THE LEGAL REGULATION OF BIOSAFETY RISK: A REVIEW OF THE SOCIO-ECONOMIC ISSUES

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ABSTRACT

This paper examines the socio-economic consideration as part of the Key biosafety issues from the Cartagena Protocol on Biosafety to the Convention on Biological Diversity that governs the transboundary movement of living modified organisms (LMO) for the protection of human health and the environment. This doctrinal research reiterates the benefits and risks from the modern biotechnology products together with the precautionary principle for the uncertain areas of science. This paper finds that bioethics and the formal inclusion of socio-economic consideration into the biosafety decision-making process that lays down the foundation of good biosafety governance apart from the risk assessment. In conclusion, the institutionalisation of bioethics will contribute to a more effective implementation of the Key Protocol issues from the socio-economic perspective that need to be translated into the national biosafety laws as biosafety does not just pose scientific risk but socio-economic issues as well.

Keywords: biosafety, biotechnology, regulation, socio-economic, transboundary

INTRODUCTION AND BACKGROUND ON BIOSAFETY

The biosafety awareness on modern biotechnology came into prominence during the negotiations of the Convention on Biological Diversity (CBD) before it was signed on 5th June 1992 at the United Nations Conference on Environment and Development (UNCED).

CBD acts as a general treaty on biodiversity (De Chazournes, 2009) with the objective as follows:

> *…the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding* (Article 1 of CBD).

Thus Article 19 of CBD reflected the agreement on biotechnology that '…the Contracting Parties shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities.' The developing countries that provide the genetic resources for research were particularly affected. Article 19(3) states that the countries shall consider a Protocol for '…safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity'. The countries by natural or legal persons are to provide use, safety regulations and information on the potential adverse impacts for the handling of such organisms (Article 19(4). The CBD later led the development of negotiations of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as Cartagena Protocol on Biosafety).

According to Cartagena Protocol on Biosafety, the term 'biosafety' is used to describe the efforts in reducing and eliminating potential risk such as producing newer toxins and allergens, resulting from biotechnology and its products.Cartagena Protocol on Biosafety was negotiated by

various countries to protect the potentially harmful effects of modern biotechnology products that affect human health and the environment (Article 1).

Modern biotechnology is defined in Article 3(i) of the Cartagena Protocol on Biosafety as the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Law is identified as one of the enabling mediums in realising the potential and avoiding the risks of GMOs (Glowka et.al., 2003).

The products of modern biotechnology are mainly either living modified organisms (LMOs) or genetically modified organisms (GMOs) such as GM corn, potato, tomato, rice, drugs, human insulin and many others. This product comes with benefits resulted from the used of modern biotechnology namely increased micronutrients levels and removal of food allergens. However, there is also a potential risk to human health and the environment since it can produce newer toxins and allergens.

DEFINITION OF BIOSAFETY

Biosafety, while not clearly defined in the Cartagena Protocol on Biosafety but stated in the introduction as the Objective, it is referred to as a concept that refers to the need to protect the human health and environment from the adverse effects of modern biotechnological products. However, that concept is precise and general in explaining the term 'biosafety' as biosafety can cover extensive areas of application. The biosafety definition is said to be very general as there is no 'best' approach to biosafety analysis (McLean et al.,2002).Biosafety can be defined as the regulatory systems and risk analysis process that is designed to perform proper risk assessments, mitigation and communication of GM products to ensure their safe use (Falck-Zepeda, 2009).

BENEFITS AND RISKS OF MODERN BIOTECHNOLOGY AND LMOS

The Cartagena Protocol on Biosafety in its preamble focuses on the regulation of modern biotechnology and its products, i.e. GMO or LMO and not specifically on genetic engineering. Thus, it is vital to summarise the benefits of the modern biotechnology products.

The benefits of modern biotechnology and its products

The benefits of modern biotechnology can be summarised as follows (Ratledge, 2006) (the list is not exhaustive):

1) GM plants that are insect resistance (Schuler, 1998) and herbicide tolerance (Shah,1986).
2) GM plants contain better traits of food (Nuffield Council on Bioethics, 1999) that can feed the growing population in the world (Conway, 1999).
3) GM plants have increased micronutrients levels, (Bouis et al., 2003) removal of food allergens (Eliot, 2003) and productions of vaccines (Nuffield Council on Bioethics, 1999).
4) Genetic modification that extends beyond foodstuffs for example cotton has been modified to resist essential pests such as boll weevil (beetle which feeds on cotton buds and flowers).

The scientific risks of modern biotechnology and its products

On the other hand, despite the known benefits, there are some products of genetically modified organisms as a result of modern biotechnology is also said to pose higher risks in the following ways (Sateesh, 2008):

a) genetically modified organisms (GMOs) can adapt and multiply in the ecosystem compared to native flora (Prakash, 2011).
b) GMO can transfer genes (Prakash, 2011) related to virulence (the degree of pathogenicity of a microorganism as indicated by case fatality rates and/or its ability to invade the tissues of the host) (Dictionary of Medicine, Nursing, and Allied Health, 2003) or pathogenesis (the development of morbid conditions or of disease; more specifically the cellular events and reactions and other pathologic mechanisms occurring in the development of disease) (Dictionary of Medicine, Nursing, and Allied Health, 2003) into native microbial(relating to a microbe or to microbes (a unicellular or small multicellular organism including bacteria, protozoa, some algae and fungi, viruses, and some worms, esp. those that are injurious to other organisms) (Medical Dictionary ,2009) flora.
c) GMO can produce newer toxins (a noxious or poisonous substance that is formed or elaborated either as an integral part of the cell or tissue (endotoxin), as an extracellular product (exotoxin), or as a combination of the two, during the metabolism and growth of certain microorganisms and some higher plant and animal species) (Dictionary of Medicine, Nursing, and Allied Health , 2003)
d) and allergens (Bawa et al., 2013)
e) GMO can transfer the new traits to the related microbes (Sateesh, 2008)

As a consequence, these organisms create situations which are unpredictable, unexplained, uncontrolled and unmanageable. However, this is not always accurate as it can happen to unmodified organisms as well.

PRECAUTIONARY PRINCIPLE

Another problem with modern biotechnology also associated with biosafety risk of scientific knowledge is that there are still some grey areas and uncertainty in science. Thus, in this area precautionary principle as stated in the preamble of Cartagena Protocol on Biosafety is being reaffirmed as stated by Principle 15 of Rio Declaration on Environment and Development. Principle 15 states that to protect the environment, precautionary principle shall be used by states according to their capabilities. When there are threats of severe irreversible damage, lack of full scientific certainty shall not be reasons to postpone taking cost-effective measures to prevent environmental degradation.

POTENTIAL ADVERSE EFFECTS OF MODERN BIOTECHNOLOGY ON SOCIO-ECONOMICS

The discussion of the socio-economic considerations which is part of Cartagena Protocol on Biosafety can be broad likewise complicated and convoluted. These issues are called the ‘fourth criterion’ (Ratledge, 2006) as they are ‘non-scientific’ issues and concerns advocated by some groups and seen as inadequate measures but yet becoming part of the decision making process. It is to be seen how these socio-economic considerations will be placed in the regulation and taken into consideration by the regulators.

These socioeconomic issues seem to be in line with the socio-economic considerations suggested by the Explanatory Guide (Mackenzie, 2003). According to the International Union for Conservation of Nature (IUCN), not all socio-economic considerations may be taken into consideration but limited only to those LMOs affecting the biodiversity. Article 26 of the Cartagena Protocol on Biosafety is said to identify some particular socio-economic considerations

that are expected to be taken into account namely the '…especially about the value of biological diversity to indigenous and local communities'. The Explanatory Guide suggested to include '…the ability of indigenous and local communities to make use of the biological diversity upon which their community's survival and traditional livelihood depends'.(Mackenzie, 2003, p. 164)

The socio-economic considerations can be further elaborated and summarised as follows:

a) the continued availability and biodiversity range in the areas inhabited or used by indigenous or local communities;
b) the erosion of genetic and other natural resources, previously available to indigenous or local communities in their territories; or
c) the loss of cultural traditions, traditional knowledge, and practices in a particular indigenous or local community as a result of the loss of biodiversity in their areas (Mackenzie, 2003).

The discussion of socio-economic considerations in this paper is limited to these three (3) broad issues listed as follows:

a) Socio economic consideration
b) Moral and ethical issues
c) Cultural and religious issues

Socio-economic considerations on modern biotechnology

1 Definition of socio-economics

The term 'socio-economic' seems to be used very broadly as to include social and economic factors (Armin, 2010). Such considerations are important in part because they are related to values that many countries have already officially acknowledged as being relevant and vital in international or domestic law.Taking them into account in biosafety decisions is therefore consistent with such values and law.

2 Legal recognition of socio economic considerations in Cartagena Protocol on Biosafety

The primary convention on biosafety the Cartagena Protocol on Biosafety legally recognised socio-economic considerations as it is stated in Article 26 of the Protocol. According to Article 26 of Cartagena Protocol on Biosafety on socio-economic considerations:

1. *The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.*
2. *The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.*

However, the definition of 'socio-economic' is nowhere defined in the Cartagena Protocol on Biosafety. The only important socio-economic consideration issue that is stated in Article 26 is the impact of the living modified organisms (LMOs) on the 'conservation and sustainable use of biodiversity especially about the value of biodiversity to indigenous and local communities'. Moreover, it is mentioned in the next part of the Protocol that the Parties are expected to collaborate on research and information exchange on such issues of socio-economic. The socio-economic considerations leave a room for broad interpretation.

Biosafety risk assessment procedures are now an established prerequisite for transboundary movements of GM materials, also for research, developments and release of LMO

into the environment. Although Cartagena Protocol on Biosafety focused on the potential effects and harms of the GMO on the environment as it is the scope of the Convention on Biological Diversity, the Protocol allows the possibility of including of other considerations such as food safety and socio-economic considerations. Furthermore, it is true that Cartagena Protocol on Biosafety is not the only guidance document about risk assessment of GMO, as other treaties and agreements exist, such as Codex Alimentarius. However, Cartagena Protocol on Biosafety due to the negotiations between parties has indeed broadened the narrower environmental scope of the Protocol (Falck-Zepeda, 2009). Jaffe (2005) however argues that Cartagena Protocol on Biosafety limits its scope to factors affecting biodiversity.

3 An analysis of the socio-economic considerations according to the Cartagena Protocol on Biosafety

Article 26 of the Protocol does not detail out on how this socio-economic considerations is to be taken into account, but it must be consistent with their international obligations such as World Trade Organisation (WTO) as it might create trade barriers (Mackenzie, 2003).However, the broad language of Article 26(1) enables the states to take socio-economic considerations into account during:

i) a decision on import under the Protocol or
ii) under its domestic measures implementing the Protocol

Thus, parties may take relevant socio-economic considerations when implementing some provisions according to the Protocol (Mackenzie, 2003, p.165) and also in accordance to its domestic measures in implementing the Protocol to protect the impact of the LMOs on its biodiversity.

4 The pros and cons of including socio-economic considerations in the biosafety decision-making process

The inclusion of the broader socio-economic considerations into GMO biosafety analysis decision-making process is controversial. Falck Zepeda (2009) highlights that there are two opposing views on the issue of inclusion of socio-economic considerations in the biosafety risk assessment.

The most important opinion against the inclusion of socio-economics in the biosafety decision-making process is that it will serve as a ‘blanket justification’ to reject GM technologies without a clear statement or reason. In this regard, socio-economic considerations may follow the regulatory development pathway in which some countries used the precautionary principle that allows them not to make a regulatory decision and/or as pre-emptive measures to reject GM technologies. Paarlberg (2008) presents similar arguments in this line of thought. The view states that the inclusion of socio-economic view states that a broad, undefined socio-economic consideration will be disruption to technology development and transfer.

On the other hand, socio-economic consideration is important to protect the negative impact of GM products towards local and indigenous people. This view includes not just the scientific risk assessment but also broader socio-economic considerations including ethical, philosophical and religious concerns and by doing so this position potentially aligned itself to the precautionary principle.

In essence, for the inclusion of socio-economic considerations to be successful and fruitful into the biosafety and biotechnology decision-making process it is useful to characterise the so-called functional biosafety system by Jaffe (2005) which are transparent, well defined, protective and understood by all actors and stakeholders. These biosafety regulation aims should serve as a general guide for inclusion of the socio-economics in biosafety decision-making.

In realising socio-economic considerations into biosafety, the decision-making process is to identify what are the socio-economic issues at stake and why there is the need for these issues to be taken into account. Then after agreeing on the relevant issues, next questions will be how are they to be realised, how to implement them and at what point of decision-making are they relevant. These are general issues when socio-economic considerations are to be broadly included in the biosafety decision-making process.

Moral and ethical perspectives on biosafety risks from modern biotechnology application

1 Moral issues

This moral issue is another controversial issue as the technology used in modern biotechnology, especially genetic engineering and the genetically modified products. The issues of moral, ethical and cultural are closely related and have connections in which case to some community, religions shape their belief. However to those who have no belief in religion, moral is their perception and judgment of good and evil or perhaps the current socially accepted norms.

Social norms serve as foundations of social order, helping to ensure that people will act in ways considered pro-social by their society, for example from taking care of their children to paying their taxes (Etzioni, 2000).While in the law and technology regulation context, social norms might not play an important role, because layman is clueless on the modern biotechnological scientific process, only to depend on the information supplied by the science community.

The moral is the concept of right or wrong. There are some underlying moral issues regarding genetically modified organisms and the genetic engineering mainly: Are humans allowed to intervene the God's creations?

While these issues are controversial and debatable and different religions might have slightly different views on these issues, these questions might not be relatively easy to answer. However, the general view based on religions is that humans are not allowed to change God's creation. However, if the change for instance through science and technology is for human good then the process and product is morally acceptable. Therefore, religions might permit it to be done perhaps subject to some limitations. Thus, this fundamental issue will then lead to this issue: If we humans create better creations than the original creation of genetic engineering. Are we better than God Himself then? This issue is somewhat thought-provoking but should be borne in mind, morally at least.

While it is claimed that scientific intervention especially the robust technology as in modern biotechnology contradicts with moral belief to change God's original creation sometimes the intervention leads to better life, better crops, it then made humans tolerate with that intervention and accept it.

2 Ethical issues in modern biotechnology

Ethics is defined as the system of moral principles (BBC, 2015). Ethics is the way how people make decisions and lead their lives usually derived from religious belief, philosophies and cultures.

While natural science attempts to tackle the scientific issues systematically, ethical dilemmas are not usually dealt with in a systematic framework (Macer, 2014) and regarded as 'too vague'. While the ethical argument is regarded as vague, the discussion on ethical issues on genetically modified organisms is valid and sound in principle. The peer-reviewed paper by Macer (1995) is of relevance here even though it relates to genetic engineering in public health. Genetic engineering process is part of producing genetically modified organisms that discuss

primarily the same core ethical issues. In the author's opinion, the paper brilliantly laid down fundamental basic ethical principles in GM-related issues with the idea of resolving ethical dilemmas.

There are some essential ethical principles in modern biotechnology which can be summarised as follows:

a) animal rights concerns
b) consent issues
c) access to information and benefit
d) autonomy, ethics of technology choices and knowledge development
e) intellectual property rights and technology transfer
f) the inducement to participation
g) environmental ethics

3 Bioethics

Bioethics, which was coined by Van Rensselaer Potter in 1971 at the University of Wisconsin (Reich, 1994) is the study of ethical aspects of the biology, medical research and practice (Bobyrov). In the context of biosafety, bioethics had been institutionalised leading the Bioethics Council to be established and advising various ethical issues in modern biotechnology.

Bioethics is defined as the broad terrain of the moral problems of the life sciences, ordinarily taken to encompass medicine, biology and some essential aspects of the environmental, population and social sciences. The traditional domain of medical ethics would be included within this array, accompanied now by many other topics and problems (Encyclopedia of Bioethics, n.d.).

Therefore, bioethics is the more specific, relevant and direct moral issues associated with life science, especially modern biotechnology.

Bioethics can be viewed as descriptive, prescriptive and interactive bioethics (Macer, 2003). Descriptive bioethics is how people view their life, moral interactions and responsibilities with living organisms in their life. Prescriptive bioethics is informing people what is ethically good or bad and vital principles involved in decision-making process. Interactive bioethics is debate and discussion between people, groups and communities about descriptive and prescriptive bioethics.

There are some fundamental theories of ethics namely consequence, actions and motives (Macer, 2003). The consequential arguments apply to assess the ethics of biotechnology applications whether they contribute to well-being or not by looking at the outcome. The action-based ethics looks at the morality of the act itself without looking at the consequences. The motive-based theories judged the ethics by looking at the motive of the action for instance whether it was done with good intentions or not.

The underlying ethical principle that is vital in modern biotechnology is that it should not harm the human health and the environment, regardless of the good motive and benefit it offers. The harm could be done to the animals, humans, plants, environment and public. Also, by looking at the fundamental theories of ethics, they might conflict among themselves for example in the application of modern biotechnology field, for instance, using genetic engineering that involves cross gene between animals and plants with the good motive of producing better traits of plants. Therefore, the bioethics is to weigh the benefits and disadvantages of advising on genetic engineering process or genetically modified food. Thus, careful decision-making should be made (O'Mathúna, 2007).

The establishment of bioethics has been in practice in the developed countries, whereas in developing countries bioethics might range to almost unheard of due to lack of information, knowledge and expertise, to development and education process. In developing countries, it is only in recent years references were made to Bioethics Council in matters concerning sciences as it is quite commonplace for them to adopt and adapt the practice from the developed countries. However, it is interesting to see the development of bioethics in protecting humans, animals, biodiversity from excessive manipulations by human themselves.

Cultural and religious issues in modern biotechnology

To some communities, culture is closely associated with religious belief as it is the religions that shape their cultural perspective regarding habits, rituals and beliefs. The cultural and religious perspectives must be taken into account not just to acknowledge the religions that humans profess but perhaps a more significant issue of the acceptance and marketing or business prospect of the GM products. In the case of GMOs, the religious and ethical concerns will be the most controversial issues in the countries where religions remain a robust societal force (Dano, 2007). For example on the acceptability of the GM products, the concept of *'halal'* (permissible, lawful) (Halal Food Authority (HFA), 2016) or *'haram'* (unlawful, forbidden) (Al Quran, Al Maidah 5:3) sets the tone for debate in Muslim societies (Mohd Safian, 2005).

It is essential to see how much cultural and religious issues shape the agricultural landscape of a region and the legality of these measures. Although cultural perspectives have been largely ignored for the sake of development, modernisation, urbanisation and so, cultural issues can interestingly be seen in the case of taro plant in Hawaii. Taro (A tropical Asian plant of the arum family which has edible starchy corms and edible fleshy leaves, especially a variety with a large central corm grown as a staple in the Pacific) according to the Hawaiian people is a belief as the incarnation of their ancestors. To modify the genetics of Hawaiian taro is to alter that which is divine therefore sparked resistance towards GM taro in Hawaii (Coe, 2014).

In the bigger context of religion, there are some known features of dietary requirement worldwide. For example, the Buddhists who are vegan and vegetarian do not consume animals at all. Hindus do not consume beef as cows are regarded as their Gods whereas Muslims are prohibited from consuming pork and liquor as those are banned according to the Al Quran (Noble Book of the Muslims).Therefore these social value~~s~~ issues are vital to be addressed especially when the target marketing areas such as the Muslim Middle East countries whereby the issue of labelling plays a vital role. The biosafety aspect of the GM products is not an issue here but more on the choice of the consumers in either consuming or not the GM products that might contain pork, liquor, beef even allergens like nuts, gluten that would not be accepted by the consumer due to allergies, cultural and religious belief. The religious issue would be a legitimate concern on labelling of GM product with similar concern on the conventional food. If these concerns are neglected, the producers themselves will be losing potential customers. Thus it is of great importance apart from food safety issue to take into account of these cultural and religious concerns which could reasonably be achieved by a proper labelling that enables the consumer to be educated about the products and then to make choices whether to consume or not. It is submitted that it is also ethically wrong not to provide the necessary, relevant content of the GM products by labelling due to cultural and religious concerns although there are some countries do not make labelling a requirement in importing these GM products.

Labelling is good enough to address the cultural and religious concerns on the content of the GM products. However as to the issues of the process of GE technology that might have controversial issues, perhaps other measures should be taken to address this concern. Apart from *'halal'* issues in Islam for food consumption the objectives of the *Shari'ah* (Islamic law), the

issues are discussed in much broader scope which is the benefits of protection and preservation of the religion, life, of intellect, of progeny, of property, and of the environment (Abu Sway, 1998).

On the other hand still in the context of food interestingly enough, under Jewish dietary laws (called *Kashrut*), safety and healthiness of food are not necessarily an overriding factor when determining if something is '*kosher'* (of food, or premises in which food is sold, cooked, or eaten, satisfying the requirements of Jewish law) (Coe, 2014).

Any consequences of those risks and concerns if they become a reality will cause irreversible damage to the human and environment as a whole. Therefore, there is an essential need for this area of modern biotechnology in general and biosafety in specific to be adequately regulated.

BIOSAFETY RISK REGULATION: RISK ASSESSMENT AND SOCIO-ECONOMIC ISSUES

Risks can be defined as the possibility that something unpleasant or unwelcome will happen (Oxford Dictionaries, 2015). However, it is important to note here that these are only risks that can be foreseen to happen or not happened yet. On the issue of regulation, biosafety is very much a risk regulation type.

It seems that risks identified as above are managed by risk assessment and management. Thus, the question is whether that assessment solved the scientific biosafety issues especially in the areas of scientific uncertainty. Another concern is the 'non-scientific' issues such as the socio economic that includes mainly ethics, moral, religious and cultural issues as to how these issues should be managed within the biosafety decision-making process.

Thus, some suggested that there is the need for 'socio-economic assessment' to be introduced in the biosafety risk assessment. Prima facie the inclusion of the so-called 'socio-economic assessment' will look daunting as it perhaps adds cost to the existing risk assessment and management. However, perhaps as a start, these socio-economic risks should be part of the biosafety decision-making process. For instance, to be raised and included in the risk assessment themselves. Thus, the justification and explanation for the socio-economic issues should be made clear to all parties concerned. As stated above some even suggested the socio-economic impact assessment (SEIA) to add further to the bureaucracy process (Stabinsky, 2000).

CONCLUSION

In conclusion, this paper while outlines the basic definitions and background of biosafety, biotechnology, modern biotechnology and controversial issues related to it, in order to understand the real biosafety risks either scientific risks or socio-economic issues. The background of the GMOs or LMOs needs to be understood first before laying out the acceptable rules and regulations also an institutional framework for biosafety governance. The biosafety issues in Europe and the United States significantly influenced other countries as those are the primary worldwide events that shaped the food safety, GMOs, modern biotechnology later biosafety rules and regulation internationally.

Cartagena Protocol on Biosafety covered mostly environmental biosafety. The Cartagena Protocol on Biosafety regulated the transboundary movement of LMOs and introduced some procedures namely Advanced Informed Procedure (AIA), Living Modified for Food, Feed, Processing (LM-FPP) and Notifications.

The risks and benefits from the scientific perspective are assessed by risk assessment and management. Thus, the socio-economic issues that affect the society from modern biotechnology and its products remain in the grey areas. Thus, this paper examines the essential socio-economic

issues and suggested that bioethics and the formal inclusion of socio-economic issues will further strengthen the biosafety regulation at the national and international level. The legal and institutional aspects of socio-economic should be enhanced for the protection of human health and environment to cater for the effects and risks of biosafety.

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