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Status of Bio-safety Practices for Genetically Modified Organisms in Sudan: Bt (*Bacillus thuringensis*) Cotton Variety (Seeny-1) as model

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Abstract

The research aimed at highlighting the bio-safety practices and regulation followed for the release of the first genetically modified cotton variety Seeny-1 in Sudan. The need for GM food and safe crop handling, trans-boundary movement and release into environment are being addressed through investigating the procedures followed in the release of seeny-1 for the farming community in Sudan. Results revealed that:

-Scientists who were actively enrolled in GMO bio-safety issues for more than ten years represented 46% while those working for more than five years were 24%.

-Ninety percent of scientists working on GMO agree with international protocols for handling modern biotechnology procedures and biosafety regulations.

-sixty seven percent of scientists agree that they are not experienced with scientific, legal and regulatory procedures of GMO bio-safety in Sudan.

-The majority of scientists (64%) disagreed with the procedures which lead to quick release of the GMO variety and revealed that more information was needed on environmental, biodiversity and socioeconomic impacts.

-The status of biosafety regulations in Sudan need to stream line with globally accredited institutions to safeguard trade, health precautions, natural resources and environmental issues with clear risk\benefit analysis approach.

-The degree of coordination among different actors and committees working in the bio-safety mechanisms is weak considering adherence to the ratified Cartagena protocol on bio-safety.

Keywords: (*Bacillus thuringensis*, Bio-safety, Cotton, GMO, Seeny-1)

1. Introduction

The human adaptability with nature has developed a green revolution based on high productivity and food quality enhancement for healthy life. Consequently, in this last decade of technology, scientists were involved in biotechnology of genetic modification of plants, animals, and microorganisms genomes. This enabled them to transfer desired genes of specific features to the target organism genome to

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attain specific character phenotypes and desired genotypes which finally constitute genetically modified organisms/living (GMO/GML), transgenic, or a recombinant-DNA organism. This is defined according to Cartagena Protocol (2003) on biodiversity as "An organism in which the genetic material has been changed through *in vitro* nucleic acid technique, including recombinant deoxyribonucleic acid (DNA), and direct injection of nucleic acid into cells, or organelles beyond its classification family".

Biotech crops contribution to food security, sustainability, and climate change. Starting from 1996 to 2011, biotech crops contributed to food security, sustainability and climate change by increasing crop production valued at US $ 98.2 billion, providing a better environment by saving 473 million kg a. i. of pesticides. In 2011 alone reducing CO2 emission by 23.1 billion kg, equivalent to taking 10.2 million cars off the road; conserving biodiversity by saving 108.7 million hectares of land; and helped alleviate poverty by helping more than 15.0 million small farmers, and their families totally more than 50 million people who are some of the poorest people in the world. (Clive, 2012).Biotech crops also contributed to food security through reduction in pesticides used due to breeding with increased yield while reducing the use of pesticides, and improving plant adaptation to unfavorable environment. (Hug, 2008). Some genetic modification of plant or microorganisms may provide in situ remediation of polluted soils, sediments, surface waters, and aquifers. Transgenic plants can increase removed of toxic heavy metals from polluted soils and waters and sequesters these in plant tissue available for harvest, or can transform pollutants into less toxic forms. (Wolfenbarger, 2000).

Biotechnology as an artificial practice interferes with the origin of nature’s basic components (genomes). It has raised many issues of bio-safety interests on genetically modified organisms (GMO's)

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release, consumption, and health (FAO/WHO, 2007). These issues concern the transformation of genetic material between organisms and causing agents and neglects the impacts on environment and health. So that, interested communities take effective strategies to regulate and assess the risk/safety aspects of genetically modified foods (GM-food). Products which were engineered had enormous benefits of improvements for crops, animal, & genetic-therapy. Genetically modified crops and animal has spread worldwide in the last decades, increasingly (Clive, 2013). And genetically modified microorganisms (GMM's) such as bacteria & viruses have been used in cancer therapy, and many pharmaceutical studies and preparation Nevertheless, biotechnology is a great discipline of open-option field for man in competing with nature within related safety limits.

Bio-safety is an emergent discipline built from traditional risk assessment and risk management rationale organizing from chemistry, toxicology, microbiology, epidemiology, ecology, human and veterinary medicine, agronomy and all related basic or engineering science. It is composed of spectrum of ways of thinking from the science, ethical issues, economics, and sociology.

Bio-safety is basically a case-by-case methodology exploiting pertinent safety criteria embedded in the history of sciences and of human practices. There are three aspects of bio-safety which are complementary and mutually beneficial if properly managed. Risk assessment is the first step of bio-safety which must be science-based only.

Bio-safety concepts which focus on genetic modifications have raised awareness in two aspects; health & environmental concerns. The first concerns with genetic material incorporation mechanisms and the later concerns the unintended impacts of genetic modification stability and genes flow from GM-crops to conventional varieties. (EFESA, 2008)

Many strategies were evolved globally to satisfy the status of GMO's bio-safety

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regulation and assessment practices at international level on health and environmental issues (CBD, 2003), which developed laterally as a scientific validation of standard operating procedures (SOP's) to approve the GMO's products to be release on environment and identify post-marketing.

After adoption of the Cartagena protocol on bio-safety national, regional, and international agencies have recognized that successful implementation of the protocol is contingent on the development of national bio-safety capacity in countries that have yet to establish, or are in the process of establishing bio-safety system. The protocol makes clear that parties to protocol must develop or have access to "the necessary capacities to act on and respond to their rights and obligation". The protocol provides considerable flexibility as to how importing countries may meet their obligation with respect to risk management decision making and to the implementation of these decision. As stated in article 16 which deals with risk management, each party has obligation to "establish and maintain appropriate mechanisms, measures, and strategies to regulate, manage and control risks identified in the risk assessment provision (CBD 2003)

Inherent in all current regulatory frameworks for transgenic plants are the concept of conducted a risk assessment prior to environmental release. The risk assessment is based on science and is applied case-by-case. The type and quality of data that is acceptable for the risk assessment can be outlined in regulation either based on national narrows or based on international guidance.

In general, most countries will make reference to data quality as being of acceptable scientific quality, often, referring to quality of data expected by scientific publications. While there is certainly a need for having scientifically sound, verifiable data, it's worth noting that the objection of a risk assessment of a transgenic plant for commercial release are not the same as those of scientific research. While both activities are hypothesis driven forms of

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structured, empirical inquiry. The objective of risk assessment is to address the relative safety of a product intended for release use, rather than an exhaustive safety of quest of knowledge. (Wolfenbarger, 2000)

The concepts and application of bio-safety of GMO's undergo precise practices with scientific evidence to approve an application of genetic modification for target organisms in aspects of health and environment for Intended and unintended impacts. Furthermore, the discipline of GMO's safety assessment elucidated details on GMO's characterizations, which include; the description of the recombinant-DNA organisms, host & donor organism(s), the genetic modification(s) characterization, & the complete protocols of safety assessment and other considerations (FAO/WHO, 2007. EFESA, 2008) .

This study intends to evaluate the current status of GMO's safety assessment, regulations, and potential framework practices undertaken on concerned bodies of bio-safety in the Republic of Sudan which has access to the conference on biological diversity (CBD) in 2003, and to the Cartagena protocol on biosafety (CBD) in 2003, and has drafted the national bio-safety framework (NBF) in collaboration with (UNEP/GEF, 2003 and Abdelbagi, 2008)

Recently, there have been some aspects of awareness of GMO bio-safety regulation in local political and different scientific panels which resulted in the emergence of a draft of national bio-safety law in 2010. The draft determines the national competence authority, and the national technical committee to review the procedures of GMO handling, transportation, and safety analysis in case of any events. On other hand, many events related to modern biotechnology and GMO have been reported in the Sudan; like Chinese GM BT cotton trails in Elfaw region and Gedarif state, Eastern Sudan, and the raised discussion by decision-makers and interested scientists about importation procedures of GM-contained food in official media and scientific forum. Nevertheless, the national

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Agriculture Research Center has created special a center of biotechnology and bio-safety research in 2009 which enhance and supervise many research degrees about GMO in the center.

The study hypothesized that, Sudan has regulations which were not put under implementation, & non-potential policy on biosafety decision making, and still practice a conservative action on risk/safety assessment with mal-capacity building in this issues. The study purposes is to highlight statistically the status of biotechnology safety assessment practices and regulations activity encounter the safe use, release, handling, & application of transgenic organisms and its products. An importance of the study emerges off the crucial concerns about present resources, health, and environment. Which raise a scientific curiosity to determine how we, in The Sudan, encounter the modern biotechnology products of genetically modified organisms, and how we interact on its handling, and safely regulate it's use, control its trans-boundary movement to our resources environment. This crucial necessity is the main focus of the study corresponding to international concerns on biosafety practices toward the critical risks which rose with modern biotechnology of genetic modification (Mackenzie, 2003).

1.1 Currently grown commercial varieties in Sudan:

Cotton "*Gossypium*" is the major natural textile fiber crop worldwide and the main cash crop in the Sudan grown in about one million acres. Cotton has been grown for centuries. The cotton plant is indigenous and a number of its wild relatives exist in various parts of the country, as well as, it is a way of life, reduced poverty and encouraged the settlement in rural areas.(Babiker, 2006).The introduction of cotton in the central Sudan (Gezira,1925) was preceded by the establishment of the cotton based Agricultural Research (Shambat,1904 and Medani,1918) where basic scientific information had been availed on agricultural environment, varieties, cultural

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practices and crop protection. Up to the 1980th cotton had been the predominant research area of ARC, due to the government priority and full support for commercial cotton production at that time. (Latif, et al, 2012) The framework of the cotton research is pillared upon the following specialties:

a. Variety improvement.
b. Cotton stickiness and testing technology
c. Agronomy and crop physiology
d. Plant protection (in co-operation with the plant Protection Center)
e. Soil and Water Management. (In co-operation with Soil and Water Center).
f. Mechanization (in co-operation with Agriculture Engineering Program**.**

The objective of variety improvement program is to develop varieties that are resistant to diseases and pest, of higher yield and better quality More than 50 varieties and registered lines had been released. However, only 7 varieties are currently grown either commercially or in limited propagation plots. These are: Barakat90(EFC),Barakat(EFC) ,ShambatB(FC),Nour(HCA),B arac(67)B(MC),Albar(57)12(C C)
and Acrain(CC). More recently (2004/05 and 2005/06), nine varieties were released as listed here under according to (Babiker, 2006):

1 .Abdin: (BB-80)

The fine-count cotton variety Abdin, derived from the cross (Barac (67) B BLCA B PD8S-1-90) F1 (Shambat collection 19-95-1 CAHUGARPIH-1-88) F1, was evaluated across ten environments in the Sudan in 2003-2005. Abdin gave average lint yield advantage over Shambat-B of 61%. It had a ginning out turn percentage of 36.0 compared to 29.0 for Shambat-B. It has a growth period of 150-160 days, 15-25 days earlier than Shambat-B. Abdin possesses (*B2B3B6B7*) gene combination that confers resistance to both bacterial blight disease races prevalent in the Sudan and had a higher degree of tolerance to Jassids.

2. Wagar:

Wagar gave average seed cotton and lint yield advantage over Shambat-B, Barac (67) B and Nour, of 36%, 25% and 15%; and 73%, 21% and 16%, respectively and gave comparable seed cotton and lint

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yield to Hamid. Moreover, Wager exhibited higher ginning out turn surpassing that of Hamid.

3. Burhan: (BB-65):

Burhan gave average lint yield advantage over Albar A (57) 12, Almac (80) 15 and Acrain of 37%, 29% and 21 %, respectively. Stability measures found Burhan to be most stable, and widely adaptable to rain-fed cotton growing areas of the Sudan.

4 Khalifa: (Damazin):

Khalifa excelled Albar (57) 12, Almac (80) 15 and Acrain by 32%, 30% and 30 % and 50%, 41% and 32 % for seed cotton and lint yield, respectively. Khalifa was found adaptable to cotton growing areas of the tested environments and had stable seed cotton and lint yield. Khalifa was found earlier than other genotypes tested as demonstrated by its shorter days to first flowering. Khalifa was resistant to both old and new races of *Xanthomonascompestris*var. *malvacearum*.

5. Hamid: (BB-82):

This a medium count, high yielding, early maturing genotype that showed resistance to bacterial blight, JassidS, low preference to whitefly and harboring less population of ABW, emerged as a suitable choice for short duration low management system. Hence it can be recommended for Integrated Crop Management (ICM) due to its open canopy, low leaf-area, medium hairiness and earliness. It can also be fitted into short-season production system in rain-fed areas, where problems of late drought are anticipated.

6. Knight: (BB-90)

This a medium count cultivar .Because of its additional improvements in yield, resistance to bacterial blight, and yarn strength, BB90 is recommended for irrigated areas, to cater for bacterial blight in areas more prone to high disease incidence (B2B3B6B7B9) and to enhance the deteriorating fiber bundle strength of medium staple cotton .

7.Kheiralla: (CRP-12):

This is a high count Acala (HCA), jassid resistance, excelling Nour (93) in yield and fineness. It is a bacterial blight resistance and harboring less whitefly (lower stickiness).

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8.Siddig (Sudan Pima):

It is a selection from a cross between Barakat –90 and Pima. This is a Fusarium Wilt resistance variety. It is an extra – fine count cultivar excelling Barakat-90, in length strength and fineness.

9.Hadi: (Okra-leaf Barakat):

It is a selection from a cross between Barakat-90 and Pima Okra. It is a fine count cultivar, early maturing, high yielding and has better (GOT) as compared to Barakat 90.

1.2 Statement of the problem:

The research problem focuses on biosafety concerns worldwide for safe use and handling of genetically modified organisms and its probable risks that evolved as an out-comes of innovated biotechnology. So that, the research problem emphasizes on safety procedures for the release of genetically modified varieties for the farming community in Sudan .The problem raises critical questions including; what is present status of GMO's bio-safety potential practices and regulation strategies involving in the Sudan? Did it conform to international bio-safety procedures? Is it outlined with a broad capacity? What is the role of research institution and regulatory bodies to handle the topic of modern biotechnology?

This problem relatively interferes with importance to determine the present biosafety practices followed in Sudan focusing on management and analysis of safety of innovated genetic modification to encounter health and ecological risks.

1.3 Significance and Scope of the study:

The study focus highlights the concern about the release of the first GMO variety in Sudan-(Seeny1).The debate on pros and cons of genetically modified plant material and its impact on farmers is the focus of the study. Consequently, the research limits its scope in resolving the safety issues framed in descriptive analysis of virtual presence of bio-safety framework procedures that are being recognized in the relevant population of the study inquiry. The study scope is a qualitative inquiry embodied in a semi-structured questionnaire to investigate theoretical &

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practical objectives of bio-safety practices followed in the Sudan.

1.4 Study hypothesis:

The study proposes that Sudan has the potential to biosafety framework practices, and yet the practice is still conservative in biosafety decision-making coupled with mal-infrastructures. The hypothesis emerges from the status of the drafted national biosafety framework (NBF) & the national bio-safety law, and acceded to global conventions which still unimplemented or encouraged at both level of legislation and practical procedures.

1.5 Study objectives:

The objective of this study is to evidence the critical necessity to comprehensive system of determination of the GMO's safety/risk assessment and bio-safety practices status encounter officially to safe health and ecological resources, and safe use of the modern biotechnology benefits. This purposes predict to conduct suitable review on the topic of biosafety status in the Sudan to visualize comprehensively the possible capacity of GMO's inter-changeable & introduce into our environment resources with safety/risk recognition to probable consequences in short and long-term.

2.Material and Methods

2.1 Review of literature:

The study reviewed discussions implying the following literature;

1. Bio-safety assessment practice of GMO's; history & principals.
2. Bio-safety regulations procedures worldwide.
3. Global status of genetically modified organisms & Bio-safety.
4. Ethical issues concerning GMO's Status
5. Bio-safety regulations practices in the Sudan.
6. Importance of the research in this field and highlight its status.

2.2 Study Methods:

For this qualitative study, a sample of forty experts & decision-makers individuals involved in modern biotechnology of genetically modified organisms bio-safety research and regulations

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institutions. The participants were selected on the basis of their awareness and enrolment in bio-safety and biotechnology R&D, or working on regulation decision-makers in the Sudan (e.g. National bio-safety council, National GMO food bio-safety technical committee, bio-safety and biotechnology research center, and the national environmental ministry which represent the national focal point for the Cartagena protocol on bio-safety and bio-safety clearing house). In addition to national experts & academia, A questionnaire form was prepared in two format of hard copy and online survey and questionnaire tool branded as (Kwiksurvey®) which is a free online survey tool made easy to build in questionnaire and lunch it freely for suggested period and analyze the completed responses with statistical frequency, percentage rate, and its preferred charts. Moreover, it's supported spreadsheet Excel (Microsoft office package) option to extract result report. Additionally, it provides security of information with registration and cost effective to reach target participants who are in abroad. The survey was send by email contain unique resources location (URL) to launch a survey , and a few of them conducted as hard copy papers for three members of the national technical committee of GMO food bio-safety where they has no contact citation in national directory information. The format of questions was close-ended system and multiple answers conducted in three sections (A, B, and C) after general question of qualifications, institution or occupation, and age group which represented an enquiry of the study problem questions. Namely, section A question constructed to analyze the perception of GMO's bio-safety for respondents capacity and their institution. Second section questions were constructed for GMO bio-safety analysis and regulations status in the Sudan: objectives and potential implementation of bio-safety procedures. Lastly, section D questions were focused in GMO BT Cotton which released in the Sudan as study model of GMO event of bio-safety regulation procedures carried-out in the

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Sudan. In order to identify and clarify the main theme of questions, any section has been headed with introduction. The survey was written in English to make appropriate sense for the targeted study sample of scientists and experts. Prior to send the survey online and gathering available contacts database, some participants of authorized regulatory and researchers preferred to participate by email than form papers, and some of interested institution heads were in abroad. So that survey was sent out by email to available contacts on 21 May, 2014 and collecting data through June, 16, 2014. A questionnaire was sent to forty individuals enrolled potentially in different GMO bio-safety R&D institutions, and only fourteen (14) responses were return, either by email or hard copy papers. Only three forms of hard copy papers completed immediately on meeting of the national technical committee of GMO food bio-safety in Sudanese standards and metrology organization (SSMO).

4. Results

Almost of the participants were a post-graduate. As shown in (figure 1) 47.06% of whom were professors participates in other occupation as biotechnology academic (29.41 %) and authenticated regulators (11.76 %) in their institutions according to a multiple choice answers question about study sample demographic characters. Ten of participants were aged between 41-65 years (71.43 %), and four were 21-40 years (28.57%)

4.1 GMO bio-safety perceptions:

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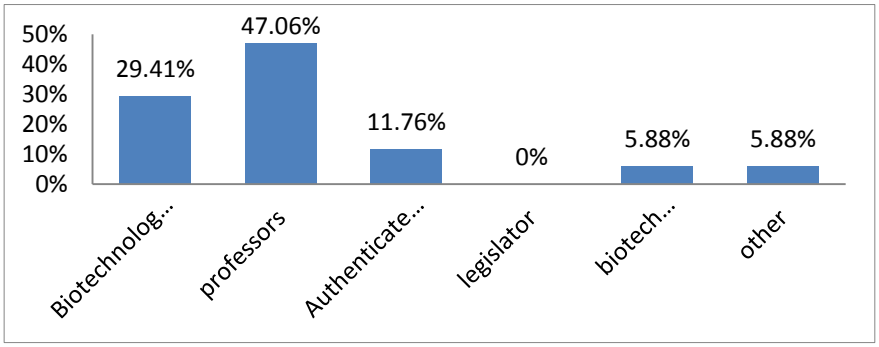

Fig. 1: identification of Participant's institutions or occupation.

To analysis the status of GMO bio-safety in the Sudan, the participants they asked about their interesting and adherent interaction with knowledge of modern biotechnology and genetic modification of organisms. 100 % of participants were strongly interesting in GMO bio-safety and related biotechnology, and the majority (92.31 %) were adherent with the topic except one respondent (7.69 %) (Fig.2).

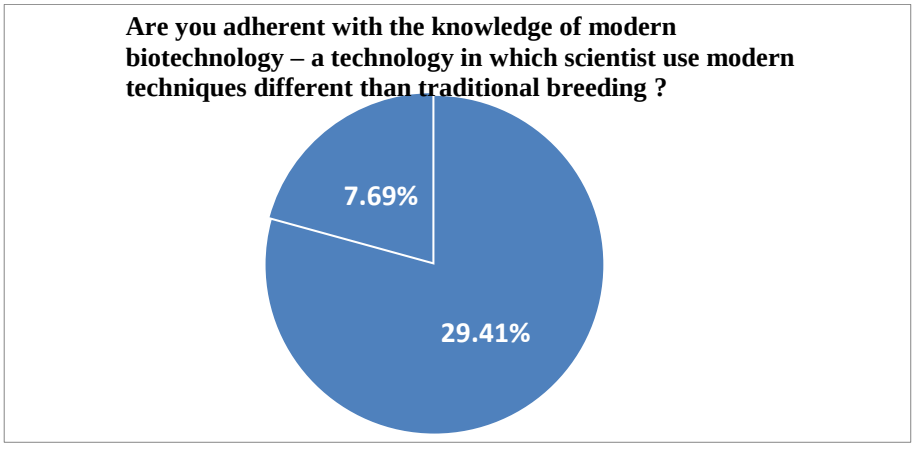

Fig. 2 Perception of modern biotechnology bio-safety in the Sudan:

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Furthermore, 46.15% of respondents has studied, or discussed formally in scientific manner the topic of GMO bio-safety for more than ten years, and 23.08 % were since five years ago.(Figure 3)

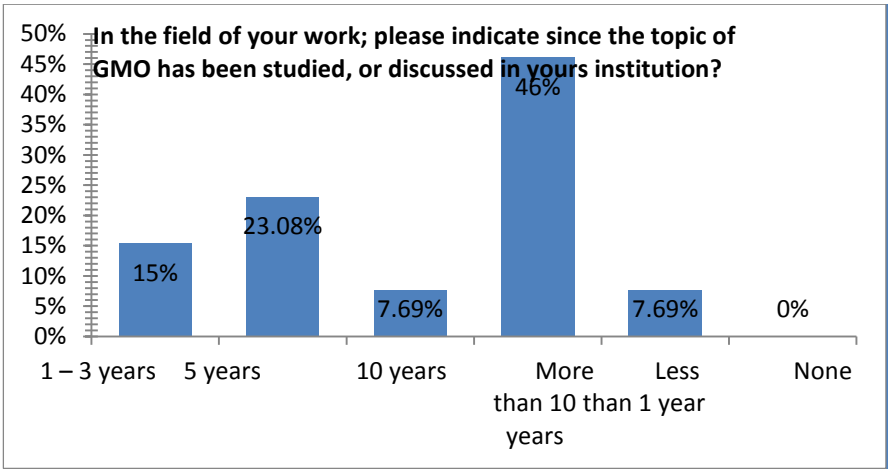

Fig 3 show the period since GMO studied, or discussed in Participants institutions.

Fig. 4 show the response to question about perception of GMO techniques, 40 % percent were accepted GMO techniques as providing benefits wit controllable risks, and a total of two answers options were 26.67 % (6.67&, 20%) recognized GMO techniques as worst alteration in nature and risk overweight benefits perception. respectively. In contrast, 20%, and 13.33 % look to the techniques as innovated and useful for human being.

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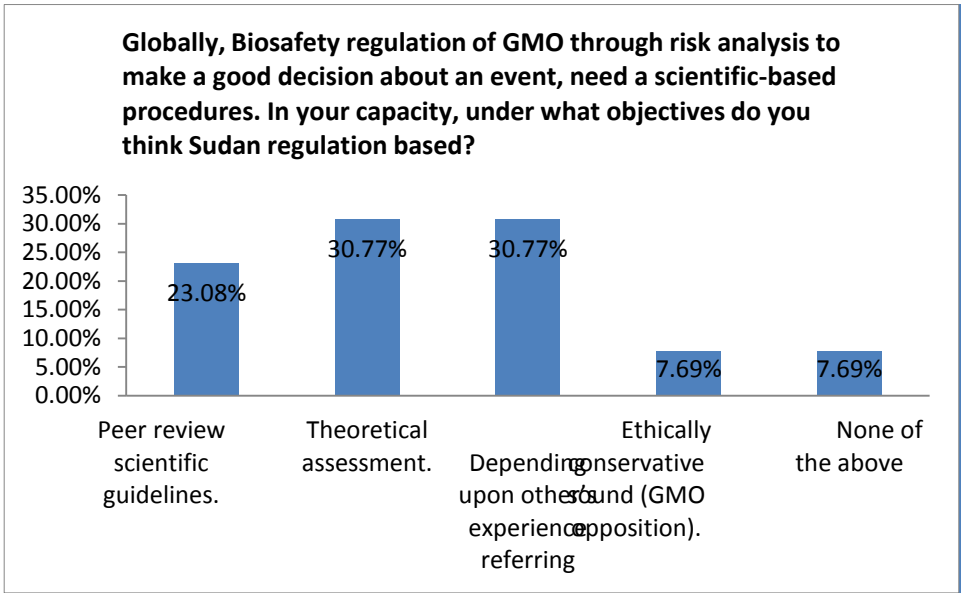

Fig. 4 shows participants responses GMO techniques perception

On other hand, over half (69.23%) of whom responded to the question for our need to such techniques in the Sudan were positive, and only 30.77% reject it. (Fig. 5)

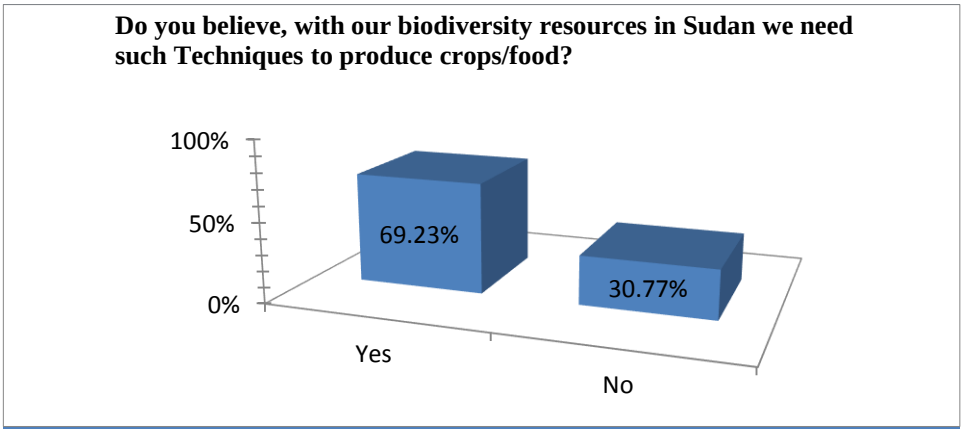

Fig. 5 shows responses to GMO techniques need to produce crops/food in Sudan

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4.2 Status of GMO bio-safety regulation procedures in the Sudan:

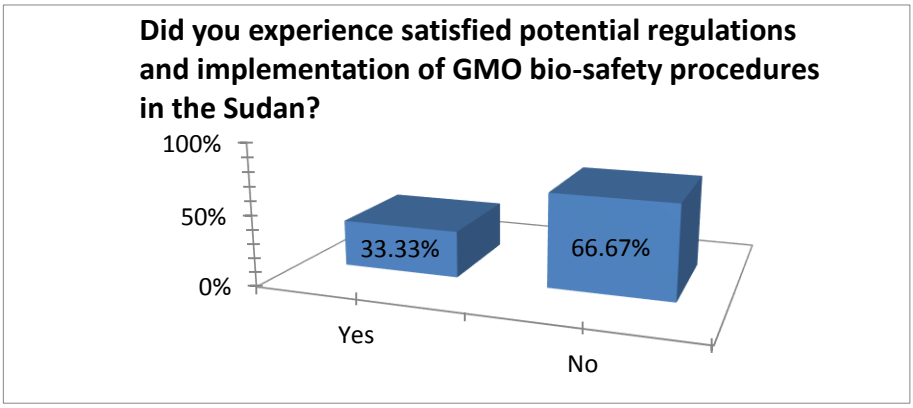

Fig. 6 Show satisfactions with potential of GMO bio-safety procedures in the Sudan

The status of GMO bio-safety potential regulations and implementation was not satisfied an experience of 66.67% of participants (Fig. 6). Where 35.17% stated that the mandatory policy of bio-safety regulation in the Sudan is politically driven institution, whereas 28.57% indicate that its specialized national bio-safety committee and authority, other response to this question of 14.29% claim uncoordinated and not clear specialization authority that mandate regulation procedures with same 14.29% percent were not sure about bio-safety policy mandatory in the Sudan. Only 7.14% indicate that it is non-potential theoretical authority. (Fig. 7)

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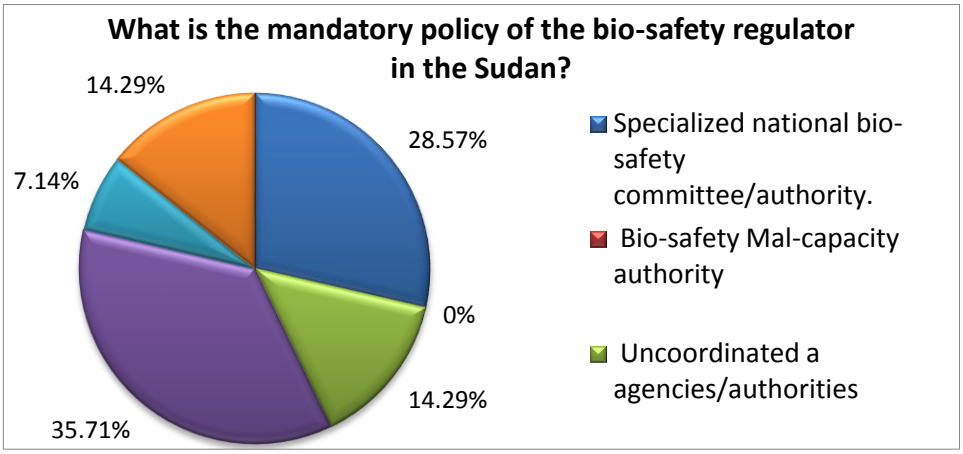

Fig. 7 characteristic of bio-safety mandatory in Sudan

Additionally, Fig. 8 indicates participants responded when asked about objectives of GMO bio-safety procedures (Risk analysis guidelines) to make a good decision with regulations based in the Sudan. Two equal percentage rates of 30.77% indicate responses for theoretical assessment procedures, and depending upon other's experience and referring, respectively. One participant (7.69%) stated the ethical conservative sound (GMO opposition) with anther that was not sure about the objectives of bio-safety procedures in the Sudan. while 23.08% describe the objectives as peer-review scientific guidelines.

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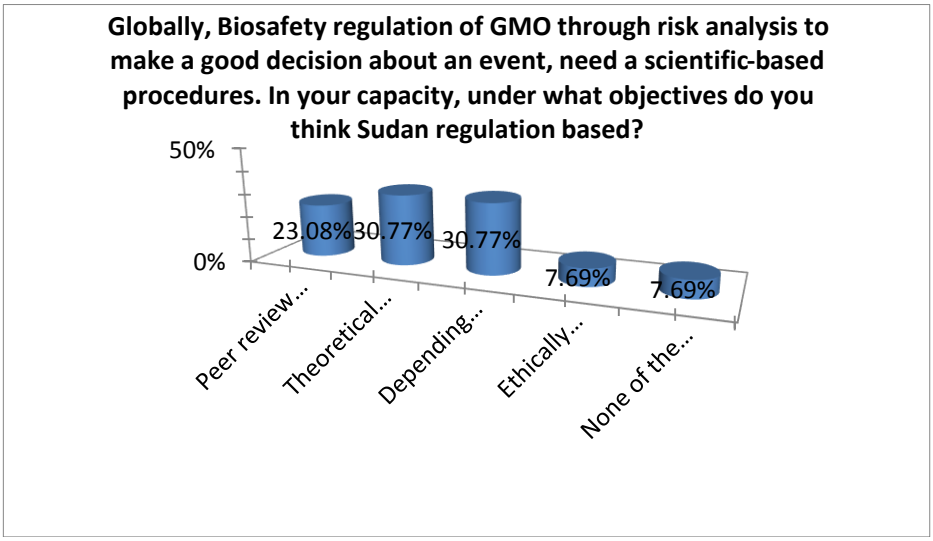

Fig. 8 shows the bio-safety regulation objectives

Lastly, in this section participants asked to view how they evaluate the status of GMO bio-safety regulations and practices in the Sudan. As in (Fig.9), the majority of 38.46% evaluates it as just workable steps of bio-safety regulations, and equal percent rate of 15.38% indicate that it is full implementing, under implementation, and not functioned practices, subsequently. While an half of those responded to describe the availability of GMO bio-safety capacity building resources nominate its scientific weakness (Fig. 10), and two equal responses 16.67% indicate the shortage of resources and its availability to elite group of persons. With one participant, stated that it is not available resources of bio-safety capacity building.

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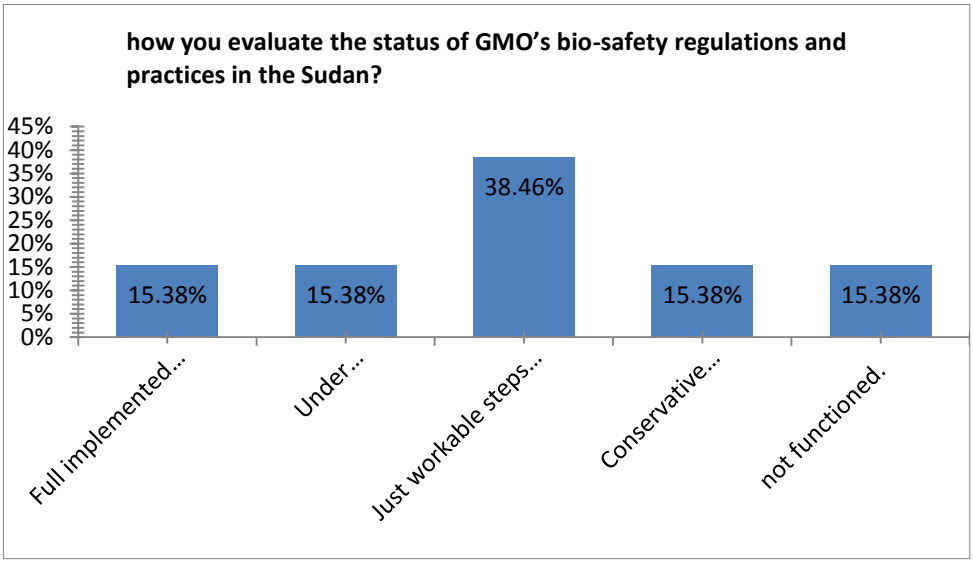

Fig. 9 shows the participant's evaluation of GMO's bio-safety status in the Sudan

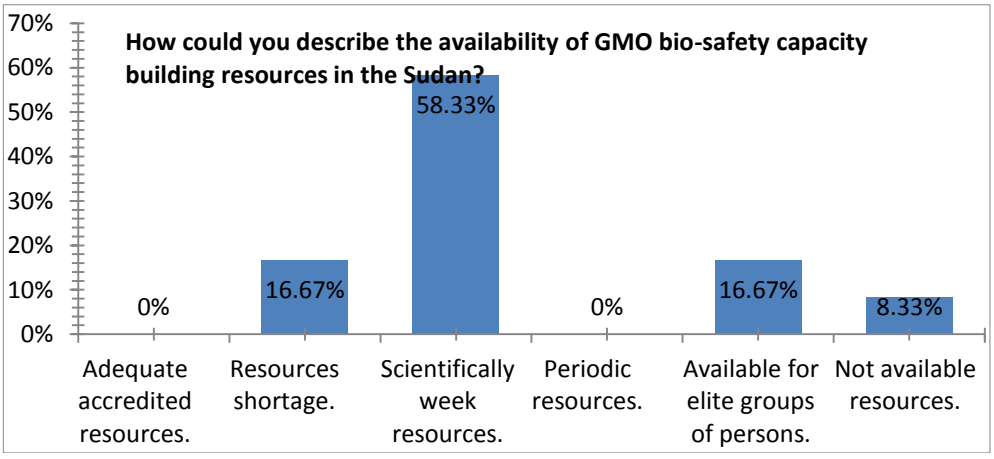

Fig.8 Shows availability of GMO bio-safety capacity building resources in the Sudan

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4.3 The case of recently released Bt Cotton (Seeny 1 variety) as Model:

This section of the questionnaire constructed to review the case of approved Chinese Bt Cotton (Seeny 1 variety) which released in 2012, in Sudan as indicator for the status of GMO bio-safety regulation procedures implemented and carried out in the Sudan. Fig. 11 show that the majority of 63.64% percent responded the question of method adopted to approval and released of Bt Cotton (Seeny 1 variety) according to global accredited bio-safety analysis and regulation procedure negatively not agreed with the procedures that followed for adaptation. In contrast, 36.3% percent participants satisfied positively with it.

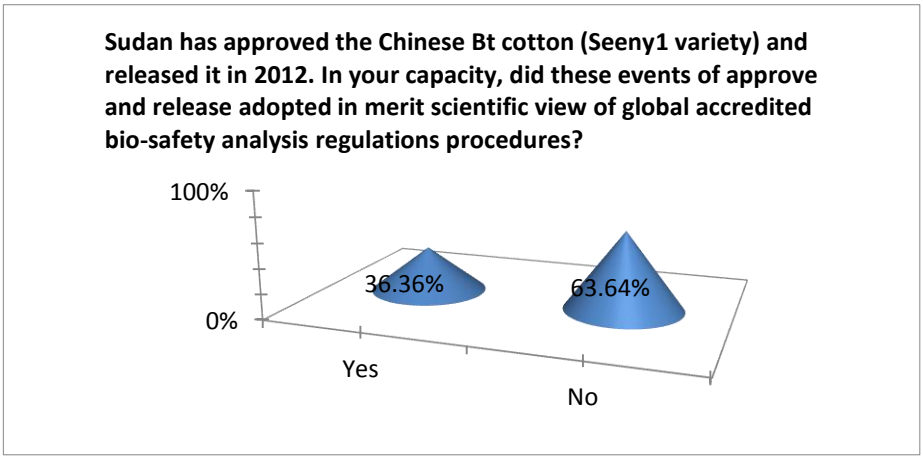

Fig. 11 Shows views of participants to adoption of Bt Cotton in Sudan according to global methods

Nevertheless, fig. 12, show that, almost three-quarters of the participants (72.73% percent) not appreciate the safety and stability of the released Bt Cotton in our endogenous habitats, biodiversity, and natural resources. While a minor quarter of participants, (27.27%) indicate that an adaptation of Bt Cotton

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enhances benefits and saturate needs for it and related techniques.

Finally, from the view to socio-economic impacts on Bt Cotton farmers after released and growing Bt Cotton in the Sudan. There were 36.36% percent indicate that the impacts is risky out-comes, while 27.27% percent reveal worth benefits of Bt Cotton adaptation, and the same response percentage (27.27%) commented as not sure with one participant expressed unclear indications results. Fig. 13

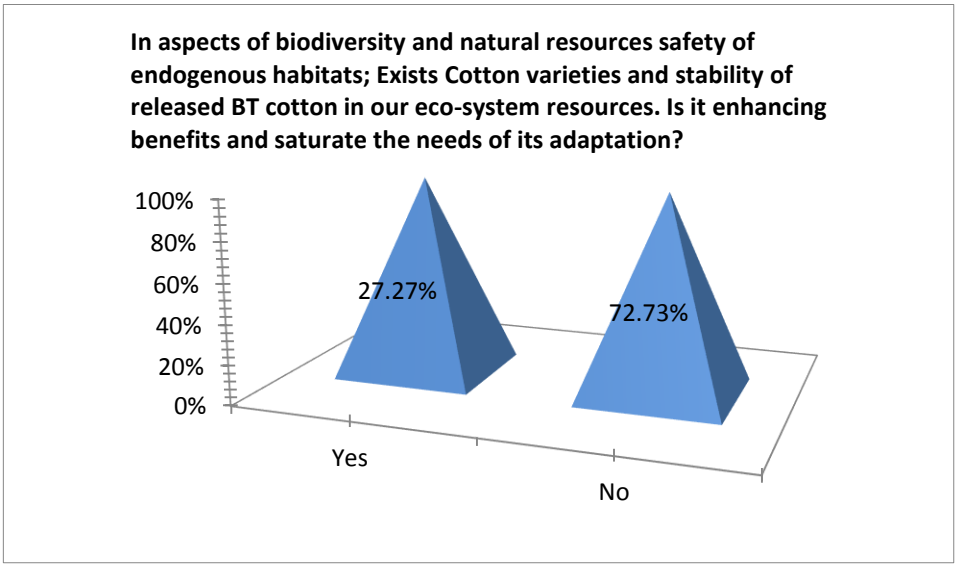

Fig. 12 Show bio-safety views of Bt Cotton introduced in Sudan biodiversity

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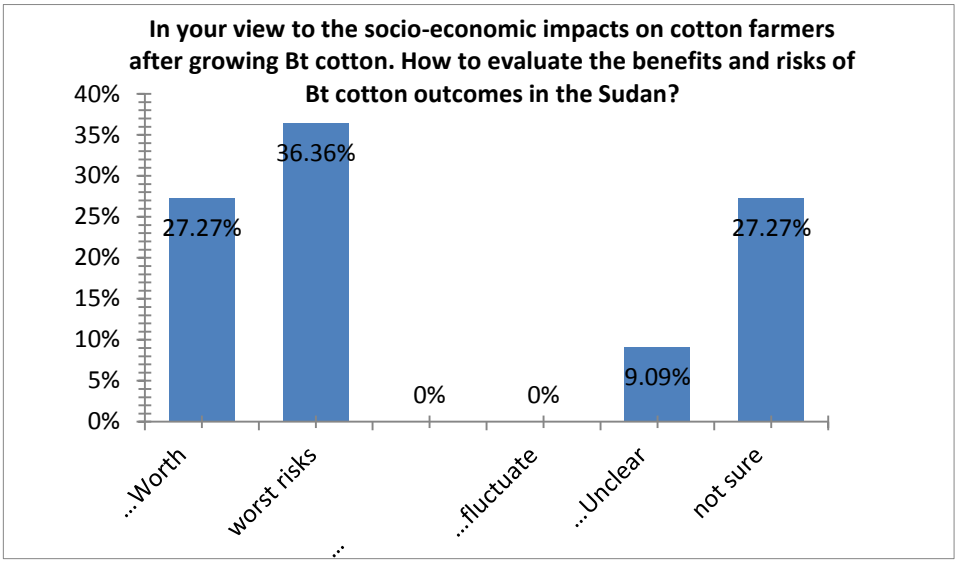

Fig. 13 Evaluation responses of socio-economic impacts of Bt Cotton on farmers

5. Discussion

This study aims to analytical description of genetically modified organisms (GMO's) bio-safety regulations practices status in the Sudan. As mentioned in literature review, the importance analyze the situation of bio-safety for innovated biotechnology is emerge due to its environmental and health effects which arises global concerns and debates of both scientific policy makers panels whom organized in the Cartagena protocol of bio-safety (CPD , 2003).

The results of this study represent three sections of constructed questionnaire as hypothesis and study problems which were discussed as follow as: GMO bio-safety perception in the Sudan, bio-safety regulations practices and procedures, and Bt Cotton variety released in the Sudan (Seeny 1).

5.1 GMO bio-safety perception in the Sudan:

The results show great interesting of surveyed participants on bio-safety of GMO and related biotechnology with 100%

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percent positive responding which may explained by their occupation as researcher and regulators in bio-safety institutions for more than five and ten years. Which is according to (Abdelbagi, 2007) there are steady increase in biotechnology labs and staff in the Sudan in recent years. But in spite of this majority of interesting and enrolment, we may notice that less than 50 % of participants who has discussed formally and scientifically any papers on bio-safety in the past years since Sudan has ratify Cartagena protocol on bio-safety, and that may due to recent construction of bio-safety laws and research organizations development in the Sudan. On the question of bio-safety perception the study found that there are increased trend to recognize GMO techniques as benefits with controllable risks which was contradict to hypothesis of perception as conservative and ethically opposite GMO conceptions with still some decision-maker and researcher insight on GMO as worst alteration in nature, or has risks overweighing its benefits which may explain the conservative minor sense to keep our resources due to unsatisfied controllable resources in Sudan.

5.2 Status of GMO bio-safety practices in the Sudan:

In accordance with study problem and hypothesis, the finding of GMO bio-safety regulations status was not satisfied an experience of two-third of scientific researcher and decision-maker regulators who enrolled on GMO bio-safety in the Sudan. This result may explain the necessity of bio-safety regulations procedures to adequate legal authorities transparency and participatory with scientific-based procedures. And not depend upon policy driven one as 35.17% percent of participants claim with other who reported uncoordinated and not clear specialization, or non-potential theoretical competent authority. This result may explained by inactive national council of bio-safety which is authenticated by draft the national bio-safety law in 2010 under mandatory of environmental ministry (Abdelbagi, 2007). This

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council still has no guidelines, framework, or an even official office to receive and proceed with public and stakeholders, and only referring and coordinate with committee of GMO food bio-safety under welfare of the Sudanese and metrology organization (SSMO) which represents the national quality control body (personal communication). In contrast, there were 28.57% percent of the participants reveal that there are specialization national bio-safety committee and authority which may they refer to the same ineffective or in action committee and council of bio-safety. Furthermore, this findings of ineffective objectives of GMO bio-safety procedures to make good decision to safe environment and health with precautionary regulations planned in the Sudan with (GEF-UNEP) project of National bio-safety framework (NBF) in accordance with first article of precautionary approach and objectives of Cartagena protocol on bio-safety (CPD, 2003). Nevertheless, with bearing in mind above mentioned recognition findings of bio-safety objectives and procedures. According to this study prediction, almost of participants evaluate the status of GMO bio-safety regulations and practices in the Sudan as un-functional and just workable steps of procedures. This finding conform with survey results of from the international center for genetic engineering and biotechnology (ICGEB) which identified gaps in bio-safety in Sub-Saharan Africa (SSA) including Sudan (before Sudan separation) they indicate a large dispersal in functionality of the bio-safety regulatory system in (SSA). The status of regulations, technical and scientific knowledge, and previous access to training opportunities need more attention. The later explains and supports our results about bio-safety capacity building resources which was reported as scientifically week, in shortage, and deemed only for elite group of persons.

In general, therefore, it seems that the status of bio-safety regulation in the Sudan has no yet functioned scientific-based bio-safety analysis procedures

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according to global accreditation methods to safe our natural resources and biodiversity genetic competitive invasion, and health precautions, nor has implemented potential practices to carry out GMO bio-safety decisions. With implications of untransparent policy roles of bio-safety institutions and mandatory bodies, May could affirm that the available baselines of scientific information and experts will not encourage develop good bio-safety scientific-based authorization.

5.3 The released Bt Cotton variety (Seeny 1) in Sudan as model:

Sudan has become the fourth country in Africa to commercialized Bt Cotton in 2012 after adoption of Chinese variety (Seeny 1) which raised controversy debates of interested researchers and scientific panels due to adaptation methods of released. Which were confirmed the results of this study on bio-safety regulation status in the Sudan. Where the majority of scientific opinions disagreed with adoption and released testing trails procedures on our biodiversity and natural resources environment. These neglect controversies of most participants may explain by similar notes discussed in scientific papers, press media, and forums which summarized as follow (Alwakeel, 2014):

.1 The National Variety Release Committee is not Competent Authority.
.2 The National Council for Bio-safety was established later after the release.
.3 The duration of confined greenhouse testing was inadequate.
.4 Animal feeding testing was inadequate.
.5 The feed test was for cotton foliage and not for seed cake.
.6 No cotton seed oil analyses.
.7 The period from initial testing to release into the environment was very short.

Nevertheless, as shown in (fig. 13) 36.36% percent of participants reported risky impacts of socio-economic outcome of Bt Cotton on farmers with a two similar ratings of.27% which indicated benefit outcomes and others

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who were not sure about the final outcome. However, this view may be bias from really reported outcomes of Bt Cotton impacts on farm-level and general income, and that, in according to (personal communication) with the head of national bio-safety council – The mandated bio-safety regulators did not have official evaluation study, nor the study of socio-economic impacts on farm-level were evident .Up-to-date risk/benefits analysis was also not performed. Therefore it can be assumed that the case of Bt Cotton as study model enhance the descriptive analytical hypothesis of non-potential bio-safety regulations practices in the Sudan. This may clear the view of GMO bio-safety regulations defects and obstacles to frame an accredited competent scientific panels and authorization to undertake bio-safety regulations to conserve our environment, health, and endogenous habitats of rich diversity. Hence, these findings suggest that more coordination and adequate legislation and scientific support may enforce the capacity of bio-safety regulations in The Sudan.

6. Conclusion

This study has described analytically the status of GMO bio-safety regulations practices in the Sudan with modeling case of Bt Cotton variety which was adopted recently. The purpose of current study was to comprehensively analyze and describe the above status in view of environmental safety of hypothesized study problem which answered raised questions such as: Has Sudan implemented accredited bio-safety regulation according to what is ratified and billed? What was the potential practices framework? How are the procedures of GMO bio-safety applied in the case of Bt Cotton?

The study has described a considerable bio-safety information baselines perception with mal-capacity building resources, and uncoordinated bio-safety regulations, and absence of strict mandates, or transparent guidelines. The qualitative findings have been in conformity with the study hypothesis to the case of Bt Cotton released recently in the Sudan.

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This study is undertaken for the first time to describe the status of GMO bio-safety in the Sudan and clarify the implications of bio-safety drafted frameworks guidelines and legislatives potential implementations. This contributes to the growing body of literature on bio-safety regulation status in the Sudan. Finally, the major limitations of this study lies in the narrow range of GMO bio-safety disciplines coupled with limited-capacity of bio-safety which is restricted to the main bio-safety process of public participatory and analysis communications. Further research will be needed to explore the impacts of introduced GMO events like Bt Cotton, and investigate the need to rigorous follow-up procedures for bio-safety guidelines process.

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