ethanol (Table 1.2). Improvement in carbohydrate context is intended to have an impact in developed countries to combat obesity. For example, a starch dense potato is being developed so that 'French fries' can retain less oil during cooking and be less fattening (Stark *et al*., 2006).

1.3.1.4 The use of GM technology to improve oil and fatty acid content of food crops

Fatty acids play an important role in cardiovascular disease, arthritis, immune response, the regulation of blood pressure and brain function (Tocher *et al*., 1998). Although essential fatty acids (EFAs) are abundant in a range of foods such as fish, canola, olives, linseed, sunflower and safflower, they are not readily available in food

staples. As a result, genetic engineering is being used to increase the production of EFAs in canola, cotton, linseed, maize, palm, peanut, rice, soybean, safflower and sunflower. GM technology is also being used to make oils more resistant to oxidation as a result of heat degradation by increasing the levels of mono-saturated, poly-unsaturated and non trans fatty acids fats like lauric, myristic, oleic and stearic acids (Damude and Kinney, 2008; Newell-McGloughlin, 2008).

1.3.1.5 The use of GM technology to improve protein quality and essential amino acid content of food crops

Genetic modification is currently being used to increase the protein content and levels of essential amino acids in food crops. Maize event LY038, has been genetically modified to produce higher lysine content and has already been approved for environmental release in Australia, Canada, Japan and the USA (Table 1.2). It is estimated that doubling the lysine content in maize could improve USA feed exports to the value of US$360 million (Johnson *et al*., 2001). It is also argued that people in developing countries will benefit from the GM improvement of amino acid content in crops, since their diets are grain-based (Newell-McGloughlin, 2008). However, Millward (1999) concluded that calls for lysine enrichment and higher animal production to provide more protein in developing countries is ‘unjustified’ since cereal-based diets are able to supply sufficient levels of protein. It is also important to remember that food fermentation, which increases protein digestibility and quality, is common practice in most African countries. While it may be argued that developing countries need GM technology for food security, food safety, gene patenting, trade,

acceptance and management of genetic modification are all factors that also need to be considered.

1.3.1.6 Considerations of food safety for nutritionally enhanced GM crops

While genetic engineering may offer great potential in making a positive contribution to food nutrition, food safety is one of the key issues that needs to be addressed (MacKenzie *et al*., 2007; Finamore *et al*., 2008; Kroghsbo *et al*., 2008). Current GMOs on the market are considered safe for use as they have undergone risk assessment prior to release (Siegel, 2001). However, it must be recognised that our understanding of food safety is largely based on 'history of use' and is quite limited in terms of the proteome.

An example of the lack of understanding of food safety is evident in publications on the safety of GM crops. Based on risk assessments, including data on feeding studies, nutritional analysis as well as allergenicity and acute toxicity testing, GM crops are generally regarded as safe and nutritious as conventional crops (Siegel, 2001). However, there are studies that, although they do not directly indicate that GM crops pose health risks, raise questions as to our understanding of food safety. For example, in a 90-day feeding study on rats testing the immunomodulating effect of Cry1Ab protein in Bt rice, it was found that the GM fed rats had an increase in IgA as well as mesenteric lymph node weight compared to non-GM fed rats (Kroghsbo *et al*., 2008). In a study on mice fed Bt maize, there were alterations in the immune response of the gut and peripheral sites of especially old and weaning mice compared to mice fed conventional maize (Finamore *et al*., 2008). Similarly, a two-year study

concluded that there is a cumulative long-term effect on liver morphology and function in mice fed HT GM soybeans (Event GTS 40-3-2) (Malatesta *et al*., 2008a). Additional studies on cell morphology from mice fed with HT GM soybeans attributed morphological changes to residue from the herbicide glyphosate (Vecchio, *et al*. 2004; Malatesta *et al*., 2008b). Recently Paganelli *et al*. (2010) reported that there is a direct effect of glyphosate on teratogenesis in the embryos of vertebrates. Although none of these studies have concluded that GM food is unsafe, they provide evidence that our understanding of food safety in terms of genetic engineering is extremely limited.

The safety assessment of GM foods with enhanced nutrition is more complex than current first generation GM crops since the nutritional context also has to be considered. Alterations in the metabolome of a plant can result in unpredictable unintentional effects and could result in harmful side-effects (Nielsen and Myhr, 2007). For example, the derivatives of beta-carotene are known teratogens that could result in birth defects if present at sufficient levels. Additionally the wrong nutritional balance can be just as harmful as a nutritional deficiency (Teelman, 1989; DellaPenna and Pogson, 2006). For example, the introduction of a GM crop with increased iron content could result in an iron overload and the risk assessment would have to take into account consumption patterns (WHO VIT, 2004). Sometimes the effect of nutrition combined with other factors can be quite unpredictable. In another study it was found that smokers had an increased risk of developing lung cancer when their diet was supplemented with beta-carotene. When supplemented with vitamin E it was found that smokers had increased risk of heart failure (Beta-carotene Cancer Prevention group, 1994; Lonn *et al*., 2005). Therefore, it is important to apply a

holistic approach to the risk assessment of GM crops intended to improve food nutrition so as to prevent unintended harmful effects (Cockburn, 2002).

1.3.1.7 The role of nutritionally enhanced GM crops and the alleviation of world hunger

After 10 years of GM crop production, there is no indication that GMOs will promote food security or result in cheaper food (Engel *et al*., 2002). One problem is that GM crops must be seen in the context of world agriculture and trade. For example, agriculture is heavily subsidised in developed countries where there is ready access to agricultural inputs, compared to developing countries where there are minimal subsidies and access to inputs are limited. Furthermore, the use of food crops such as maize for bio-fuel production may contribute to world food shortages and has been criticized by the UN as it places food security at risk (Rosenthal and Martin, 2008; Rosenthal, 2008). Finally, it is important to consider that world hunger has little to do with food production but with food distribution, political instability, corruption, wars and lack of education (Botha and Viljoen, 2008). It would therefore be unfair to expect this problem to be solved through the use of GM technology.

1.3.1.8 Additional considerations of nutritionally enhanced GM food

There are several considerations that will determine the potential impact of nutritionally enhanced GM foods on society. These include consumer and farmer acceptance, the impact of gene patents and the requirement for trait segregation. How consumers will perceive nutritionally enhanced GM food is unknown. However,

given current trends and the growing consumer requirement for food to be 'natural', it is likely that these products will be met with mixed reaction unless accompanied by consumer education (Siegrist, 2008). There are also ethical, religious or cultural considerations in terms of the acceptance of GM food. These issues cannot be dismissed as ignorance and require careful deliberation and understanding. Furthermore, farmer acceptance will depend on additional premiums paid for such products, since nutritionally enhanced GM crops tend to be lower yielding than conventional crops (Jefferson-Moore and Traxler, 2005). In order to maintain the unique traits of nutritionally enhanced GM crop from 'farm to fork', segregation systems will be required. In many countries such systems do not exist for current GMOs and it is arguable whether developing countries would be able to deal with this issue (Falk *et al*., 2002).

Most developing countries do not have adequate laws, regulations or technological and financial resources to manage GMOs. For this reason, developing countries were very active in the negotiations of the Cartagena Protocol on Biosafety, which is an international instrument that requires countries to regulate activities involving genetic engineering particularly with respect to the transboundary movement of GM products referred to as LMOs. While most African countries are Party to the Protocol on Biosafety, the major producers of GM crops are not. This may result in unapproved LMOs entering African countries through grain imports and food aid. Since developing countries do not have the capacity to identify or monitor shipments of grain, illegal GMOs may enter and contaminate the food chain. This is especially problematic when dealing with second and third generation crops. It is also important to consider that food labelling for crops with improved nutritional traits would be very difficult to

manage in developing countries. GM food labelling for current GMOs is a contentious issue internationally and there is a difference of opinion whether labelling should be voluntary or mandatory. It is debatable whether resource poor developing countries that have not implemented biosafety frameworks will have the capacity to regulate GM food in terms of the next wave of GM developments.

1.3.1.9 Conclusion to nutritionally enhanced GM food

Second generation GM crops can make a contribution to food nutrition, but need to be considered holistically in the context of the problems being addressed. As such it is accepted that GM technology will never be the only solution to malnutrition (Zhu *et al*., 2007). It is also important to balance the cost of this technology with its potential efficacy on a case-by-case basis, also taking alternative solutions into consideration since a single food crop cannot replace a balanced diet (Botha and Viljoen, 2008). Many countries, especially developing countries, lack the capacity to monitor research and development activities and trends, conduct risk assessments and determine the health, environmental and socio-economic implications of GMOs. The introduction of the next generation GM food crops poses several regulatory challenges for developed countries in terms of GM food labelling and monitoring for illegal GMOs (Spök, 2006). These issues will be even more difficult for developing countries to overcome due to a lack of basic infrastructure and expertise. Furthermore, nutritionally enhanced GM foods may also have additional safety considerations in terms of exposure to higher levels of vitamins, amino acids or minerals. Thus, the promises of what GM technology can achieve should be tempered within the context of food nutrition and the additional burden of managing these GMOs.

1.3.2 Can GM sorghum impact Africa?[1]

1.3.2.1 Introduction to GM crops in Africa

Considering that over 4.3 million people in Southern Africa are currently surviving on food donations, genetic engineering of sorghum holds the promise for the alleviation of hunger and improved nutrition (http://www.wfp.org). The application of recombinant DNA technology in traditional African crops, especially sorghum, is considered to represent a 'second Green Revolution' that will 'benefit those passed by the first' (Nuffield Council on Bioethics, 2003). Thus, genetic modification holds the potential to improve the livelihoods of resource-poor farmers and dramatically increase the average yield of the poorest countries in Africa.

GM technology has often been criticised because of a lack of focus on traditional African crops (Huang *et al*., 2002). It is argued that in order for GM technology to improve food shortages in Africa, it should be applied to indigenous African food crops such as millet, cassava, beans and/or sorghum (Huang *et al*., 2002). Sorghum (*Sorghum bicolor* (L)) is the fifth most important grain crop in the world and the second most produced grain on the African continent (http://faostat.fao.org). In the developed world, sorghum is produced predominantly for animal feed, while in Africa it is produced by subsistence farmers and is consumed by more than 500 million people in more than 30 African countries (http://faostat.fao.org). In 2005, Africa produced 22 million tons of grain sorghum compared to Asia and the USA with 10 and 11 million

[1] Botha GM and Viljoen CD (2008) Can GM Sorghum impact Africa? *Trends in Biotechnology* 26(2):64-69.

tons, respectively. Despite high production in Africa, yield is low with an average of 8.49 hg/ha of sorghum recorded in 2006 for central Africa, compared to 10.27 hg/ha in Asia and 43.12 hg/ha in the USA (http://faostat.fao.org).

The elevated sorghum yield in the USA is a result of using improved varieties under favourable farming conditions. With the introduction of the combine harvester in 1960, cultivars in the USA were specifically developed for higher yield through conversion or breeding programmes that utilise a series of selection and backcross methods (Miller, 1982; Doggett, 1988; Rosenow and Dahlberg, 2000). These conversion programmes made use of genes in African germplasm to improve local varieties suited to agriculture in USA (Miller, 1982). Unfortunately, Africa never benefited from the conversion programmes and traditional African cultivars are not high yielding and breeding improvement has received little or no attention and/or investment due to the lack of international commercial value (Carr, 2001; Mgonja, 2003).

1.3.2.2 Current investment in GM crop development for Africa

In 2007, the Bill and Melinda Gates Foundation made a US$450 million commitment to the African Biotechnology Sorghum (ABS) project (Biosorghum, 2007). This project is also supported with an additional $27.1 million from the Wellcome Trust, as well as US$4.5 million from the Canadian Institute of Health Research (O'Kennedy *et al*., 2006). The project consists of a consortium including Pioneer Hi-Bred (a DuPont subsidiary), the University of California, four South African based members and three central and east African members (http://biosorghum.org) (Table 1.5). The overall aim of this project is to use transgenic technology to improve the health and wealth of

people in the world's poorest countries by means of a more nutritious and easily digestible sorghum that contains increased levels of essential amino acids, especially lysine, increased levels of vitamins A and E as well as increased availability of iron and zinc (O'Kennedy *et al*., 2006). The ABS project justifies its objectives based on traits with high efficacy in transgenic maize on the premise that these will also result in the significant improvement in sorghum (http://biosorghum.org). Thus, the nutritional improvement intended through transgenic sorghum is comparative to current efforts to combat vitamin A deficiency (VAD) through transgenic rice.

Table 1.5 ABS Project consortium partners (http://biosorghum.org).

Consortium partner	**Function**
Project steering committee	
Africa Harvest Biotech Foundation International (AHBFI)	• Overall project coordination • Product development, technical affairs, finance and business development, communications and public acceptance and regulatory affairs
DuPont, through Pioneer Hi-Bred	• Intellectual property • Principal Investigator providing scientific leadership
Council for Science and Industrial Research (CSIR)	• Technology transfer
Additional consortium members	
International Crops Research Institute for the Semi-Arid Tropics (ICRISAT)	• Product development, laboratory and field trials
African Agricultural Technology Foundation (AATF)	• Managing technology audits and the negotiation of intellectual property
Forum for Agricultural Research in Africa (FARA) the technical partner of New Partnership for Africa's Development (NEPAD)	• Developing an appropriate product distribution mechanism
University of Pretoria (UP)	• Nutritional analysis as well as developing food preparation techniques and menus
Agricultural Research Council (ARC)	• Community input and participation in project design
University of California, Berkeley (UC Berkeley)	• Research into improving the digestibility of sorghum

1.3.2.3 Lessons learnt from other GM developments for developing countries

It is estimated that over 2 million people go blind each year and of these, 60% of cases in India, China and Sub-Saharan Africa are a result of VAD (http://www.unsystem.org/scn) (Gilbert and Foster, 2001; Spivey, 2001). Interventions to prevent VAD associated blindness include health care education, vitamin supplementation, home gardening, nutritional feeding programmes and GM rice containing enhanced levels of pro-vitamin A (http://www.unsystem.org/scn) (Gilbert and Foster, 2001; Ahmed, 1999). GM rice, known as 'Golden Rice' due to its yellow colour, has been developed to produce enhanced levels of pro-vitamin A (beta-carotene) (Ye *et al*., 2000). Due to low expression levels in the first version of Golden Rice, 'Golden Rice II' was developed with a 37-fold increase in beta-carotene (Paine *et al*., 2005). Golden Rice is the first example of a GM crop that provides a direct benefit to consumers, something that first generation GM crops have failed to do (Potrykus, 2001; Datta *et al*., 2003 Paine *et al*., 2005). This rice has been publicised as being able to prevent millions of deaths and blindness in the 'poorest of the poor' (Potrykus, 2001; Datta *et al*., 2003 Paine *et al*., 2005).

Ironically, Golden Rice faces similar problems in Asia as GM sorghum does in Africa. These include concerns over the environment, patents, efficacy and social acceptance. In terms of the environment, there is a concern that Golden Rice will contaminate traditional varieties as well as wild relatives, since Asia is the centre of origin for rice (Lu *et al*., 2003; Chen *et al*., 2004). Although marketed as royalty free, Golden Rice is controlled by several international patents held by multinational companies. To accommodate resource poor farmers these companies have

generously agreed to waiver royalties, as long as earnings from the GM rice are less than US$10,000 a year (Grain, 2001; Paul and Steinbecher, 2003). However, it is doubtful if resource-poor farmers could implement such as system given the culture of saving seed and a lack a resources to account for their income.

Although Golden Rice is being suggested as an alternative to combat vitamin A deficiency, the principles of food nutrition are unfortunately being overlooked (Dawe *et al*., 2002). Beta-carotene undergoes several enzymatic reactions before being converted to retinol, the form of vitamin A absorbed by the body. As a result, the general bioavailability of vitamin A from beta-carotene is 10% or less (Nestle, 2001; IOM, 2002). The recommended dietary allowance (RDA) of vitamin A is between 900 to 700 µg retinol per day (IOM, 2002). Thus, a person would need to consume 250 g of uncooked Golden Rice II per day to achieve the required RDA, assuming 10% efficiency in conversion (Paine *et al*., 2005). Furthermore, the conversion of beta-carotene to vitamin A requires the presence of lipids, especially unsaturated fatty acids (Olson, 1998; Frei and Becker, 2004). Ironically, brown rice already contains beta-carotene and the required lipids on the inner layers of the husk. However, this is removed during milling to produce white rice (Frei and Becker, 2004). Therefore, while Golden Rice contains beta-carotene in the endosperm which is not lost during milling, it does not contain the fatty acids required for absorption. Finally, due to its golden colour, Golden Rice may probably be as socially unacceptable as brown rice.

Are there alternatives to combat VAD if ‘all that glitters is not gold’ applies to Golden Rice? The United Nations Standing Committee on Nutrition (SCN) has emphasised the need for ‘integrated interventions’ in combating nutritional deficiencies

(http://www.unsystem.org/scn). Vitamin supplementation has already had a substantial impact in alleviating VAD amongst children in projects in Nepal and Bangladesh (Ahmed, 1999; Bishai *et al*., 2005). Thus, given the problems with nutrition, bioavailability and social acceptance, it is questionable whether Golden Rice will have the intended effect on VAD. Similarly, GM sorghum faces many if not all of the problems associated with Golden Rice and its actual ability to 'improve the lives of millions of the poorest people in the world is also questionable (Nash, 2000).

1.3.2.4 Relevance of traits intended for GM sorghum

There is an important parallel in the application of GM sorghum in Africa to GM rice in Asia. Proposed transgenic traits in sorghum include increased levels of vitamin A and E, increased availability of iron and zinc as well as improved protein quality. GM sorghum with agronomic traits such as HT and IR as well as increased lysine content has already been developed, but not released (Ye *et al*., 2000; Zhao *et al*., 2000). However, it is important to distinguish between GM traits that are suited to commercial agriculture and those that have relevance for subsistence farmers. Herbicide tolerance is not suited to subsistence farming since it requires additional chemical inputs in an already chemical resource poor environment. IR has the potential to decrease crop losses due to insect damage, but could also lead to the emergence of secondary pests which in the absence of access to additional chemical control would prove problematic for resource-poor farmers (Morse *et al*., 2006).

Nutritional traits such as lysine, increased levels of vitamin A and E, iron and zinc and protein quality are important traits for human nutrition in Africa. However, sustainable

nutrition requires a well balanced diet and one food crop cannot replace all vital components (http://www.unsystem.org/scn) (Rigby, 2005). Although efforts have been limited, plant breeding has already been used to increase the beta-carotene content in sorghum (Reddy, 2005). Ironically, none of the GM sorghum traits under development are aimed at increasing yield, which is one of the greater problems facing sorghum production in Africa. While it has not been necessary to use GM sorghum to elevate yields in the USA to 4.31 tons per ha, currently the highest in the world, it is thought that the introduction of GM sorghum can achieve this in Africa (http://fao.org).

1.3.2.5 Sustainability of GM sorghum in Africa

Although projects to develop GM sorghum have high and noble ideals, a number of different issues need to be addressed to ensure sustainability. These include the resource requirements of farmers, the impact of GM gene flow on the environment, intellectual property rights as well as social acceptance of GM sorghum. The potential impact of GM technology must also be evaluated in the background of current limitations in agricultural practice in Africa. Despite the potential impact that GM traits could have on sorghum production and nutrition, it is important to take cognisance of the actual needs of Africa in terms of sorghum improvement.

In a study by Laswai (2003) and colleagues to investigate the needs of sorghum farmers in Africa, it was found that the main constraints include difficulties with grain storage, birds damaging kernel heads as well as a lack of processing facilities for de-hulling and threshing. The survey also identified limitations in terms of the availability of processing equipment, organised marketing and product development. Because of

these constraints, maize is favoured above sorghum by subsistence farmers (Laswai *et al*., 2003). Thus, it is ironic that considerable resources are being used to develop transgenic sorghum with attributes that have already been developed in maize – especially since maize, wheat and rice are preferred above sorghum in Africa (http://faostat.fao.org). This highlights the reality that Africa is once again being given what the world thinks it needs and not what it wants.

An important consideration is regarding the introduction of sorghum in Africa is the conservation of indigenous sorghum germplasm. Sorghum cultivation originated in Africa with the development of land races, before the slave trade (http://faostat.fao.org). Cultivated sorghum (*Sorghum bicolor* subsp. *Bicolor*) comprises five main races namely bicolor, kafir, guinea, durra and caudatum, specifically adapted to the different regions in Africa where they originated (Doggett, 1988). Gene flow from GM sorghum to land races would threaten a valuable genetic resource (Doggett, 1988; Schmidt and Bothma, 2006). A risk assessment by Schmidt and Bothma (2006) determined that sorghum gene flow could occur up to 2315 m. In addition, pollen mediated gene flow of transgenic wild relatives, such as Johnsongrass (*Sorghum halepense*), would have unpredicted effects on biodiversity and agricultural management (Arriola and Ellstrand, 1997; Jenczewski *et al*., 2003). Thus the introduction of GM sorghum will definitely impact on gene flow to landraces and wild relatives.

Intellectual property rights and ownership through patenting are concepts that are totally alien in African culture, as is the requirement to buy commercial seed every year. Thus, the requirement to pay royalties on patented seed becomes a barrier for

farmers to access recombinant DNA technology. A good case study for this is the introduction of insect resistant Bt cotton to rural farmers in the Makhatini flats in South Africa (Ismael *et al*., 2002; Hofs *et al*., 2006). Although quickly adopted, these farmers have had to deal with the increased cost of GM seed and an international slump in the price of cotton due to overproduction, resulting in increased debts and dependency on seed companies (Thirtle *et al*., 2003). Although farmers still share excess seed amongst each other, the requirement to obtain commercial seed each year can destroy their tradition of variety development and seed conservation.

It is important to note that the majority of sorghum consumption in Africa is actually in the form of sorghum beer and traditional fermented foods (Doggett, 1988; Belton, 2003). The use of sorghum in the production of beer and food is an African tradition as old as sorghum cultivation (Doggett, 1988). Malting and fermentation of any sorghum increase the nutritional value and protein quality and it is questionable whether the enhanced nutrition from genetic modification will have any further nutritional benefit (Belton, 2003). It has also never been established whether the introduction of GM sorghum would be culturally acceptable. Current indications are that this is unlikely given the fact that South Africa and Egypt are the only countries currently growing GM food crops in Africa (James, 2009).

GM sweet potato is an example of GM technology to improve an indigenous African food crop. A project was launched in 1995 by the Kenyan Agricultural Research Institute (KARI) and Monsanto to develop a transgenic virus resistant sweet potato variety (Biosafety Information centre, 2004). In 2000, a virus resistant GM variety was produced at an estimated cost of US$6 million. Although field trials have been

ongoing, there is no expected release data available (Biosafety Information centre, 2004). It has been speculated that field trials failed because the virus resistance was against a USA strain of the virus, which is ineffective for the African strain (Biosafety Information centre, 2004). Furthermore, the transgenic variety used was unpopular amongst farmers (Gathura, 2004). This emphasises the need to modify solutions developed by the first world to the realities facing the third world.

1.3.2.6 Conclusion to the impact of genetic modification in Africa

Africa is technology resource poor. Most countries lack basic infrastructure in agricultural management and practice. Crop varieties are outdated and in need of basic breeding improvement that GM technology cannot provide, especially in terms of yield and environmental adaptation. Unlike farmers in the EU and USA, African farmers are not subsidised and basic chemical inputs are not affordable or readily available. Thus, the added cost of GM technology places an additional financial burden on African farmers. Africa has close ties to Europe and anxieties surrounding export losses because of unregulated GMOs continue to play a role. Africa's lack of capacity to manage the introduction of GM food crops in terms of illegal contaminations as well as insufficient GM labelling practices may endanger Africa's already fragile economy.

It must be recognised that poverty in Africa is exacerbated by social factors such as poor governance, corruption, armed conflict and lack of education (Robinson, 1999). Thus, for any traditional GM African crop to have a desired impact, it needs to form part of an integrated approach that addresses the issues associated with agriculture in

Africa (Table 1.6). This begs the question whether the philanthropic donation of millions of dollars is just a publicity exercise to promote GM technology without taking into account the actual needs in Africa. Thus, unless these issues are addressed, the introduction of GM sorghum into Africa will prove futile.

Table 1.6 Constraints and solutions surrounding the introduction of genetic modification in Africa.

Issues	Solutions
Farming resources • Lack of farming subsidies and access to credit • Farmers do not have ready access to agricultural inputs • Diverse farming communities consisting of mainly subsistence farmers	• Farming subsidies in the developed world should be eliminated and systems established to give African farmers access to resources without tying them into a cycle of debt
Variety improvement • There is no effective system to ensure that new varieties are released to farmers • New varieties are often developed to suit commercial farming conditions • Breeding improvement does not always consider cultural preferences • Varieties developed in first world countries are not adapted to the African environment	• Variety improvement should begin by assessing the needs of the farmer and community • Programmes should incorporate farmers' knowledge of crops as well as locally adapted land races
GM traits • The selection of GM traits is not based on identified needs	• Drought and heat tolerance as well as grain quality have been identified as important traits
Nutrition • One food crop cannot provide balanced nutrition	• Nutritional education is as important as technological solutions
Environmental management • Gene flow to wild relatives and land races	• Implementation of guidelines by African governments for the safe application and use of biotechnology • Apply a precautionary approach in genetically engineering indigenous germplasm and land races
Intellectual property rights • African countries cannot afford to access intellectual property owned by companies in developed countries	• An unconditional withdrawal of patents in developing countries or a complete waiver of all royalties

1.4 Societal aspects in terms of the introduction of GM food crops

The same social issues surrounding GM food in the developed world are applicable to Africa. The introduction of genetic engineering has an impact on every sector of the food production chain from the primary producer or farmer up to the consumer and influences all spheres of society (Dano, 2007). Although farmers benefit from first generation GMOs and consumers are promised gain from second generation GMOs, the impact of GMOs on society overall are more complex. Societal aspects including the safety of GMOs to human health and the environment, consumers' perceptions towards GM food and how this impacts trade and regulations, should be considered as important to society as economic gains promised by GM technology.

Ever since the introduction of GM food crops, proponents of the technology have raised objection to why it should be treated differently to conventional food crops (OECD, 1993; Chassy, 2002). Without an understanding of the societal and socio-economic considerations regarding GMOs, concerns raised by consumers may seem irrelevant. However, societal issues regarding GM foods are complex and not necessarily well understood or clearly defined (Frewer *et al*., 2004; Dano, 2007). While protagonists of genetic engineering may consider GM foods equivalent to conventional counterparts – substantially so – it remains a fact that specific regulations exist in most countries to govern the transfer, handling, use and labelling of GMOs and this in itself indicates that despite claims to the contrary, they are considered different.

1.4.1 Novelty of GM foods

Genetic modification entails the transfer of a specific gene across species boundaries and clearly distinguishes it from conventional breeding techniques of which there is a history of safe use (EEA, 2001). Transgenic plants contain a novel combination of genetic elements not found in naturally occurring organisms including the use of viral control elements and antibiotic resistance marker genes that could alter gene expression or have unintended effects (Myhr and Traavik, 2002). Furthermore, the random insertion of a gene into gene-rich regions of the eukaryote host genome is known to result in mutations due to the interruption or alteration of functional genes and overall changes in metabolite levels and composition (Myhr and Traavik, 2002; Cellini *et al*., 2004; Rischer and Oksman-Caldentey, 2006). Such changes may have unintended or unpredictable effects on the organism and risk assessments are carried out in order to identify and evaluate possible adverse effects on the environment and human health (Falck-Zepeda, 2009).

A risk assessment of GM crop includes identifying potential adverse effects, assessing the likelihood of an adverse effect occurring and evaluating the potential consequences (König *et al*., 2004). This is especially important when dealing with GM food, since the organism as a whole is being consumed and any potential risks identified should be taken into consideration for post-release monitoring. Catastrophic incidents from history including the use of asbestos, the potato famine and “mad cow disease” has resulted in a precautionary approach to new technologies, especially in Europe, to deal with scientific or industrial uncertainties and potential hazards (EEA, 2001). Therefore, the scrutiny of GM food may be justified in terms of the novelty and

potential unintended effects on human health and/or the environment in order to balance benefits and risks.

1.4.2 Consumer response to GM food

Consumers appear to have mixed reactions to GM food, despite the regulatory requirements to ensure the safety of these products. An increasing body of literature reports on how consumers could potentially respond to GM food, how consumers perceive GM technology and how this would ultimately influence acceptance or rejection of GMOs (Curtis *et al*., 2004). For the most part, consumer perceptions differ between counties and cultural groups. For example, studies in the USA found consumers to be more accepting of GM food compared to the EU (Lusk *et al*, 2001; McHughen and Wager, 2010). This is understandable since the reasoning mechanisms behind consumer attitudes are influenced by issues like perceived risks and benefits, trust in science or regulatory bodies, religion, ethics, lifestyle choice, quality, price and perceived naturalness. However, whatever the reasons, consumer autonomy in response to GM food has to be respected (Siipi and Uusitalo, 2010).

A number of publications elude to positive attitudes towards GM in the USA (Lusk et al, 2001; Pew Initiative, 2003; Falk *et al*., 2002; Curtis *et al*., 2004; Onyango and Nayga, 2004; Finucane and Holup, 2005; Costa-Font *et al*., 2008). One of the reasons suggested for this is trust in the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) responsible for determining the safety of GM food (Pew Initiative, 2003; Falk *et al*., 2002; Curtis *et al*., 2004; Finucane and Holup, 2005; Costa-Font *et*

al., 2008). However, surveys show that most USA consumers are unaware that they are consuming GM food. Of those surveyed in one study, 62% said that they had never eaten GM food even though it is estimated that at least 60% of all processed foods in the USA contains GM ingredients (Pew Initiative, 2003). Nelson (2001) suggested that the general acceptance of substantial equivalence of GM foods to conventional foods as well as trust in governmental institutions is responsible for the limited regard over GM food safety issues. However, the indifference of USA consumers to GM food may simply be because of a lack of awareness.

Compared to the USA, EU consumers are generally opposed to GM food for various reasons (Finucane and Holup, 2005; Costa-Font *et al*., 2008; Siegrist, 2008). It has been suggested that consumer attitudes in the EU to GM food is the result of a complex cumulative interaction of risk and benefit perception coupled with institutional mistrust (Costa-Font and Gil, 2009). It is thought that health scares, including that of asbestosis, the potato famine and “mad cow disease”, have resulted in consumer mistrust to new technologies and the institutions responsible for determining food safety (Finucane and Holup, 2005). It appears that European consumers have a “better safe than sorry” attitude toward GM foods because of uncertainties involving health and/or environmental risks, and would rather follow a precautionary approach (Curtis *et al*., 2004). Despite differences between consumers in the USA and EU, it is apparent that while consumer awareness of genetic modification may not necessarily result in a negative perception toward GM food, consumers will still want to have such products labelled in order to have a choice (Botha and Viljoen, 2009).

Consumer studies have also been conducted in Kenya, Nigeria and South Africa, to test perceptions towards GM food in Africa (Kimeju and de Groote, 2004; Kushwaha *et al*., 2004; Rule and Ianga, 2005). In Kenya, 38% of consumers were aware of GM crops and approximately 51% were concerned that it would affect the environment and result in loss of local varieties (Kimeju and de Groote, 2004). Approximately 40% of respondents expressed fears over health effects such as allergic reactions to GM food (Kimeju and de Groote, 2004). Despite this, 68% of participants indicated that they would buy GM maize meal if it were the same price as non-GM brands (Kimeju and de Groote, 2004). Compared to this, approximately 90% of Nigerian consumers were aware of GM food. Of these, 70% completely disapproved of GM technology due to the perceived risks involved, including ethical considerations as well as concerns over endangerment to indigenous crop species (Kushwaha *et al*., 2004). Ironically, in surveys to determine consumer perceptions towards GM food in South Africa, 82% of consumers did not know what was meant by the term 'biotechnology' and 63% were unaware that they had ever consumed GM food (Rule and Ianga, 2005). This is surprising since South Africa is the largest producer of GM crop in Africa and with a 85% GM soybean, 72% GM yellow maize and 55% GM white maize production, it is likely that most consumers are being exposed to GM food (James, 2009). Similar to trends in other consumer surveys that indicate diverse perceptions to GM food, 42% of South African consumers polled had no opinion regarding the risks of biotechnology, 26% felt the technology posed no risk to society, while 21% agreed that it did (Rule and Ianga, 2005). Irrespective of consumer perceptions, it should be recognised that the principle of consumer autonomy – giving the individual access to information on food in order to make their own choice – should be considered a fundamental right. Consumer choice is based on a combination of

influences, including perceptions of safety, considerations for naturalness, life style choice, ethical considerations and belief (Curtis *et al*., 2004). In a democratic society where choice is accepted as the norm, consumers will not buy products that they perceive to be harmful to their health or the environment or against their ethical and/or religious considerations (Frewer *et al*., 2004).

1.5 International agreements and regulatory approaches to GM food

While genetic engineering promises great potential, concerns remain over safety to human health and the environment. As a result it has become a regulatory requirement to manage the activities involving GMOs. At international level, the most prominent instruments are the Cartagena Protocol on Biosafety and the Codex Allimentarius. In addition to this, countries also have national laws in terms of managing GMOs.

1.5.1 Cartagena Protocol on Biosafety

The Biosafety Protocol was adopted in Montreal in 2000 by Parties to the Convention on Biological Diversity. The Protocol provides an international regulatory framework to manage GMOs, referred to as LMOs[2], to ensure safe transfer including transboundary movement, handling and use of GMOs by taking into account safety to the environment and human health in order to achieve sustainable use of biological diversity (http://www.cbd.int/biosafety).

[2] The term LMO was adopted in the Cartagena Protocol on Biosafety instead of GMO, partly as a political compromise and to refer to the living or propagating form of a GMO.

Currently 160 countries are Party to the Cartagena Protocol on Biosafety. One of the major challenges with the implementation of the Biosafety Protocol is that of the major GM crop producing countries, only Brazil, India, China, Paraguay and South Africa are Parties. Notably the biggest genetic modification producers, including the USA, Canada, Argentina and Chilli, are not. This makes fulfilling requirements under the Protocol difficult when dealing with non-Parties, especially for imports.

Within the Biosafety Protocol, provision is made for an enabling environment to manage LMOs. This includes the following:

- National regulatory frameworks (Article 2)
    - The Protocol requires the appropriate legal and administrative measures to implement obligations under the Protocol.
- Notification (Article 8)
    - The Party of export is required to notify the Party of import in writing of intended transboundary movements of LMOs.
- Risk assessment and risk management of LMOs (Article 15 and 16)
    - The Protocol requires a risk assessment, in terms of provisions in Annex III as well as risk management, to ensure the objectives of the Protocol to ensure the safety of LMOs to the environment and human health.
- Unintended transboundary movement of LMOs (Article 17)
    - The Protocol requires notification by Parties where unintentional transboundary movement of LMOs has occurred as well as emergency measures in order to minimise adverse effects on the conservation and sustainable use of biological diversity taking into account risks to human health.

- Handling, transport, packaging and identification of LMOs (Article 18)
    - The Protocol requires the identification of LMOs intended for food, feed and processing, contained use and introduction into the environment.
- Information sharing and the Biosafety Clearing House (BCH) (Article 20)
    - The Protocol established a clearing house mechanism to facilitate exchange of scientific, technical, environmental and legal information on LMOs to assist Parties to implement the protocol. Under Article 20, Parties are required to make available to the Biosafety Clearing House any laws, regulations or guidelines for the implementation of the Protocol as well as summaries of risk assessments and final decisions regarding the importation or release of LMOs.
- In addition, the Protocol also addresses other supplementary aspects of biosafety including capacity building for developing country Parties (Article 22), public awareness and participation in decisions taken under the Protocol (Article 23), socio-economic considerations that arise from the impact of LMOs (Article 26) and liability and redress for damage resulting from transboundary movements of LMOs (Ariticle 27).

Thus in terms of requirements under the Protocol, GM detection is an important aspect for LMO identification as well as to determine unintentional transboundary movement or escape of LMOs under conditions of contained use. The Protocol provides the minimum requirements for activities regarding LMOs and Parties may include additional considerations in national regulations and laws. However, the Biosafety Protocol makes no provision for GM food labelling for consumer choice and it is up to individual countries to determine their approach to this issue.

1.5.2 Codex Allimentarius

Codex Allimantarius was established jointly by the FAO and WHO in 1963, to develop standards, guidelines and related texts such as codes of practice for food, food production and packaging (www.codexalimentarius.net). The main objective of Codex is to set food standards that will protect consumers' health and ensure fair trade in food (www.codexalimentarius.net). Furthermore, it aims to coordinate international food standards and has delivered the following:

- Guidelines for hygienic practices from start of manufacture through to final production.
- Guidelines for risk assessment of GMOs including considerations of intended and unintended effects as well as assessment of allergenicity for GM plants and micro-organisms.
- Standard for food labelling that applies to the labelling of all pre-packaged foods to be offered to the consumer, including labelling of GM food for nutritional and health claims.
- Guidelines for the production, processing, labelling and marketing of organic food. The guideline considers GM crops not compatible with the principles of organic production.
- A Codex committee was established to develop guidelines on performance criteria and validation for detection and identification of specific DNA and protein sequences in foods. Including those derived from modern biotechnology (that includes genetic engineering). The guideline is still in development.

1.5.3 Country specific approaches to the approval of GM crops

Most countries enact laws governing the development, use, production and release of GMOs whether they are a Party to the Biosafety Protocol or not. However, the approach to regulating GMOs may differ considerably between countries. The EU, a Party to the Biosafety Protocol, is considered to have the strictest system for regulating GMOs, compared to the USA, a non-Party to the Biosafety Protocol, which regulates GMOs similarly to other agricultural products (Davidson and Berteau, 2007). The following section analyses the different regulatory approaches in the EU and the USA compared to South Africa (Table 1.7).

Table 1.7 Summary of national regulatory instruments in the USA, EU and South Africa.

Regulatory aspect	EU	USA	South Africa
Cartagena Biosafety Protocol	Party	Non-party	Party
Regulatory body	European Commission, EFSA and Member States	USDA – APHIS, EPA and FDA	Department of Agriculture, Forestry and Fisheries (DAFF), Department of Environmental Affairs DEA)
Legislation / act / policy	Regulation (EC) 258/97	1992 (57 FR 22984)	GMO Act 1997and Amendment Act 2006, NEMA (Amendment Act No. 8 or 2004) and NEMBA (Act No. 10 or 2004)
Biosafety Frameworks for GMOs	Yes	Yes[1]	Yes
Approach to risk assessment	Event	Gene product	Event

[1] GMOs are treated similarly to conventional crops in the USA.

1.5.3.1 Approach to GM crop approval in the USA

In the USA, GMOs are regarded as substantially equivalent to conventional food crops and are treated similarly in terms of safety assessment (Davidson and Berteau, 2007). Three agencies are responsible for the oversight of GM crops in terms of ensuring safety to human health and the environment (http://usbiotechreg.nbii.gov/index.asp):

- The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for the environmental safety in terms of agricultural applications including GM crops. APHIS is also responsible for the regulation of field trials, interstate movement and importation of GM crops (http://www.aphis.usda.gov).
- The Environmental Protection Agency (EPA) has regulatory oversight over GM crops that produce plant pesticides and these are regulated in the same manner as chemical spray pesticides (König *et al*., 2004). In order for a company to register a pesticide, the EPA has to evaluate it to determine that it will "not pose unreasonable risks or harm to human health and the environment" (http://ww.epa.gov/pesticides/biopesticides).
- The Food and Drug Administration (FDA) is responsible to ensure "safety and proper labelling of all plant-derived foods and feeds, including those developed through bioengineering" (http://www.fda.gov/Food/Biotechnology/default.htm). Since GM crops are considered substantially equivalent to convention crops no regulation is required and companies may follow a voluntary consultation process in which safety data submitted is reviewed by the FDA.

In the USA, GM food crops are not required to undergo safety assessment unless they have insect resistant properties under the requirements of the EPA while safety assessment in terms of the FDA is considered voluntary. Currently, there are 105 GM crop events (excluding stacked and non-food crops) that have completed all recommended or required reviews for food, feed or planting use in the USA (http://usbiotechreg.nbii.gov/database_pub.asp). The USA is not a Party to the Biosafety Protocol and regulatory systems do not incorporate all the requirements stipulated by the Protocol like in the EU and South Africa. For example, there is no obligation to notify the Party of import of transboundary movements of LMOs (Article 8) or identify LMOs in bulk grain shipments – this poses a challenge to receiving countries. In terms of risk assessment, environmental safety is regulated by APHIS if the GM crop produces a plant pesticide. The requirement to determine safety to human health is dealt with by the FDA and is a voluntary process. The USA system allows for public participation, however, no sharing of information to the BCH is required, although information is available on the USDA database (http://usbiotechreg.nbii.gov/database_pub.asp). Most of the Articles under the Biosafety Protocol are not viewed as relevant in the USA, since GM crops are considered equivalent to conventional counterparts.

1.5.3.2 Approach to GM crop approval in the EU

Contrary to the USA, the EU is not only a Party to the Biosafety Protocol, but has also introduced additional laws to regulate GMOs in terms of traceability and labelling in food (Phillips and McNeil, 2000). The response to GMOs in the EU is largely a result of previous food safety scares, including most recently that of “mad cow disease”

(Finucane and Holup, 2005). Consequently the objective of genetic modification technology legislation in the EU is to provide the highest level of health and environmental protection.

In the EU, GMOs are approved on a case by case basis considering the risks to human health and the environment. Companies wanting to release or market a GM event apply for approval by submitting a risk assessment to the EC through one of the member states according to regulation (EC) 1829/2003. Thereafter, the dossier is evaluated by the European Food Safety Authority (EFSA), the findings of which are then sent to the EU Commission and circulated to all the Member States. The 27 member states decide on the authorisation by majority voting. However, if the member states cannot reach consensus, the decision is referred back to the European Commission ((EC) 1830/2003). The application process may take between three months and an indefinite period depending on the time applicants take to respond to requirements for additional information in the risk assessment (Nap *et al*., 2003). Compared to the 105 GM crop events (excluding stacked events and non-food crops) in the USA, 25 have been approved in the EU (Waiblinger *et al*., 2010) (www.cera-gmc.org). While most, if not all, of the requirements in the EU to determine the safety of GM events are in the fulfilment of obligations according to the Biosafety Protocol, it is how this process is managed between the member states and the EC that makes it rather tedious

1.5.3.3 Approach to GM crop approval in South Africa

South Africa, a Party to the Cartagena Protocol on Biosafety, has implemented laws to fulfil its obligations under the Protocol. All activities involving GMOs in South Africa are regulated by the Genetically Modified Organisms Act 1997 (Act No.15 of 1997) and the Genetically Modified Organisms Amendment Act (Act No. 23 or 2006), through a permit system that is administered by the National Department of Agriculture, Forestry and Fisheries (DAFF, 2010b). Under the GMO Act, permits are granted for different categories of activity that include general release (where GMOs are released into the environment without any restrictions), commodity clearance (where GMOs are used for food or feed but cannot be cultivated), trial release (where the release of a GMO into the environment is limited for the purpose of field testing) and contained use (where a GMO may be used within a laboratory or glass house only). Currently, no provision is made for the regulation of GM events in processed foods (personal communication with the DAFF). In addition to the GMO Act, the National Environmental Management Biodiversity Act (Act No. 10 or 2004) (NEMBA) and the National Environmental Management Act (Amendment Act No. 8 or 2004) (NEMA) function to monitor environmental impacts of GMO release. The GMO Act fulfils all the obligations under the Cartagena Protocol on Biosafety, which is included as an annex to the Amendment Act (Act No. 23 or 2006). Under the GMO Act, 11 events have been approved for general release, 10 for commodity clearance and more than 80 for trial release in South Africa since 1997 (DAFF, 2010b). Thus, as one of the few GMO producers in Africa, and the eighth biggest GMO producer in world, South Africa is evidence that the Biosafety Protocol can be implemented without it being in opposition to genetic engineering development.

1.5.3.4 Challenges in asynchronous regulation of GMOs

Since the introduction of genetic engineering, different countries have applied different regulatory procedures and time frames for the approval of GMOs for environmental release or use as a commodity (Holst-Jensen, 2009; Stein and Rodriguez-Cerezo, 2010). As a result, the release of GMOs in different countries is asynchronous. It has been suggested that the asynchronous approval of GM crops may result in economic losses for traders in terms of the loss of markets if a GM event does not have the same approval status in both trading countries (Stein and Rodriguez-Cerezo, 2010). While asynchronous approval has not resulted in food shortages, it has posed challenges especially for developing countries, in terms of managing genetic modification in food imports and food aid.

1.5.4 GM monitoring of the food chain

There is an opinion that GM labelling of food products cannot be achieved and that GM and non-GM products cannot co-exist (Kershen, 2010). The reality is that in order to maintain regulatory requirements for GMOs already present in most countries in a traditionally non-GM environment, GM labelling and monitoring are needed (Fagan, 2007). In addition, the requirement to label GM food also makes the monitoring for the unintended presence of GM in food products necessary (Heinemann *et al*., 2004; Dinon *et al*., 2008; Park *et al*., 2010). Thus, the challenge lies in the distinction between non-GM and GM food to maintain the identity of value added GM traits, or to ensure that GM industrial or pharmaceutical crops do not contaminate the food chain.

1.5.4.1 Labelling of genetic modification in food

Food labelling to indicate GM content allows consumers to make an informed choice between GM and non-GM products. This affords consumers the opportunity to make their own decisions by taking into account ethics and perceived risks compared to the benefit of GM products (Baker and Burnham, 2002; Carter and Gruère, 2003; Cheftel, 2005). GM labelling is applied in a mandatory manner, where a product must be labelled if it contains genetic modification above a predetermined threshold, or voluntary manner, that allows companies to decide whether to label products for GM content based on the perceived requirements of consumers. It is argued that mandatory GM labelling can result in a negative perception of genetic modification by consumers and does not provide consumers with choice, since mandatory labelling in the EU has resulted in an absence of GM products on supermarket shelves (Carter and Gruère, 2003; Gruère and Rao, 2007). However, countries including Brazil and China, have successfully applied mandatory GM labelling without such apparent concerns (Phillips and McNeill, 2000; Gruère and Rao, 2007).

Of the 42 countries where GM labelling is applied, 39 of these make use of a mandatory approach (Gruère and Rao, 2007). Some of the major GMO producers, including Brazil, China and South Africa, apply mandatory GM labelling compared to other GMO producers, including Canada, Argentina and the USA, that follow a voluntary GM labelling system (Cheftel, 2005). Thus, there is no coherent distinction between how GMO producing countries apply mandatory versus voluntary GM labelling.

Countries with mandatory GM labelling apply different thresholds, as a level of tolerance for the adventitious presence of authorised GMOs. For example, countries in the EU use 0.9% compared to 5% in Japan, as a trigger for GM labelling. Compared to this, countries where voluntary GM labelling applies have no GM labelling threshold, and companies label GM content in food at their own discretion. Furthermore, countries applying voluntary GM labelling do not regulate the application of GM labelling, and the concern is that this may result in inconsistent labelling practice that would mislead consumers (Viljoen, 2005). The application of threshold levels are not based on scientific guidelines, but rather have to do with consumer perceptions, practical limits of detection and possible cost implications (Bansal and Ramaswami, 2007).

It is often argued that mandatory GM labelling will result in an increase in food costs, due to a need for comprehensive management, compared to voluntary labelling, where the cost is borne by the discerning consumer (KPMG, 2000; De Leon *et al*., 2004; Gruère and Rao, 2007). A study conducted in the Philippines has shown that mandatory labelling may potentially result in a cost increase of up to 10% in food products (De Leon *et al*., 2004). However, similar studies that indicate a high cost implication to consumers have made the following the assumptions that elevate theoretical labelling costs:

- It is assumed that all products would be included, irrespective whether they contained the crops types for which a GM equivalent had been developed or not.

- It is also assumed that expensive systems, such as identity preservation (IP) and segregation as well as exhaustive GM testing for verification, would be required (Jaeger, 2002)

Based on the application of GM labelling in the EU, a NERA (2001) study estimated that the cost increase for mandatory GM labelling was approximately US$0.23 per person per year. Gruère and Rao (2007) made a summary of all the studies that have considered the cost implications for mandatory GM labelling and depending on the management system required, a cost of between US$1 and US$10 per person per year was estimated. However, the latter still assumes exhaustive unnecessary management of products that do not currently have GM equivalents, or would be expected to have in future. Despite this, studies in the UK have shown that consumers would still be willing to pay for products labelled to indicate an absence of genetic modification (Spence and Townsend, 2006).

One of the most important considerations of mandatory GM labelling not considered by protagonists of GM technology opposed to GM labelling, is consumer autonomy. It is often argued that mandatory GM labelling, is a barrier against GM technology (Paarlberg, 2004; Paarlberg, 2010). Additionally, it is implied that consumers in poor countries should have less of a choice between GM and conventional products due to their economic circumstances (McHughen, 2000; Zerbe, 2004). However, providing consumers with choice, between GM and non-GM derived products has no bearing on the view of GM technology. It should be recognised that food labelling for consumer autonomy encompasses considerations regarding the right to information that refers to the intrinsic value of transparency, ethical and religious concerns and ultimately the

sovereignty of the consumer (Klintman, 2002). The consumers' "right to know" has become an established right in modern society regardless of socio-economic status and this should include information on the GM contents of food (Klintman, 2002).

1.5.4.1.1 GM labelling approach in the USA

In the USA, voluntary labelling is applied for GM products (Table 1.8). Labelling of GM food is only required by the FDA "if the GM products hold potential risk to human health or the environment" (Statement Policy: Foods derived from New Plant Varieties") (FDA, 57 FR 22984). However, since the FDA does not consider GM food crops different to conventional crops, no special labelling is required for GMOs. Despite this, the FDA has received requests for guidance regarding voluntary GM labelling and consequently released a document, providing guidance to industry. The FDA suggest examples of GM food labels including "genetically engineered" or "developed thought biotechnology" (FDA, 2001). The use of "GM free" or "Zero GM" is discouraged since it may be misleading if either no GM counterpart exists for the product or due to the possible adventitious presence of genetic modification. Despite the fact that the voluntary GM labelling is applied by companies in the USA there is very little information on the actual success of the application of voluntary GM labelling compared to that of mandatory GM labelling.

Table 1.8 Summary of national GM labelling regulations in the USA, EU and South Africa.

	EU	USA	South Africa
Type of labelling	Mandatory	Voluntary	Mandatory
Regulatory body	European Commission (EC)	FDA	Departments of Health (DOH)[1]/ Trade and Industry (DTI)[2]
Act or regulation	Regulation (EC) 1139/98	FDA guidance document (57 FR 22984)	Foodstuffs, Cosmetics and Disinfectants Act[1] and Consumer Protection Act[2]
Labelling threshold	0.9%	No threshold for voluntary GM labelling, 5% for organic production[3]	5% according to draft regulations to the Consumer Protection Act[2]

[1] Department of health (2004b)

[2] SACPA (2008)

[3] There is an organic production guideline.

5.4.1.2 GM labelling approach in the EU

EU regulations mandate the labelling of foods that contain approved GM events above a threshold of 0.9% ((EC)1829/2003) (Table 1.8). Furthermore, traceability is mandatory for processed products ((EC)1830/2003). Traceability is used to follow GM ingredients through all the stages of production to ensure that even though the final processed ingredient may not contain detectable GM protein or DNA, it is still labelled correctly. Traceability requires the producer or seller to inform the buyer of the GM nature of the product and keep a register of buyers. For labelling of highly processed products including canola oil or soybean lecithin in which the GM protein or DNA may be undetectable, to trace the GM status of the product Traceability is especially useful (Davidson and Bertheau, 2007).

The EU regulations make provision for all GMOs that have received authorisation for use as a commodity, for food and feed and environmental release. Meat produced

from GM feed or food produced from a GM enzyme, for example cheese, do not require GM labelling. Some EU countries, including the UK, have also extended GM labelling regulations to food additives and preservatives (Postnote, 2002).

5.4.1.3 GM labelling approach in South Africa

In South Africa, GM labelling is applied to warn consumers of the health considerations of GM food where necessary as well as to provide for consumer choice (Table 1.8). Regulation 25 (2004) under the Foodstuffs, Cosmetics and Disinfectants Act (1972), makes provision for the mandatory labelling of GM foods that are not substantially equivalent to conventional products in terms of nutritional composition or storage and preparation, or if it contains an allergen or a human or animal gene (Department of health, 2004b). This regulation also makes provision for labelling GM products with value added traits for consumers such as improved nutrition or reduced allergenicity. In practice, this regulation has proven irrelevant since no GM crop would ever be approved if it contained a known allergen. Furthermore, the regulation provides no basis for determining substantial equivalence and it is unlikely that GM crops would differ from their conventional counterparts in terms of storage and preparation. As a result, no GM foods have been considered for GM labelling based on this regulation.

In 2008, mandatory GM labelling was introduced in the Consumer Protection Act (2008) (Table 1.8). According to the Consumer Protection Act, “the presence of any genetically modified ingredients or components thereof should be labelled, in a prescribed manner and form, in accordance with applicable regulations” (SACPA,

2008). Proposed regulations to this act were published on the 29th November 2010 and prescribe the use of a threshold level of 5% (SACPA Proposed Regulations, 2010). In terms of labelling terminology it is suggested to use "Contains at least 5% genetically modified organisms". While "Genetically modified content is below 5%" may be applied to a product or ingredient if it contains less than 5% genetic modification. Additionally, if it is impossible or not feasible to test products or ingredients, the product may be labelled as "May contain genetically modified ingredients" (SACPA Proposed Regulations, 2010). These regulations allow mandatory GM labelling to be applied in a cost effective manner and does not require verification of labels. Thus managing the integrity of GM food labels will be up to the companies themselves, as well as consumers and consumer groups.

5.4.2 Illegal or unintended GM events in food crops

A GMO is considered illegal or unauthorised for various reasons. It can be because a country has not approved a GM event, or it is only authorised for a specific use (e.g. food and feed, but not for environmental release). A combination of the asynchronous release of GM events as well as the lack of regulation or monitoring can result in the illegal presence of GMOs in trade commodities. Since the first introduction of GM crops, a number of accidental or unintentional releases of unapproved GM events have occurred. Most of the cases of GM contamination were discovered by GM detection laboratories performing routine GM testing (personal communication with international GM detection laboratories). Some of the most publicised examples of unapproved events found in the human food chain include:

- StarLink Maize in 2000 (containing *cry9c* for IR). This was the first major recorded case of GM contamination. StarLink maize had been approved in the USA by the EPA for animal feed, but not for human consumption because of concerns over potential allergenicity. By the time the contamination of StarLink was discovered in the USA, the contaminated products had already been exported to several countries including Japan, Korea, Nicaragua, and Mexico (Greenpeace International, 2007). Food found to contain StarLink maize had to be recalled at a cost of half a billion to one billion US$ (Clapp, 2006).
- Prodigene Maize in 2002 (GM maize engineered to produce a pig vaccine). Prodigene maize was found to be commingled with soybean in Iowa USA. Prodigene was fined an undisclosed amount and 61 ha of surrounding maize crop was destroyed for fear of possible cross pollination to conventional maize (Cohen, 2002).
- Bt10 Maize in 2005 (containing the *cry1Ab* gene for IR and *amp* for antibiotic resistance) (Clapp, 2006). By the time the contamination was discovered by an independent seed manufacturer in the USA, the contaminated seed had been sold to farmers for four years. It is estimated that at least 15,000 ha had been planted and introduced into the food supply. Syngenta, the company involved was fined US$375,000.
- Bt63 Rice in 2005 (containing the *cry1Ab* and *cry1Ac* genes for IR). Bt63 rice was discovered in commercial rice production in southern China, even though it had not been approved for environmental release. Despite the Chinese Government's attempt to contain the contamination, it was found in food products across China, Japan as well as in Europe in 2006. The source of

contamination was a seed company, owned by a university developing new agricultural technologies.

- LibertyLink Rice (LL601) in 2006 (containing *bar* for HT). Although not approved for food, LL601 was detected in 2006 in the USA in long grain commercial rice. LL601 was also detected in 19 European countries, the United Arab Emirates, the Philippines and Russia. Rice exports from the USA practically ceased and farmers initiated lawsuits against Bayer Crop Science, the company responsible. Ironically, the USDA approved LL601 for human consumption in November 2006, after the contamination had been discovered, despite the European Food Safety Authority finding the safety data of LL601 insufficient to determine that it is safe for human consumption (Clapp, 2008).

Three of the most publicised cases of unapproved GMOs, StarLink maize, Bt10 maize and LLRICE601, originated in the USA (Clapp, 2008). In contrast the EU, even though it has been criticised for strict GM regulations, has not been responsible for GMO contamination elsewhere in the world (Davidson, 2010). Therefore, if at national level a lack of sufficient regulations exists in terms of the development and release of GMOs or if these regulations are not enforced, incidents of illegal GMOs will be inevitable.

The impact of GM contamination is potentially disastrous and includes the following:

- Social impacts: GM contamination adds to the consumer mistrusting the ability of regulatory systems to efficiently manage GMOs. Furthermore, it places suspicion on the ability of biotechnology companies to manage GM technology (Clapp, 2008).

- Economic impacts: Contamination of food products with illegal GM events results in product recalls and impacts export markets.
- Environmental impacts: Environmental contamination may have serious impacts in terms of the contamination of wild relatives and land races (Quist and Chapela, 2001). Furthermore, the presence of GM contamination in the environment may have unanticipated consequences (Nielsen and Myhr, 2007).
- Health impacts: Contamination of the food supply can have serious health effects if unapproved GM events that have not been determined to be safe are consumed. Furthermore, the contamination of the food chain with GM pharmaceutical crops would be hazardous to humans.

Without efficient GM detection systems, the examples of reported GM contamination would not have been discovered. Laboratories in first world countries are constantly monitoring for illegal GMOs. In comparison, developing countries do not have the necessary infrastructure to cope with monitoring of illegal GMOs. Furthermore, there are many initiatives to produce GM varieties applicable to Africa, for Africa, in Africa. However, without the correct monitoring tools and GM management, including GM detection technology, contamination of the food chain is inevitable. If an incidence of contamination should occur, the economic impact on Africa would be disastrous considering the resulting closure of markets to Europe and Asia.

1.6 State of the art in GM detection

The need for post-release monitoring and GM labelling as required by national and international regulations necessitate analytical GM detection methodologies that allow

for accurate, standardised determination of the presence and content of GMOs in food and feed products (Miraglia *et al*., 2004). While there are several different technologies that can be used for GM detection, including DNA microarray detection, Surface Plasmon Resonance etc, the focus of this section is on common detection methods used routinely by detection laboratories (Feriotto *et al*., 2002; Cardarelli *et al*., 2004; Nesvold *et al*., 2005; Dinon *et al*., 2008; Bahrdt *et al*., 2010).

1.6.1 GM detection methodology

Analytical methods to detect (qualitative or yes/no answer) and quantify (percentage content) GMOs fall into two main categories: protein analysis – to detect the specific protein expressed by the transgene in the GMO through the use of ELISA (enzyme-linked immunosorbent analysis) and lateral flow strip tests or DNA analysis – to detect the specific transgene in the GMO or specific elements associated with the transgene (Viljoen, 2005).

1.6.2 Protein based testing

Protein identification requires the use of antibodies raised against the transgenic protein. Protein methods can be used on raw and semi-processed samples, as long as the protein is not denatured or destroyed by processing (Anklam *et al*, 2002). Protein testing is generally applied in two ways, through a lateral flow strip test (strip test) or ELISA.

When using the lateral flow test, the sample is homogenised to the appropriate particle size, buffer added for simplified protein extraction and the strip placed into the sample/buffer. After several minutes, a positive result is indicated by a discoloured test line due to antibody-protein recognition (Ahmed, 2002). This is the simplest method to qualitatively detect a GMO. Enzyme-Linked Immunosorbent Analysis (ELISA) requires a basic protein extraction followed by antibody detection in a micro-well plate. Positive reactions are determined by a colour reaction that can be read visually or by an optical reader for qualitative analysis as well as quantitatively with the inclusion of standards (Lipp *et al*., 2000). Antibody recognition identifies a protein product of a specific transgene (Miraglia *et al*., 2004; Viljoen, 2005). Thus in order to determine that a product is non-GMO, different tests must be used for as many different transgenes as are commercially available. Protein testing is often performed using only selected target proteins as an in-house initial screen. While protein testing is considered reasonably simple to apply, it is limited by the development and availability of protein antibodies for all types of available transgenes in the form of commercial kits and cannot identify event-specific GMOs (Viljoen, 2005).

1.6.3 DNA based testing

DNA identification makes use of the polymerase chain reaction (PCR) (Ahmed, 2002; Anklam *et al*, 2002; Holst-Jensen *et al*., 2003). For PCR detection of GMOs, sequence specific primers and DNA polymerase are used to amplify a target region in the DNA sequence. Raw and processed products can be tested with the PCR method, as long as DNA can be extracted from the sample. The basic process for screening with PCR is DNA extraction, PCR amplification of the target sequences and

visualisation of the amplified target DNA. The selection of target sequence for PCR depends on the type of specificity required for GMO detection, namely GMO screening, transgene-specific, construct-specific and event-specific detection (Miraglia *et al*., 2004). GMO screening is used to determine whether a sample contains GMO through the detection of regulatory elements (promoter and terminator sequences) commonly associated with GMOs. For example the 35S promoter and NOS terminator are found in more than 90% of all commercial maize and soybean GMOs. Transgene-specific identification identifies a specific gene, for example *cry1Ab*, *cry9c* (IR) or *epsps* (HT). Construct-specific methods target the region between two DNA elements found within a particular transgene construct, such as the promoter and gene. The most specific method to identify a GMO is event-specific detection where the PCR target sequence is a junction between the host DNA and the inserted gene construct (Viljoen, 2005).

1.6.4 DNA based quantification

The most frequently used method to quantify genetic modification is quantitative Real-time PCR (Holst-Jensen, 2009). The quantification process is called Real-time PCR because amplification of the target DNA sequence is visualized during PCR in “real-time”. Detection of the amplicon is made possible by the use of fluorescent dyes or fluorescent probes. Sets of standards with known concentration or copy number are included to plot a standard curve of threshold cycle of amplification (Ct value) to DNA concentration or copy number. The threshold cycle is the number of cycles at which the amplification reaches a specific threshold. For GMO quantification it is preferable to use specific detection probes to avoid problems of non-specific amplification. The

use of probes has a further advantage in that it allows a one-step detection and verification of the target sequence (Viljoen, 2005).

1.7 Conclusion

GMO production is on the increase in the world. Although currently only eight countries are major producers of GM crop, it is expected that this will increase in future. Research developments in pharmaceutical and nutritionally enhanced GMOs are also increasing, especially in countries where GM technology has already been introduced. Furthermore, the major countries involved in GM production and developments are also major traders in agricultural commodities. Thus, even though a country may not have introduced GMOs, it still has to manage GM technology through imports – as a result of asynchronous approval, and monitor for illegal GMOs as a result of research developments. The presence unapproved GMOs may result in economic losses for traders and pose challenges for developing countries, in terms of managing genetic modification in food imports and food aid. This means that developing countries need regulatory frameworks to manage GMOs in terms of monitoring to ensure regulatory compliance and not to jeopardize food security and/or trade.

The Biosafety Protocol, to which 160 countries are Party, requires that countries establish regulatory frameworks to manage the use, handling and placing on the market of LMOs as well as trade. Under the Cartagena Protocol on Biosafety, countries are required to identify LMOs in transboundary movements and by implication this includes monitoring for illegal GMOs in food imports and exports.

However, countries in Africa do not have the resources to deal with the presence of illegal or unapproved GM food in either imports or exports.

GM technology has already had far-reaching impacts on society. These impacts do not just include considerations of the adverse effects of genetic modification on human health or the benefits thereof, but also need to take socio-economic considerations into account. Consumer perceptions with regard to GMOs are influenced by factors that have little to do with the technology itself, but how this is perceived in terms of an ethical and/or religious context.

Many countries have introduced GM labelling in order for consumers to express a choice regarding GM products. Most countries apply mandatory labelling even though there are concerns over the cost implication to food prices. However, current mandatory labelling practice does not appear to have caused an increase in food costs. Furthermore, consumer autonomy and access to information, including the GM content of products, has become expected practice.

GM detection methods are being used to support GM monitoring and ensure compliance to regulations. However, there are challenges in the application of GM detection, including a lack of access to information on new releases of GM events and access to reference material. Despite becoming well established in some developed and developing countries, many African countries lack access to GM detection technology as an enabling tool to support GM monitoring activities.

Despite the high adoption rate of GM crops as well as the rapid rate of GM developments, there are regulatory systems that can effectively be used to manage GM technology. In this regard GM detection has a supportive role to play in monitoring for illegal GMOs as well as compliance to GM labelling requirements. Contrary to the view of some proponents of genetic engineering technology, efforts to regulate GMOs in whatever form is an inherent right and should not be viewed as a barrier to GM technology *per se*.

CHAPTER 2

DETECTION OF GMOs IN FOOD PRODUCTS IN SOUTH ARICA[3,4]

Abstract

Genetically modified (GM) crops currently account for 29% of crop production worldwide. South Africa is currently the only country in Africa to commercially grow GM crops. Despite a lack of regulations to provide for food labelling that allows for consumer preference, many products carry negative or positive labels with regard to genetic modification. The aim of this study was to test different maize and soybean products to determine the uptake of GM food into the human food chain as well as the validity of "non-GMO" (genetically modified organisms), "GMO free" or "organic" labels, on local as well as imported products. Of the 58 products selected and sampled randomly, 44 tested positive for the presence of GM. Furthermore, of the 20 products with a GM related label, 14 tested positive for GM. These results demonstrate the extent of GM in the human food chain in South Africa and highlight the need for effective regulations to protect consumers against misleading claims.

[3] This study was undertaken prior to the development of the Consumer Protection Act that mandates GM labelling. This paper served to inform the discussions regarding the introduction of GM labelling in South Africa. Although I am not the first author of this publication, I played an integral role in the formulation and execution of this research.

[4] Viljoen CD, Dajee BK and Botha GM (2006) Detection of GMOs in food products in South Africa: Implications of GMO labeling. *African Journal of Biotechnology* 5(2): 73-82.

2.1 Introduction

With the advent of modern biotechnology, specifically genetic engineering, it has become possible to transfer a specific gene, called a transgene, from one organism to another across or within species boundaries, through a process called gene transformation. Genetically engineered crops are referred to as GM (genetically modified) and/or as GMOs (genetically modified organism). Transgenic organisms that are able to replicate (seeds or living organisms) are referred to as LMOs (living modified organisms). Genetic engineering has the potential to produce improved varieties in terms of quality and yield traits, more quickly than traditional breeding (Uzogara, 2000; Sharma *et al*., 2002).

The first generation of GM crops currently available contain input-traits with agronomic benefits to farmers but no direct benefit for consumers. Second generation GM crops involve health and nutritional properties that will benefit consumers, while third generation crops are aimed at the production of “nutraceuticals" and pharmaceuticals (Smyth *et al*., 2002). In 2004, GM crops accounted for 29% of global crop production (James, 2004). It is estimated globally that 56% of soybean, 28% of cotton, 19% of canola and 14% of maize is GM (James, 2004). Currently, two GM traits are found in commercial GM crops, namely herbicide tolerance (HT) (in 75% of GMOs) and insect resistance (IR) (in 25% of GMOs). The countries growing 99% of GM crops are the USA (growing 59% of global GM crops), Argentina (growing 20% of global GM crops), Canada (growing 6% of global GM crops), Brazil (growing 6% of global GM crops), China (growing 5% of global GM crops), Paraguay (growing 2% of global GM crops), India (growing 1% of global GM crops) and South Africa (growing 1% of global GM crops) (James, 2004).

South Africa is unique in terms of growing commercial GMOs on the African continent. The GMOs available in South Africa include insect resistant and herbicide tolerant maize, insect resistant and herbicide tolerant cotton and herbicide tolerant soybean (Department of Agriculture, 2005). It is estimated that biotech crops account for 24% of yellow maize, 10% of white maize, 50% of soybean and 85% of cotton production in South Africa (James, 2004).

Despite GMOs being grown commercially in South Africa since 1997, there is very little consumer awareness – even with government and non-government organizations (NGOs) making information on GMOs available (Table 2.1). A Human Science Research Council (HSRC) client survey in 2004, found that 7 out of 10 respondents from a sample of 5639 who completed a questionnaire, had never heard of a definition for biotechnology (Rule and langa, 2005). In addition to this, it is evident from this and other surveys to determine consumer attitudes towards genetic modification that consumers have mixed opinions of GM food (Kempen *et al*., 2003; AfricaBio, 2004; Rule and langa, 2005). In contrast to this, there is strong consumer opposition to GM foods in the European Union (EU) and Japan (Carter and Gruère, 2003).

Table 2.1 Government departments and NGOs involved with disseminating information on GM foods to consumers in South Africa.

Government Department	Description	Website
Department of Heath (DOH)	To achieve a caring and humane society in which all South Africans have access to affordable, good quality health care which includes food labelling	www.doh.gov.za
Department of Agriculture, Forestry and Fisheries (DAFF)	Ensuring access to sufficient safe and nutritious food and to provide an integrated national management system in support of sustainable use of genetic resources for food and agriculture including the approval of GMOs through the Directorate Genetic Resources	www.nda.agric.za
Department of Science and Technology (DST)	The development of science and technology expressed through the enabling mechanism of the National System of Innovation, for communities, researchers, industry and government	www.dst.gov.za
Public understanding of Biotechnology (PUB)	To promote a clear understanding of the potential of biotechnology and to ensure broad public awareness, dialogue and debate on its current and potential future applications, including Genetic Modification (GM)	www.pub.ac.za
NGO		
African Centre of Biosafety (ACB)	Campaigns on the African Continent for GMOs to be subject to the most stringent biosafety measures and is committed to promoting the publication of the views and concerns of African civil society groups on the African continent and world wide on issues relating to biosafety and solidarity amongst these groups	www.biosafetyafrica.net
AfricaBio	A biotechnology association for the safe, ethical and responsible research, development and application of biotechnology and its products. The Association also serves as a forum for informed dialogue on biotechnological issues in Africa	www.africabio.com
Earthlife Africa (ELA)	A membership driven organization of environmental and social justice activists, founded to mobilize civil society around environmental issues in relation to people	www.earthlife-ct.org.za
GRAIN (Genetic Resources Action International	An international NGO which promotes the sustainable management and use of agricultural biodiversity based on people's control over genetic resources and local knowledge	www.grain.org
National Consumer Forum Trust (NCF)	Dedicated to the protection and promotion of consumer rights and interests in South Africa	www.ncf.org.za
SAFeAGE (South African Freeze Alliance on Genetic Engineering)	Committed to ensuring a ban is imposed on genetic engineering in food and farming to ensure sufficient assessment and understanding is gained for all the implications it may have for consumers, farmers and the environment	www.safeage.org

In response to consumer pressure, many countries have introduced labelling regulations for GM foods (Table 2.2). Although GMO labelling does not have any bearing on the safety aspect of GMOs, it is used to give consumers a choice, between GM and non-GM, allowing them to balance concerns of morality and perceived risk (Ahmed, 2002). All GM food labelling uses predetermined thresholds, as it is not possible to ensure zero GM in a product once GMOs are present in the production system (Bullock and Desquilbet, 2002). Positive labelling is used to indicate that a product contains genetic modification in excess of a predetermined threshold and is labelled as "GM" while negative labelling is used to indicate that a product is "non-GM" when the GM content is below a specified tolerance level. Labelling can either be mandatory or voluntary. A problem with the use of threshold labelling is that different countries use different tolerance levels and apply terminology differently. For example, "GM free" and "non-GM" labels are used alternatively. Depending on the regulatory body, "GM free" can imply zero GM or below a predetermined threshold (Partridge and Murphy, 2004). The confusion persists with the use of "organic". In the EU, "organic" implies zero GM while the USDA (United States Department of Agriculture) uses a 5% threshold for "organic" (Partridge and Murphy, 2004; United States Department of Agriculture, 2002).

Table 2.2 GM food labelling regulations and thresholds for different countries.

Country	Labelling	% Threshold	Scheme
Australia and New Zealand[1]	Mandatory	1	GM
Brazil[1]	Mandatory	1	GM
Canada[1]	Voluntary	5	Non-GM or GM
China[1]	Mandatory	1	GM
European Union[2]	Mandatory	0.9	GM
Indonesia[1]	Mandatory	5	GM
Japan[1]	Mandatory	5	GM
Philippines[1]	Voluntary	n/a	n/a
Russia[1]	Mandatory	0.9	GM
Saudi Arabia[1]	Mandatory	1	GM
South Korea[1]	Mandatory	3	GM
Taiwan[1]	Mandatory	5	GM
Thailand[1]	Mandatory	5	GM
USA[1]	Voluntary	n/a	n/a
		5	Organic

[1]Gruère and Rao (2007)

[2](EC) 1830/2003

Wagner and Walchli (2002) argue that labelling GM products not only provides consumers with choice, but also communicates the benefits of genetic modification and encourages the diffusion of GM products. However, Carter and Gruère (2003) question whether mandatory labelling gives EU consumers a choice, since the understanding of retailers and processors of consumer perceptions, has lead to a total absence of "GM" food products. They argue rather that voluntary labelling provides consumers with a choice as long as their willingness to pay for non-GM products exceeds the price premium required for such products. It is assumed that the absence of GM labelling regulations and the high level of GM food production in the USA corresponds to widespread consumer acceptance of genetic modification.

However, in a 2003 survey it was found that 58% of USA consumers polled, believed that they had never eaten GM food (Pew Initiative, 2003). In another USA study it was found that 30% of respondents wished to avoid GMOs (Baker and Burnham, 2002). This makes the assumption of USA consumer acceptance of GM food questionable. Baker and Burnham (2002) suggest that mandatory labelling could provide consumers with a choice but note the possibility that this may raise concerns among consumers and thus stigmatize GM foods. They also note that mandatory food labelling would be opposed by biotechnology advocates in the food industry due to fears over consumer rejection (Uzogara, 2000). Despite fears on labelling perceptions, GM labelling could be a key step in consumer education if applied accurately with consideration of consumer understanding.

According to the regulations of the Foodstuffs, Cosmetics and Disinfectants Act in South Africa, GM labelling is mandatory only for products that: differ significantly from the characteristic composition and nutritional value of the corresponding existing foodstuff; the mode of storage, preparation or cooking of such a foodstuff differs significantly from that of the corresponding existing foodstuff; contains an allergen; is derived from plant material containing animal nucleic acid(s) or protein(s) derived from a human or from an animal or animal material containing animal nucleic acid(s) or protein(s) derived from a human or from a different taxonomic animal family (Department of Health, 2004b). It is also possible to label GM foods with regard to improved or enhanced characteristics such as composition, nutritional value and reduced causation of allergens using the wording “genetically-enhanced foodstuff” or “genetically-improved foodstuff”. Thus, no GM foods in South Africa currently qualify for mandatory labelling, as the transferred genes in GM foods are from microbes and

not animals or humans, are not known allergens and do not confer improved or enhanced characteristics in terms of composition or nutritional value.

Although no provision is made for labelling that allows consumers the choice of preference between GM and non-GM foods in South Africa, many products can be found in retail and health outlets with “non-GM”, “GMO free”, “organic” and even “may be genetically modified” labels. Presumably the type of label being used is aimed at perceived consumer perception and preference, especially products marketed for vegetarians. However, since no regulations exist for GM labelling in South Africa, there is no system to verify such claims and consumers must take the labels at face value. The aim of this study was to test different maize and soybean products to determine the uptake of GM food into the human food chain as well as the validity of “non-GMO”, “GMO free” or “organic” labels, on local as well as imported food products.

2.2 Materials and methods

2.2.1 Product selection and sampling

A total of 58 food products representing a variety of processing steps for maize and soybean were selected and sampled randomly from retail stores including Pick ‘n Pay, Shoprite Checkers, Spar and Woolworths as well as small retail outlets including health food shops according to product availability (Table 2.3, 2.4 and 2.5).

Table 2.3 Selection of maize products, description and manufacturer.

Product name	Description	Producer
Amazon corn flakes	Cereal	Woolworths (Nature's Food)
Corn flakes	Cereal	Bokomo Foods
Corn flakes	Cereal	Kellog Company
Corn flakes	Cereal	Woolworths
Ace	Maize four	Tiger Food Brands
Blue Bird	Maize four	Sasko
Impala	Maize four	Premier Foods
Iwisa	Maize four	Premier Foods
Knorr Pap mix	Maize four	Robertsons
Maize meal	Maize four	Woolworths
Plaas Pap	Maize four	Nola
Pride	Maize four	Pride Milling
Summer Cream	Maize four	Premier Foods
White maize meal	Maize four	Earth Products
White Mealie meal	Maize four	Nature's Choice
White Star	Maize four	Sasko
Yellow Mealie meal	Maize four	Nature's Choice
Maizena Corn flour	Maize starch	Robertsons
Sheridans Corn flour	Maize starch	Retailer Brands
Corn Thins	Puffed cake	Real Foods
Plain rice cakes	Puffed cake	Woolworths
Golden Cloud	Self-raising wheat flour	Tiger Food Brands
Self-raising flour	Self-raising wheat flour	Woolworths
Snowflake	Self-raising wheat flour	Premier Foods
Old El Paso Taco Kit	Taco shells	General Mills
Baby corn	Vegetable maize	Woolworths
Organic baby corn	Vegetable maize	Woolworths
Sweet corn	Vegetable maize	Woolworths

Table 2.4 Selection of soybean products, description and manufacturer.

Product name	Description	Producer
Soya beans	Soybeans	Health Connection Whole Foods
Soya beans	Soybeans	Nature's Choice
Soya crisps	Soybean crisps	Woolworths
Soya flour	Soybean flour	Health Connection Whole Foods
Dew Fresh soya milk	Soybean milk	Dew Fresh Products
Nutribev	Soybean milk	Hovennuts
Simply soy	Soybean milk	Soyex
Soy milk	Soybean milk	Good Hope
Soya milk	Soybean milk	Pick 'n Pay
Soya milk	Soybean milk	Woolworths
Soysense	Soybean milk	Woolworths
Cape Creamy	Soybean milk powder	Nature's Choice
Diabet-Mill	Soybean milk powder	Cape Nutraceuticals
So Fresh	Soybean milk powder	So Fresh International
Soya milk powder	Soybean milk powder	Health Connection Whole Foods
SPP	Soybean milk powder	Specialised Protein Products
Knorrox soya mince	Soybean mince	Robertsons
Royco Vita mince	Soybean mince	Master Foods
Soya chunks	Soybean mince	Health Connection Whole Foods
Braai flavour sausages	Soybean protein	Fry Group Foods
Chic Burger	Soybean protein	Soyatech
Vegetable Sausages	Soybean protein	Sultan's
Spiced Burgers	Soybean protein	Fry Group Foods
Spicy Soya Burger	Soybean protein	Sun-C Foods
Vegee Viennas	Soybean protein	Penniken Health Food Manufacturers
Vegetarian chicken	Soybean protein	Yuh-der Industries
Vegetarian Schnitzel	Soybean protein	Woolworths
Vegi Steak	Soybean protein	Trident Foods
Soya drinking yogurt	Soybean yogurt	Woolworths
Strawberry yogurt	Soybean yogurt	Fairfield Dairy

Table 2.5 Summary of products tested in terms of GM related labelling.

Product description	Negative label	Positive label	Total products
Maize			
Cereal	1	1	4
Maize four	1	1	13
Maize starch	0	1	2
Puffed cake	1	0	2
Self-raising wheat flour	0	0	3
Taco shells	0	0	1
Vegetable maize	1	0	3
Total	4	3	28
Soybean			
Soybeans	1	0	2
Soybean crisps	0	0	1
Soybean flour	1	0	1
Soybean milk	2	0	7
Soybean milk powder	4	0	5
Soybean mince	1	0	3
Soybean protein	4	0	9
Soybean yogurt	0	0	2
Total	13	0	30

2.2.2 DNA isolation

DNA was extracted in duplicate from homogenized samples, using the cetyltrimethylammonium bromide (CTAB) method according to Lipp *et al*. (1999) with modifications. DNA was extracted from 2 g sample by the addition of 10 ml CTAB and 30 µl proteinase K [20 mg/ml]. After incubation at 60ºC for 2 hrs, 900 µl sample/buffer solution was incubated at 80ºC for 5 min after which 5 µl RNAse [100 mg/ml] was

added and further incubated for 15 min at 60ºC. To the sample/buffer mixture 600 µl chloroform was added and centrifuged for 10 min until the phases separated. The aqueous phase was retained and 500 µl of isopropyl alcohol added to precipitate the DNA. The pellet was retained and washed with 500 µl 70% ethanol followed by centrifugation at 14,000 rpm for 5 min. The DNA was dissolved in 50 µl sterile medical grade water. The DNA was further cleaned using a Qiagen micro-spin column according to Anklam *et al*. (2002). The extracted DNA was run on a 1% agarose gel, in TAE buffer [40 mM Tris-HCl, 40 mM acetic acid and 1 mM EDTA (pH8.0)] at 180 V for 25-30 min. The resolved DNA in the gel was visualized under UV light, after staining in 2.55 mM ethidium bromide for 10 min, followed by documentation with the GelLogic200 (Biorad) system.

2.2.3 Screening for genetic modification

The extracted DNA was screened for the presence of the transgenic 35S CaMV sequence (5'-CCACGTCTTCAAAGCAAGTGG-3' and 5'-TCCTCTCCAAATGAAATGAACTTCC-3') using 50 amplification cycles to detect transgenic material with a limit of detection (LOD) of 0.01% according to the validated method of Lipp *et al*. (2001). Duplicate extraction samples, two blank controls and two positive controls with known amounts of target DNA were subjected to the following conditions: 10 min at 95ºC, followed by 50 cycles of 25 sec at 95ºC, 30 sec at 62ºC and 45 sec at 72ºC with a final extension step of 7 min at 72ºC using an Applied Biosystems GeneAmp PCR System 9700. Amplification reactions were performed in a final volume of 25 µl containing 0.8 U AmpliTaq Gold polymerase (Applera), 1.5 mM $MgCl^2$, 160 µM of each dNTP, sample DNA (25-100 ng), and 0.6 µM of each primer (Lipp *et al*., 2001). The PCR products were separated by gel electrophoresis at 180 V

for 40 min on a 2% agarose gel in TAE buffer [40 mM Tris-HCl, 40 mM acetic acid and 1 mM EDTA (pH8.0)] followed by staining in ethidium bromide. The resolved PCR products were visualized and documented under UV light using the gel GelLogic200 (Biorad) system.

Products were only scored for the presence or absence of genetic modification, if the positive and negative controls were as expected and resulted in the presence and absence of the expected amplification product, respectively. Samples were only scored if duplicate results were uniform. To minimize the risk of cross-contamination, individual steps were performed separately in terms of physical space and equipment. PCR inhibition of individual product DNA was determined by spiking an additional set of sample assays with control DNA.

2.3 Results and discussion

Out of 58 off-the-shelf food products sampled randomly from different retail and health outlets, 76% tested positive for genetic modification (Tables 2.6, 2.7 and 2.8). It must be noted that the sampling used did not take batch effects into account. For maize, genetic modification was detected in 63% of local and 90% of soybean products (Table 2.8). These results indicate that the current GMO production in South Africa may be higher than the estimated 24% for yellow maize, 10% for white maize and 50% for soybean (James, 2004). However, the South African Grain Laboratory determined that for 2003/2004, only 3% white maize and 2% yellow maize was found to contain genetic modification (South African Grain Laboratory, 2005). This suggests that either there is a delay of genetic modification entering the food chain possibly due

to the existence of reserves or that a diffusion of genetic modification is occurring in non-GM product in the food chain during processing.

Table 2.6 Detection of genetic modification in labelled food products.

Product name	Description	GM / Organic claim	Certification Body	Origin	GM result
Maize products					
Amazon Corn flakes	Cereal	Organic	QAI[1]	USA	+
Corn flakes	Cereal	May be genetically modified	n/a	South Africa	-
Maize meal	Maize four	May be genetically modified	n/a	South Africa	+
White maize meal	Maize four	GMO free and Organic	n/a	South Africa	+
Corn Thins	Puffed cake	GMO free	n/a	Australia	+
Self-raising flour	Self-raising wheat flour	May be genetically modified	n/a	South Africa	-
Organic baby corn	Vegetable maize	Organic	Ecocert	Zambia	-
Soybean products					
Soya beans	Soybeans	Not genetically modified	n/a	South Africa	-
Soya flour	Soybean flour	GMO free	n/a	South Africa	-
Soya milk	Soybean milk	Non-GM	n/a	South Africa	+
Soysense	Soybean milk	Organic	QAI[1]	USA	+
Cape Creamy	Soybean milk powder	GM free	n/a	South Africa	+
Diabet-Mill	Soybean milk powder	GMO free	n/a	South Africa	+
Soya milk powder	Soybean milk powder	GMO free	n/a	South Africa	+
SPP	Soybean milk powder	Non-GM	n/a	South Africa	-
Soya chunks	Soybean mince	GMO free	n/a	South Africa	+
Braai flavour sausages	Soybean protein	GMO free	n/a	South Africa	+
Chic Burger	Soybean protein	GMO free	n/a	South Africa	+
Spiced Burgers	Soybean protein	GMO free	n/a	South Africa	+
Vegi Steak	Soybean protein	GMO free	n/a	South Africa	+

[1]Quality Assurance International

Table 2.7 Detection of genetic modification in unlabelled maize and soybean food products.

Product name	Description	Origin	GM result
Maize products			
Corn flakes	Cereal	South Africa	Negative
Corn flakes	Cereal	South Africa	Negative
Ace	Maize four	South Africa	Positive
Blue Bird	Maize four	South Africa	Positive
Impala	Maize four	South Africa	Positive
Iwisa	Maize four	South Africa	Positive
Knorr pap mix	Maize four	South Africa	Positive
Plaas Pap	Maize four	South Africa	Positive
Pride	Maize four	South Africa	Positive
Summer Cream	Maize four	South Africa	Positive
White Mealie meal	Maize four	South Africa	Positive
White Star	Maize four	South Africa	Positive
Yellow Mealie meal	Maize four	South Africa	Positive
Maizena Corn flour	Maize starch	South Africa	Negative
Sheridans Corn flour	Maize starch	South Africa	Negative
Plain rice cakes	Puffed cake	South Africa	Negative
Golden Cloud	Self-raising wheat flour	South Africa	Negative
Snowflake	Self-raising wheat flour	South Africa	Positive
Old El Paso Taco Kit	Taco shells	Australia	Positive
Baby corn	Vegetable maize	South Africa	Negative
Sweet corn	Vegetable maize	South Africa	Negative
Soybean products			
Soya beans	Soybeans	South Africa	Positive
Soya crisps	Soybean crisps	South Africa	Positive
Dew Fresh soya milk	Soybean milk	South Africa	Positive
Nutribev	Soybean milk	South Africa	Positive
Simply soy	Soybean milk	South Africa	Positive

Table 2.7 (Continued)

Product name	Description	Origin	GM result
Soybean products			
Soy milk	Soybean milk	South Africa	Positive
Soya milk	Soybean milk	South Africa	Positive
So Fresh	Soybean milk powder	South Africa	Positive
Knorrox soya mince	Soybean mince	South Africa	Positive
Royco Vita mince	Soybean mince	South Africa	Positive
Vegetable Sausages	Soybean protein	South Africa	Positive
Spicy Soya Burger	Soybean protein	South Africa	Positive
Vegee Viennas	Soybean protein	South Africa	Positive
Vegetarian chicken	Soybean protein	South Africa	Positive
Vegetarian Schnitzel	Soybean protein	South Africa	Positive
Soya drinking yogurt	Soybean yogurt	South Africa	Positive
Strawberry yogurt	Soybean yogurt	South Africa	Positive

Table 2.8 Summary of product testing with regard to maize and soybean products, local and imported products, with and without GM labels as well as negative and positive GM labels.

Total products	**Number of products**	**Genetic modification detected**
Maize	28	61%
Soybean	30	90%
Total	**58**	**76%**
Local products		
Maize local	24	63%
Soybean local	29	90%
Total	**53**	**77%**
Imported products		
Imported maize	4	
Imported soybean	1	100%
Total	**5**	**60%**
Product labels		
Maize without label	21	62%
Soybean without label	17	100%
Total without label	**38**	**79%**
Maize with label	7	57%
Soybean with label	13	77%
Total with label	**20**	**70%**
GM label type		
Maize negative label	4	50%
Soybean negative label	13	77%
Total negative label	**17**	**71%**
Maize positive label	3	67%
Soybean positive label	0	n/a
Total positive label	**3**	**67%**

Of the products tested, 7 maize and 13 soybean products carried a GM related label (Table 2.5). Genetic modification was detected in 57% of labelled maize and 77% of labelled soybean products (Table 2.8). Two out of the three maize products with a "may be genetically modified" label were found to contain genetic modification (Table 2.7). Genetic modification was also detected in 71% of all products with either a "non-GM", "GMO free" and/or "organic" label. Of the products with a negative GM label, genetic modification was present in 50% maize and 77% soybean products (Table 2.8). Only three products carried information on the certification scheme or body that applied. It must be noted that the level of genetic modification in products was not quantified in this study, thus it is possible that a product tested positive for genetic modification, but was below a certain threshold. These results suggest that consumers may misinterpret GM labels on food products, as the terms "GMO free", "non-GM" and/or "organic" have not been defined in South Africa and differ from country to country. Thus it may be necessary for products with negative GM related labels to carry additional information to substantiate the claims being made as suggested by the Department of Health especially for the term "GMO free", the use of which is not considered acceptable in South Africa (Department of Health, 2004a).

The retail stores and producers, whose products were tested, were asked for comment on these results (Table 2.9). Of the companies that replied, most indicated that in the absence of specific guidelines for food labelling in South Africa, companies have to devise their own terms of reference. Thus, it is evident from the responses that the terms "non-GM", "GM free" and "organic" should be clarified in a South African context instead of the current ad hoc approach.

It appears that the vacuum in regulations for consumer preference in terms of non-GM food has also left a vacuum in the use of such labels. It is important to note that the presence of GM in a "non GM" or "organic" product does not necessarily indicate a contravention of the label but depends on the terms of use of the certifying scheme as previously explained. It is important to note that "GMO free" may not indicate zero genetic modification. For example, in the USA, the Food and Drug Administration (FDA) define "free" in terms of very low minimum levels (Partridge and Murphy, 2004). Partridge and Murphy (2004) suggested that for "GM free" a threshold of 0.2% could be set. In terms of organic foods, the Joint FAO/WHO (Food and Agriculture Organization of the United Nations and World Health Organization) Food Standards Programme of the United Nations, Codex Alimentarius, has published guidelines for Organically Produced Foods (2001) wherein it is stated that GMOs "are not compatible with the principles of organic production (either the growing, manufacturing, or processing) and therefore are not accepted under these guidelines" (FAO/WHO, 2001). This implies a zero tolerance for genetic modification in organic foods as opposed to a tolerance of 5% under USDA guidelines (United States Department of Agriculture, 2002). However, in the absence of a statutory definition in South Africa for "GMO free", the common interpretation is zero GM. Thus, it remains to be seen whether the international community will ever reach a consensus on GM food labelling.

There are additional considerations for the co-existence of GM and non-GM crops in terms of adventitious co-mingling. Adventitious co-mingling can result from pollen-mediated gene flow from GMOs to conventional plants unless specific precautions are taken to minimize volunteer GM plants and maintain isolation distances; at harvesting if equipment is not cleaned properly; as well as during storage, transport and

packaging (Smyth and Phillips, 2002; Snow, 2002). Unless specific precautions are taken in the production chain, co-mingling is inevitable.

2.4 Conclusion

This study has shown that GM maize and soybean is present in a higher than expected number of products, taking the level of GM production into account. Despite a lack of awareness to GM technology in South Africa, there are already some products aimed at the non-GM market for discerning consumers. Although GM food is here to stay, consumer preference in South Africa has not really begun to assert itself considering current levels of consumer awareness. Thus, an increased awareness of biotechnology in general will also increase consumer demand for choice between GM and non-GM. In order to offer consumers a choice, even if they are willing to pay extra for it, will require definite guidelines for the use of terminology and a system of verification to ensure consumer protection and prevent product misrepresentation.

Table 2.9 Response from South African retail stores and producers of products with GM related labels to the results of off-the shelf testing of food products.

Company	Policy on GM food labelling	Label validation system	Comment
Retail Stores			
Pick ‘n pay	To ensure compliance with legislation	Respond to complaints about misleading or illegal labelling and encourage suppliers to make the necessary changes	The use of "GMO free" is considered misleading due to possible adventitious contamination in products. In the absence of guidelines for voluntary non-GM labelling it is difficult to provide consumers with accurate and meaningful information on the GM status of all products
Woolworths	To "remove , replace or label" ingredients from GM crops in foods	1) Require independent certification of organic products by suppliers, 2) Require IP and PCR verification for ingredients from potential GM crops	Consumers require and are entitled to sufficient and accurate food label information to make informed purchasing decisions
Producers			
Earth products	Produce non-GM products	Rely on supplier affidavits	Have instituted the verification of non-GM product through independent testing
Fry group foods	Produce non-GM products	Use suppliers with in-house certification and testing	In the absence of South African guidelines the suppliers certify products according to European Union standards for non-GM product (below 0.9%)
Good hope international	Produce non-GM products	Rely on supplier integrity and affidavits	Have instituted the verification of non-GM product through independent testing
Nature’s choice	To label ‘GMO free’ products	Rely on supplier integrity and affidavits	There is need of a national regulatory authority. Are concerned about the spread of GMO foods in the food chain

CHAPTER 3

SOUTH AFRICA: A CASE STUDY FOR VOLUNTARY GM LABELLING[5,6]

Abstract

South Africa is the only country in Africa growing genetically modified (GM) crops, yet, consumer knowledge of GM technology is limited and labelling regulations regarding consumer preference is lacking. In the absence of mandatory GM labelling, voluntary GM labelling is being used as a marketing strategy to attract discerning consumers. The aim of this study was to detect and quantify the GM content in food products in South Africa, specifically labelled to indicate an absence of genetic modification. Of the products labelled 'GMO free', 'non GM' and 'organic', it was found that 31% had a GM content above 1% and 20% a GM content above 5%. Product batches differed by up to 40% in terms of GM content. In the absence of specific regulations, voluntary GM labelling is not providing discerning consumers with the choice intended. Thus, unregulated GM labelling is not a viable alternative to a regulated approach in terms of consumer protection.

[5] This study was undertaken prior to the development of the Consumer Protection Act that mandates GM labelling. This paper served to inform the discussions regarding the introduction of mandatory GM labelling in South Africa.

[6] Botha GM and Viljoen CD (2009) South Africa: A case study for voluntary GM labelling. *Food Chemistry* 112: 1060-1064.

3.1 Introduction

South Africa, the only country in Africa to produce genetically modified (GM) food since 1997, is ranked eighth in terms of global biotech production (James, 2006). Current GM food crops include white and yellow maize and soybean with an estimated production of 44%, 50% and 75%, respectively (James, 2006). White maize is an important staple consumed by the majority of people in South Africa and that soybean, similar to international practice, is used extensively in processed foods.

Despite significant levels of GM food crop production, the majority of South Africans are not aware of the existence of GM foods (Joubert, 2001; Cole, 2003; Mulder, 2003; Rule and Ianga, 2005). Furthermore, most South Africans are also not aware that they are consuming GM food (Rule and Ianga, 2005). Thus, it is difficult to determine consumer preference for GM food in South Africa when most consumers are oblivious to genetic modification. However, it is ironic that despite a lack of awareness of genetic modification, several food products in South Africa are labelled in terms of GM content, most of these to indicate an absence thereof (Viljoen *et al*., 2006).

The South African Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (Regulation 25 of 2004) mandates the labelling of GM food if it differs from its conventional counterpart in terms of nutritional composition, storage and preparation, or if it contains an allergen or a human or animal gene (Department of Health, 2004b). In addition, voluntary GM labelling is allowed for products with consumer value added traits such as improved nutrition or reduced allergenicity. However, no provision is currently being made for GM labelling in terms of consumer preference, even though some South African companies are applying voluntary GM labelling. South Africa is

therefore a good case study to determine whether voluntary GM labelling is practical to meet the needs of discerning consumers.

The argument against mandatory GM food labelling for consumer preference in South Africa, is that it could result in a negative perception of the technology (Personal communication, Department of Science and Technology). This incorrectly suggests that ignorance and acceptance are synonymous, and implies that knowledge of genetic modification would result in rejection of GM food by consumers. It is also argued that GM labelling is not feasible for 'poor' developing countries as it would increase the cost of food unnecessarily (Bullock and Desquilbet, 2002). Ironically, it is accepted practise to label food products in terms of additives and colorants, even though these do not pose any health risk, as well as life style choice, such as Halal, Kosher or vegetarian, without any consideration of cost (Klintman, 2002; Carlsson *et al*., 2004; Cheftel, 2005). Furthermore, it is argued that voluntary and not mandatory GM labelling gives discerning consumers a choice without prejudicing non-discerning consumers in terms of cost (Bullock and Desquilbet, 2002). However, a problem with the application of voluntary GM labelling throughout the world is that it is currently not being regulated and may result in consumers being misled.

Currently in South Africa, 'GMO free', 'non GM' and 'organic' labels are being used to indicate an absence of genetic modification despite the fact that no definitions exist for these terms in a regulatory context (Viljoen *et al*., 2006). The absence of specific definitions for voluntary GM labelling is exacerbated by the use of these terms in a mandatory context in other countries. For example, the European Union (EU) applies a 0.9% ((EC)1829/2003; (EC)1830/2003) GM threshold for 'non-GM' while in Japan it

is 5% (Viljoen *et al*., 2006). Thus, unless specifically defined, companies may apply their own definition to what constitutes 'GMO free', 'non GM' and 'organic'.

In a study of off-the-shelf food products in South Africa, Viljoen *et al*. (2006) determined that genetic modification was present in 76% of products carrying a 'GMO free', 'non GM' or 'organic' label. They concluded that in the absence of specific guidance or regulations for voluntary labelling, companies would apply their own systems to satisfy perceived consumer demand and that although the presence of genetic modification, in a 'GMO free', 'non GM' or 'organic' product, is not illegal in South Africa, it may be misleading to discerning consumers. However, this study did not determine the percentage GM content in the food products tested and it could arguably have been extremely low as found in studies in other countries (Partridge and Murphy, 2004; Abdullah *et al*., 2006; Ujhelyi *et al*., 2008). Thus the aim of this study was to detect and quantify the GM content in 'GMO free', 'non GM' or 'organic' labelled food products and determine the validity of GM food labels in a voluntary GM labelling environment as well as to determine the batch effects on sampling for laboratory testing.

3.2 Materials and methods

3.2.1 Product selection and sampling

A total of 23 food products labelled 'GMO free', 'non GM' or 'organic' were selected from retail chain outlets including Pick 'n Pay, Shoprite Checkers, Spar and Woolworths as well as small retail outlets such as health food shops according to product availability during 2006/2007 (Table 3.1). Each product was re-sampled after a period of approximately between three to six months to test batch variability.

Table 3.1 Products with an 'Organic', 'Non GM' or 'GMO free' label in South Africa.

Product Name	Description	Label
Amazon Corn flakes	Maize cereal	Organic
Baby corn	Raw maize	Organic
Envirokids Organic Munch	Maize cereal	Organic
Soysense	Soybean milk	Organic
Soya chunks	Processed soybean	Non GMO
Soy Shake	Soybean milk	Non GMO
Cape Creamy	Soybean milk powder	GMO free
Swiss Cream	Dairy free milk powder	GMO free
Chick Burger	Soybean protein	GMO free
Corn Thins	Puffed maize	GMO free
Just protein	Protein	GMO free
Soy flour	Soybean flour	GMO free
Soya milk powder	Soybean milk powder	GMO free
Vegetarian Hot Dogs	Soybean protein	GMO free
Vegetarian Burgers	Soybean protein	GMO free
Braai flavour sausages	Soybean protein	GMO free
Chunky strips	Soybean protein	GMO free
Cutlets	Soybean protein	GMO free
Golden Nuggets	Soybean protein	GMO free
Schnitzels	Soybean protein	GMO free
Spiced Burger	Soybean protein	GMO free
Traditional Burgers	Soybean protein	GMO free
Veggie mince	Soybean mince	GMO free

3.2.2 DNA isolation

DNA extraction was performed with 2 g of homogenized sample in 10 ml cetyltrimethylammonium bromide (CTAB) with the addition of 30 µl proteinase K [20

mg/ml], in duplicate according to a modified method described by Lipp *et al*. (1999). The mixture was incubated at 60ºC for 2 hrs followed by centrifugation at 14,000 rpm for 10 min. Thereafter 1.5 ml of supernatant was heat treated at 80ºC for 5 min, where after 5 µl RNAse [100 mg/ml] was added followed by a further incubation of 15 min at 60ºC. Extracted DNA (450 µl) was purified using the DNeasy plant mini kit (Qiagen) by the addition of 675 µl Buffer AP3 and applying it to the silica-gel spin column. The column was then centrifuged at 14,000 rpm for 2 min. Wash steps were performed by the addition of AW1 and AW2 wash buffers followed by centrifugation at 14,000 rpm for 1 min, respectively. The DNA was eluted with 50 µl elution buffer. The extracted DNA was visualised on a 1% agarose gel using TAE buffer [40 mM Tris-HCl, 40 mM acetic acid and 1 mM EDTA (pH8.0)], staining with 2.55 mM ethidium bromide, followed by visualization and documentation under UV light with a GelLogic200 (Kodak) system.

3.2.3 Screening for genetic modification

GMO screening was performed using the 35S CaMV promoter sequence (5'-CCACGTCTTCAAAGCAAGTGG-3' and 5'-TCCTCTCCAAATGAAATGAACTTCC-3') for maize products and the *epsps* sequence (5'-GGGATGACGTTAATTGGCTCTG-3' and 5'-GGCTGCTTGCACCGTGAAG-3') for soybean products according to the method of Lipp *et al*. (2001) and Grohmann *et al*. (2009). The limit of detection was 0.01%. PCR reactions were performed on a GeneAmp 9700 (Applera) thermal cycler with the following cycling conditions: 10 min at 95ºC, followed by 50 cycles of 25 sec at 95ºC, 30 sec at 62ºC and 45 sec at 72ºC with a final extension step of 7 min at 72ºC. The PCR assay consisted of sample DNA (25-100 ng), 0.8 U AmpliTaq Gold polymerase (Applera), 1.5 mM $MgCl^2$, 160 µM of each dNTP and 0.6 µM of each

primer made up to a final volume of 25 µl (Lipp *et al*., 2001). The amplified products were then subjected to electrophoresis on a 2% agarose gel in TAE buffer [40 mM Tris-HCl, 40 mM acetic acid and 1 mM EDTA (pH8.0)] at 180 V for approximately 20-30 min. After electrophoresis, the gel was stained with 2.55 mM ethidium bromide, visualized under UV light and documented using the GelLogic200 (Kodak). For quality control purposes, each sample were tested in duplicate and two blank, positive and extraction controls were included.

3.2.4 Real-time PCR quantification of genetic modification

Total GM content was quantified, in GM positive samples, in duplicate according to the content of 35S CaMV promoter for maize products and *epsps* for roundup ready soybean products on the ABI 7500 Real-time PCR system. The standard curve consisted of four data points in duplicate with a minimum correlation of 0.98 using the GMO Quant 35S Corn and the GMO Quant RoudupReady Soy kit, respectively (Eurofins GeneScan). The limit of quantification (LOQ) was 0.05%. Reaction conditions were as follows: 10 min at 95ºC, followed by 45 cycles consisting of 15 sec at 95ºC and 90 sec at 60ºC (ISO 21569:2005). The GM content was calculated relative to the total amount of plant DNA by determining the absolute number of GM copies compared to the total number of genome copies using a GM and species specific set of primers and probes, respectively. Two dilutions of each sample were tested to check for sample inhibition. To minimize the risk of cross-contamination, individual steps were performed in separate work areas and the necessary negative and positive controls included with each reaction.

Products previously identified in the Viljoen *et al*. (2006) study with a 'GMO free', 'non GM' or 'organic' label were compared to the results of products tested in this study to determine whether any change in the use of GM labelling had occurred. Food producers and retailers whose products were identified and tested in this study were sent the tabulated results and invited to make comments in order to understand their rationale in the application of GM labelling.

3.3 Results[7]

A total of 23 off-the-shelf products were identified with a 'GMO free', 'non GM' or 'organic' label. Twenty of these were soybean based and three were maize based. Of these, 17 carried a 'GMO free', two a 'Non GM' (also labelled 'No GM ingredients' or 'Non-GMO') and four an 'Organic' label (Table 3.1).

Genetic modification was detected in 56% (25 out of the total 45 sample batches) of sampled food products labelled to indicate an absence of genetic modification (Table 3.2 and 3.3). Of the total product batches tested, 31% had a GM content above one percent and 20% a GM content above five percent (Table 3.2 and 3.3). Genetic modification was detected in one of eight product batches with an 'Organic' label but was below the limit of quantification (0.05%) (Table 3.2 and 3.3). Of the 'GMO free' labelled product batches, 64% tested positive for genetic modification of which two product batches tested below the limit of quantification, eight contained genetic modification below one percent, 13 contained more than one percent genetic modification and nine had a GM content above five percent (Table 3.2 and 3.3). Of

[7] Results and discussion are separate in this chapter, since it was required by the journal in which the article was published.

the four product batches with a 'Non GM' label, 75% contained genetic modification, of which two product batches had a GM content below one percent and one a GM content above one percent (Table 3.2 and 3.3).

Table 3.2 GM detection and quantification in food product batches.

Product Name	Description	Label	% GM	
			Batch 1	Batch 2
Amazon Corn flakes	Maize cereal	Organic	Nd	Nd
Baby corn	Raw maize	Organic	Nd	Nd
Envirokids Organic Munch	Maize cereal	Organic	Nd	Nd
Soysense	Soybean milk	Organic	Nd	0.03
Soya chunks	Processed soybean	Non GMO	0.18	0.15
Soy Shake	Soybean milk	Non GMO	2.47	Nd
Cape Creamy	Soybean milk powder	GMO free	>5.00	>5.00
Swiss Cream	Dairy free milk powder	GMO free	Nd	Nd
Chick Burger	Soybean protein	GMO free	3.23	nd
Corn Thins	Puffed maize	GMO free	Nd	Nd
Just protein	Protein	GMO free	Nd	Nd
Soy flour	Soybean flour	GMO free	1.20	0.03
Soya milk powder	Soybean milk powder	GMO free	>5.00	0.55
Vegetarian Hot Dogs	Soybean protein	GMO free	1.03	0.11
Vegetarian Burgers	Soybean protein	GMO free	4.23	0.05
Braai flavour sausages	Soybean protein	GMO free	Nd	Nd
Chunky strips	Soybean protein	GMO free	0.34	0.32
Cutlets	Soybean protein	GMO free	>5.00	Nd
Golden Nuggets	Soybean protein	GMO free	>5.00	Nd
Schnitzels	Soybean protein	GMO free	0.24	0.03
Spiced Burger	Soybean protein	GMO free	>5.00	>5.00
Traditional Burgers	Soybean protein	GMO free	>5.00	>5.00
Veggie mince	Soybean mince	GMO free	Nd	Nd

Nd – Genetic modification not detected.

Table 3.3 Summary of GM detection and quantification results according to label type ('Organic', 'Non GM' or 'GMO free').

	Number of samples			% GM content[1]			
Label	**Total Product batches**	**GM detected**	**% GM detected**	**<0.05**	**0.05 – 1.00**	**>1.00 – 5.00**	**>5.00**
Organic	8	1	13	1 (13%)	0 (0%)	0 (0%)	0 (0%)
GMO free	33	21	64	2 (6%)	8 (24%)	13 (39%)	9 (27%)
Non GMO	4	3	75	0 (0%)	2 (50%)	1 (25%)	0 (0%)
Total	**45**	**25**	**56**	**3 (7%)**	**10 (22%)**	**14 (31%)**	**9 (20%)**

[1] The percentage in brackets refers to the percentage number of samples that fall within the interval group as indicated.

Table 3.4 Products in the current study that have kept the same GM label compared to Viljoen *et al*. (2006).

Product Name	**Description**	**Label**	**Viljoen *et al*. (2006)**	**Current study**
			GM result	**GM result**
Amazon Corn flakes	Cereal	Organic	Detected	Nd
Baby corn	Raw corn	Organic	Nd	Nd
Soysense	Soybean milk	Organic	Detected	Nd
Cape Creamy	Soybean milk powder	GMO free	Detected	Detected
Braai flavour sausages	Soybean protein	GMO free	Detected	Detected
Chick Burger	Soybean protein	GMO free	Detected	Detected
Corn Thins	Puffed corn	GMO free	Nd	Nd
Soy flour	Soybean flour	GMO free	Nd	Detected
Soya milk powder	Soybean milk powder	GMO free	Detected	Detected
Spiced Burger	Soybean protein	GMO free	Detected	Detected

[1] Nd - Genetic modification not detected

Of the products tested by Viljoen *et al*. (2006), 10 were found to have retained the same GM related label and five were not available or their GM labels had been

removed (Table 3.4). Of the seven food producers and four retail outlets whose products were tested in this study, only three responded (Table 3.5).

Table 3.5 Response to the results of this study from producers and retailers, whose products were tested.

Company	Company policy on GM labelling	System to validate GM labels	Comments
Producer of health food products 1	No response		
Producer of health food products 2	No response		
Producer of health food products 3	No specific policy	No system	Seed supplier should provide GM certificate that must accompany produce from point of origin to retail supplier.
Producer of soybean food products 1	No response		
Producer of soybean food products 2	No response		
Producer of soybean food products 3	No response		
Producer of soybean milk products	Conform to (EC) 1829/2003 that provides a threshold of 0.9% for GM presence	Rely on supplier for verification and “non-GM” certification	Recommend a threshold level of 5% for presence of GM in “non-GM” food or feed in labelling legislation
Retailer 1	No response		
Retailer 2	Requested that comments not be included		
Retailer 3	Requested that comments not be included		
Retailer 4	To "remove , replace or label" ingredients from GM crops in foods	Supplier has procedures in place. 1) Raw material tested with a threshold level of 1% GM, 2) Identity Preservation process to ensure traceability	Products are labelled for customers to be accurately and sufficiently informed about products, in order to make informed buying choices.

3.4 Discussion

Voluntary labelling, as applied in South Africa, does not appear to be providing discerning consumers with a choice between GM and non-GM products when 56% of

product batches that are labelled 'GMO free', 'non GM' or 'organic' contain genetic modification (Table 3.2 and 3.3). Furthermore, 31% of product batches contained above 1% genetic modification while 20% contained above 5% genetic modification. These results are in contrast to other studies, in other countries with low GMO production, where low level GM contamination was detected in food products (Partridge and Murphy, 2004; Ujhelyi *et al*., 2008). Possible explanations for the high levels of genetic modification in 'GMO free', 'non GM' or 'organic' food products in South Africa is that there is no segregation of GM and non-GM grain, there are no regulations that control GM labelling for consumer preference and voluntary GM labelling is applied without any requirement for third party validation (DAFF, 2010c).

There appears to be a lack of consistency between batches with a 40% difference in results (including GM negative or positive as well as changes between below LOQ, below 1%, above 1%, below 5% or above 5%). This suggests that the internal systems companies use to validate the GM content of these products is not sufficient, validation is not being performed or not performed on each batch of product or that the correct sampling strategy is not being applied. Be that as it may, consumers are not guaranteed that the GM content of food labelled 'GMO free', 'non GM' or 'organic' will consistently be below a specific threshold of GM content.

From producer and retailer comments (Table 3.5) it is clear that in an absence of regulations, different systems will be applied to GM labelling – possibly based on the perceived requirement of the specific niche market being serviced. The label 'GMO free' was used in 75% of products to indicate an absence of genetic modification despite the guideline to not use this term by the Department of Health (Department of Health, 2004a). Although South African companies may not be aware of the existence

of the Department of Health guideline, the use of 'GMO free' in terms of the guideline is not illegal. However, this does suggest that the use of guidelines instead of regulations in voluntary GM labelling will result in incoherent labelling practice by companies.

Although there are no definitions for GM labelling in a South African context, the common interpretation for 'organic' and 'GMO free' imply zero genetic modification (Viljoen *et al*., 2006). The problem is that in the absence of specific regulations, companies may apply existing systems taken from other countries (Table 3.5). For example, from 2009, 'organic' in the EU may contain up to 0.9% adventitious genetic modification (currently 0.0%) whereas in the USA it may contain up to 5% genetic modification. However, discerning consumers in South Africa may have a different expectation of the GM content of the products they are buying, especially since 'Organic', 'Non GM' or 'GMO free' labels are not being qualified on the label. Although there are exceptions, with 56% of 'Organic', 'Non GM' or 'GMO free' product batches containing above 1% genetic modification, voluntary GM labelling has failed in South Africa.

Compared to the study of Viljoen *et al*. (2006), of the 17 products previously tested which were labelled to indicate an absence of genetic modification, 10 were still available and the GM related label had been removed from three products, White maize meal, Soya chunks and Soya beans (Table 3.4). In addition, 13 new products were found with an 'Organic', 'Non GM' or 'GMO free' label. This suggests that the demand for GM labelling is increasing in South Africa. Furthermore, it does not appear that the results of the previous study, sent to all the producers and retailers involved, has made any significant change to the validity of the GM labels being used

(Viljoen *et al*., 2006). Thus without mandatory regulations, there is currently no external incentive or obligation for companies to ensure the validity of their products in terms of the GM label.

3.5 Conclusion

The introduction of GM food has established a new niche market for 'Organic', 'Non GM' or 'GMO free' products throughout the world. Irrespective of whether voluntary or mandatory GM labelling is applied, the definition of the GM label being used should be clear to consumers. The problem is that the application of voluntary labelling is not being regulated, not in South Africa or the rest of the world compared to mandatory labelling that inherently requires regulation. In the absence of regulations under voluntary GM labelling, there is also no requirement for product validation and hence no form of consumer protection. Furthermore, the lack of consistency between product batches suggests that some companies are not applying sufficient internal control to ensure that the product complies with the GM label. Thus in the absence of specific regulations, there appears to be an inconsistent application of the definition for 'Organic', 'Non GM' or 'GMO free' and this may result in consumer expectations, regarding the GM content of food, not being met and is not only applicable in South Africa. Voluntary GM labelling, without regulation and validation, will not provide discerning consumers with the choice they require. Finally, in terms of ensuring consumer protection, unregulated GM labelling is not a viable alternative to using a regulated approach, either voluntary or mandatory.

CHAPTER 4

APPLICATION OF MANDATORY GM LABELLING IN SOUTH AFRICA

Abstract

The purpose of genetically modified (GM) food labelling is to inform consumers of the GM content in a food product. In South Africa, voluntary GM labelling has been applied until now. However in 2008, the South African Consumer Protection Act 68 of 2008 was passed into law, mandating the labelling of GM ingredients in packed goods. Thus the aim of this study was to evaluate the potential impact of mandatory GM food labelling in terms of the Consumer Protection Act by determining what products currently on the market would be implicated. A total of 46 food products from different companies was selected and sampled randomly with an emphasis on those containing canola, maize and soybean, since GM varieties have been approved in South Africa for these crops in terms of the GMO Act of 1997. The products were screened for the presence of genetic modification and, if positive, quantified. Genetic modification was detected in 50% of products, including seven out of 14 (50%) products labelled to indicate an absence of genetic modification. The results from this study indicate that the use of either a 1% or 5% GM labelling threshold would require 20 or 19 out of the 46 products to be labelled for their GM contents, respectively. Of the 14 products labelled to indicate an absence of GM, five would mandatory GM labelling. This raises the issue of compliance, since no provision has been made in the Consumer Protection Act for formal monitoring. In the feedback from companies, whose products were tested, it was apparent that there is a concern of the cost

implication of mandatory GM labelling. Considering current consumer attitudes towards GM food in South Africa and cost effectiveness of mandatory GM labelling, it is suggested that the term “may contain genetic modification” be used on ingredients from crops with genetic modification approval in South Africa to reduce the cost from GM testing.

4.1 Introduction

In 2009, the South African Consumer Protection Act 68 of 2008 (SACPA, 2008) was passed into law. The aim of the Act is to protect consumers in South Africa from unfair trade practices, improve consumer awareness and confidence through a legal framework that also provides a system for consumer redress (SACPA, 2008). The Act includes various aspects of fundamental consumer rights, including the consumer’s right to equality, privacy, choice, the disclosure of information, fair and responsible marketing, fair and honest dealing, just and reasonable terms and conditions, fair value, good quality and safety as well as requiring supplier accountability. A notable inclusion in the Act is the mandatory labelling of GM products or ingredients in food. According to section D:24 of the Act, “any person who produces, supplies, imports or packages any prescribed goods must display on, or in association with the packaging of those goods, a notice in the prescribed manner and form that discloses the presence of any genetically modified ingredients or components of those goods in accordance with applicable regulations” (SACPA, 2008). The inclusion of mandatory GM labelling in the Act was highly contested by interest groups and its retention is considered a victory for the consumer’s right to information on the GM content in food.

South Africa has become one of 39 countries to have introduced mandatory GM labelling (Gruère and Rao, 2007). South Africa joins countries in the EU, China, and

Brazil, of which the latter two are major producers of GM crops. Three of the other major GMO producers, Canada, Argentina and the USA, follow a voluntary GM labelling approach (Gruère and Rao, 2007). However, GM labelling remains a contentious issue and its application is expected to have an impact on consumers and the food industry alike.

The application of GM labelling differs among countries, mainly in terms of terminology, inclusion and exclusion criteria as well as threshold levels that trigger labelling. Negative labelling, where the absence of genetic modification is indicated as, for example, “non-GM” or “GM-free”, is usually applied in voluntary GM labelling, whereas the presence of genetic modification is indicated for products in mandatory labelling. In a voluntary GM labelling system, a combination of negative and positive labelling with a range of terminology can be applied, since voluntary labelling is not regulated and companies label according to their discretion (Botha and Viljoen, 2009). Compared to this, mandatory GM labelling regulates the use of thresholds and terminology. Furthermore, countries apply different inclusion and exclusion criteria. For example, in the EU GM content in flour, oil, starch or syrup must be labelled according to (EC) 1829/2003, while meat or eggs from animals fed with GM grain are excluded. Thresholds to allow a tolerance for the adventitious presence of approved GMOs with mandatory GM labelling range from 0% (China), 0.9% (EU and Russia), 1% (Brazil, Australia, New Zealand and Saudi Arabia), 3% (South Korea) to 5% (Japan, Indonesia, Taiwan and Thailand). These thresholds, used to trigger mandatory GM labelling, are not based on health and food safety considerations, but rather on consumer perceptions, practical limits of detection and cost implications (Bansal and Ramaswami, 2007).

Consumer choice relates to the right of exercising a choice based on the knowledge of whether the ingredients or products they want to buy have been genetically modified. The choice consumers make is based on numerous considerations, including health perceptions, environmental and ethical considerations as well as religious convictions (Curtis *et al*., 2004). It has been argued that mandatory labelling does not provide consumers with choice, since it can result in a negative perception of genetic modification and cause an absence of GM products on supermarket shelves (Carter and Gruère, 2003). Additionally it has been suggested that GM labels provide consumers with redundant information that may increase food prices or even result in a negative perception of genetic modification (Gruère and Rao, 2007; Bansal and Ramaswami, 2010). However, there has been no report of an increase in the price of food, in GMO producing countries such as Brazil and China, due to the application of mandatory GM labelling (Phillips and McNeill, 2000; Gruère and Rao, 2007). Furthermore, it has been estimated that in the EU, US$0.23 is added to the cost of food per person per year resulting from mandatory GM labelling (NERA, 2001). Based on this and the fact that the draft regulations, for mandatory GM labelling in South Africa, does not require that the GM content in food or ingredients thereof be verified, the additional cost for GM labelling in South Africa is expected to be minimal.

A consideration for the application of GM labelling in South Africa is the extent of GM crop production as well as GM crop imports. South Africa is currently ranked eighth in the world in terms of GMO production based on production area. Currently, South Africa has commercialised four GM crop types: canola, cotton, maize and soybean (DAFF, 2010a). In terms of the area planted in 2008, it is estimated that 92% of cotton, 56% of white and 55% of yellow maize as well as 75% of soybean in South Africa was genetically engineered (James, 2009). In addition to this, South Africa also imports

potentially GM containing canola, maize and soybean commodities (FAOSTAT, 2010). Therefore, locally produced as well as imported products will potentially require GM labelling according to the South African Consumer Protection Act 68 of 2008.

The Consumer Protection Act will enter into force in April 2011 and as a result regulations are currently in development. Draft regulations published on 29 November 2010 provide for mandatory labelling of GM products or ingredients at a 5% threshold using the terminology “Contains at least 5% genetically modified organisms” or, if laboratory GM testing is not possible or feasible, “May contain genetically modified organisms” (SACPA Proposed Regulations, 2010). The latter option is considered to become the preferred option for companies since this does not add the cost of laboratory GM testing. Additionally, if a product or ingredient contains less than 5% GMO, the label “Genetically modified content is below 5%” can be used (SACPA Proposed Regulations, 2010). It is unknown how these regulations will impact consumers and the food industry.

There are several considerations for the implementation of GM labelling in South Africa. These include a consumer corps that is largely unaware of GM technology, a previous absence of consumer related regulations and a food industry that is self-regulating. Thus, the application of mandatory GM labelling in South Africa should be cost effective, not require excessive regulatory management and use terminology that can be easily understood and communicated to consumers, while at the same time not resulting in an unnecessary mistrust of GM products. The aim of this study was to determine the impact of mandatory GM labelling in South Africa which includes the perceptions of food retailers.

4.2 Materials and methods

4.2.1 Product selection and sampling

Food products, generally available throughout South Africa, were randomly selected from retail chain outlets, supermarkets and health food shops according to product availability during 2010. Product groups were based on crop types for which GM events have received approval status in South Africa including canola, maize and soybean (Table 4.1).

Products containing ingredients from more than one crop type for which a GM equivalent has been approved, were not selected, due to the complexity of detecting and quantifying the level of genetic modification in mixed crops, especially since the GM quantification systems is crop specific. No cotton products could be found without the inclusion of other GM crop types and as a result these products were excluded from this study. A further distinction was made between unlabelled and labelled products in terms of GM content.

Table 4.1 Approved GM events in South Africa under the South African GMO Act (1997) and the South African GMO Amendment Act (2006) (GMO act, 2008; DAFF, 2010a).

Event	Crop	Type of approval	Promoter	Gene	Terminator
Topas 19/2	Canola	Commodity[1]	35S	*Pat*	Not present
Ms1Rf1, Ms1Rf2, Ms8Rf3	Canola	Commodity[1]	Not present	*Pat*	NOS
MON810	Maize	Environmental[2]	35S	*cry1Ab*	Not present
NK603	Maize	Environmental[2]	35S	*c4epsps*	NOS
Bt11	Maize	Environmental[2]	35S	*cry1Ab, pat*	NOS
MON810 x NK603	Maize	Environmental[2]	35S	*cry1Ab, c4epsps*	NOS
Bt176	Maize	Commodity[1]	35S	*cry1Ab, bar*	35S
T25	Maize	Commodity[1]	35S	*pat*	35S
GA21	Maize	Commodity[1]	Not present	*c4epsps*	NOS
TC1507	Maize	Commodity[1]	35S	*cry1F, pat*	NOS
MON810 x GA21	Maize	Commodity[1]	35S	*cry1Ab, c4epsps*	NOS
GTS40-3-2 (Roundup Ready Soy)	Soybean	Environmental[2]	35S	*c4epsps*	NOS
A2704-12	Soybean	Commodity[1]	35S	*pat*	Not present

[1] Commodity clearance – where GMOs are used for food and feed but cannot be cultivated

[2] Environmental release – where GMOs are released into the environment without any restrictions

4.2.2 DNA isolation

Food samples were homogenised in a food blender to a maximum particle size of 2.5 mm^2. DNA was isolated from food products in duplicate with the use of cetyltrimethylammonium bromide (CTAB) according to the method of Lipp *et al*. (1999) with modifications. Duplicate extraction controls were included in the DNA isolation process. CTAB buffer (10 ml) and 30 µl proteinase K [20 mg/ml] was added to 2 g of sample, followed by incubation at 60ºC for 2 hrs. The sample/buffer mixture was centrifuged for 5 min at 14,000 rpm and 900 µl of supernatant treated with 5 µl RNAse

[100 mg/ml] for 15 min at 60ºC. The DNA/buffer mixture (650 µl) was then further purified with a DNeasy spin column. After centrifugation, the column bed was washed twice with AW buffers, by centrifugation at 14,000 rpm for 1 min after which the DNA was eluted with 50 µl medical grade water (Qiagen) (Anklam *et al*., 2002). Oil samples (2 g) were mixed with 10 ml of hexane and 2 ml lysis buffer according to Consolandi *et al*., (2008). After centrifugation of 10 min at 14,000 rpm, the aqueous phase was retained and the DNA precipitated by the addition of 500 µl absolute isopropanol and incubation at room temperature for 1 hr. After 15 min centrifugation at 14,000 rpm, the pellets were washed with 70% ethanol and finally re-suspended in 50 µl medical grade water (Consolandi *et al*., 2008). The isolated DNA was resolved on a 1% agarose gel in TAE buffer [40 mM Tris-HCl, 40 mM acetic acid and 1 mM EDTA (pH8.0)] for 25-30 min at 180 V and visualised under UV light, after staining in 2.55 mM ethidium bromide for 10 min, followed by documentation with a gel GelLogic200 (Kodak) system.

4.2.3 Screening for genetic modification

Sample DNA was screened for the presence of genetic modification using conventional gel based PCR. Canola and maize samples were screened for the 35S promoter from the cauliflower mosaic virus (CaMV) and the NOS terminator from *Agrobacterium tumefaciens*. Soybean samples were only screened for the presence of 35S, since all GM soybean events approved in South Africa contain 35S. The primer sequences used for GM screening include the 35S promoter (5'-CCACGTCTTCAAAGCAAGTGG-3' and 5'-TCCTCTCCAAATGAAATGAACTTCC-3') and NOS terminator (5'-GCATGACGTTATTTATGAGATGGG-3' and 5'-GACACCGCGCGCGATAATTTATCC-3') (ISO21569: 2005). PCR reactions were performed on a GeneAmp 9700 (Applera) thermal cycler with the following cycling conditions: 10 min at 95ºC, followed by 50

cycles of 25 sec at 95ºC, 30 sec at 62ºC and 45 sec at 72ºC with a final extension step of 7 min at 72ºC (ISO21569: 2005). PCR reactions were made up to a final volume of 25 µl containing sample DNA (25-100 ng), 0.8 U AmpliTaq Gold polymerase (Applera), 1.5 mM $MgCl^2$, 160 µM of each dNTP and 0.6 µM of each primer (Lipp *et al*., 2001). For quality control purposes, PCR reactions for two blank controls, two positive controls, two extraction controls, each sample in duplicate and two controls were set up and performed on the Applied Biosystems GeneAmp 9700. The limit of detection and inhibition was determined by the addition of 10 copies of control DNA to each sample. PCR products were separated by electrophoresis on a 2% agarose gel at constant voltage of 180 V for 25-30 min in TAE buffer [40 mM Tris-HCl, 40 mM acetic acid and 1 mM EDTA (pH8.0)] followed by staining with ethidium bromide [2.55 mM] for 10 min. The DNA was visualised under UV light and documented using the GelLogic200 (Kodak) imaging system.

4.2.4 Real-time PCR quantification of genetic modification

GM content was quantified in maize and soybean products using the GMO Quant 35S Corn and the GMO Quant RoudupReady Soy kit, respectively (Eurofins GeneScan). The kits include copy number standards and a 1% GM certified reference control. The standard curve consisted of four data points in duplicate with a minimum correlation of 0.98 and limit of quantification (LOQ) 0.05%. The GMO Quant 35S Corn kit quantifies the total GM content in maize products using the *hmg* (High Mobility Group) as reference, 35S CaMV promoter as target and 1% MON810 Corn DNA from CRM ERM-BF413d as reference control while the GMO Quant RoundupReady Soy kit quantifies the GM Roundup Ready content using the *lectin* as reference, *cp4epsps* as target and 1% Roundup Ready Soybean DNA from CRM ERM-BF410d as reference control.

Both quantification systems employ TaqMan probes for amplicon detection. Real-time PCR reactions conditions were as follows: 10 min at 95ºC, followed by 45 cycles consisting of 15 sec at 95ºC and 90 sec at 60ºC (ISO 21569:2005). The amount of genetic modification present in a sample was determined relative to the total content of plant DNA. Two dilutions of each sample were tested to determine sample inhibition. To minimise the risk of cross-contamination, individual steps were performed in separate work areas and blank and positive controls included with each reaction.

4.2.5 Perceptions of mandatory GM labelling in South Africa by food producers and retailers whose products were tested in this study

Food producers and retailers (a total of 22 companies) whose products were tested in this study were provided with the results and invited to make comments as well as participate in a basic questionnaire on their perceptions of the application and impact of the South African Consumer Protection Act 68 of 2008 in terms of mandatory GM labelling (Appendix A).

4.3 Results and discussion

A total of 46 off-the-shelf food products was screened for the presence of genetic modification, to determine the extent of products that would be impacted by mandatory GM labelling in South Africa (Table 4.2 and 4.3). Of these, 23 products tested positive with a GM content of up to 97% in some products. From this study it is evident that primarily maize and soybean products will be implicated by mandatory GM labelling in South Africa.

Table 4.2 Results of the detection and quantification of genetic modification in food products that are not labelled in terms of GM content.

Product Name	Description	35S	NOS	% GM[3]
Canola				
Canola oil 1	Canola oil	-	-	n/a
Canola oil 2	Canola oil	-	-	n/a
Canola oil 3	Canola oil	-	-	n/a
Maize[1]				
Coarse maize grits	Raw white maize	+	+	73.14 ± 0.89
Maize meal 1	Raw white maize	+	+	59.27 ± 4.16
Maize meal 2	Raw white maize	+	+	48.94 ± 2.29
Instant maize meal 1	Raw white maize	+	+	37.34 ± 0.08
Yellow maize meal	Raw yellow maize	+	+	22.05 ± 0.98
Instant maize meal 2	Raw white maize	+	+	49.37 ± 3.19
Polenta	Raw yellow maize	+	+	45.71 ± 1.34
Corn flakes 1	Processed maize	-	-	n/a
Corn flakes 2	Processed maize	-	-	n/a
Soybean[2]				
Soybean milk 1	Soybean milk liquid	-	n/a	n/a
Soybean milk 2	Soybean milk liquid	-	n/a	n/a
Soybean milk 3	Soybean milk liquid	-	n/a	n/a
Soybean milk powder 1	Soybean milk powder	-	n/a	n/a
Soybean milk powder 2	Soybean milk powder	-	n/a	n/a
Soybean milk powder 3	Soybean milk powder	+	n/a	81.70 ± 7.41
Tofu 1	Soybean curd	+	n/a	71.93 ± 1.30
Tofu 2	Soybean curd	+	n/a	0.04 ± 0.01
Soybean paste 1	Soybean paste	-	n/a	n/a
Soybean sauce 1	Soybean sauce	-	n/a	n/a
Soybean sauce 2	Soybean sauce	-	n/a	n/a
Soybean sauce 3	Soybean sauce	-	n/a	n/a
Soybean sauce 4	Soybean sauce	-	n/a	n/a

Table 4.2 (Continued)

Product Name	Description	35S	NOS	% GM
Soybean lecithin granules 1	Soybean lecithin	-	n/a	n/a
Lecithin granules	Soybean lecithin	+	n/a	39.09 ± 4.03
Soybean flour 1	Soybean flour	+	n/a	97.30 ± 10.79
Soybean flour 4	Soybean flour	+	n/a	92.56 ± 0.93
Soybean chunks	Dried Soybean mince	+	n/a	84.40 ± 1.68
Soybean mince 1	Dried Soybean mince	+	n/a	33.69 ± 2.61
Soybean nuggets	Dried Soybean mince	+	n/a	66.68 ± 2.94

[1] GM quantification was performed using the GMO Quant 35S Corn kit (www.genescan.de).

[2] GM quantification was performed using the GMO Quant RoudupReady Soy kit (www.genescan.de).

[3] The % GM content indicated is followed by the standard deviation between duplicate samples.

Table 4.3 Results of the detection and quantification of genetic modification in food products labelled to indicate an absence of GM content.

Product Name	Description	GM Label	35S	NOS	% GM
Maize[1]					
Corn pasta	Processed maize	GMO Free	-	-	n/a
Corn thins	Processed maize	Non GMO	-	-	n/a
Corn flakes 3	Processed maize	Organic	+	+	0.80 ± 0.34
Soybean[2]					
Soybean milk 4	Soybean milk liquid	Non-GM	+	n/a	83.64 ± 1.14
Soybean milk 5	Soybean milk liquid	Non-GM	-	n/a	n/a
Soybean milk 6	Soybean milk liquid	Organic	-	n/a	n/a
Soybean milk 7	Soybean milk liquid	Non-GM	-	n/a	n/a
Soybean milk powder 4	Soybean milk powder	GM-Free	+	n/a	0.03 ± 0.01
Soybean paste 2	Soybean paste	Organic	-	n/a	n/a
Soybeans	Raw soybeans	GMO-Free	+	n/a	85.57 ± 1.07
Soybean lecithin granules 2	Soybean lecithin	GMO-Free	-	n/a	n/a
Soybean flour 2	Soybean flour	Organic	+	n/a	0.02 ± 0.01
Soybean flour 3	Soybean flour	GMO-Free	+	n/a	7.32 ± 0.52
Soybean mince 2	Dried soybean mince	Non-GM	+	n/a	47.80 ± 0.67

[1] GM quantification was performed using the GMO Quant 35S Corn kit (www.genescan.de).

[2] GM quantification was performed using the GMO Quant RoudupReady Soy kit (www.genescan.de).

Although the percentage threshold for mandatory GM labelling in South Africa is yet to be finalised, interest groups are motivating for either 1% or 5%, respectively. If a 1% threshold is used, 20 products tested would require GM labelling compared to 19 for 5% (Table 4.2 and 4.3). Thus, although some groups advocate for the use of a higher percentage threshold – presumably under the assumption that less products would be implicated – the results of this study suggests otherwise. A motivation for choosing a 1% threshold is the effect that this may have food exports, since most of South Africa's trade partners apply mandatory labelling using a 0.9% or 1% threshold. Thus, it would be prudent to harmonise the percentage threshold used for mandatory GM labelling to that for non-GM certification of exports.

As a result of the previous practice of voluntary GM labelling in South Africa, companies have made use of negative or non-GM labelling to indicate the absence of GM content in food (Botha and Viljoen, 2009). The draft regulation for mandatory GM labelling in South Africa does not make provision for the terms "GMO free", "non-GM" or "organic". However, terminology indicating the absence of genetic modification below a specific threshold, "Genetically modified content is below 5%", has been included. There are four products currently labelled to indicate an absence of genetic modification, which would not be exempt from GM labelling based on either a 1% or 5% threshold. While the South African Consumer Protection Act makes provision for a resolution of disputes and/or redress by means of a tribunal, it makes no provision for active monitoring to ensure compliance. Instead, consumers or consumer groups have the right to approach the tribunal with complaints in terms of infringements (SACPA, 2008). Thus, the application of the Act will be self-regulating unless consumers or consumer groups take it upon themselves to challenge incorrect claims.

Only seven of the out of 22 companies responded when asked to provide comments on the GM content of their products and to participate in a basic questionnaire on their perceptions of the application of mandatory GM labelling in South Africa. One reason for this may be that most food companies in South Africa have little or no expertise on GM labelling. Notably, there was also no response by some companies whose products were labelled "GMO free" or "non-GM" but that had an excess of 5% GM. In any event, it appears that the introduction of mandatory GM labelling will prove challenging to the food industry in South Africa. From the responses that were received, it is evident that food companies in South Africa have differing opinions on the impact of mandatory GM labelling. However, while most respondents agreed that consumers have the right to know of the presence of GM ingredients in food, some felt that most South African consumers would find this information irrelevant. While it is true that consumer surveys have shown that South Africans are undecided in their opinion of GM food, it must also be noted that most consumers are unfamiliar with GM (Rule and Ianga, 2005). Based on this, it is not expected that mandatory GM labelling will result in an absence of GM products on supermarket shelves, as was the case in the EU where consumers were adverse to GM food. It is also expected that the application of mandatory GM labelling may contribute to consumer awareness in South Africa (Viljoen *et al*., 2006).

Of concern to the food industry is the cost of GM labelling as a result of laboratory testing. These concerns are based on studies that exaggerate the cost estimates of GM labelling due to excessive requirements, including segregation and identity preservation of GM and non-GM products. Furthermore, these assumptions do not apply to South Africa since there is no indication that either the food industry or the consumers will suddenly require segregation and identity preservation of non-GM

products with the introduction of mandatory GM labelling. One way to apply mandatory GM labelling in a simple and cost effective manner would be to label ingredients based on crop type, taking into account approved GM events in South Africa, without the need for laboratory testing. Compared to this, there will be a cost consideration for companies wanting to provide discerning consumers opposed to GM technology with non-GM products. However, it has been estimated that mandatory GM labelling in Europe, where the market is almost exclusively non-GM, has added approximately US$0.23 to the cost of food per person per year (NERA, 2001). Thus compared to the situation in the EU, the non-GM market in South Africa is negligible and the cost consideration for mandatory GM labelling will be low.

A further consideration for mandatory GM labelling is the use of inclusion and exclusion criteria. In terms of mandatory GM labelling under the Consumer Protection Act the inclusion criteria is “packaged goods” containing an ingredient or product for which a GM crop type has been approved in South Africa (SACPA Proposed Regulations, 2010). The challenge is that without monitoring, it is possible that unapproved GM events may enter the food chain, either through research and development or importation. This problem is further exacerbated by the fact that although legislation controls the development, use and import of GMOs in South Africa, there is no control of the import of GM events in processed food products. In terms of exclusion criteria, the EU excludes animals fed GM grain or GM enzymes, used in a process where they do not form part of the final product, from GM labelling ((EC)1829/2003). By default, these exclusions also apply according to the draft regulations for mandatory GM labelling in South Africa.

In terms of terminology, the draft regulation for mandatory GM labelling in South Africa requires that products or ingredients that contain more than 5% GM be labelled "Contains at least 5% genetically modified organisms". The draft regulation also makes provision for the use of "May be genetically modified" where it is not feasible or possible to test for the presence of genetic modification in products or ingredients thereof. This would presumably apply to products where the GM content is unknown or cannot be determined due to processing (SACPA Proposed Regulations, 2010).

The advantage of applying the suggested terminology is that it will allow mandatory GM labelling to be cost effective, without the requirement of excessive regulation. Furthermore, it will provide sufficient information to discerning consumers but not result in a negative connotation by consumers that are not aware of genetic modification. Unfortunately, it does mean that given the extent of GM production for maize and soybean in South Africa, companies that want to produce "non-GM" food for these crop types will have to bear the additional cost for laboratory testing and segregation. It also means that the role of policing the integrity of the GM labels on food products will be up to the companies themselves, as well as consumers and consumer groups.

4.4 Conclusion

Of the products tested, primarily maize and soybean products will be implicated by mandatory GM labelling in South Africa. Genetic modification was found in 67% of the maize products tested and 48% of soybean products. One point of discussion is the use of threshold for GM labelling. It was found that 67% and 58% of maize products contained more than 1% and 5% genetic modification, respectively. Compared to this 39% soybean products contained genetic modification above 1% and 5%. This

suggests that while the majority of these products are implicated by the South African Consumer Protection Act 68 of 2008 in terms of mandatory GM labelling, the use of either 1% or 5% threshold, would not make a considerable difference in terms of the amount of products implicated. However, an important consideration is the harmonisation in the use of threshold for GM labelling and for non-GM certification for export purposes. It is therefore suggested that 1% be used a GM labelling threshold. This study has also shown that of the products labelled to indicate an absence of genetic modification, 28% would need to be labelled to contain genetic modification in terms of the South African Consumer Protection Act clause 24(6), irrespective of whether a 1% or 5% threshold is used.

The Consumer Protection Act only applies to packaged goods and by default other food products including fast foods are excluded (SACPA Proposed Regulations, 2010). Current draft regulations require a 5% GM threshold for labelling compared to 0.9% in the EU. Proposed regulations also make provision for "May contain genetically modified organisms" if it is impossible or not feasible to test the product (SACPA Proposed Regulations, 2010). Although provision is made for a tribunal that will investigate allegations of non-compliance, no other specific provision is made for ongoing compliance monitoring. Therefore, in terms of mandatory GM labelling, it will be in the hands of companies to police themselves or consumers or consumer groups to fulfil the role of watchdog.

The feedback from companies whose products were involved in this study indicated that they are mainly concerned about the cost implication of mandatory GM labelling. However, based on the suggestion that allows companies to label ingredients as "May contain genetic modification" for crop types with approved GM events in South Africa,

most of the cost concerns would be irrelevant. In addition to this, undue responsibility for GM labelling would not be placed on the informal food sector or restaurants and fast food outlets, since their products are not packaged. Finally, although what South Africa has put forward for mandatory GM labelling may be considered far less rigorous than that used in the EU, it does provide an alternative and could be used as a case study for resource poor countries.

CHAPTER 5

MONITORING THE FOOD CHAIN FOR UNAPPROVED GM EVENTS IN SOUTH AFRICA

Abstract

A genetically modified (GM) event is considered illegal if it has not received regulatory approval. Regulatory approval includes a risk assessment to determine the safety of the genetically modified organism (GMO) to human health and the environment. Thus, monitoring the food chain for unapproved GM events is necessary to ensure that GMOs not determined to be safe, do not enter the food chain as well as to ensure compliance with obligations under the Biosafety Protocol. A combination of the asynchronous release of GM events, the lack of regulation and/or monitoring can result in the illegal presence of GMOs in food products. Since the global introduction of GM crops, a number of accidental or unintended releases of unapproved GMOs have occurred and have had major economic repercussions. Thus the aim of this study was to develop a scheme to detect illegal GMOs that could be used in routine monitoring. A monitoring system for illegal GMOs that is practical, cost effective, take the availability of global commercialized GM events and the regulatory status of the particular country into consideration was established. The monitoring system was consequently applied on 94 off-the-shelf food products in South Africa. Even though no illegal GM events were detected, a potential illegal import of GM soybean event

A2704-12 was found. This study highlights the importance of monitoring the food chain for unapproved GM events.

5.1 Introduction

The contamination of food crops with unapproved genetically modified (GM) events is a concern for safety to human health and the environment as well as having economic implications (Clapp, 2006). Illegal GM events may have safety considerations for human health and the environment since these have not been determined to be safe by the regulatory system. Over the last 10 years there have been several incidents of food contamination (RASFF, 2009). Most of these have occurred in developed countries that have the capacity to identify and consequently contain such incidents. However, such a situation would be more difficult to manage if it occurred in a resource poor country. Developing countries would be particularly impacted by the presence of unapproved GMOs because they rely on agricultural production for staple foods as well as trade in grain for revenue (Clapp, 2006). Thus, monitoring the food chain for illegal genetically modified organisms (GMOs) may be a challenge for developing countries, to ensure food safety.

With an increasing amount of GM crop being produced globally, by more countries, it is unsurprising that 149 notifications of illegal GM events have been reported in the EU during 2009 (RASFF, 2009). Some of the most publicized examples of GM contamination include GM rice event LibertyLink 601 and GM maize events Bt10 and StarLink, originating in USA, as well as GM rice event Bt63 from China, that spread to Europe and the rest of the world (Clapp, 2008; RASFF, 2009). Another notable

example of GM contamination was that of a pharmaceutical GM soybean developed by Prodigene in the USA (Cohen, 2002). All of these incidents had economic implications with product recalls, fines to the companies involved, crop losses where contaminated crop had to be destroyed and losses in export markets.

The legal status of a GMO is determined by the regulatory system. The approval process usually includes some form of risk assessment to ensure safety to human health and the environment before approval is given. Thus, if a particular GM event has not received regulatory approval in a specific country, it is considered illegal, even though it may be approved in other countries. GMOs are often regulated for different categories of intended use including, contained use (for planting in an enclosed glass house), trial release (controlled field trials), as a commodity (for use as food or feed), or for release into the environment (agricultural production). Thus, unapproved GMOs may enter the food chain through food imports and/or GM research and development activities.

South Africa, similar to many other developing countries imports considerable amounts of GM crop as commodities including rice and wheat from major GMO producing countries (Table 5.1). Maize, rice, soybean, wheat and products thereof, fall under the top ten commodities imported by South Africa in terms of volume (Table 5.1). In addition to this, in 2009, a total of 296 permits were issued under the GMO Act by the Department of Agriculture, Forestry and Fisheries. Of these, 138 were for the import and 120 for the export of LMOs as well as 14 permits for commodity use and trial release, respectively (GMO Act Annual Report, 2008). Thus, all of these

activities could be potential sources of unapproved GMOs entering the food chain in South Africa.

Table 5.1 Top ten commodities imported by South Africa in terms of weight in 2007 (FAOSTAT, 2010).

Rank	Commodity	Quantity (tonnes)	Value (1000 $)
1	Maize	1,234,173	207,578
2	Wheat	1,098,444	260,662
3	Rice	943,347	290,641
4	Cake of soybeans	941,984	209,355
5	Palm oil	299,092	196,081
6	Soybean oil	272,707	209,182
7	Chicken meat	210,153	173,840
8	Sunflower oil	166,522	124,356
9	Sunflower cake	122,753	15,286
10	Soybeans	117,828	34,217

Detecting the presence of unapproved GMOs in the food chain is considered to be a major regulatory challenge (Holst-Jensen, 2009). In order to monitor for the presence of illegal GMOs in bulk grain shipments or food products the following needs to be considered:

- Illegal GM events may be present due to the rapidly increasing amount of GM events released asynchronously throughout the world.
- Food may also be contaminated with experimental GM events from research and development activities.
- In genetic modification producing countries, distinction must also be made between approved and illegal GM events.

- The global status of GM developments, especially in trade partners.
- The lack of complete genetic information on approved GM events, especially for those developed in countries that are non-Parties to the Biosafety Protocol.
- The heterogeneous nature of bulk grain shipments containing several GM events of a particular crop type as well as the undeclared presence of other crop types.

GM crop events can be detected using regulatory sequences, such as the 35S promoter and/or the NOS terminator or selection genes such as the kanamycin resistance marker gene (*nptII*) (Ahmed, 2002). Additionally, trait specific gene sequences such as herbicide tolerance (HT), including *cp4epsps* (from *Arabidopsis tumfaciens strain CP4*), *bar* (from *Streptomyces hygroscopicus*) and *pat* (from *Streptomyces viridochromogenes*) can be utilized (Waiblinger *et al*. 2010). However, given the current status of available GM events in the world, it is difficult to determine what combination of detection systems must be used in order to screen grain and processed food products for illegal GM events. Furthermore, the development of detection systems can be tedious and costly and GMO detection laboratories rely on the sharing of detection methods, for example in the EU, through the European Network of GMO Laboratories (ENGL) and more recently in Southern Africa, the newly established Southern African Network of GM Detection Laboratories (SANGL).

To overcome the challenges in detecting illegal GMOs, a number of detection approaches have been suggested (Mano *et al*., 2009; Reiting *et al.*, 2010; Tengs *et al*., 2010; Waiblinger *et al*., 2010). The detection system for rice described by Reiting *et al.* (2010) as well as the multiple crop matrix detection system by Waiblinger *et al*. (2010) takes into consideration the approval status of GM events and incorporates

screening for regulatory GM sequences and/or gene sequences followed by GM event specific identification. However, such schemes are only as effective as their application and most countries, especially in the developing world, cannot afford continual monitoring. Instead, many countries such as those in the EU, rely on the notification of unauthorized GM0s through the Rapid Alert System for Food and Feed (RASFF). Unfortunately, such systems do not exist in developing regions.

Very few countries actively monitor for the presence of illegal GM events in food imports outside of the EU. In South Africa, approved GMOs are imported through a permit system under the GMO Act (1997) and the GMO Amendment Act (2006) (DAFF, 2010a) for food and feed (Table 5.2). However, this system only applies to living modified organisms (LMOs) and GM events in processed commodities are not regulated unless considered to have health considerations (personal communication from the National Department of Health). Furthermore, no routine GM detection is performed on GM imports or non-GM imports to ensure that unapproved events are not present. South Africa, as one of the few countries in Africa producing and trading in GM products, can therefore be considered as a case study for developing countries in terms of monitoring for illegal GMOs. Thus the aim of this study was to develop a practical scheme to detect unapproved GMOs that could be used in routine monitoring, and to apply this to off-the-shelf food products in South Africa.

Table 5.2 GM events in food crops approved for environmental release and commodity use in South Africa since 1997 (DAFF, 2010a).

Event	Year approved	Approval Status	Trait	Introduced gene	Promoter	Terminator
Canola						
Topaz 19/2	2001	Commodity clearance	HT	*pat*	35S	35S
Ms1 x Rf1, Ms1 x Rf2, Ms8 x Rf3	2001	Commodity clearance	HT	*bar*	NOS	Not present
Maize						
MON810 x NK603	2007	Environmental release	HT and IR	*cry1Ab, cp4epsps*	35S	NOS
Bt11	2003	Environmental release	IR	*cry1Ab, pat*	35S	NOS
NK603	2002	Environmental release	HT	*cp4epsps*	35S	NOS
MON810	1997	Environmental release	IR	*cry1Ab*	35S	Not present
MON810 x GA21	2003	Commodity clearance	HT and IR	*cry1Ab, Maize epsps*	35S	NOS
TC1507	2002	Commodity clearance	HT and IR	*cry1F, pat*	35S	35S
GA21	2002	Commodity clearance	HT	*Maize epsps*	Not present	NOS
T25	2001	Commodity clearance	HT	*pat*	35S	35S
Bt176	2001	Commodity clearance	IR	*cry1Ab, bar*	35S, PEPC	35S
Soybean						
GTS40-3-2	2001	Environmental release	HT	*cp4epsps*	35S	NOS
A2704-12	2001	Commodity clearance	HT	*pat*	35S	Not present

5.2 Materials and methods

5.2.1 Detection scheme for unapproved GM events

A detection system was established based on current GM events approved in South African per crop type. The scheme takes GM elements in approved events in SA as well as GM elements in global GM events into consideration. The monitoring system also makes provision for the possibility that non-GM crop types can become co-mingled with approved GM crop (Table 5.3 to 5.7).

5.2.2 Product selection and sampling

The detection scheme was then tested on a total of 94 off the shelf products, including three canola, 12 maize, 32 rice, 31 soybean and 16 wheat food products, selected randomly from retail outlets including health food shops, according to product availability. Products containing more than one type of crop for which a GM equivalent already exists, were excluded from this study, due to the complexity of testing such products that would require excessive event specific testing. Furthermore, products that contained cotton oil were only found in combination with other GM crop types and were therefore excluded from this study.

Table 5.3 GM canola events with regulatory approval in at least one country in the world as well as the genetic elements and genes used in the detection scheme. Event specific information was obtained from Waiblinger *et al*. (2010) and www.cera-gmc.org.

Event name	Trait[1]	Gene[2]	GM detection elements		
			35S	NOS	FMV
23-18-17 (23-198)	LA and MA	*TE*[2]*, nptII*	+		
Falcon GS40/90	HT	*pat*	+		
GT200	HT	*cp4epsps*			+
GT73, RT73	HT	*cp4epsps, gox*			+
Topaz 19/2[3] (HCN92)	HT	*pat, nptII*	+		
HCN10	HT	*pat, nptII*	+		
Liberator L62	HT	*pat*	+		
Ms1, Rf1, Rf2, Ms1 x Rf1, Ms1 x Rf2[3]	HT	*bar, barnase, barstar*		+	
Ms8, Rf3, Ms8 x Rf3[3]	HT	*bar, barnase, barstar*		+	
OXY 235	HT	*bxn*	+	+	
T45	HT	*pat*	+		
HNC28	HT	*pat*	+		

[1] Traits are indicated as LA for Laurate acid production and MA for Myristic acid production

[2] List of genes and genetic elements p. xii

[3] Event with regulatory approval for use as a commodity in South Africa (Table 5.2).

Table 5.4 GM maize events with regulatory approval in at least one country in the world as well as the traits, genetic elements and event specific screening used in the detection scheme. Event specific information was obtained from Waiblinger *et al*. (2010) and www.cera-gmc.org.

Event name	Trait[1]	Gene[2]	GM detection elements						
			Regulatory		Event specific screening				
			35S	NOS	FMV	T14	DAS-59122-7	MON863	Bt10
3272	Amy	*amy797E*		+					
676, 678, 680	HT	*pat, dam*	+						
Bt11[3]	IR	*cry1Ab, pat*	+	+					
Bt10[4]	IR	*cry1Ab, pat, amp*	+	+					+
B16	HT	*bar, bla*	+						
Bt176[5]	IR	*cry1Ab*	+						
CBH-351 (StarLink)	IR and HT	*bar, cry9C*	+	+					
DAS-062758	IR and HT	*bar, cry1F*	+						
DAS-591227	IR and HT	*cry34Ab1, pat*	+				+		
DBT418 (Bt-Xtra)	IR and HT	*cry1Ac, pat, bla*	+						
GA21[5]	HT	*Maize epsps*		+					
LY038	Lys	*cordapA, nptII*							
MIR162	IR	*vip3Aa19e, pmi*		+					

Table 5.4 (Continued)

Event name	Trait[1]	Gene[2]	GM detection elements						
			Regulatory		Event specific screening				
			35S	NOS	FMV	T14	DAS-59122-7	MON863	Bt10
MIR604	IR	*cry3A, pmi*		+					
MON80100	IR	*cry1Ab*	+	+					
MON802	IR	*cry1Ab*	+	+					
MON809	IR and HT	*cry1Ab, cp4epsps*	+	+					
MON810[3]	IR	*cry1Ab*	+						
MON832	HT	*cp4epsps, nptII*	+	+					
MON863	IR	*cry3Bb1, nptII*	+	+				+	
MON88017	HT	*cry3Bb1, cp4epsps*	+	+					
MON89034	IR	*cry1A, cry2Ab*	+	+	+				
MON87460	DT	*cspB*	+	+					
MS3	HT	*bar, barnase, bla*	+	+					
MS6	HT	*bar, barnase, bla*	+	+			+		
NK603[3]	HT	*cp4epsps*	+	+					
T14	HT	*pat, bla*	+			+			
T25[5]	HT	*pat, bla*	+						

Table 5.4 (Continued)

Event name	Trait[1]	Gene[2]	GM detection elements						
			Regulatory		Event specific screening				
			35S	NOS	FMV	T14	DAS-59122-7	MON863	Bt10
TC1507[5]	IR and HT	*cry1F, pat*	+						
DP098140-6 (Event89140)	HT	*gm-hra, gat462*	+						

[1] Traits are indicated as Amy for amylase production, Lys for lysine production and DT for drought tolerance

[2] List of genes and genetic elements p. xii

[3] Event with regulatory approval for release into the environment in South Africa (Table 5.2).

[4] Event Bt10 is not regulated in any country but has been reported as contaminant

[5] Event with regulatory approval for use as a commodity in South Africa (Table 5.2).

Table 5.5 GM rice events that have received regulatory approval in at least one country in the world as well as genetic elements and genes screened in the detection scheme. Event specific information was obtained from Reiting *et al*. (2010) and www.cera-gmc.org.

Event name	Trait	Gene[1]	GM detection elements	
			35S	NOS
LL62, LL06 (LibertyLink)	HT	*bar*	+	
LL601	HT	*bar*	+	
Bt63[2]	IR	*cry1Ab, cry1Ac* fusion		+
KeFeng6[3]	IR	*cry1Ab, hpt*	+	+
KMD1	IR	*cry1Ab*	+	+

[1] List of genes and genetic elements p. xii

[2] Bt63 rice is not regulated in any country but has been reported as a contaminant

[3] KeFeng6 rice is not regulated in any country but has been reported as a contaminant

Table 5.6 GM soybean events that have received regulatory approval in at least one country in the world as well as genetic elements and genes screened in the detection scheme. Event specific information was obtained from Waiblinger *et al*. (2010) and www.cera-gmc.org.

Event name	Trait[1]	Gene[2]	GM detection elements			
			35S	FMV	*bar*	*pat*
DP356043	HT	*Gat4601, Gm-hra*	+			
A2704-12[3]	HT	*Pat*	+			+
A2704-21	HT	*Pat*	+			+
A5547-35	HT	*Pat*	+			+
A5547-127 (Event 127)	HT	*pat, bla*	+			+
G94-1, G94-19, G-168	OAP	*gm-fad2-1, gus, bla*	+			
GTS 40-3-2 (Roundup Ready)[4]	HT	*cp4epsps*	+			
GU262	HT	*pat, bla*	+			+
MON89788 (RReady2Yield)	HT	*cp4epsps*		+		
W62, W98	HT	*bar, gus*	+		+	

[1] Traits are indicated as OAP for oleic acid production

[2] List of genes and genetic elements p. xii

[3] Event with regulatory approval for use as a commodity in South Africa (Table 5.2).

[4] Event with regulatory approval for release into the environment in South Africa (Table 5.2).

Table 5.7 GM wheat events that have received regulatory approval in at least one country in the world as well as genetic elements and genes screened in the detection scheme. Event specific information was obtained from Waiblinger *et al*. (2010) and www.cera-gmc.org.

Event name	Trait	Gene[1]	GM detection elements	
			35S	NOS
MON71800	HT	*cp4epsps*	+	+
AP205CL	HT	*als2*		
AP602CL	HT	*als 1*		
BW255-2, BW238-3	HT	*als 1*		
BW7	HT	*als 1*		
SWP965001	HT	*als 1*		
Teal 11A	HT	*als 1*		

[1] List of genes and genetic elements p. xii

5.2.3 DNA isolation

Samples were homogenized where necessary, using a food blender to a maximum particle size of 2.5 mm^2. Extraction of DNA was performed in duplicate on 2 g of sample using the cetyltrimethylammonium bromide (CTAB) method according a modified method by Lipp *et al*. (1999) with the addition of 30 µl proteinase K [20 mg/ml] and after 2 hrs at 60ºC. Thereafter, 5 µl RNAse [100 mg/ml] was added to 900 µl of the sample/buffer for 15 min at 60ºC. The extracted DNA was purified using a silica column (Qiagen) according to the manufacturer's specifications (Anklam *et al*., 2002). DNA extraction from oil samples was performed according to a modified method by Consolandi *et al*. (2008) by the addition of 10 ml hexane with 2 ml lysis buffer to 2 g oil. The mixture was vortexed and then centrifuged for 10 min at 14,000 rpm and the aqueous phase retained and incubated for 1 hr after the addition of 500 µl absolute isopropanol. This was followed by centrifugation at 14,000 rpm for 15 min. Thereafter, the pellet was washed with 70% ethanol followed by centrifugation for 5 min at 14,000 rpm. The remaining pellet was re-suspended in 50 µl medical grade water (Consolandi *et al*., 2008). The extraction was also performed on extraction controls in duplicate. The isolated DNA was resolved in a 1% agarose gel in TAE buffer [40 mM Tris-HCl, 40 mM acetic acid and 1 mM EDTA (pH8.0)] for approximately 25-30 min at 180 V, where-after it was visualized under UV light after staining with 2.55 mM ethidium bromide for 10 min, and documented with a GelLogic200 (Kodak) documentation system.

5.2.4 Gel based PCR screening for genetic modification

Isolated DNA was screened using gel based PCR screening for the presence of GM regulatory elements including the 35S promoter from the Cauliflower mosaic virus, the NOS terminator from *Agrobacterium tumefaciens* and the FMV promoter from the Figwort mosaic virus that are commonly used in GM crops. In addition to this, screening was also performed for *pat* (that encodes phosphinotricin-N-acetyltransferase from *Streptomyces hygroscopicus,* for HT) and *bar* (that encodes phosphinotricin-N-acetyltransferase from *Streptomyces viridochromogenes*, for HT). Maize samples were additionally screened for the presence of specific GMO events including DAS-591227, MON863, T14 and Bt10 to identify the most likely unapproved maize events in South Africa based on developments in trade partners (Table 5.8). PCR reactions were performed in 25 µl containing approximately 25-100 ng of sample DNA, 0.8 U AmpliTaq Gold polymerase (Applera), 1.5 mM $MgCl^2$, 160 µM of each dNTP and 0.6 µM of each primer (Table 5.8) (Lipp *et al*., 2001). PCR assays were performed on a GeneAmp 9700 (Applera) thermal cycler with the following cycling conditions: 10 min at 95ºC, followed by 50 cycles of 25 sec at 95ºC, 30 sec at 62ºC and 45 sec at 72ºC. This was followed by a final extension of 7 min at 72ºC. For quality control, a blank control, a positive control and extraction control was included with each PCR assay in duplicate, respectively. Sample inhibition was determined by the addition of 10 copies of positive control DNA to each sample, in duplicate. The limit of detection was 0.01% or 10 copies and positive control DNA was obtained from Eurofins GeneScan (www.genescan.de). PCR products were resolved by on a 2% agarose gel electrophoresis in TAE buffer [40 mM Tris-HCl, 40 mM acetic acid and 1 mM EDTA (pH8.0)] for approximately 25-30 min at 180 V, where-after it was visualized under UV

light after staining with 2.55 mM ethidium bromide for 10 min. The GelLogic200 (Kodak) image analysis system was used to visualize and photograph images of gels.

Table 5.8 Primers and probe sequences used to detect GM elements.

Element / Event / Gene	Primer name	5'–3' sequence	Size	Reference
35S	35S-F	CCACGTCTTCAAAGCAAGTGG	123 bp	ISO 21569:2005
	35S-R	TCCTCTCCAAATGAAATGAACTTCC		
NOS	NOS-F	GCATGACGTTATTTATGAGATGGG	118 bp	ISO 21569:2005
	NOS-R	GACACCGCGCGCGATAATTTATCC		
FMV	Proprietary information[1]			
DAS-591227	Proprietary information[1]			
T14	Proprietary information[1]			
MON863	Proprietary information[1]			
Bt10	Bt10-F	CACACAGGAGATTATTATAGGGTTACTCA	117bp	CRL, 2010
	Bt10-R	ACACGGAAATGTTGAATACTCATACTCT		
bar	bar-F	ACAAGCACGGTCAACTTCC	60 bp	Grohmann *et al*., 2009
	bar-R	GAGTGGACGGACGACCTC		
pat	Proprietary information[1]			
hmg	*hmg* -F	TTGGACTAGAAATCTCGTGCTGA	79 bp	ISO 21569:2005
	hmg-R	GCTACATAGGGAGCCTTGTCCT		
	hmg-Probe	CAATCCACACAAACGCACGCGTA		
lectin	lec-F	CCAGCTTCGCCGCTTCCTTC	74 bp	ISO 21569:2005
	lec-R	GAAGGCAAGCCCATCTGCAAGCC		
	lec-Probe	CTTCACCTTCTATGCCCCTGACAC		

[1] Eurofins Genescan (www.genescan.de)

5.2.5 Real-time PCR screening for genetic modification

Samples from crop types without regulatory approval, were screened using real-time PCR to determine crop types, maize and soybean, for which there are approved GM events in South Africa. Real-time PCR was performed using *hmg* (High Mobility Group) for maize and the *lectin* for soybean. Real-time PCR reagents supplied by Eurofins Genescan included positive controls from certified reference material (CRM) ERM-BF413-3 for maize and GTS 40-3-2 CRM ERM-BF410D for soybean (Table 5.8). Real-time PCR reactions were set up to a final reaction volume of 25 µl containing 5 µl sample DNA (5-20 ng/µl) and 20 µl reagent master mix supplied by the manufacturer (Eurofins Genescan). Real-time PCR reactions were run on an ABI7500 (Applera) according to the following cycling parameters, 10 min at 95ºC, followed by 45 cycles of 15 sec at 95ºC and 90 sec at 60ºC (ISO 21569:2005). The limit of detection was 0.01%. To minimize the risk of cross-contamination, individual steps were performed in separate work areas and blank and positive controls included with each reaction.

5.3 Results and discussion

5.3.1 Detection system for unapproved GM events

A screening system for illegal GMOs needs to be practical, cost effective and take the availability of commercialized global GM events into consideration as well as the regulatory status of GM events in a particular country. Although the detection system for unapproved GM events developed in this study is similar to those suggested by Reiting *et al*. (2010) and Waiblinger *et al*. (2010), there are specific differences. Firstly,

the previously published detection scheme by Reiting *et al*. (2010) is only for GM rice while that of Waiblinger *et al*. (2010) includes crop types such as canola, cotton, maize, potato, papaya, soybean, sugar beet and tomato. The problem with the latter is that GM crop types such as potato, sugar beet, tomato and papaya are not produced in considerable amounts commercially and/or relevant to South Africa, and testing these crops may therefore add unnecessary cost to monitoring. Secondly, the published schemes do not take into consideration that crop types for which there are no approved GM events, can become co-mingled with approved GM crop type such as maize or soybean.

The current scheme is based on screening for GM regulatory elements to firstly establish the presence of genetic modification (Figure 5.1). This first step is to identify GM positive products by testing for the minimum number of regulatory elements present in the largest number of GM events, taking the extent of commercial production into account. To achieve this, PCR screening was performed for 35S and NOS in order to detect GM canola, maize, rice, soybean and/or wheat (Tables 5.4. to 5.7). Additional GM screening was performed for FMV in canola and soybean products taking the global status of commercial GM events for these crops into consideration (Table 5.3). The advantage of this process is that it eliminates products that are GM negative for further testing. A disadvantage of any detection scheme is that it is possible that unknown GM events may not necessarily contain these common GM elements and will not be detected. Unfortunately, the latter problem is without solution. Thus, the initial step to determine the presence of genetic modification in the products being tested reduces the amount of testing required and minimizes cost.

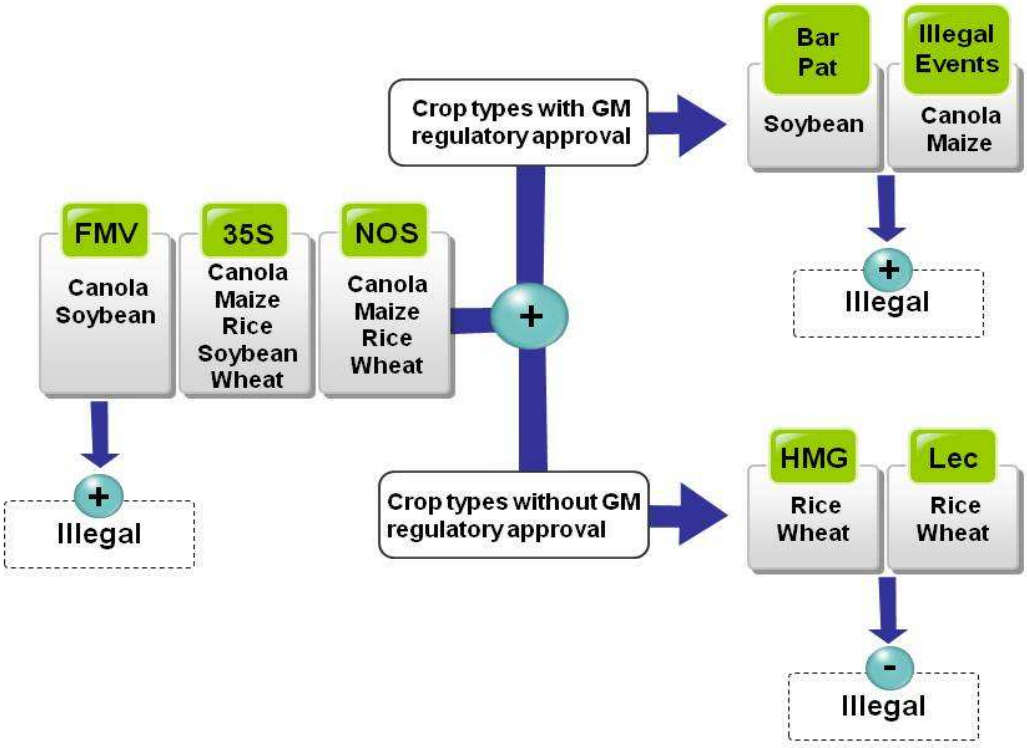

Figure 5.1 Schematic for the detection of unapproved GM events in South Africa. The first step is to identify the GM positive products by testing for the regulatory elements common to the largest number of GM events per crop type. In South Africa, these elements are FMV, 35S and NOS. The presence of FMV in canola and soybean would immediately be categorized as an illegal GM event. All other crop products positive for 35S and NOS are screened according to the regulatory status of the specific crop type. The presence of *bar* and *pat* in soybean indicates an illegal event. Illegal event specific detection is necessary for maize and canola products, depending on the approval status in each country. Products from crop types without GM regulatory approval are screened with crop type specific genes, in order to eliminate the presence of approved GM crop types as a result of co-mingling. If approved crop types are not present in such products then the GMO can be considered as illegal. The presence of trace amounts of approved GM crop can be confirmed through crop type and event specific testing.

After determining the presence of genetic modification in a product, it is further analyzed according to the regulatory status of GM events in terms of crop type (Figure 5.1). However, the more GM events that have regulatory approval for a particular crop type, the more difficult and costly it becomes to determine the presence of illegal GMOs, since more event specific GM screening is required. This is a very important consideration, since screening samples for the presence of unapproved GM events becomes more difficult as more GM events receive regulatory approval. For example, the detection of any genetic modification in wheat or rice in South Africa would indicate the potential presence of an illegal GMO since no events for these crop types have received regulatory approval (Table 5.7). In comparison, there are several approved GM maize events and the detection of GM maize needs to be followed by extensive event specific detection to determine the presence of unapproved GMOs. A further important consideration for crops types without approved events is the presence of approved GM events as a result of co-mingling during storage or transport. Thus, putative positive results for crops that have no GM events with regulatory approval needs to be confirmed by eliminating the presence of other approved GM crop types using crop specific screening.

The detection of illegal GM events is particularly difficult in crop types for which there are approved GM events such as maize, soybean and canola in South Africa (Table 5.2. to 5.4. and 5.6). For example, the presence of 35S and NOS in maize and soybean would not necessarily indicate the presence of an unapproved GM event due to the presence of these constructs in approved events. Thus in order to identify illegal GM events in crop types, for which there are GM events approved by the regulatory system, event specific screening for unapproved events or gene specific screening (*bar*

and *pat*) has to be performed on GM positive products. The complexity of this problem was the major motivation for not selecting food products with more than one GM crop type as ingredient.

5.3.2 The application of a detection system for unapproved GMOs in South Africa

To test the detection system, a total of three canola, 12 maize, 32 rice, 31 soybean and 16 wheat food products were screened using the least amount of GM regulatory and gene sequences required to detect the widest range of GM events also taking crop type into consideration (Tables 5.3. to 5.7). Of these, eight maize, two rice, 15 soybean and two wheat samples tested GM positive and were subjected to further testing depending on the crop type as well as the regulatory approvals for that specific crop (Figure 5.1) (Tables 5.9. to 5.13).

Table 5.9 Screening results for canola products.

Product name	Product description	35S	NOS	FMV
Canola oil	Canola oil	-	-	-
Canola cooking and salad oil	Canola oil	-	-	-
Every day canola oil	Canola oil	-	-	-

Table 5.10 Screening results for maize products with generic and event specific GM elements.

Product name	Product description	35S	NOS	FMV	T14	DAS-59122-7	Bt10	MON863
Coarse maize grits	Raw white maize	+	+	-	-	-	-	-
Maize meal 1	Raw white maize	+	+	-	-	-	-	-
Maize meal 2	Raw white maize	+	+	-	-	-	-	-
Instant maize meal 1	Raw white maize	+	+	-	-	-	-	-
Yellow Maize Meal	Raw yellow maize	+	+	-	-	-	-	-
Instant maize meal 2	Raw white maize	+	+	-	-	-	-	-
Polenta	Raw yellow maize	+	+	-	-	-	-	-
Corn pasta	Processed maize	-	-	n/a	n/a	n/a	n/a	n/a
Corn thins	Processed maize	-	-	n/a	n/a	n/a	n/a	n/a
Corn flakes 1	Processed maize	-	-	n/a	n/a	n/a	n/a	n/a
Corn flakes 2	Processed maize	-	-	n/a	n/a	n/a	n/a	n/a
Corn flakes 3	Processed maize	+	+	-	-	-	-	-

Table 5.11 Screening results of rice products for generic GM elements and crop specific elements.

Product name	Product description	35S	NOS	*bar*	*hmg* (maize)	*lectin* (soybean)
Long grain white rice	Raw rice	-	-	n/a	n/a	n/a
Long grain rice 1	Raw rice	-	-	n/a	n/a	n/a
Long grain rice 2	Raw rice	-	-	n/a	n/a	n/a
Parboiled rice	Raw rice	-	-	n/a	n/a	n/a
Long grain rice 3	Raw rice	-	-	n/a	n/a	n/a
White rice 1	Raw rice	-	-	n/a	n/a	n/a
White rice 2	Raw rice	-	-	n/a	n/a	n/a
Long grain rice 4	Raw rice	-	-	n/a	n/a	n/a
White rice 3	Raw rice	-	-	n/a	n/a	n/a
Rice flour 1	Raw rice flour	-	-	n/a	n/a	n/a
Rice flour 2	Raw rice flour	-	-	n/a	n/a	n/a
Rice milk powder 1	Processed rice	+	+	-	-	+[1]
Rice milk powder 2	Processed rice	+	+	-	-	+[1]
Rice milk liquid	Processed rice	-	-	n/a	n/a	n/a
Rice crumbs	Processed rice	-	-	n/a	n/a	n/a
Rice pasta spirals	Processed rice	-	-	n/a	n/a	n/a
Rice pasta	Processed rice	-	-	n/a	n/a	n/a
Noodles	Processed rice	-	-	n/a	n/a	n/a
Instant noodles	Processed rice	-	-	n/a	n/a	n/a
Vermicelli	Processed rice	-	-	n/a	n/a	n/a
White rice cake	Processed rice	-	-	n/a	n/a	n/a
Rice cakes 1	Processed rice	-	-	n/a	n/a	n/a
Rice cakes 2	Processed rice	-	-	n/a	n/a	n/a
Rice cakes 3	Processed rice	-	-	n/a	n/a	n/a
Rice cakes 4	Processed rice	-	-	n/a	n/a	n/a
Rice cakes 5	Processed rice	-	-	n/a	n/a	n/a
Rice cakes 6	Processed rice	-	-	n/a	n/a	n/a

Table 5.11 (Continued)

Product name	Product description	35S	NOS	*bar*	*hmg* maize	*lectin* Soybean
Puffed rice	Processed rice	-	-	n/a	n/a	n/a
Popped rice 1	Processed rice	-	-	n/a	n/a	n/a
Popped rice 2	Processed rice	-	-	n/a	n/a	n/a
Popped rice 3	Processed rice	-	-	n/a	n/a	n/a
Popped rice 4	Processed rice	-	-	n/a	n/a	n/a

[1] Presence of soybean event GTS 40-3-2 (Roundup Ready) confirmed.

Table 5.12 Screening results of soybean products for generic GM elements and genes.

Product name	Product description	35S	FMV	*bar*	*Pat*
Soybean milk 1	Soybean milk liquid	-	-	n/a	n/a
Soybean milk 2	Soybean milk liquid	-	-	n/a	n/a
Soybean milk 3	Soybean milk liquid	-	-	n/a	n/a
Soybean milk 4	Soybean milk liquid	+	-	-	+[1]
Soybean milk 5	Soybean milk liquid	-	-	n/a	n/a
Soybean milk 6	Soybean milk liquid	-	-	n/a	n/a
Soybean milk 7	Soybean milk liquid	-	-	n/a	n/a
Soybean milk powder 1	Soybean milk powder	-	-	n/a	n/a
Soybean milk powder 2	Soybean milk powder	-	-	n/a	n/a
Soybean milk powder 3	Soybean milk powder	+	-	-	-
Soybean milk powder 4	Soybean milk powder	+	-	-	-
Tofu 1	Soybean curd	+	-	-	-
Tofu 2	Soybean curd	+	-	-	-
Soybean paste 1	Soybean paste	-	-	n/a	n/a
Soybean paste 2	Soybean paste	-	-	n/a	n/a
Soybean sauce 1	Soybean sauce	-	-	n/a	n/a
Soybean sauce 2	Soybean sauce	-	-	n/a	n/a
Soybean sauce 3	Soybean sauce	-	-	n/a	n/a

Table 5.12 (Continued)

Product name	Product description	35S	FMV	*bar*	*Pat*
Soybean sauce 4	Soybean sauce	-	-	n/a	n/a
Soybeans	Raw Soybeans	+	-	n/a	n/a
Soybean lecithin granules 1	Soybean lecithin	-	-	n/a	n/a
Soybean lecithin granules 2	Soybean lecithin	-	-	n/a	n/a
Lecithin granules	Soybean lecithin	+	-	-	-
Soybean flour 1	Soybean flour	+	-	-	-
Soybean flour 2	Soybean flour	+	-	-	-
Soybean flour 3	Soybean flour	+	-	-	-
Soybean flour 4	Soybean flour	+	-	-	-
Soybean mince 1	Dried soybean mince	+	-	-	-
Soybean chunks	Dried soybean mince	+	-	-	-
Soybean mince 2	Dried soybean mince	+	-	-	-
Soybean nuggets	Dried soybean mince	+	-	-	-

[1] The presence of the *pat* gene indicates the presence of the following GM soybean events, A2704-12, A2704-21, A5547-35 and A5574-127.

Table 5.13 Screening results of wheat products for generic GM elements.

Product name	Product description	35S	NOS	*hmg* maize	*lectin* Soybean
Cake flour 1	Wheat flour	-	-	n/a	n/a
Cake flour 2	Wheat flour	-	-	n/a	n/a
Cake flour 3	Wheat flour	-	-	n/a	n/a
Whole-wheat couscous	Processed wheat	-	-	n/a	n/a
Couscous 1	Processed wheat	-	-	n/a	n/a
Couscous 2	Processed wheat	-	-	n/a	n/a
Bran flakes 1	Processed wheat	-	-	n/a	n/a
Bran flakes 2	Processed wheat	-	-	n/a	n/a
Wheat cereal	Processed wheat	-	-	n/a	n/a
Instant noodles	Processed wheat	+	+	-	+[1]
Spaghetti	Processed wheat	+	+	-	+[1]
Pasta shells	Processed wheat	-	-	n/a	n/a
Penne rigate	Processed wheat	-	-	n/a	n/a
Macaroni	Processed wheat	-	-	n/a	n/a
Elbow macaroni	Processed wheat	-	-	n/a	n/a
Rigatoni	Processed wheat	-	-	n/a	n/a

[1] Presence of soybean event GTS 40-3-2 (Roundup Ready) confirmed.

The only products containing canola as a single crop ingredient available in South Africa was canola oil. The efficacy of extracting DNA from oil was evaluated by Consolandi *et al*. (2008), who compared the extraction method using hexane with three other commercial oil extraction methods. It was found that the method using hexane yielded comparable amounts of DNA to other methods (Consolandi *et al*., 2008). Canola products were screened using 35S, NOS and FMV since the combination of these elements would detect 11 of the 12 GM canola events currently commercialized globally (Table 5.3). *Bar* and *pat* sequences could also be used to screen for the presence of genetic modification in canola. However, since canola events approved in

South Africa for use as a commodity, Ms1 x Rf1, Ms1 x Rf2 and Ms8 x Rf3 as well as Topaz 19/2, contain *bar* and *pat,* these genes were excluded from the detection scheme. No genetic modification was detected in the canola oil and so no additional testing was performed. If genetic modification had been detected in the canola oil, event specific screening for illegal GM canola events would have had to be performed.

Of the 12 maize products screened, 8 of these were positive for 35S and NOS (Table 5.10). This was expected given the commercial production of more than 50,000 ha of GM maize in South Africa, that includes MON810, NK603, BT11 and NK603 x MON810 (James, 2009). Thus, based on the extent of approved GM events containing 35S and NOS in South Africa, it would be necessary to perform event specific detection for up to 26 GM events for each product, in order to detect unapproved GM events (www.cera-gmc.org). Since this is very costly, it was decided to eliminate possible illegal GM events, based on the reporting of unapproved GM events in Europe as well as GM production in the country of import, by making use of additional FMV screening, to identify MON89034, combined with event specific detection of T14, DAS-591227, MON863 and Bt10 (Table 5.4). No unapproved GM events were detected in the maize products but it must be noted that only exhaustive GM event screening would be able to exclude all possible unapproved GM events, which becomes increasingly costly as the number of events for a particular crop type increases. In such cases, it may be more feasible to access information from communication systems reporting the presence of unapproved GMOs such as the Rapid Alert System for Food and Feed (RASFF) used in the EU (http://ec.europa.eu/food/food/rapidalert/index_en.htm). Unfortunately, such alert

systems only report of the detection of unapproved GM events in the EU and this may not be applicable to all countries.

It is possible to detect all commercial GM rice events based on the presence of 35S and NOS (Table 5.5). Furthermore, since no GM rice events have been approved in South Africa, the presence of any GM rice can be considered illegal. Two of the 32 rice products tested positive for both 35S and NOS. The products in question were both rice milk (Table 5.11). However, as noted previously, it is possible that the presence of genetic modification in the rice may be the result of another GM crop type (Figure 5.1). As a result, additional testing for maize and soybean was conducted on the rice products and they were found to test positive for *lectin*, indicating the presence of soybean (Table 5.11). The presence of GM soybean was further confirmed by event specific screening for event GTS 40-3-2 (Roundup Ready GM soybean) that was present in trace amounts (data not shown). The presence of trace amounts of GM soybean could be due to co-mingling during storage, transport or production.

Of the 31 soybean products screened with 35S and FMV, 15 tested positive for 35S (Table 5.12). This was expected since approximately 85% of soybean production in South Africa is estimated to be GM (James, 2009). The GM positive samples were further tested for the presence of *bar* and *pat* (Table 5.6). *Pat* was detected in one of the soybean milk products, indicating the potential presence of one the following GM soybean events, A2704-12, A2704-21, A5547-35 and/or A5574-127 (Table 5.12). Since A2704-12 is a GM soybean event approved in South Africa for commodity clearance, the only way to exclude other events containing the same regulatory

sequences and genes, as A2704-21, A5547-35 and A5574-127, would be to perform event specific detection (Table 5.2). However, although soybean event A2704-12 has approval as a commodity, it must be imported with a permit from the Department of Agriculture Forestry and Fisheries. There has been no permit issued for the import of GM event A2704-12 since 2001 and it appears that this event has been imported illegally (DAFF, 2010b).

Of the 16 wheat products tested in this study, a sample of noodles and pasta, produced in China and South Africa, respectively, screened positive for 35S (Table 5.13). Although no GM wheat events have been approved in South Africa, considering that South Africa imports 464,184 tonnes of wheat annually from the USA, the incidence of the accidental import of GM wheat may be possible (FAO, 2010). The only GM wheat event, MON71800, approved for use as food and feed in the USA, contains the 35S promoter and the NOS terminator (Table 5.7). In addition, several GM events developed in Canada, that do not contain either 35S or NOS, were excluded from this study since they are not produced commercially (personal communication). Because of the possible contamination of wheat with GM maize and/or soybean, the presence of 35S does not necessarily indicate the presence of an illegal GM event. The GM positive samples were screened according to the detection scheme for the presence of *lectin* for soybean and *hmg* for maize. Even though, soybean was not indicated in the ingredients list, It was found that soybean was present in both GM positive samples and the presence of GM soybean event GTS 40-3-2 (Roundup Ready soybean) was confirmed. The presence of GM soybean in the wheat products may be the result of co-mingling during storage, transportation or processing.

5.4 Conclusion

In addition to approved GM activities in a particular country, there is the possibility of exposing the food chain to illegal events through the import of commodities, especially major GM crop types including canola, cotton, maize and soybean, as well as rice and wheat. Thus it is important that countries monitor for the presence of unapproved GMOs to prevent contamination of the food chain, in terms of regulatory requirements, as well as to ensure compliance with obligations under the Biosafety Protocol. Monitoring for unapproved GMOs, in a specific crop type, is relatively simple if no GM events have been approved. However, the situation becomes more complex and costly, once GM events have received approval. Considering global developments in genetic engineering, the number of GMOs released into the environment will continue to increase and with it the complexity of detecting illegal GM events, especially since new genetic elements are being used in conjunction with existing ones. Despite this, monitoring for unapproved GM events should be performed since these have not been shown to be safe for human health and/or the environment.

The scheme presented in this study for the detection of unapproved GM events in canola, maize and soybean, as well as rice and wheat, is also applicable to other countries. The scheme initially screens for regulatory sequences present in most GM events, taking crop type into consideration (Figure 5.1). This system is cost effect since it excludes GM negative samples from further analysis. Where genetic modification is detected in crop types without regulatory approval, the possibility of co-mingling with approved GM crop types must be determined through the use of crop specific assays. The second step of the detection scheme for positive GM samples

combines the use of GM gene and event specific detection. This step is particularly useful for monitoring for the presence of unapproved GM events in countries such as South Africa, where a number of GM events have already been approved. One further advantage of this approach is that it can be adjusted according to the approval status of GM events in a particular country.

In this study, 94 off-the-shelf products were tested for the presence of unapproved GM events. Products with ingredients from more than one crop type, for which a GM equivalent exists, were excluded, due to the difficulty of distinguishing these from each other without the need to perform up to 65 GM event specific tests on each product (based on the number of global GM events approved in major crops such as canola, cotton, maize and soybean, as well as rice and wheat). A potential illegal import of GM soybean event A2704-12 was found in soybean milk powder. While the event in question is approved, the import is illegal since no recent permits were granted. Furthermore, the regulatory system in South Africa makes no provision for the import of GM events in processed food products. This suggests that the current regulations for and monitoring of imported food products may not be sufficient to prevent the illegal import of GMOs in South Africa.

Monitoring the food chain for unapproved GM events has become an important consideration to ensure regulatory compliance as well as ensure food safety by not allowing unapproved GM events to enter the food chain (Anklam *et al*., 2002). However, although monitoring of unapproved GMOs in the food chain is a difficult task that is not expected to become easier, it is possible to manage this process in a cost effect manner. Finally, despite the best efforts to monitor for the presence of

unapproved GMOs in the food chain, it must be noted that no scheme can detect GM events that use hitherto unknown genetic elements. In this regard, reporting networks such as the RAFF can also be used to trigger GM event specific monitoring when necessary.

CHAPTER 6

GENERAL DISCUSSION AND CONCLUSION

At the time the research for this thesis was initiated, there was no information regarding the extent of genetic modification in the food chain even though genetically modified organisms (GMOs) had been grown commercially in South Africa since 1996. It was assumed that little genetic modification was in the food chain since production levels were below 50% and it was thought that most genetically modified (GM) production was for animal feed. There was also very little or no consideration of mandatory GM labelling at that time in South Africa. However, the first study determined that a considerable amount of GM crop was present in the food chain (Chapter 2). Additionally, genetic modification was also detected in food products labelled to indicate an absence of genetic modification in a preliminary study to determine the application of voluntary GM labelling in South Africa.

Based on results from the first study (Chapter 2), it was decided to focus on the efficacy of using voluntary GM labelling with South Africa as a case study since it is often argued that mandatory GM labelling does not provide consumers with choice and can result in consumers having a negative perception of genetic modification (Chapter 3). The effect of sampling in terms of product batches was also investigated to determine product consistency in terms of GM content. From this research it was concluded that voluntary GM labelling in South Africa was not successful in providing discerning consumers with a choice between GM and non-GM food products and was

instead resulting in consumers being misled. It was also found that considerable differences existed between product batches in terms of GM content and this is an indication that companies are not applying sufficient measures in order to consistently maintain the non-GM status of their products. From producer and retailer comments in both of the studies (Chapters 2 and 3), it was clear that in the absence of regulations, there was an inconsistent application of GM labelling by companies. These studies (Chapters 2 and 3) were used to inform discussions between 2006 and 2008 on GM labelling in South Africa among stake holders, the result of which was a decision to include mandatory GM labelling in the Consumer Protection Act 68 of 2008. The inclusion of mandatory GM labelling can be considered a major victory for consumer rights.

After the inception of the Consumer Protection Act of 2008 and the consequent requirement for mandatory GM labelling in SA, it became apparent that there was as uncertainty as to how this would affect the food industry. As a result it was decided to determine to what extent food products, especially for maize and soybean or ingredients thereof, would be impacted and require GM labelling. Results have shown that as expected most maize and soybean products or ingredients thereof will have to be labelled for GM content (Chapter 4). It has also been shown that the use of either a 1% or 5% threshold does not make a considerable difference in terms of the number of products implicated. Thus, a higher percentage threshold will not make any difference in the obligation of the food industry to label products or ingredients for GM content. Therefore, a 1% threshold should rather be used since this is in line with international developments and is currently the level used to certify non-GM products

for export – and will have the least impact on the export market compared to the use of a 5% threshold.

However, there are several considerations that the draft regulations for mandatory GM labelling appear not to have addressed. For example, third party validation of GM labelling is not required. This implies that companies would have to take measures to ensure the validity of product labels in terms of GM content themselves, or consumers or consumer groups would have to become responsible for policing the application of GM labelling. Additionally, although no exclusion criteria are specified by the draft regulations, by implication only packaged goods containing approved GM crop types are included. This means that no undue responsibility will be placed on the informal food sector to label GM food, since their products are not packaged. The draft regulations also make no reference to the additional use of terms such as “GM free”, “Non GM” or “Organic” and instead it is suggested that the label “Genetically modified content is below 5%” be used.

The final research chapter investigates the challenge of monitoring the food chain for unapproved or illegal GM events since these may hold unknown health risks for consumers (Chapter 5). A scheme to detect the presence of unapproved GM events has been developed for the major GM crops including canola, maize, rice, soybean and wheat. The scheme also takes into consideration the fact that a country similar to South Africa has approved GM events. The detection scheme for unapproved GM events is designed to be cost effective and can be used as a blue print to monitor the food chain for illegal GMOs in other countries. However, any detection scheme is only as effective as the implementation thereof. Unfortunately in South Africa there is no

regulatory monitoring for unapproved GMOs in the food chain and it is inevitable, given international GM developments and production, that consumers in South Africa will be exposed to unapproved GMOs.

In conclusion, although mandatory GM labelling has now become a reality, the results presented in this thesis have shown that in general South Africa has little experience in dealing with GM labelling. Since there is no external policing of the Consumer Protection Act, consumers and consumer groups will need to perform a watchdog role to ensure compliance, especially for GM labelling to indicate the absence of genetic modification below the specified threshold. Since there is currently no regulatory monitoring of the food chain for illegal GMOs, it is expected that consumers in South Africa will at some point be exposed to unapproved GM events that have not been shown to be safe for human consumption. However, the research presented has demonstrated that although monitoring for unapproved GMOs can be challenging, it is nevertheless achievable. Thus, with the necessary resources and regulatory support, regular monitoring could be performed in a cost effective manner to safe guard the food chain against unnecessary exposure to unapproved GM events.

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SUMMARY

Globally, South Africa is the eighth largest producer of GM crops and also imports GM food. In addition to the promise of increased agricultural production, the introduction of GM crops is also having an impact on society in terms of consumer acceptance and trade. As a result, most countries manage GMOs in terms of development, use and application as well as require mandatory GM labelling for consumer preference. With an increase in GM developments, monitoring the food chain in terms of GM labelling and unapproved GM events will continue to pose a regulatory challenge.

The aims of this thesis were the following:

1. To determine the uptake of GM food into the food chain;
2. To study the application of voluntary GM labelling;
3. To investigate the impact of mandatory GM labelling; and
4. To establish a monitoring system to detect illegal GMOs in South Africa.

Until 2005 it was assumed that there were only low levels of GM crop in the food chain, based on production volumes. However, results from this thesis have shown that 76% of food products tested positive for the presence of GM in 2005. There was also no consideration of mandatory GM labelling as it was thought that voluntary GM labelling was successfully being applied in South Africa. Despite this, 31% of products labelled to indicate an absence of GM, such as “GMO free”, “non-GM” and “organic”, contained genetic modification above 1%, and 20% of these contained more than 5% genetic modification. These results demonstrated the extent of GM in the food chain

in South Africa and highlighted the fact that voluntary GM labelling does not protect consumers against misleading claims.

In 2008, the Consumer Protection Act mandated the labelling of GM in food products and ingredients. However, there was a lot of uncertainty as to how this would impact the food industry. The subsequent research on the impact of mandatory GM labelling in South Africa determined that 67% of maize and 54% of soybean products will have to be labelled for GM content. In addition to this, GM was also detected in 50% of products labelled to indicate an absence of GM. Furthermore, results indicated that the use of either a 1% or 5% threshold does not make a considerable difference in terms of the number of products implicated. The use of the term “may contain genetic modification” as suggested by draft regulations to the Consumer Protection Act may provide a cost effective manner in which GM labelling can be applied in a developing country similar to South Africa, as it would reduce costs in terms of GM detection. The draft regulations for the Consumer Protection Act also make provision to indicate the absence of GM below a threshold that does not included terminology such as ”GMO free” or “non-GM”. Furthermore, the draft regulations do not require third party verification and compliance will mainly be self-regulating. The implication of this is that consumers or consumer groups will become responsible for policing the application of GM labelling in South Africa.

Finally, this thesis presents a GM monitoring scheme for unapproved GMOs, that have not been proven safe for human health and/or the environment. The scheme has the advantage of being cost effective and can be applied to the regulatory situation in any country, taking approved GM events into consideration. The scheme

was applied to off-the-shelf food products in South Africa to determine the presence of illegal GMOs. Even though no unapproved GM events were detected, a potential illegal import of GM soybean event A2704-12 was found. It was also found that an approved GM soybean event was comingled with rice and wheat products, although not indicated in the ingredients.

The research emanating from this thesis has contributed to inform discussions that have resulted in the inclusion of mandatory GM labelling in the Consumer Protection Act 68 of 2008. It is hoped that the research on the application of mandatory GM labelling and the monitoring for unapproved GM events in the food chain will have a similar impact on the regulatory system in South Africa.

OPSOMMING

Wêreldwyd is Suid-Afrika die agtste grootste produsent van geneties gemodifiseerde (GM) gewasse en voer ook GM-voedsel in. Tesame met die belofte van verhoogde landbouproduksie het die bekendstelling van GM-gewasse ook ’n impak op die samelewing in terme van verbruikeraanvaarding en handel. Die gevolg is dat die meeste lande geneties gemodifiseerde organismes (GMO’s) in terme van ontwikkeling, gebruik en toepassing bestuur, asook die verpligte GM-etikettering vir verbruikersvoorkeur. Met ’n toename in GM-ontwikkelings sal die monitering van die voedselketting in terme van GM-etikettering en onwettige GM-gewasse ’n toenemend regulatoriese uitdaging bied.

Die doelwitte van hierdie proefskrif was die volgende:

1. Om ’n opname van GM-voedsel in die voedselketting te bepaal;
2. Om die toepassing van vrywillige GM-etikettering te bepaal;
3. Om die impak van verpligte GM-etikettering te ondersoek; en
4. Om ’n moniteringsisteem daar te stel om onwettige GMO’s in Suid-Afrika te bespeur.

Tot en met 2005 was dit aanvaar dat daar slegs lae vlakke van GM-gewasse in die voedselketting teenwoordig is, gebaseer op produksievolumes. Die resultate van hierdie tesis het egter getoon dat 76% van voedselprodukte in 2005 positief vir die teenwoordigheid van GM getoets het. Daar was ook geen oorweging van verpligte GM-etikettering nie, aangesien daar aanvaar is dat vrywillige GM-etikettering

suksesvol in Suid-Afrika toegepas is. Ten spyte hiervan het 31% van produkte geëtiketteer om die afwesigheid van GM aan te dui, soos “GMO-vry”, “nie-GMO” en “organies”, genetiese modifikasie van meer as 1%, en 20% van produkte het meer as 5% genetiese modifikasie bevat. Hierdie resultate het die omvang van GM in die voedselketting in Suid-Afrika gedemonstreer, en die feit uitgelig dat vrywillige GM-etikettering in Suid-Afrika nie verbruikers teen misleidende aannames beskerm nie.

In 2008 het die Wet op die Beskerming van Verbruikers die etikettering van GM in voedselprodukte en bestanddele verpligtend gemaak. Daar was egter baie onsekerheid oor hoe dit die voedselindustrie sou beïnvloed. Die resulterende navorsing oor die impak van verpligte GM-etikettering in Suid-Afrika het bepaal dat 67% van mielies en 53% van sojabone vir GM-inhoud geëtiketteer sal moet word. Tesame hiermee was GM ook in 50% van produkte gevind wat geëtiketteer is om die afwesigheid van GM aan te dui. Voorts het resultate aangedui dat die gebruik van hetsy ’n 1%- of ’n 5%-drempel nie ’n beduidende verskil maak in terme van die hoeveelheid produkte geïmpliseer nie. Die gebruik van die term “kan genetiese modifisering bevat” soos voorgestel deur die konsepregulasies tot die Wet op die Beskerming van Verbruikers kan ’n koste-effektiewe manier voorsien waarby GM-etikettering in ’n ontwikkelende land soos Suid-Afrika toegepas kan word, aangesien dit die koste van GM-bespeuring kan verminder. Die konsepregulasies vir die Wet op die Beskerming van Verbruikers maak ook voorsiening vir die aanduiding van die afwesigheid van GM onder ’n drumpel maar terminologie soos “GMO-vry” of “nie-GMO” word nie insluit nie. Voorts vereis die konsepregulasies nie derdeparty-verifiëring nie en gehoorgewing sal grootliks selfregulerend wees. Die implikasie

hiervan is dat verbruikers of verbruikersgroepe verantwoordelik sal word vir die polisiëring van die toepassing van GM-etikettering.

Laastens bied hierdie tesis ’n GM-moniteringskema vir onwettige GMO’s, wat nie as veilig vir menslike gesondheid en/of die omgewing bewys is nie. Die skema het die voordeel dat dit koste-effektief is en toegepas kan word op die reguleringsituasie in enige land, met inagneming van GM-gewasse. Die skema is op van-die-rak-af-produkte in Suid-Afrika toegepas om die teenwoordigheid van onwettige GMO’s te bepaal. Alhoewel geen ongoedgekeurde GM-gewasse gevind is nie, is ’n potensieel onwettige invoer van GM-sojaboongewas A2704-12 gevind. Dit is ook gevind dat ’n goedgekeurde GM-sojaboongewas met rys- en koringprodukte vermeng is, alhoewel dit nie in die bestanddele aangedui is nie.

Die navorsing voortspruitend uit hierdie tesis het bygedra om besprekings in te lig wat gelei het tot die insluiting van verpligte GM-etikettering in die Wet op die Beskerming van Verbruikers 68 van 2008. Daar word gehoop dat die navorsing oor die toepassing van verpligte GM-etikettering en die monitering van ongoedgekeurde GM-gewasse in die voedselketting ’n soortgelyke impak om die reguleringsisteem van Suid-Afrika sal hê.

APPENDIX A

The application of mandatory GM labelling **in terms of the Consumer Protection Act clause 24(6)** **(Please note: Your response will be treated anonymously)**		
Company	Contact	
Tel.	Fax.	
Email		
Please complete the following survey:		
1. Is your company aware of clause 24(6) of the Consumer Protection Act that mandates the labelling of GM content?	**YES**	**NO**
2. Do you perceive that clause 24(6) of the Consumer Protection Act will have any impact on :		
2.1. Consumers? (Please comment)		
_____ _____		
2.2. Industry? (Please comment)		
_____ _____		
3. How would your company prefer to apply clause 46(6) of the Consumer Protection Act, based on the results presented in this study?		
_____ _____		
4. Based on international applications of mandatory GM labelling we propose the following approach and request your comments thereof:		
4.1. A labelling system needs to fulfil the following criteria:		

4.1.1.The labelling system must be cost effective so as not to impact food prices negatively.	**YES**	**NO**
4.1.2.The labelling system must be simple and not require excessive policing.	**YES**	**NO**
4.1.3. The terminology used must not be confusing to consumers.	**YES**	**NO**
(Comments) _____ _____		

4.2. A GM labelling system should address the following consumer needs:		
4.2.1. Consumers who have the right to know whether the ingredients of a product are genetically modified, but that will not necessarily change their buying habits in terms of this knowledge.	**YES**	**NO**
4.2.2. Consumers who purposefully discern GM containing from non-GM containing products and whose preference is for non-GM.	**YES**	**NO**
(Comments) _____ _____		

4.3. In addition to mandatory GM labelling in terms of clause 46(6), provision should also be made to indicate an absence of GM content on packaging.	**YES**	**NO**
(Comments) _____ _____		

4.4. The following inclusion criteria should be applied for what should be regulated in terms of mandatory GM labelling:		
4.4.1. Ingredients, irrespective of the level of processing, of packaged goods for which a GM variety has been approved for release or commodity import under the GMO Act of 1997.	**YES**	**NO**
(Comments) _____ _____		

4.5. The following exclusion criteria should be applied to what is not regulated in terms of mandatory GM labelling:		
4.5.1. Animal feed.	**YES**	**NO**
4.5.2. Food products produced and sold within the informal sector, home industry, farmers markets, fresh produce markets, restaurants and fast food outlets. In these cases the product ingredients are usually not listed even though the goods may be packaged and consumers are able to enquire directly as to the GM content of the ingredients.	**YES**	**NO**
4.5.3. Animal products produced from animals fed GM grain.	**YES**	**NO**
4.5.4. Goods produced through the use of GM enzymes but where the product is not made up of GM ingredients.	**YES**	**NO**
4.5.5. Non food products.	**YES**	**NO**
(Comments) _____ _____ _____		
4.6. Terminology:		
4.6.1. “May be genetically modified” be used for all ingredients to which the inclusion criteria applies.	**YES**	**NO**
4.6.2. “Non-GM” to indicate the absence of GM in the ingredients of a product. “GM-Free” should be excluded, since it cannot be scientifically determined.	**YES**	**NO**
(Comments) _____ _____ _____		
4.7. Threshold levels:		
4.7.1. Any ingredient containing more that 1% GM content.	**YES**	**NO**
4.7.2. Or the assumption that the ingredient may contain GM based on the regulatory status of GM crop in terms of the GMO Act of 1997.	**YES**	**NO**

4.7.3. For the use of “non-GM” terminology, the product or ingredient must contain less than 1% GM content irrespective of the percentage the ingredient contributes to the final packaged product.	**YES**	**NO**
(Comments) _____ _____ _____		
4.8. Regulatory procedure for mandatory GM labelling:		
4.8.1. Any person who produces, supplies, imports or packages any prescribed goods, is required to indicate “May be genetically modified” if the ingredients or components thereof fall within the inclusion criteria irrespective of the level of processing.	**YES**	**NO**
4.8.2. No verification is required for the use of the term “May be genetically modified”	**YES**	**NO**
(Comments) _____ _____ _____		
4.9. Regulatory procedure for an exemption to mandatory GM labelling to indicate the absence of GM content in an ingredient:		
4.9.1. The producer, supplier, importer or packager wanting to indicate the absence of GM content would need to apply to the DTI for an exemption to the mandatory labelling system in terms of GM content.	**YES**	**NO**
4.9.2. The producer, supplier, importer or packager would have to produce verified evidence that the product may be exempted based on the GM content of the ingredient being less than 1%.	**YES**	**NO**
4.9.3. For processed products the producer, supplier, importer or packager must be able to show that the verification of the “non-GM” content is appropriate to the level of processing.	**YES**	**NO**
(Comments) _____ _____		
5. May your comments be included anonymously in a publication?	**YES**	**NO**