- By Douglas W. Miano

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Contents

1. Biosafety Regulations

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Biosafety Regulations

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Content

- History of biosafety regulations
- Instruments used in biosafety regulations
- Biosafety Regulations in Kenya

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History

Early breakthroughs in genetic modification

- 1973: Successful transfer of viral DNA into Bacterium
- 1973: Yeast genes expressed in *E. coli*
- 1978: Recombinant human insulin is first produced
- 1983: First genetic transformation of plant cells by *agro*
- 1986: First field trials of GE plants (tobacco)
- 1994: FLAVRSAVR tomato approved for release
- 1996 to date: many trials and commercial planting of GM crops

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Beginning of biosafety regulations

- Regulations for rDNA activities Asilomar Conference, USA, 1975
- At the conference, scientists raised concerns over possible adverse effects of the nascent rDNA research activities; and voiced the need to proceed with appropriate s
- Recombinant DNA Safety Considerations, Published in the 'Blue Book' - the basis for regulation of GMOs in the Western world – 1986
- Recommended a step-by-step process of assessing risk
- This marked the beginning of instruments used in biosafety regulations

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Instruments used in biosafety regulations

- Convention on Biological Diversity
- Cartagena Protocol on Biosafety
- WTO Agreements
- International Plant Protection Convention (IPPC)IPPC
- Codex Alimentarius Commission (CAC)
- Office International des Épizooties (OIE)
- Aarhus Convention

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Convention on Biological Diversity (CBD)

- CBD was adopted in Nairobi
- Opened for signature in Rio
- Came into force Dec. 1993
- CBD *Secretariat* hosted by UNEP
- Decisions made by Parties during COP/MOP

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Convention on Biological Diversity

Objectives

… are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising out of utilization of genetic resources

… via access to genetic resources and by appropriate transfer of relevant technologies …

- With respect to modern biotechnology and biosafety, TWO Articles of the CBD are worthy of note:
- Article 8(g) of the Convention obligates contracting parties to establish means (in-country) to manage risks associated with use of LMOs resulting from biotechnology …
- Article 19(3) … need for and modalities of a protocol setting out *appropriate procedures … AIA… in the field of safe transfer, handling and use of living modified organisms resulting from biotechnology that may have adverse effect on conservation and sustainable use of biological diversity…".*

Meeting CBD Obligations

- Development of National Biodiversity Strategies
- Development of National Environmental Action Plans (NEAP)
- Enactment of comprehensive legislative and Institutional Frameworks on environmental affairs (e.g. NEMA in Kenya)
- Participation at International Fora e.g. COP/MOP Meetings

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Cartagena Protocol on Biosafety

- Negotiated, adopted, signed and ratified separately from the CBD

- Protocol aims at … contributing to ensuring an adequate level of protection in the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account human health …

  - Protocol focuses on transboundary movement of LMOs (…*Scope*)

  - Premised on the precautionary approach; AIA; decisions informed by the need to carry out Risk Assessment (Annex III)

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– Precautionary Approach

- Based on ‘principle of prevention’ as golden rule for environmental protection
- Lack of scientific certainty should trigger preventive measures
- Lays burden of proof regarding safety on proponents of a given action

But…. Can also be deter use of science if taken to extreme

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- Advance Informed Agreement

- Transboundary movement of LMOs to be based on prior informed consent (exporter vs importer)
- Inform, 90 days to acknowledge, 270 days to respond
- Decision may call for Risk Assessment
- **Notes, exceptions
  - 1st intentional movement of LMOs
  - Does not apply to some LMOs (those in transit, for contained use, LMO-FFPs)

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- Risk Assessment

- Protocol requires Party of import to base decisions on Risk Assessment carried out in a transparent & science-based manner (Annex III)

- *<u>Methodology</u>*
  - *Identification of potential adverse effects*
  - *Evaluation of likelihood of occurrence*
  - *Evaluation of consequences*
  - *Estimation of overall risk*
  - *Recommendation of risk mitigation*

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- Key Obligations of Parties to CPB

- Article 2 (1) … Each Party shall take necessary and <u>appropriate legal, administrative and other measures</u> to implement its obligations…
- Protocol also refers to Competent Authorities, Focal Points, etc

Mechanism for developing an NBF

- **A Policy on Biotechnology/Biosafety**
- **A legislation on biosafety**
- **A System for handling requests or notifications**
- **A System for monitoring & enforcement**
- **Mechanisms for Public Awareness, Education & Participation**

- Key Obligations of Parties to CPB

- Article 2 (1) … Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations…
- Requires the formation of Fully Functional National Biosafety Framework (FBF)
- Protocol also refers to Competent Authorities, Focal Points, etc

Mechanism for developing an NBF

- A Policy on Biotechnology/Biosafety
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- Status of NBFs in SSA

Four categories of countries:

1. countries with fully-functional NBFs,
2. countries with interim NBFs
3. countries whose NBF is ‘work-in-progress’
4. countries with little progress on NBFs.

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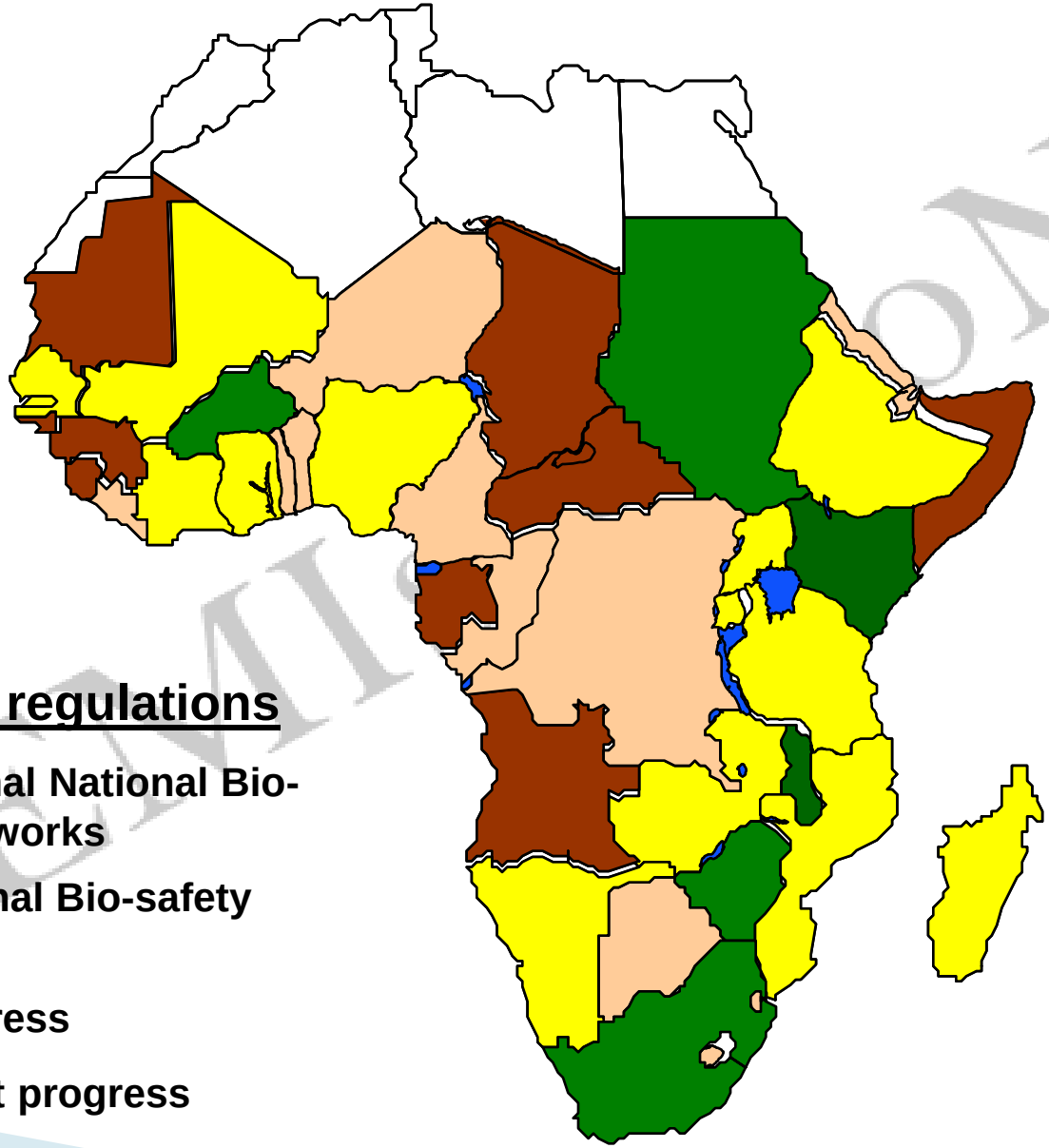

Status of GM regulations

- Fully functional National Bio-safety Frameworks
- Interim National Bio-safety Frameworks
- Work in progress
- No significant progress

WTO Agreements

- WTO is a global organization dealing with rules of trade between nations
- Formed in 1948 in Havana (Cuba) – GATT
- Seeks to bring about 'fairness' in rules of trade through agreements, negotiated, signed and ratified by Member countries
- WTO Members are expected to abide by a 'package' of multilateral trade agreements…
- Two agreements apply to biosafety of LMOs:
    1. WTO-SPS
    2. WTO-TBT

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- WTO – SPS Agreements

- WTO-SPS Agreement covers all '*necessary*' measures taken by Member states to protect *human, animal* and *plant health* from risks arising from *food additives, toxins, pests and diseases*

- SPS measures have to be *non-discriminative (Art. 2.3);* based on *Necessity (Art. 5.6)* and be *scientifically justifiable*

- WTO contracting parties are obligated to ensure that any SPS measures are based on existing international standards (IPPC, Codex, OIE) or other such standards based on RA

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- WTO-TBT Agreement

- The WTO-TBT Agreement covers all *technical regulations*, standards and conformity assessment procedures (e.g. *packaging, marking, labelling* requirements) that do not fall under the SPS Agreement

- TBT Agreement tries to ensure that regulations, standards and certification procedures are not slanted so as to create unnecessary obstacles to international trade by:
  - encouraging the practice of 'standard equivalence' between countries
  - promoting use of international standards
  - mandating Member countries to establish enquiry points and national notification authorities

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International Plant Protection Convention (IPPC)

- A multilateral treaty for cooperation in plant protection
- Aims at securing common and effective action for preventing the introduction and spread of pests of plants and plant products, and at promoting appropriate measures for their control
- Adopted by FAO (1951); came into force 1952; revised … further revised in 1997
- A legally binding international instrument requiring Member governments to cooperate through development and adoption of International Standards for Phytosantinary Measures (ISPMs)
- Since November 1993, when the first ISPM was approved, a total of 24 standards a covering a wide range of topics
- ISPM No. 11 was developed to address *Pest Risk Analysis For Quarantine Pests Including Analysis of Environmental Risks and Living Modified Organisms (LMOs).*

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Codex Alimentarius Commission

- Administered jointly by FAO/WHO since 1963; has 175 members
- sets sanitary and technical standards for food safety, codes of hygienic, limits for pesticide residues in foods, and standards for contaminants and food additives
- CAC protects the health of consumers and ensures fair trade practices in food trade

- Regarding GMOs CAC has published:
  - Principles for Risk Analysis on food derived from modern biotechnology (FAO/WHO, 2003a)
  - Guideline for food safety assessment of food derived from recombinant-DNA plants (FAO/WHO 2003b)
  - Guideline for food safety assessment of food produced using recombinant-DNA microorganism (FAO/WHO, 2003c)

- Codex guidelines are non-binding
- CAC approach is based on concept of familiarity, comparative approach and substantial equivalence

Office International des Épizooties (OIE)

- World Organization for Animal Health
- OIE deals with animal health and zoonoses
- Covers biotech applications such as recombinant vaccines, animal cloning etc
- Tasked to work and publishes sanitary standards for the international movement of animals and animal products

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Aarhus Convention

- Convention on Access to Information, Public Participation and Access to Justice in Environment Matters
- Adopted in 1998, entered into force in 2001
- Provides for developing access to information, public participation and access to justice with respect to GMOs
- Guidelines prepared were initially voluntary

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Biosafety Regulations of GMOs

Case of Kenya

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Biosafety Act and Regulations

- Kenya signed Cartagena Protocol (2000&2003)
- Biotechnology Development Policy-2006
- Biosafety Act No. 2:- 12th February 2009
- Establishment of National Biosafety Authority (NBA) in 2011

1. Contained Use (2011)
2. Environmental Release/ Placing on the market (2011)
3. Import, Export and Transit (2011)
4. Regulations for Labeling (2012)
5. Draft: Handling, Storage, Packaging and Transportation

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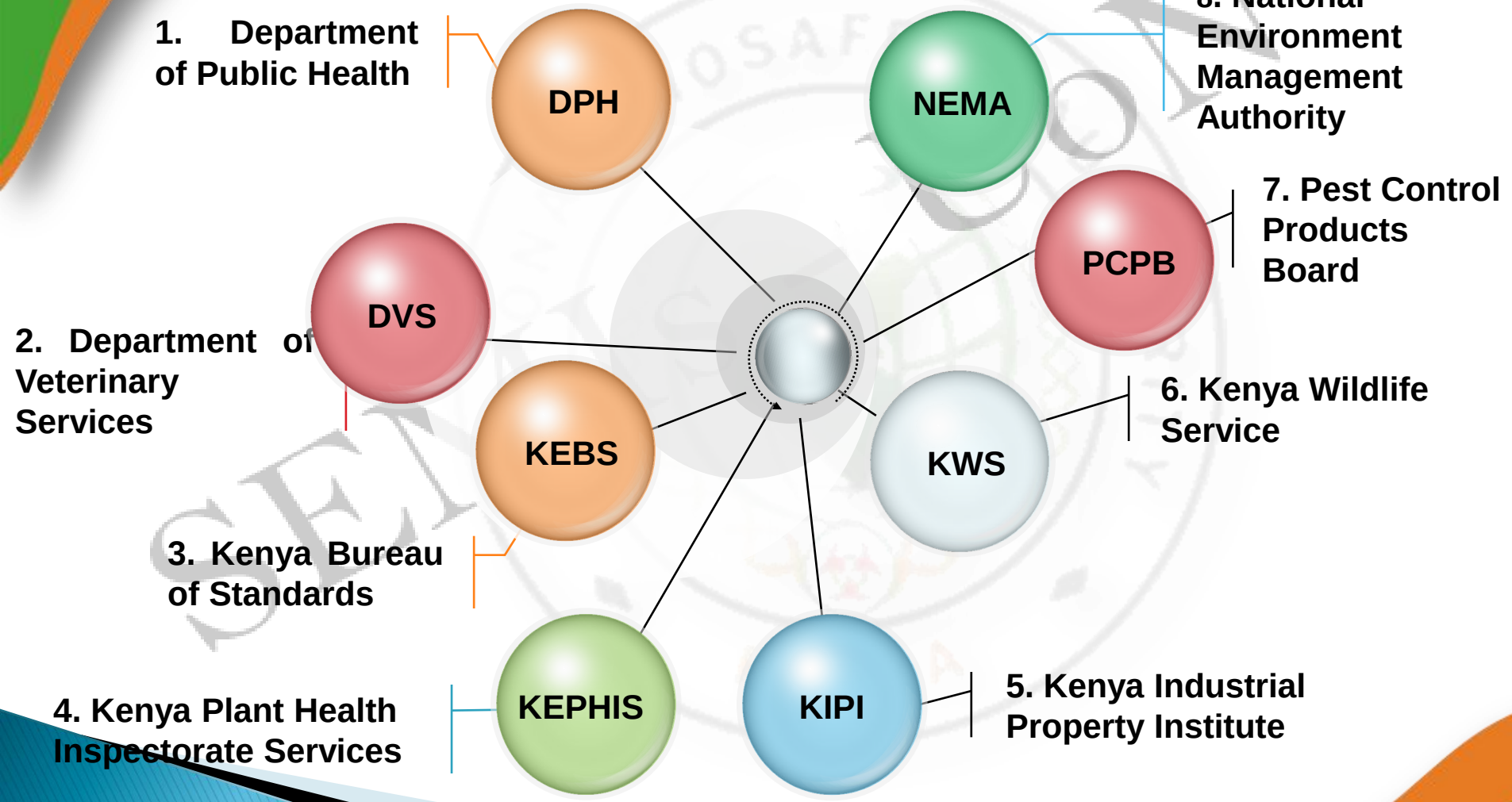
Regulatory Agencies (RAs)



STAGES IN REGULATORY PROCESS

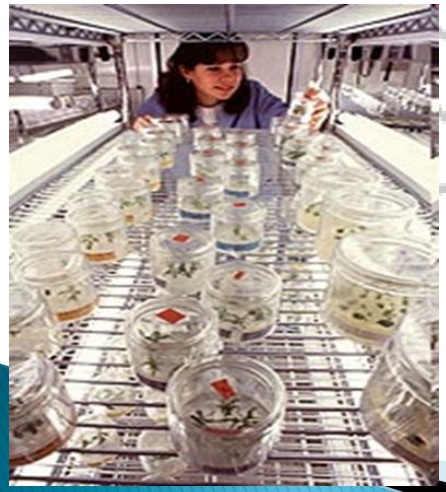
Environmental Release

Commercialization

Contained-use

CFT

BSL2: Lab.



BSL2:Greenhouse

DUS, NPT, Variety Release

Post-release monitoring to detect environmental risks

Goal: to **ensure** that products of biotechnology are considered safe to human and animal health and the environment.

Objectives of Regulations

1. **Contained Use / Environmental Release (2011)**
   - Ensure that potential adverse effects of GMOs are addressed to protect human health and the environment when *conducting experiments in the Lab., GH or CFT (contained use)/ environmental release.*

2. **Import, Export and Transit (2011)**
   - Ensure *safe movement* of GMOs into and out of Kenya while protecting human health and environment.

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3. Labeling (2012)

- To ensure that consumers are aware that food/feed or product is GMO for informed choice

- To facilitate traceability of GMO products towards enforcement of appropriate management measures

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Sources of GMOs Products in the country

- Through imports
  - Safety assessment dependent on history of safe use

- Through research from within the country
  - Goes through the whole process of product development including containment and Environmental release / placement in to the markets

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Contained use

- Includes activities done in the laboratory, greenhouse and confined field trials
- Must be done in at least a biosafety level II facility
- Contained Use regulations must be followed

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Environmental Release

- This entails production of GM products in the open fields and placement of products in to the markets
- In Kenya, any GM products must be labelled if it contains more than recommended levels GMO
- Risk assessment / analysis and socio-economic considerations must be done
- Varieties must go through the normal process of variety release, may be considered an Essentially Derived Variety depending on the background

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Offences and Penalties

- Several offences have been created under the Act; -
  - makes contained use of, releases into the environment, places on the market, imports or exports a genetically modified organism without the approval of the Authority
  - uses a GMO in a manner inconsistent with the approval granted by the Authority or for unethical purposes
  - obstructs or fails to assist the Officers of the Authority in the performance of their duties under this Act
- The penalty is Ksh. 20 million and/ or imprisonment of up to ten years or both

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