



african centre for biosafety

www.biosafetyafrica.net

The African Centre for Biosafety (ACB) is a non-profit organisation, based in Johannesburg, South Africa. It was established to protect Africa's biodiversity, traditional knowledge, food production systems, culture and diversity, from the threats posed by genetic engineering in food and agriculture. It has in addition to its work in the field of genetic engineering, also opposed biopiracy, agrofuels and the Green Revolution push in Africa, as it strongly supports social justice, equity and ecological sustainability.

The ACB has a respected record of evidence based work and can play a vital role in the agroecological movement by striving towards seed sovereignty, built upon the values of equal access to and use of resources.

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### 1. Introduction

Investigations conducted by the African Centre for Biosafety (ACB) during March 2012, have revealed that four sampled household food products have tested positive for genetically modified organisms (GMOs).

The ACB contracted an independent GMO testing facility to conduct several qualitative PCR screenings (GMO double screens). The Certificates of Analysis¹ show the following sample results:

Product	Species	Test Results	% GM given as a % of the total of that species
Futurelife Energy Meal	Maize	Transgenic DNA sequences characteristic for the 35S promoter of the Cauliflower Mosaic Virus (CaMV) detected.	100%
	Soybean	Transgenic DNA sequences characteristic for the CP4 EPSPS gene in soybean detected (GTS40-3-2).	36%
Impala maize meal	Maize	Transgenic DNA sequences characteristic for the 35S promoter of the Cauliflower Mosaic Virus (CaMV) detected.	66%
Wheat free Pronutro	Maize	Transgenic DNA sequences characteristic for the 35S promoter of the Cauliflower Mosaic Virus (CaMV) detected.	90%
	Soybean	Transgenic DNA sequences characteristic for the CP4 EPSPS gene in soybean detected (GTS40-3-2).	71%
Cerelac Honey (Nèstle)	Maize	Transgenic DNA sequences characteristic for the 35S promoter of the Cauliflower Mosaic Virus (CaMV) detected.	77%
	Soybean	Soybean not detected (ND)	ND

None of these products have been labelled in accordance with the requirements of the Consumer Protection Act<sup>2</sup> (CPA) and regulation 7 of the Consumer Goods Regulations<sup>3</sup>, and that as a consequence consumers are unable to make informed choices according to their individual wishes and needs.

In response, the Consumer Goods Council of South Africa (CGCSA), representing companies importing, producing, packing and supplying consumer goods in South Africa, issued a press statement on 14 March 2012. The statement acknowledged that the CGCSA's members are directly affected by regulation 7 of the Genetically Modified (GM) food labelling regulations, and advised that it had been seeking clarity on the issue. In particular, it was seeking clarity on whether its members are obliged to 'label only the four varietals of maize, cotton, soybean and rape seed (canola) according to the provisions or is the intention that they label even products of which these varietals or ingredients or components'.

The CGCSA stated that it has formally requested the National Consumer Commissioner's (NCC) office for clarification on these and other issues, but that no formal response had been received and that 'attempts to clarify these issues have been unsuccessful'. The CGCSA also states that, in response

to questions from the audience at the annual NCC conference in October 2011, the NCC had indicated that it would not enforce the CPA due to lack of clarity and unclosed loopholes. The CGCSA stated further that a Task Team had been appointed consisting of 'DTI, DAFF and DoH members' to clarify legal uncertainties and ambiguities, and that no response had been received.

### 2. What the law provides

### 2.1 Applicability of the GM labelling provisions of the CPA and Consumer Goods Regulations

#### (a) Legislative Context

(i) Consumer Protection Act

The CPA commenced on 31 March 2011.4 Amongst other things, the CPA contains provisions relating to labelling and trade descriptions for goods. Section 24(6) provides that 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 GM ingredients or components of those goods in accordance with applicable regulations. [own emphasis]

#### (ii) The Consumer Goods Regulations

On 1 April 2011, the Minister of the Department of Trade and Industry (DTI) promulgated the Consumer Goods Regulations in terms of section 120(1) of the CPA. Regulation 7 stipulates that the Consumer Goods Regulations apply to goods approved for commercialisation<sup>6</sup> by the Executive Council for GMOs.<sup>7</sup>

The regulation applies to all such goods which contain at least 5% of GMOs (irrespective of whether they were made or manufactured in the Republic or elsewhere), and to marketing material in respect of such goods. Such goods may not be produced, supplied, imported or packaged unless a notice meeting the requirements of section 229 of the CPA is applied to such good or marketing material, in a conspicuous and easily legible manner and size stating, without change, that the good or ingredient or component "contains Genetically Modified Organisms". Organisms". Organisms".

With regard to goods that are intentionally and directly produced using genetic modification processes, the goods or marketing material must be labelled, meeting the requirements of section 22 of the Act, without change, as "Produced using genetic modification"."

The regulations prohibit a section 22 notice from stating that a good or ingredient or component does not contain GMOs unless it contains less than 1% GMOs,<sup>12</sup> but may state that the level of GMOs contained is less than 5%.<sup>13</sup>

The regulations go on to provide that, if it is scientifically impractical or not feasible to test such goods for the presence of GMOs or ingredients, the section 22 notice must state in a conspicuous and easily legible manner and size that the goods "May contain genetically modified ingredients".<sup>14</sup>

The regulations came into effect six months after the commencement of the Act. <sup>15</sup> The CPA was assented to on 24 April 2009, and commenced on 31 March 2011. This means that the Consumer Goods Regulations came into effect on 1 October 2011.

(iii) National Consumer Commission Rules: Exemption Applications
Rules regulating the functions of the National Consumer Commission (NCC) have been promulgated in the Gazette. In addition to providing further details regarding procedural issues (including complaints) handled by the NCC, the regulations also stipulate procedures relating to exemption applications in terms of section 5(3) of the CPA. These relate to exemptions by the regulatory authority for an industry-wide exemption from one or more provisions of this Act on the grounds that those provisions overlap or duplicate a regulatory scheme administered by that regulatory authority in terms of any other national legislation; or any treaty, international law, convention or protocol.

Banks, the Pension Fund Industry, the Collective Investment Schemes Industry and the Security Services Industry have been exempted from various provisions of the CPA.<sup>17</sup> These do not relate to GMO labelling requirements.

A search of applicable legislation did not reveal any exemptions being granted in respect of GM labelling. Information provided by the ACB also supports a conclusion that no GM labelling exemptions have been applied for by the regulatory authority. In any event, the National Consumer Commission has been quoted in the Saturday Star as saying the following "the NCC has at no time given any person or entity an exemption from the compliance with the provisiosn of the GMO regulations. We actually do not have the authority to grant any such exemptions." 18

#### (b) Intepretation and analysis

It clear from the CPA that the labelling requirements apply to any person who produces, supplies, imports or packages prescribed goods. A notice (in the prescribed manner and form) must be displayed on the goods (or in association with the packaging of those goods) disclosing the presence of any GM ingredients or components of those goods in accordance with applicable regulations. Goods means, inter alia, "anything marketed for human consumption."

Regulation 7 of the Consumer Goods Regulations applies to goods containing GMOs approved for commercialisation by the Executive Council for GMOs. Although the term 'commercialisation' is not defined in the relevant legislation, the practise of the Executive Council: GMO Act in its decision making with regard to GMOs, refers to GMOs approved as commodity imports for food, feed and processing and GMOs approved for commercial cultivation and for placing on the market of such approved GMOs, as well as any product derived from such GMOs. This form of one stop approval of both the GMO and products thereof, is consistent with the provisions of the Cartagena Protocol on Biosafety as well as international biosafety best practise. Indeed, there is nothing in South Africa law, that requires that a GMO product needs to be individually and/ or separately approved from the GMO itself. The definition of "goods" in the CPA, also takes this into account. This is consistent with the intention and spirit of the legislation which is to provide consumers with accessible and transparent information concerning food they consume in the marketplace.

7(2) applies to all such goods containing 5% of GMOs irrespective of whether the goods were made or manufactured in South Africa or elsewhere. Section 24 (6) of the CPA is very clear as to the scope of the goods that must be labelled. It refers specifically to the disclosure of the presence of GM ingredients or components of GMOs and its products that have been approved by the EC, in terms of the GMO Act.

The CPA came into effect on 31 March 2011, and the Consumer Goods Regulations came into effect on 1 October 2011. A legislative search revealed no subsequent notices deferring the commencement date. While the CPA and the NCC Rules make provision for exemption applications by the regulatory authority, no evidence of any such exemption applications having been made or being granted, could be found.

In the circumstances, the labelling requirements are applicable to any GMOs approved as commodity imports or commercial growing in SA, where the presence of that genetically modified ingredient or component in food, is 5% or more.

It is an offence for any person to omit a labelling description without authority,<sup>19</sup> and any person convicted of an offence under the CPA is liable to a fine or to imprisonment for a period not exceeding 12 months, or to both a fine and imprisonment.<sup>20</sup>

#### 2.2 Remedies available to consumers in event of non compliance

#### (a) Legislative Context

#### (i) Consumer Protection Act

Section 4(1) provides that any of the following persons may approach a court, the tribunal or the Commission21 alleging that a consumer's rights in terms of the CPA have been infringed, impaired or threatened, or that prohibited conduct has occurred or is occurring:

- (a) a person acting on his or her own behalf;
- (b) an authorised person acting on behalf of another person who cannot act in his or her own name:
- (c) a person acting as a member of, or in the interest of, a group or class of affected persons;
- (d) a person acting in the public interest, with leave of the tribunal or court, as the case may be; and
- (e) an association acting in the interest of its members.

Section 69 of the CPA provides that a person contemplated in section 4(1) may seek to enforce any right in terms of this Act or in terms of a transaction or agreement, or otherwise resolve any dispute with a supplier, by:

- (a) referring the matter directly to the Tribunal, if such a direct referral is permitted by this Act in the case of the particular dispute;
- (b) referring the matter to the applicable ombud with jurisdiction, if the supplier is subject to the jurisdiction of any such ombud;
- (c) if the matter does not concern a supplier contemplated in paragraph (b):
  - (i) referring the matter to the applicable industry ombud, accredited in terms of section 82 (6), if the supplier is subject to any such ombud; or
  - (ii) applying to the consumer court of the province with jurisdiction over the matter, if there is such a consumer court, subject to the law establishing or governing that consumer court;

- (iii) referring the matter to another alternative dispute resolution agent contemplated in section 70; or
- (iv)filing a complaint with the Commission in accordance with section 71; or
- (d) approaching a court with jurisdiction over the matter, if all other remedies available to that person in terms of national legislation have been exhausted.

#### Commission

Section 71 provides that any person may file a complaint concerning a matter contemplated in section 69 (1) (c) (ii) or (2) (b) with the Commission in the prescribed manner and form, alleging that a person has acted in a manner inconsistent with this Act<sup>22</sup>. Section 71(2) provides that the Commission may directly initiate a complaint concerning any alleged prohibited conduct on its own motion, or (a) when directed to do so by the Minister in terms of section 86 (b); or (b) on the request of: a provincial consumer protection authority; another regulatory authority; or an accredited consumer protection group.

Section 72 deals with investigations by the Commission. The Commission is empowered to take various actions, including issuing a notice of non-referral to the complainant, referring the complaint for alternative dispute resolution, referring the complaint to another regulatory authority with jurisdiction, or in any other direct an investigator to investigate the complaint as quickly as practicable.<sup>23</sup>

After concluding an investigation, the Commission may issue a notice of non-referral to the complainant or refer the matter to the National Prosecuting Authority<sup>24</sup>. In the event that the Commission issues a notice of non-referral in response to a complaint, the complainant may refer the matter directly to the consumer court or the Tribunal (with leave of the Tribunal, and in the prescribed form). The exception to this is referral is refused on the grounds that the claim has prescribed.<sup>25</sup>

Alternatively, if the Commission believes that a person has engaged in prohibited conduct, the Commission can refer the matter to the equality court<sup>26</sup>, propose a draft consent order in terms of section 74, make a referral in accordance with section 73(2),<sup>27</sup> or issue a compliance notice in terms of section 100.<sup>28</sup>

#### **Tribunal**

As mentioned above, in terms of section 69 of the CPA a person may seek to enforce any right in terms of this Act or in terms of a transaction or agreement, or otherwise resolve any dispute with a supplier, by referring the matter directly to the Tribunal (provided that such a direct referral is permitted by this Act in the case of the particular dispute).

A complainant may (with leave of the Tribunal) refer a matter directly to the Tribunal in circumstances where the Commission has issued a notice of non-referral in response to a complaint (except where the matter has prescribed).<sup>29</sup>

Any such referral, as well as a referral by the Commission, must be in the prescribed form.<sup>30</sup> Various other provisions relating to the conduct of a hearing are prescribed in the CPA.<sup>31</sup>

#### Offences and Penalties

It is an offence for any person to omit a labelling description without authority.<sup>32</sup> It is also an offence to fail to act in accordance with a compliance notice.<sup>33</sup>

Any person convicted of an offence under the CPA is liable to a fine or to imprisonment for a period not exceeding 12 months, or to both a fine and imprisonment.<sup>34</sup>

The Tribunal is also empowered to impose an administrative fine in respect of prohibited or required conduct, which fine may not exceed the greater of 10 percent of the respondent's annual turnover during the preceding financial year, or one million rand.<sup>35</sup>

In the event that a complaint has been referred to the Tribunal, a complainant may apply to court or to the Tribunal for an interim order.<sup>36</sup>

#### (ii) The Consumer Goods Regulations

The CPA Regulations provide that, for the purposes of section 71(1) of the CPA, any person may submit:

- (a) information concerning an alleged contravention or instance of non-compliance in terms of or under these regulations to the Commission, in any manner or form; or
- (b) a complaint against an alleged contravention or instance of non-compliance in terms of or under these regulations to the Commission. The complaint must be submitted in the prescribed format (see Appendix A: Annexure E to the Consumer Goods Regulations), together with certified copies of any documents the Commission should consider. This form can be posted, hand-delivered, electronically filed or e-mailed (note: the delivery addresses are referred to but have not been included in the regulations). <sup>37</sup>

Upon the receipt of a complaint, the Commissioner is obliged to direct an inspector to investigate the complaint as quickly as practicable.<sup>38</sup> The Commission must (as often as may be reasonable) inform the complainant of progress or other developments in an investigation.<sup>39</sup> Upon completion of its investigation, the Commission must in writing inform the complainant of the outcome thereof and, if it is not taking the matter further, the reasons for its decision not to do so.<sup>40</sup>

In the event that the Commission considers a complaint to be frivolous or vexatious, or should the complaint not allege any facts which (if true) would constitute grounds for a remedy, or should the complaint have prescribed, the Commission may issue a 'notice of non-referral' advising that it will not refer the complaint.<sup>41</sup> The Commission may also issue a 'notice of non-referral' upon completion of the investigation.<sup>42</sup>

The Commission is also empowered to issue a 'compliance notice'.43

#### (iii) Final Enforcement Guidelines

Final Enforcement Guidelines have been published in the Gazette by the Commissioner of the NCC.<sup>44</sup> These guidelines relate to the internal enforcement functions of the Commission in order to give effect to the CPA. In terms of section 2.3 of Part A of the Guidelines, a complaint may be lodged against various classes of people, including an association or other collective, whether corporate or unincorporated, of persons voluntarily associated and organised for a common purpose or purposes. Part B of the Guidelines deals with complaints handling (including alternative dispute resolution and conciliation) and investigations, Part C deals with evidence and procedural fairness, while Part D deals with investigation case file review and audit processes.

#### (b) Interpretation and analysis

Provided that the content of any GM ingredient or component in any food is 5% or more, the appropriate remedy available is to submit a complaint to the Commissioner in the prescribed form (Appendix E to the Consumer Goods Regulations), alleging that there has been a contravention or instance of non-compliance under the Consumer Goods Regulations. Such complaints can be made by persons outlined in section 4(1) of the CPA against persons who produced, supplied, imported or packaged the goods containing GMOs in excess of the prescribed levels on or after 1 October 2011 without labelling.

Furthermore, in terms of section 2.3 of the Final Enforcement Guideline, a complaint may be lodged against an association or other collective of persons voluntarily associated and organised for a common purpose. Thus, consumers may also be be entitled to lodge a complaint against the CGCSA as the representative of companies importing, producing, packing and supplying consumer goods in South Africa.

Upon receipt of the complaint, the Commissioner will be obliged to direct an inspector to investigate the complaint, and will be required to inform the person complaining, in writing of the outcome thereof.

In the event that the Commission issues a notice of non-referral in respect of a complaint, the person compalining would be entitled (with leave of the Tribunal) to refer the matter directly to the Tribunal.

### 3. Conclusion

In conclusion, foodstuff containing 5% or more of a GM ingredient or component that is produced, supplied, imported, or packaged must labelled in a conspicuous and easily legible manner and size, stating that the good, ingredient or component "contains Genetically Modified Organisms". This requirement is applicable irrespective of whether the goods were made or manufactured in South Africa or elsewhere. Where a good, ingredient or component contains less than 5% GMOs, the notice can state that the level of GMOs is less than 5%. However, any good, ingredient or component containing less than 1% GMOs cannot be labelled as GMO free.

The CPA came into effect on 31 March 2011, and the Consumer Goods Regulations came into effect on 1 October 2011. No lawful exemption from these requirements has been applied for or is in place. The relevant provisions of the CPA and the Consumer Goods Regulations relating to labelling of GMO products are in force and should be complied with. Failure to do so is an offence.

Provided that the level of GMOs in the goods is 5% or more, the appropriate remedy to consumers is to submit a complaint to the Commissioner in the prescribed form (Appendix E to the Consumer Goods Regulations), alleging that there has been a contravention or instance of non-compliance under the Consumer Goods Regulations. A complaint could also be lodged citing the CGCSA as the respondent given that it is the representative of companies importing, producing, packing and supplying consumer goods in South Africa.

In order for a complaint to be successful, the following will have to be alleged and proven on a balance of probabilities that:

- (a) The GM food products in question have been produced, supplied, imported or packaged after the commencement of the Consumer Goods Regulations (i.e. 1 October 2011);
- (b) The GMOs detected in the food products in question have been approved for commercialisation by the Executive Council for GMOs;45
- (c) The products in question contain at least 5% GMOs; and
- (d) The products containing GM ingredients or components do not bear the notice 'contains Genetically Modified Organisms'.

### **Appendix A:**

### **Annexure E to the Consumer Goods Regulations**

Regulation 35

National Consumer Commission	
Form – Complaint – section 71 (1)	
Full names of complainant	
ID/Registration number of complainant	
Postal Address	
Physical Address	
Cell phone number	
Landline number	
Fax number	
E-mail address	
When is the best time to contact you, should this be necessary?	
Has the complainant previously filed a complaint with the NCC?	
If so, please provide the reference number	
Nature of complaint	
Provision of Consumer Protection Act or regulations promulgated under it or Code contravened (if known)	
Name of company or person against whom complaint is made	
Address of company or person against whom complaint is made	
Short description of complaint	

Details of steps taken to resolve the complaint	
List of documents relevant to complaint attached to this form	
What outcome do you propose for this complaint?	
Date	
Place	
Signature	
Office use only	
Reference number	

#### References

- 1 University of the Free State GMO *Testing Facility*, Certificate Numbers 12034926-1, 12034925-1, 12034923-1 and 12034924-1, all dated 12 March 2012.
- 2 68 of 2008.
- 3 GNR.293 of 1 April 2011.
- 4 In terms of GN917 of 23 September 2010, the Minister of Trade and Industry deferred the general effective date of the CPA until
- 5 'Prescribed' is defined as meaning 'determined, stipulated, required, authorised, permitted or otherwise regulated by a regulation made, or notice given, by the Minister in terms of this Act'.
- The term 'commercialisation' is not defined in the CPA, Consumer Goods Regulations, Genetically Modified Organisms Act 15 of 1997 (GMO Act, as amended) or in regulations made under the GMO Act (GNR.120 of 26 February 2010). 'Commodity clearance' is defined in the GMO Act as meaning the authorisation to use a GMO as a food or feed, or for processing, but excludes the planting of a GMO as a release into the environment. 'Conditional general release' is as defined as meaning a release of a GMO under specific imposed conditions to regulate or monitor the use of that genetically modified organism for a specified period of time. GMOs approved as food under a conditional general release approval and for import under a commodity clearance approval are listed in a table accessible online at: http://www.nda.agric.za/doaDev/sideMenu/biosafety/notifications. html#twelveth (last accessed 21 March 2012).
- 7 Regulation 7(2).
- 8 Regulaton 7(3)
- 9 Section 22 stipulates that the producer of *inter alia* a notice required in terms of the CPA (or any other law) must be produced, provided or displayed on that notice in the form prescribed or in plain language (if no form has been prescribed). The section goes on to specify requirements for determining whether a notice is in plain language, and provides further that the Commission may publish guidelines for assessing whether a notice satisfies these requirements.
- 10 Regulation 7(4).
- 11 Regulation 7(5).
- 12 Regulation 7(6).
- 13 Regulation 7(7).
- 14 Regulation 7(8).
- 15 Regulation 7(10).
- 16 GN489 of 3 June 2011.
- 17 GN 532 and 533 of 27 June 2011.
- 18 On the 24 February 2012, the Saturday Star reported the Commissioner's response as follows "Firstly, I have not sent out an official statement with respect to the GMO labelling. Secondly, with respect to the National Consumer Commission enforcement aspect, we are actually in discussions with the Department of Trade and Industry and have forwarded correspondence to the minister to ensure our interpretations of regualtions is correct, specifically whether the GMO give percent labelling requirement is to apply across the board irrespective of whether those goods are produced, supplied, imported or packaged locally or overseas. Once that clarity has been provided we will proceed to engage with industry and consumers to raise awareness and ensure complaince. Thirdly, the NCC has at no time given any person or entity an exemption from the compliance with the provisiosn of the GMO regulations. We actually do not have the authority to grant any such exemptions."
- 19 Section 110(1).
- 20 Section 111(1)(b).
- 21 The National Consumer Commission was established in terms of section 85 on 24 April 2010. In terms of subsections 99(b), (d) and (e), the Commission is responsible to enforce the CPA by receiving complaints concerning alleged prohibited conduct or offences, and dealing with those complaints in accordance with Part B of Chapter 3; investigating and evaluating alleged prohibited conduct and offences; and issuing and enforcing compliance notices.
- This section is confusing as there is no section 69 (1) (c) (ii) or (2) (b).
- 23 Section 72(1)(a) to (d).
- 24 Section 73(a) and (b).
- 25 Section 75.
- 26 As contemplated in section 10, if the complaint involves a matter in terms of Part A of Chapter 2.

- 27 The Commission may refer the matter: (a) to the consumer court of the province in which the supplier has its principal place of business in the Republic, if: (i) there is a consumer court in that province; and (ii) the Commission believes that the issues raised by the complaint can be dealt with expeditiously and fully by such a referral; or (b) to the Tribunal.
- 28 A section 100 **compliance notice** must set out, amongst other things, the provision of this Act that has not been complied with; details of the nature and extent of the non-compliance; any steps that are required to be taken and the period within which those steps must be taken; and any penalty that may be imposed if those steps are not taken. A compliance notice remains in force until it is set aside by the Tribunal (or a court upon a review of a Tribunal decision concerning the notice), or until the Commission issues a compliance certificate. If the requirements of a compliance notice have been satisfied, the Commission must issue a **compliance certificate**. If a person to whom a compliance notice has been issued fails to comply with the notice, the Commission may either apply to the Tribunal for the imposition of an **administrative fine**, or refer the matter to the National Prosecuting Authority for **prosecution** as an offence in terms of section 110 (2), but may not do both in respect of any particular compliance notice.
- 29 Section 75(1).
- 30 Section 75(2).
- 31 Section 75(3).
- 32 Section 110(1).
- 33 Section 110(2). However, no person may be prosecuted for such an offence in respect of the compliance notice if, as a result of the failure of that person to comply with that notice, the Commission has applied to the Tribunal for the imposition of an administrative fine.
- 34 Section 111(1)(b).
- 35 Section 112(1).
- 36 Section 114.
- 37 Regulation 35(1).
- 38 Regulation 35(3).
- 39 Regulation 35(5)(a).
- 40 Regulation 35(5)(b).
- 41 Section 72(1)(a) of the CPA, read with Regulation 36 and Annexure F.
- 42 Section 73(1)(a) of the CPA, read with Regulation 37 and Annexure G.
- 43 Section 100(1) of the CPA, read with Regulation 42 and Annexure L.
- 44 GN 492 of 25 July 2011: National Consumer Commission: Final enforcement guidelines, relating to the internal enforcement functions of the Commission in order to give effect to the Act.
- 45 In the event that the GMOs contained in the food products have not been approved by the Executive Council for GMOs, consideration will need to be given to whether this constitutes an offence under the GMO Act and regulations. This is beyond the scope of this advice, and is not dealt with here.