DISCUSSION PAPER ON LABELLING OF GM FOODS

PURPOSE: To facilitate a national discussion on labeling of GM derived food and feed to build consensus towards a national position.

SCOPE: Food and feed derived from a GMO; including but not limited to raw and processed produce.

INTRODUCTION

Food labeling refers to information displayed on food products (text, devices or pictures), for the purpose of facilitating consumer decisions during purchase and use of products; it is defined by legislation, and broadly categorized as mandatory or voluntary labeling. The general principle for labeling is to forestall false, misleading or deceptive presentation of prepackaged food, and also to prevent an erroneous impression regarding the character of the product in any respect (Codex, 2001).

Labeling information serves three main functions: i) *product information*: this comprises product names and descriptions, list of ingredients, net content/drained weight, product shelf-life, lot identification, grade/quality, details of manufacturer or distributor and country of origin. ii) *health, safety and nutrition information*: it includes instructions for safe handling, storage and use, nutrition information pertaining to composition per serving in nutritional information/facts table as well as for specific dietary uses. iii) *promotional information*: it advertises and markets a food using vignettes, promotion information and claims such as organic, natural, low fat, high source of fiber, fair trade, halal, kosher, quality management system certifications etc. (Codex, 2001 & CFIA, 2011).

Though labeling statements are ultimately driven by consumer welfare, over the years labeling standards have been initiated primarily by governments either proactively or in response to food industry initiatives that have the potential to mislead consumers. The balance between consumer needs and company labeling initiatives drives labeling standards to ensure that consumers are not exploited. In pursuance of this balance, government regulators have influenced the termination of some private labeling initiatives due to its potential to mislead the consumer (Fooducate, 2014).

The World Health Organisation (WHO), Food and Agriculture Organisation (FAO), and Organisation for Economic Co-operation and Development (OECD) considers genetically modified organisms for food, feed and processing (GMO-FFP) that have been approved in accordance with international guidelines for risk assessment of the same, are as safe as its conventional counterpart (OECD, 1993; WHO, 1991). After two-decades and a half long research commissioned by the EU, involving 130 research projects and 500 independent research groups; the report concluded that "biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies" (EU, 2010). Such consensus among international organizations and the European Union on the safety of food and feed derived from GMOs as presented above suggests the discussion of labeling *approved* GM derived food, feed and ingredients is not a health and safety issue.

In spite of this consensus on the safety of approved GM foods, consumers continue to express concern about the safety of GMOs due to concerns expressed by several articles in peer reviewed journals, the most notable being the article by Séralini *et al* (2012) on *long term toxicity of Roundup herbicide and a*

Roundup-tolerant genetically modified maize. This publication received worldwide media attention and was hailed as principal proof that GM foods are unsafe. It consequently influenced policy decisions in some African countries like Kenya where a ban on the importation and cultivation of GM foods was instituted (ACSH, 2015).

The Séralini *et al*. study was reviewed by European Food Safety Authority (EFSA) on request of the European Commission; they noted that the study's inadequate design, analysis and reporting is of insufficient scientific quality for safety assessment, and concluded as follows "the Séralini *et al*. study as reported in the 2012 publication does not impact the ongoing re-evaluation of glyphosate, and does not see a need to reopen the existing safety evaluation of maize NK603 and its related stacks" (EFSA, 2012). National competent authorities from France, Germany, Belgium, Australia and New Zealand reached the same conclusions as EFSA following their review of the Séralini *et. al.* study (ANES, 2012; HCB, 2012; VIB, 2012; BfR, 2012 and FSANZ, 2012). Following a thorough investigation of the study, the Journal of Food and Chemical Toxicology retracted the article on the inconclusiveness of the study results based on deficiencies in the study design (Wallace Hayes, 2014).

This discussion paper is aimed at highlighting the key issues to facilitate the consideration of a country position on labeling of GM foods.

LABELLING OF GM FOOD, FEED & INGREDIENTS

The call for labeling of GM derived food, feed and ingredient by environmental and civil society groups and some governments is based on a supposition that consumers have a fundamental right to know what their foods contain; to facilitate their decision to patronize or boycott such food based on one or several of the following; safety, health, nutrition, socioeconomic, ethical, religious, or environmental issues. These references also govern current labeling systems and strategies for foods and other consumer goods.

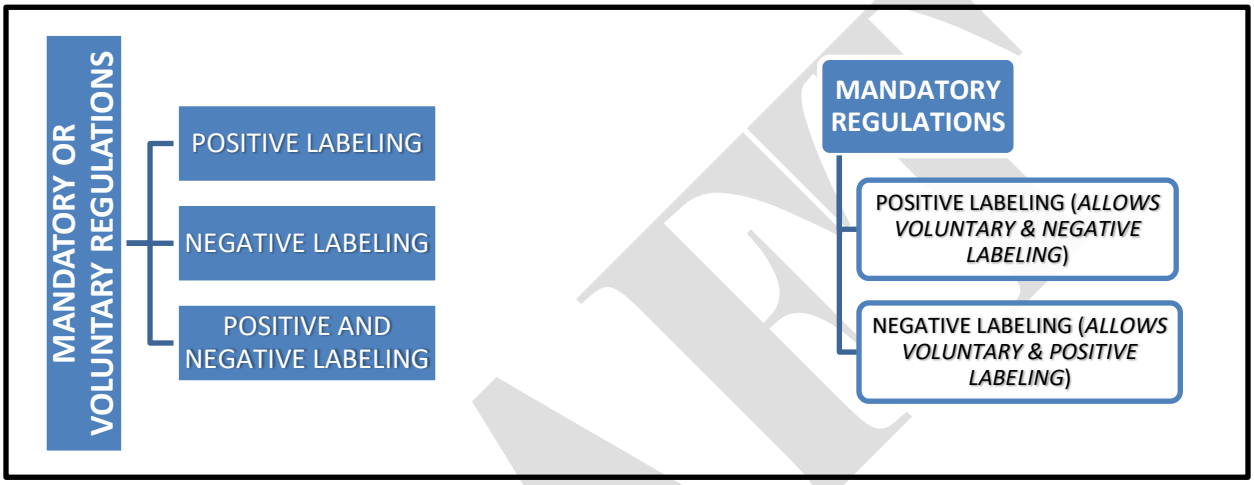
Globally there is currently no agreement, standards or guidelines on labeling of foods derived from GMOs. Following several years of discussion at the Codex Committee on Food Labeling no agreements was reached; individual countries have developed labeling regimes that meet their needs. In the development of labeling systems and requirements, several governments around the world have developed mandatory or voluntary labeling regulation on the basis of process-based or proof-based principle and the use of positive or negative labeling statements.

Mandatory labeling regulations require food products derived wholly or partially from GMOs to be labeled in accordance with guidelines; failure to comply with regulations attracts a penalty which is usually very hefty. On the other hand, voluntary regulations provide guidelines for labeling foods derived from GMOs, however, the decision to label is taken by the food product manufacturer or distributor.

For labeling regulations based on proof-based labeling principle, food products are labeled as GM in accordance with the guidelines when it contains detectable GM material, whilst for process-based regulations food products are labeled in accordance with GM labeling guidelines when the food or part of it was developed using modern biotechnology techniques.

The proof-based systems rely on product testing and the process-based systems on identity preservation systems to authentic claims of applicants. Positive labeling highlights the GM content of food products, whilst negative labeling highlights the absence of GM content by employing symbols or statements such as “contains GMO” or “non-GM”.

Figure 1 below, shows information gathered by the FAO (n.d.) from 41 countries on the various strategies employed by their labeling regulations for foods derived from GMOs. One hundred and twenty-five countries were surveyed for their labeling requirements for labeling of foods derived from



GMOs.

Fig. 1: GM Food Labeling Regulations Across 41 Countries Globally

Globally, there are varied variations to how these labeling regulations in fig. 1 are implemented on two additional levels; threshold levels and coverage of guidelines. The thresholds levels relate to the unintentional and technically unavoidable presence of approved GMOs arising from cross pollination/fertilization, volunteer plants, add mixing in machinery during planting and harvesting – low level presence. The current levels vary widely from 0.9%, 1%, 5% to undefined levels. The application of labeling regulations for the following also vary from country to country:

- List of ingredients – from top 3 to all ingredients with threshold limits.
- Additives and flavorings
- Animal feed
- Meat and products derived from animals fed with GM feed.
- Foods sold at restaurants, caterers and unpacked food

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REVIEW OF SELECTED COUNTRY LABELING REGULATIONS

UNITED STATES OF AMERICA REGULATIONS

In the US, the FDA recommends food companies to voluntary consult the agency before it markets the GM food, except for situations where the food is significantly different or gene is sourced from a known allergenic plant. The FDA does not formally approve an application or conclude whether the GM food is safe or not, however, they issue a memorandum indicating the features of the food and how it may impact the safety concerns. In 2001 a proposed mandatory premarket approval, known as the Pre-market Biotechnology Notice (PBN) was proposed but is yet to be enacted; with this system, a food company will notify the FDA 120 days prior to the commercial distribution of the food and supply all the requisite safety data irrespective of the GM content (Wong, 2003; Roberts, 2016). Until July 29, 2017, there was no obligation to label GM foods; companies were only obligated to label GM foods that were substantially different in respect of nutritional characteristics as per the 2002 voluntary labeling guidelines of the Food and Drugs Administration. There was therefore no labeling system that provided for standards, testing, certification and enforcement regarding GM foods in the US (Wong, 2003; Zainol et al, 2013).

In the absence of a US Federal Legislation for mandatory labeling, several States initiated mandatory legislation. In 2014, Vermont became the first US State to pass a law that mandates the labeling of foods derived from genetically modified crops; that comes into force on July 1, 2016 (Ford D. & Ferrigno L. (2014). Maine and Connecticut had also passed GM labeling laws but required other states to pass GM labeling laws before it could be enacted (Reuters, 2014). As more and more States push for mandatory labeling, plurality of the GM labeling strategies and requirements would create a compliance nightmare for the food industry as they will need to comply with the idiosyncratic labeling requirements of the different States; resulting in increased cost of compliance and consequently cost of products.

When the Vermont mandatory labeling law came into effect in July 1, 2016, a compromise Federal Legislation, the National Bioengineered Food Disclosure Notice, Public Law 114–216, was passed by Congress and accented to by the President on July 29, 2016 to avert the imminent chaos in the food industry. This standard requires mandatory disclosure on the label of a bioengineered food using any of the following; text, symbol, or electronic or digital link. It defines a bioengineered food, establishes exceptions from disclosure, and prevents individual states from directly or indirectly enacting laws in respect of bioengineered food disclosures. The USDA has up to two (2) years to write regulations, requirements and procedures for implementation of this federal legislation.

EUROPEAN REGULATIONS

In 1997 the EU Novel Foods Regulation 258/97 required labeling of GM foods on the *proof-based principle*. This means that only final products with detectable genetic DNA fragments were required to be labeled. Thus when DNA fragments cannot be detected due to extensive processing, such a product did not require labeling. The new GM labeling regulations of 2004, is based on a *process-oriented principle*. Under this new regulation, food products that make use of GMOs at any point during their production; whether or not the DNA fragments are detectable, are required to be labeled under this

regulation. The labeling is to provide information on the use of genetic modification irrespective of its effect on the final product composition. This process-oriented new system is stricter, labor and capital intensive than the proof-based system on the part of the regulatory system and processors due to traceability requirements along the food value chain (EU, 1997; GMO Compass, 2005).

The new EU regulation reduces the threshold value beyond which mandatory labeling is required from 1.0% to 0.9% only attributable to technically unavoidable presence. Operators must demonstrate that appropriate steps have been taken to avoid such presence to be exempt from labeling. Article 9 of Regulation (EU) 1169/2011 prescribes labeling phrases for GM component of a food or food ingredient:

- '*genetically modified'* or *'produced from genetically modified (name of the ingredient)'*
- '*contains genetically modified* (name of organism)' or '*contains* (name of ingredient) *produced from genetically modified* (name of organism)'
- '*genetically modified'* or '*produced from genetically modified (name of organism)'*

In addition Regulation (EC) No 1830/2003 prescribes the following labeling phrases for pre-packaged and non-prepackaged foods:

- '*This product contains genetically modified organisms*' or '*This product contains genetically modified* [name of organism(s)]'

The European regulations exempt the following categories

- Processing aids such as food enzymes produced using GMOs.
- Food products from animals fed with GM-feed or treated with GM medicinal products as these are produced with, but are not from a GMO. Milk, meat & eggs.
- Foods produced by fermentation using genetically modified microorganisms (GMMs) not present in the final product. CIAA (2007).

AUSTRALIAN REGULATIONS

The Food Standards Australia New Zealand (FSANZ) is responsible for GM food labelling in Australia. It considers Australia and New Zealand to have a very rigorous and progressive labeling requirements for GM food labeling. They subject all foods derived from genetic modified crops to pre-market safety assessment and approval. GM food labeling is regulated using the Standard 1.5.2 Food Produced Using Gene Technology of the Australia New Zealand Food Standard Code (the Standard). The Standard requires the labeling of food and food ingredients that contains more than 1% of GM raw materials. For single-ingredient foods the phrase "genetically modified" should be placed on the principal display panel close to the name prescribed by law for the food, whilst for multi-ingredient foods, the GM ingredient should be declared in the list of ingredients. Foods whose status as to containing GM materials cannot be established by the manufacturer, are required to be labeled "may be genetically modified" or "may contain genetically modified [ingredient name]". Exceptions to the labeling requirements are as follows:

i. When GM content is less than 1%; thus allowing for inadvertent mixing of GM and non-GM materials.
ii. Highly refined foods where the neither the DNA nor Protein is present.
iii. Foods that use GM processing aids in its manufacture but are not present in the final food.

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iv. Food prepared at the point of sale – e.g. restaurants.

Foods that differ from its conventional counterparts in respect of the following require additional labeling: composition and nutritional values, anti-nutritional factors or natural toxicants, factors known to cause allergies, its intended use or factors that may raise ethical, cultural or religious concerns (Wong, 2003).

JAPANESE REGULATIONS

New biotechnology varieties for development of new food products are required to undergo pre-market assessment by the Food Sanitation Committee of the Ministry of Health, Labour and Welfare (MHLW) in Japan. Food products that contain designated GM ingredients are required to be labeled; if it's a top 3 ingredient and constitutes more than 5% of the total weight of the product. They publish a list of approved GM ingredients (the List); it is therefore illegal to sell or import food products with unapproved GM ingredients. Japan has zero tolerance for unapproved events in its food products, as such, continuous monitoring and testing is conducted for imports and processed foods at retail level. Non-conforming shipments are returned, destroyed or diverted for non-food use.

The labeling of food products are classified as:

i. Genetically modified – This is applicable to all prepackaged foods which are required to be labeled under the Food Sanitation Law and Japanese Agricultural Standard (JAS) Law.
ii. Not segregated from GM products – This is applicable to products that may contain GM materials because they have not been handled in accordance with identify preserved basis.
iii. Non-GM – This is applicable to products that have been identity preserved to ensure it does not contain any GM material.

Categories (i) & (ii) are mandatory whilst (iii) is voluntary.

There are exemptions to the labeling regulations:

i. Food products in which the recombinant DNA and the resulting protein have been degraded due to processing. However, though the recombinant DNA or its protein is not present in high oleic acid soybean oil obtained from GM soybean, it is labelled as GM.
ii. Food products containing less than 5% of GM materials due to unintentional inclusion or adventitious presence.

Under these regulations it is prohibited to label a food product that does not have a GM counterpart and foods derived from them cannot be termed as non-GM; as this will give the erroneous impression that there are GM varieties of that crop and what is being offered is not a GM variety. It is however, permitted for the use of the phrase "at present, there is no GM [name of crop] on the market" in close proximity to the name of the product as prescribed by law. (Wong, 2003; Umeda, 2014)

HONG KONG

Hong Kong has mandatory pre-market approval for GM ingredients, and a voluntary labeling scheme. The labeling of food in Hong Kong is undertaken by Health, Welfare, and Food Bureau; part V of the

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Public Health and Municipal Services Ordinance (Chapter 132) stipulates that all food (including GM foods) intended for sale in Hong Kong must be fit for human consumption. The Government of Hong Kong has issued guidelines for labeling of GM foods and encourages trade to use the voluntary labeling guidelines; providing reference for *truthful* positive and negative labels. The guidelines also cover standard terminologies and fundamental principles underlying the guidelines (Wong, 2003; CFS, 2006).

THE DEBATE

Positive vs. Negative Labeling

The use of positive labeling in GM food labeling is perceived as a tool for market limitation, as such labeling statements, are perceived as warnings to consumers who are skeptical of GMOs. It is argued to provide limited information, and fails to accurately define the consequences of consuming or patronizing GMO products from a safety or any other standpoint. Proponents further argue that positive labeling will promote GM foods that are transformed for improved nutrition or pharmaceutical attributes (Runge, 2001 & Hoffman, 2015). For positive labeling to benefit the consumer, there is the need for a case by case labeling consideration that specifies attributes of the GM crop in question, otherwise even the benefits will be obscured by the limiting effect of consumer skepticism.

Since consumer choices for GM foods are based on either safety, health, nutrition, socioeconomic, ethical, religious, or environmental amongst other considerations, GM labeling statements should seek to directly address related consumer concerns; such a labeling statement that touches on all these concerns will be verbose, and take a lot of space on the label. Though current labeling statements provides a simplified scheme, it can contribute to the ignorance and misinformation of consumers as the effect of techniques used vary from one product to another, and consequently its impact on the issues under consideration. For instance GE crops that are drought resistant, salt tolerant, nutrient enriched or delayed ripening may not impact e.g. the environment in the same way as insect resistant and herbicide tolerant varieties for which there may be strong opposition.

GM food Labeling Policy and GM Crop Cultivation

Observations made during the review of labeling policies above corroborate other study reports of a correlation between GM food labeling policies and cultivation of GM crops. The US, Canada and Argentina who are major producers of GM crops globally have voluntary labeling regulations as opposed to mandatory labeling regulations in Europe, Japan and Australia, where little or no cultivation of GM crops takes place (Zepeda, 2002; Buttel, 2002 as cited by Wong, 2003). South Africa and Brazil are producers that have a mandatory labeling policy.

Consumer Choice: Mandatory & Voluntary Labeling Policies

Mandatory labeling is argued not to have placed products on the shelf, thus consumers do not get to make a choice. Rather it is said to have delivered processor and retailer choice, as GM food products never make it to the market on account of processor and retailer decisions. The current market situation in the EU, Japan and Australia where GM foods are not ubiquitous on the market despite the enforcement of mandatory labeling regulations (which intends to give consumers a choice), gives credence to the aforementioned assertion (Carter & Gruère, 2003a).

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For markets where anti-GMO advocacy and sentiments are very rife; it results in consumer skepticism, and the perception of positive GM food labeling statements as warnings. The perceived sales loss due to consumer skepticism, and the impact of environmental and consumer advocacy campaigns against labelled products strongly influence processors and retailer decisions to use non-GM certified materials to avoid GM food labeling.

The situation is reported to be further influenced by a relatively marginal price difference between non-GM and GM raw materials, and the fact that current traits of biotech crops are *input traits* which do not bring direct benefit to the consumers, but rather farmers and biotech companies. (Carter & Gruère, 2003a; GMO Compass, 2007a). Regulatory impact assessment carried out by Hong Kong in 2002 corroborated increased costs to trade for mandatory labeling framework; particularly for small to medium scale enterprises due to difficulties in securing contractual agreements with manufacturers in respect of GM status (Wong, 2003).

These observations suggest that mandatory labeling of GM foods may only deliver true consumer choice in markets where consumers are not extremely skeptical and/or are adequately informed through the provision of accurate information, such processors do not feel the threat of loss in using GM food ingredients. Such a case in point is Brazil, where a logo is used to identify foods derived from GMOs.

According to Carter & Gruère, 2003b only market forces are able to deliver true consumer choice; as the case is currently for Halal, Kosher, Fairtrade, Organic, Country-of-Origin, Ecolabels among others. Under a voluntary labeling scheme with guidelines for positive and negative labeling, consumers can demand for GM food and/or non-GM food to be labeled. In such an environment, sufficient demand by consumers for non-GM products will drive processors and retailers to respond to market demands.

RESOURCE REQUIREMENTS FOR MANDATORY & VOLUNTARY LABELLING SCHEME

The implementation of the mandatory labeling scheme is practically the most demanding implementation scheme of the three labeling options; as it requires continuous monitoring, documentation evaluation and/or testing of all foods that have GM variants. The following are required for the successful implementation of both mandatory & voluntary labeling schemes:

1. Legislation
    a. Principles for labeling i.e. process/proof based; mandatory/voluntary; positive/negative.
    b. Exceptions – products exempted
    c. Threshold levels
    d. Traceability
    e. Penalties
2. Monitoring and sampling plans – where, what, when, how to sample?
3. List of authorized GMOs in Ghana.
4. Testing laboratories.
5. Validated test methods.
6. Import export monitoring systems.

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A country assessment will be required to ascertain the level of preparedness; following which timelines for addressing gaps are determined. Following this assessment, the timeline for enforcement of mandatory GM labeling in Ghana will be determined.

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CONSIDERATIONS TOWARDS A GHANAIAN POSITION ON LABELLING OF GM FOODS

Current Situation in Ghana

The Biosafety Act, 2011, Act 831 requires pre-approval of GM crops for environmental release and placement on the market. The National Biosafety Authority is responsible for this process, working with several regulatory institutions through its Technical Advisory Committee and other experts. The Food and Drugs Authority and the Ghana Standards Authority through their product registration and certification schemes respectively enforce mandatory food labeling legislations in Ghana. Current labeling legislations are the Ghana Standards Board (Food, Drugs and Other Goods) General Labelling Rules, 1992, LI 1541, and GS 46: 2004 Food Technology: Labelling of Pre-Packaged Foods. These legislations have no provisions on labeling of GM food. The lack of international consensus has stalled the process at Codex, and till date no Codex guidelines on labelling GM food. Ghana may therefore need to develop guidelines for GM food labeling following a decision on labelling of same.

Developing a Country Position

According to the OECD, the Bio-Economy holds the key to emerging challenges of increase demand for healthcare and for agricultural, forestry, and fishing products associated with increasing incomes in developing countries. Several countries including Ghana in line with OECD Bio-Economy to 2030 policy agenda have adopted a biotechnology policy within its National Science and Technology Policy and set sector specific goals. The European Council in response has created an *Innovation Union* that focuses on *Building a Bioeconomy by 2020*, to help it overcome its financial and economic turmoil that occurred prior to 2010.

In this respect the EU spent over EUR 200 Million through its Framework Programme on Research over a ten (10) year period to develop agricultural management techniques for coexistence, tools for detection in and analysis of food and feed, and methods of risk assessment of GMOs in response to consumer, farmers and policy maker's needs (EU 2010).

To develop a country position, it's important for us to place our discussions in the above context. Additionally, we must assess the impact of the decision on our current trade policy with our major trading partners and their policies on labeling of GM foods. Answers to the following cascade of questions will also serve as a guide to focus the discussion on national interest and socioeconomic impact:

1. Why do we want to label GM foods?
2. Which labeling scheme will be most practical for Ghana – mandatory, voluntary and/or no labeling?
3. How will the choice made in *2 (above)* impact Ghana's National Science and Technology Policy on the promotion of biotechnology for the development of a bio-economy for Ghana.
4. What remedial measures can we put in place if the choice made in *3 (above)* hampers the achievement of the National goal of a Bio-Economy using biotechnology?

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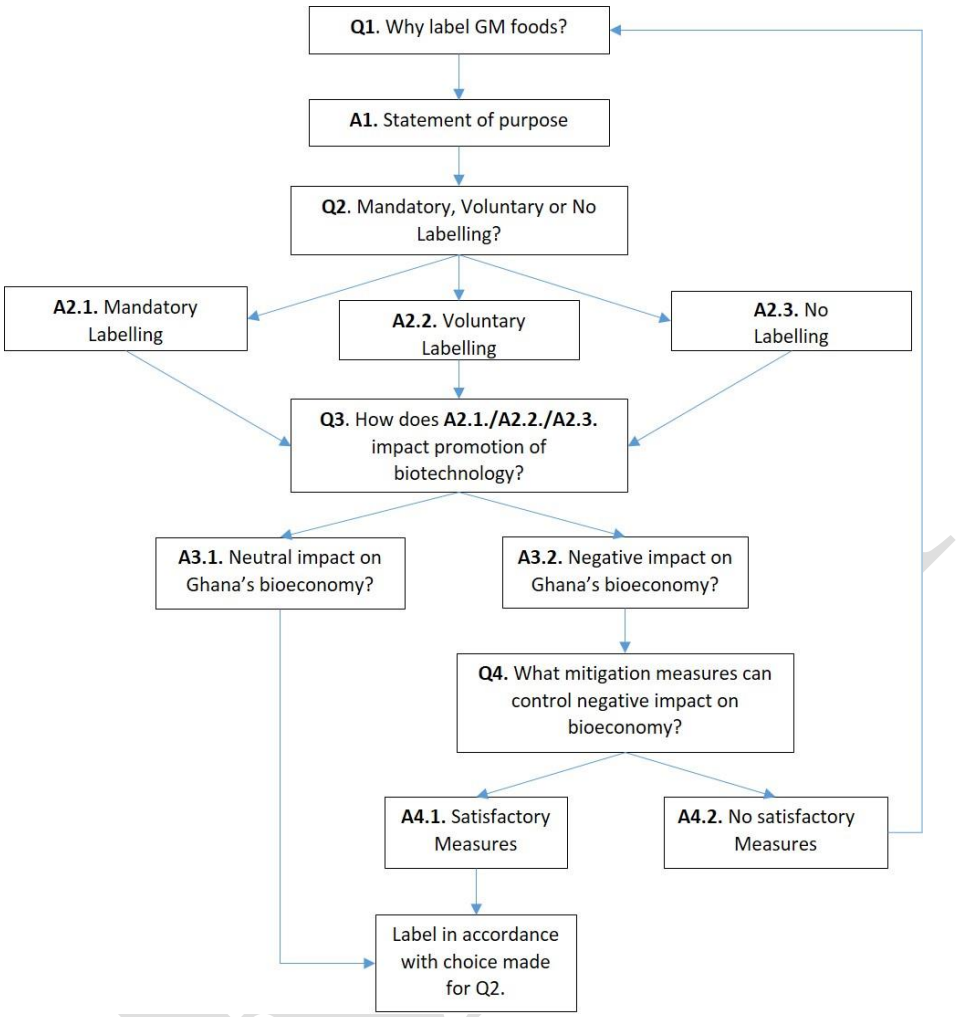

Figure 1: Decision Tree to Determine Ghanaian Position on Labelling of Foods/Feed Derived from GMOs

As a country, what do we want to achieve by labeling GM foods? The answer will provide a statement of purpose to ensure discussions are guided at all times in the context of this purpose. This will lead us to decide to either label or not, and in the case of the former whether we should adopt mandatory or voluntary scheme of labeling based on Ghana's needs.

This choice should support the derived statement of purpose, whilst considering its impact on the role of the National Science and Technology policy in driving Ghana's Bio-Economy through biotechnology innovation as well as development of resource capacity in our research institutions. This consideration is key for a country where limited financial resources is allocated for research that would drive biotechnology innovation. If we are to see our research institutions develop home grown solutions in agriculture biotechnology, it will be essential to create an environment so they can attract investment from private sector.

Cost of Labeling

The discussion on the cost of labeling goes beyond printing of labels which is negligible. The real cost of labeling lies in the proof of information declared on the label in respect of ingredient status as GM or non-GM. These include costs associated with monitoring, testing and enforcement programmes, development and maintenance of identity preservation, traceability and segregation systems, and compliance to regulations (verification of threshold levels). The cost of labeling is affected by the following factors: threshold level - low levels drive costs upward; capacity of industry to comply with regulations – low capacity drive costs upwards; and domestic production of GMOs – high local production drives costs upward. There is the need to undertake a regulatory impact assessment of the various labeling options to facilitate the decision making.

CONCLUSION

A national position for labeling is in the interest of consumers, farmers, policymakers, manufacturers, researchers and technology developers. The labeling of GM foods is an ongoing debate globally; progressive international consensus on safety of biotechnology and products of the same, particularly its use in agriculture notwithstanding, there are different national policies globally to serve idiosyncratic interests using the consumer right to know as the basis of their decision. It is important for Ghana to develop a national position and consequently a labeling scheme based on lessons drawn from the debate on the international front and establish its interest and priorities to arrive at a national position that will find its place in the international market place. To foster the development of Ghana's Bio-economy, it is essential that discussions focus on impact of proposals on indigenous research and technology companies, creating opportunity and protecting these enterprises to give them a competitive edge over large multinational companies locally and internationally.

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