Annex 7

SECTION 4.

**DISEASE PREVENTION AND CONTROL**

CHAPTER 4.X.

**BIOSECURITY**

Article 4.X.1.

Introduction

*Biosecurity* is the cornerstone of health programmes and as such should be implemented to prevent and control diseases in *populations*. In addition to reducing the risk of disease, the benefits of *biosecurity* include a reduced need for *veterinary medicinal products*; reduced *killing* of *animals* for disease control purposes; reduced economic losses; protection of livelihoods; assurance of sustainability of animal production; improved food security and food safety; promotion of animal, human and environmental health, and assurance of safe trade and business continuity.

Article 4.X.2.

Purpose and scope

This chapter provides general principles and recommendations to allow for a consistent approach that could be applied to implement *biosecurity* for a *population* or *subpopulation* irrespective of the settings or scale, such as at country, *zone*, *compartment*, *herd/flock*, farm or non-production establishment level.

The purpose of this chapter is to provide guidance to the *Veterinary Authority* and other relevant actors, as described in Article 4.X.4~~5~~., on the principles, implementation and evaluation of *biosecurity* to support disease prevention and control programmes. The chapter applies to *animals,* their gatherings and husbandry systems, to all components of animal ~~production~~keeping and to the interface between domesticated *animals*, humans and *wildlife*.

More specifically, this chapter aims to:

− describe the general guiding principles of *biosecurity*;

− identify the roles and responsibilities of the different actors in *biosecurity*;

− describe the potential sources and pathways for entry of pathogenic agents into a *population* and the exposure of *animals* and factors for the transmission of pathogenic agents;

− describe the ~~procedures and~~ components of *biosecurity*;

− provide guidance on the design, application, monitoring*,* evaluation and training with regards to *biosecurity* and *biosecurity* *plans.*

~~The chapter applies to all~~ *~~animals~~* ~~including~~ *~~wildlife~~*~~, to any type of animal gatherings and husbandry systems, to all components of animal production and commercial chains and to the interface between domesticated animals, humans and~~ *~~wildlife~~*~~.~~

The chapter does not apply to laboratories, whose approaches to biosecurity are addressed in the Terrestrial Manual.

~~Article 4.X.3.~~

~~Definitions~~

~~For the purposes of this chapter:~~

**~~All-in all-out~~** ~~is the management practice to remove all the~~ *~~animals~~* ~~prior to new~~ *~~animals~~* ~~entering a shared space with the subsequent cleaning and decontamination of the space where the~~ *~~animals~~* ~~are housed to prevent the transmission of pathogenic agents between groups of~~ *~~animals~~*~~.~~

**~~Fomite~~** ~~is an inanimate object that can carry pathogenic agents.~~

**~~External~~ *~~biosecurity~~*** ~~also referred to as bio-exclusion or bio-containment, is a set of measures that aims at preventing pathogenic agents from entering or escaping a~~ *~~population~~*~~.~~

**~~Internal~~ *~~biosecurity~~*** ~~also referred to as bio-management, is a set of measures that aims to reduce the spread of pathogenic agents within a~~ *~~population~~*~~.~~

Article 4.X.~~4~~3.

General ~~G~~guiding ~~general~~principles

*~~Biosecurity~~* ~~aims to reduce the~~ *~~risk~~* ~~of introduction, establishment and spread of pathogenic agentsbreak thecycle of~~ *~~infection~~* ~~by intervening at their source, during their transmission, or at the susceptible hosts.~~ To achieve the objective of *biosecurity*~~this~~, the following ~~principles~~should be considered:

1) The *population* for which *biosecurity* is to be implemented, including context and size, and its *animal health status*.

~~1) The~~ *~~animal health status~~* ~~of athe~~ *~~population~~*~~for which the~~ *~~biosecurity~~* ~~is being implemented should be known~~.~~, to identify where improvements to the animal health and productivity may be required~~*~~.~~*

2) *~~Biosecurity~~* ~~should be based upon~~ *~~risk analysis~~* ~~as described in Chapter 2.1. and be aligned with relevant legislative requirements.~~

~~3)~~ *~~Risk assessments~~* ~~applied to~~ *~~biosecurity~~* ~~should identify the~~ *~~hazards~~* ~~and how and where these pathogenic agents~~ The identification of the *hazards* and from where and h~~H~~ow ~~and where~~ the pathogenic agents ~~are~~ may be introduced, established and spread ~~and established~~ in the *population.*

3) The factors and frequency of events~~certain activities, which~~ that influence the introduction~~entry~~, establishment and spread ~~and establishment~~ of pathogenic agents~~, should be considered in the~~ *~~risk assessment~~*.

4) *~~Biosecurity~~* ~~should be based on~~ S~~s~~cientific evidence and proportionality to the *risk*.

5) *~~Biosecurity~~* ~~should be~~ S~~s~~ustainability~~le~~, adaptability~~le,~~ and monitoring~~ed~~. ~~and subjected to a documented routine and ongoing evaluation and should include long-term planning.~~

6) ~~A~~ *~~biosecurity plan~~* ~~is essential for ensuring consistent implementation of~~ *~~biosecurity~~*~~.~~

~~7)~~ *~~Biosecurity~~* ~~should be designed to account for~~ H~~h~~uman behaviour to maximise compliance.

7~~8~~) Evaluation of compliance ~~of~~ *~~biosecurity~~* ~~should be~~ built into the day-to-day operations.

8~~9~~) ~~The~~ S~~s~~ocio-economic impacts of *biosecurity* ~~and the context and size of the~~ *~~population~~* ~~to which the~~ *~~biosecurity~~* ~~is being appliedshould be considered.~~

9) Impacts on other *populations*~~including~~ *~~wildlife~~*~~,~~ and the environment.

10) A *biosecurity plan* that promotes consistent implementation of *biosecurity*.

11~~10~~) Engagement with, ~~T~~training and awareness of, and communication with, all actors involved in *biosecurity* ~~is essential to successful outcomes~~.

These principles of *biosecurity* apply to any type of activity (intensive, extensive, commercial or non-production); only the measures comprising the *biosecurity* should be adapted to the situation.

Article 4.X.~~5~~4

Roles and responsibilities

The roles and responsibilities of different actors in *biosecurity* should be clearly defined and communicated with consideration made to the context (e.g. country, *zone~~establishment~~*, *compartment* or *establishment* *~~zone,~~* ~~country~~ level), scale ~~of operations,~~and type of ~~production~~ operations~~and supply chain~~. Implementation of *biosecurity* requires engagement and collaboration amongst all actors involved.

1. ***Veterinary Authority***~~,~~ or ~~in collaboration with~~ other relevant *Competent Authorities~~,~~* should be responsible for the development and oversight of policy on and legislative frameworks ~~of~~for *biosecurity*. These policies should include the relative contribution and roles of *veterinarians* and *veterinary paraprofessionals* in both the private and public sectors, and provide guidance for the implementation of *biosecurity*. For international trade purposes, the *Veterinary Authority* should have an active role in the ~~development, implementation,~~ enforcement, oversight, and verification of *biosecurity* and *biosecurity plans*.
2. ***Veterinary Services*** should execute and implement policies and legislation on *biosecurity* under the supervision of the *Veterinary Authority~~ies~~* or otherrelevant *Competent Authorities.*
3. ***Veterinarians* and *veterinary paraprofessionals* and other relevant~~animal health~~  advisors** should give advice ~~to animal breeders, owners, and keepers~~ on *biosecurity* ~~which may include the design,~~ and the ~~and evaluation of~~ *~~biosecurity~~* ~~and~~ *biosecurity* *plans* ~~and training~~. This advice should be aligned with the policies and legislation ~~set by the~~ *~~Veterinary Authority~~* ~~or other~~ *~~Competent Authorities~~,* where available.
4. **~~Animal b~~Breeders, owners, managers, keepers, transporters, ~~and~~ feed producers and other relevant actors** are responsible for developing, implementing and monitoring *biosecurity* and the *biosecurity plan* and should seek advice from *veterinarians,* ~~and~~ *veterinary paraprofessionals* ~~and~~ or other ~~animal health~~ relevant advisors ~~and are responsible for developing, implementing and monitoring~~ *~~biosecurity~~* ~~and the~~ *~~biosecurity plan~~*.
5. **Training entities** should provide~~should include~~ training in *biosecurity* ~~as part of the standard programmes and the training should be tailored~~ for ~~all~~ relevant actors. Coordination between the *Veterinary Authority*, other relevant *Competent Authorities*, the *~~V~~veterinary ~~S~~statutory ~~B~~body* and veterinary educational ~~establishments~~ institutions may be required to ensure biosecurity training delivered to *veterinarians*, *veterinary paraprofessionals* and other relevant advisors meets relevant standards.
6. **~~Industry groups representing f~~Farmer associations~~Farmer~~, *~~Veterinary Statutory Body~~*~~,~~ veterinary and para-veterinary associations, ~~feed companies, live animal transport associations~~ and other relevant ~~other relevant stakeholder~~ associations ~~representatives~~**should advocate and promote *biosecurity* among their members~~, including signposting to relevant training and advice~~.

Article 4.X.~~6~~5.

Potential sources of pathogenic agents

Pathogenic agents can be ~~introduced from and~~ spread through different sources ~~of~~ *~~infection~~* which should be considered when implementing *biosecurity* and developing a *biosecurity plan*. The main sources of pathogenic agents to be considered include:

1) *animals,*

2) *germinal products,*

3) secretions and excretions,

4) *animal products,*

5) dead *animals* and parts thereof and afterbirth materials,

6) arthropods such asmosquitoes, midges, flies, lice or ticks,

7) fomites such as peoples’ clothing, boots, *vehicle*s, crates, bedding, or ~~general~~farm equipment,

8) *feed* and *feed ingredients* including forage, grazing pastures and swill,

9) water, soil~~, surfaces~~ and air,

10) *biological products,*

11) humans.

Article 4.X.~~7~~6.

Transmission pathways

Transmission of pathogenic agents can occur either through *animal*-to-*animal* contact without an intermediate (direct transmission), or through an intermediate such as fomites, water, *feed*, *animal products*, *germinal products*, *biological products*, humans and animal environment (indirect transmission). Transmission pathways of pathogenic agents should be considered when implementing *biosecurity* or developing a *biosecurity plan.* Transmission pathways are not mutually exclusive and include:

1. ~~Direct transmission through~~ *~~animal~~*~~-to-~~*~~animal~~* ~~contact including their through secretions and excretions without an intermediate. It includes contact between domesticated~~ *~~animals~~* ~~and~~ *~~wildlife~~*~~.~~
2. ~~Indirect transmission through an intermediate such as fomites, water,~~ *~~feed~~*~~,~~ *~~germinal~~**~~products, biological products,~~*  ~~humans and~~ *~~animal~~* ~~environment.~~
3. Vertical transmission ~~of pathogenic agents~~ from parents to offspring in ovo, in utero or during birth.
4. Horizontal transmission~~s~~ from one *animal* to another that ~~are~~ is not vertical.
5. Iatrogenic transmission ~~through medical interventions~~.
6. Sexual transmission ~~of pathogenic agents that are shed in~~ through reproductive secretions such as semen and vaginal fluids or transmitted directly between surfaces in contact during mating.
7. Vector-borne transmission via *vectors* including blood-feeding arthropods such as mosquitoes, flies, ticks, fleas and lice. *Vectors* may be mechanical with no biological association between the *vector* and pathogenic agent or biological where the pathogenic agent undergoes a multiplication or a developmental change within the *vector*, necessary for survival, transmission or host *infection*.
8. ~~Airborne or d~~Droplets or airborne transmission of pathogenic agents through particles suspended in the air. Pathogenic agents may travel in particles of multiple sizes ~~ranges~~ (droplets and droplet nuclei) that remain suspended in the air or deposited on surfaces. Airborne transmission may include short or long distances (which may be referred to as aerosol or wind-borne transmission, respectively).

Article 4.X.~~8~~7.

Components of biosecurity

*Biosecurity* can be applied to any type of *population.* The components of *biosecurity* focus on reducing the risk of transmission of pathogenic agents through interactions with elements outside the *population* (external *biosecurity*) and on reducing risk of transmission of pathogenic agents within the *population* (internal *biosecurity).*  All relevant components of *biosecurity* should be appliedto address all sources of pathogenic agents, transmission pathways as well as unexpected*~~risks~~* events, and may vary according to the *population*. *~~Biosecurity~~* ~~can be divided into: 1) external~~ *~~biosecurity~~*~~, and 2) internal~~ *~~biosecurity~~*~~. External~~ *~~biosecurity~~* ~~mainly focuses on interactions with elements outside the~~ *~~population~~* ~~(e.g. other farms, other regions) whereas internal~~ *~~biosecurity~~* ~~focuses on reducing risk of transmission between elements of the~~ *~~population~~*~~. The distinction between external and internal~~ *~~biosecurity~~* ~~is not absolute and can vary depending on the scale considered (e.g. country, region,~~ *~~herd/flock~~*~~).Several components of~~ *~~biosecurity~~* ~~may need to be applied to a~~ *~~population~~* ~~and~~ *~~subpopulation~~* ~~to address all sources of pathogenic agents, transmission pathways, sources of~~ *~~pathogenic agents~~* ~~and unexpected~~ *~~risks~~*~~. The components of~~ *~~biosecurity~~* ~~should be documented in a~~ *~~biosecurity plan~~* ~~when possible.~~

1. Components of external biosecurity may include the following:

1. Introduction of *animals,* *animal products* and *germinal products* should be minimised ~~as much as possible~~ and if undertaken, the *animal health status* of the *~~animal~~* ~~and their~~ source *population* should be assessed.
2. Whenever *animals* are introduced into ~~a~~ the *population*, they should go through a~~n~~ monitored isolation period of sufficient length, during which measures may be implemented to mitigate~~minimise~~ the risk of transmission of pathogenic agents.
3. ~~Direct c~~Contact between *population*s of unknown or different *animal health status* should be avoided through segregation using managerial measures, ~~or~~ physical or natural barriers.
4. Human access to the *population* should be~~managed~~ controlled. When humans come in contact with~~Thecontact between humans and~~ *animals,* they should ~~be limited where possible but when required~~  take ~~precautionary~~ measures ~~should be used~~ to mitigate~~reduce~~ the *risk* of bi-directional transmission of pathogenic agents, which includes as a minimum ~~such as~~ wearing ~~farm~~ dedicated~~specific~~ clothing and footwear, and hand hygiene.
5. Equipment used to handle or care for *animals* should not be shared between different *population*s. If shared, equipment should undergo cleaning and *disinfection* before and after use.
6. Transport vehicles in ~~direct and indirect~~ contact with *animals* or their products should undergo cleaning and *disinfection* before and after use.
7. *Animal products*, ~~F~~faeces, ~~or~~ manure or waste materials should be handled in a way to mitigate the spread of pathogenic agents.
8. Dead animals and parts thereof should be handled, ~~and~~ stored and disposed of in a way to mitigate the spread of pathogenic agents and ~~in specific containers, or in designated areas~~ to avoid contact with or attraction of other *animals* ~~in particular~~ *~~wildlife~~*and arthropods.
9. *Feed* should be produced, stored and transported in dedicated equipment to minimise the contact with potential sources of pathogenic agents~~only for the purpose of feeding~~ *~~animals~~*. Feeding of untreated swillshould be avoided. Water should originate from low-risk sources or be treated to remove or inactivate ~~with~~ pathogenic ~~inactivating~~ agents ~~prior to use~~. The safety of the water and *feed* should be checked regularly.
10. ~~Direct and indirect c~~Contacts between the *population* and pets, birds, rodents, insects and ~~birds,pets,~~ other *wildlife*~~,~~ or pests ~~and the~~ *~~population~~* should be avoided using engineering, mechanical or chemical control.
11. To minimise airborne transmission of pathogenic agents, ~~S~~sufficient distance between *populations* and ~~other~~ possible sources of pathogenic agents should be considered. In some circumstances, air treatments~~air filtration~~ might be considered. ~~when feasible and sufficient distance or other measures cannot be implemented to mitigate the risk of transmission.~~
12. When cleaning and *disinfection* or other measures are not feasible or effectiveness is undetermined, an additional period of no contact between potential ~~carriers~~ sources of pathogenic agents (e.g. ~~people~~humans, buildings, *vehicles*, equipment, materials, pastures ~~and air spaces~~) and the *population* ~~can~~ may be applied. The effectiveness of this measure will depend on the specific circumstances and should be verified.

2. Components of internal biosecurity

1. ~~Diseased~~ Sick *animals* should be isolated to prevent other *animals* from being exposed. Treatments should be administered safely to avoid iatrogenic transmission.
2. All-in all-out management should be applied to all *animals* kept in the same ~~air~~ space including cleaning and *disinfection* of the space between groups of *animals*.
3. Stocking densities that ~~may~~ result in impaired health through increased transmission rates of pathogenic agents or increased susceptibility to *infection*s should be avoided~~avoidedconsidered inthe risk analysis~~.
4. *~~Animals~~*W~~w~~ithin the *population*, *units* with different characteristics ~~such as age and immune status~~should be kept separately.
5. ~~It is advisable to organise t~~When the management of the *population* involves contact with different *units*, ~~T~~the workflow should be organised ~~according to disease the risk assessed for each animalcategory, starting at~~from the lowest ~~risk~~ to~~and ending with~~ the highest risk of *infection*, considering transmission of pathogenic agents and susceptibility of the *units*. When moving between the *units*, ~~Whenever entering into contact with a new group or new~~ *~~animal~~* ~~category,~~ *~~biosecurity~~* measures to mitigate transmission of pathogenic agents ~~such as changing footwear and clothing and conductinghand hygiene~~ should be applied~~considered~~. ~~Dedicated equipment or material should be used in each group.~~
6. Cleaning and *disinfection* of the equipment and surfaces should be applied between consecutive groups of *animals*.

Article 4.X.~~9~~8.

Biosecurity plan

A *biosecurity plan* promotes consistent implementation of *biosecurity*, and should balance practicality, cost, regulatory requirements and include necessary provisions for its maintenance. The aim~~purpose~~ of a *biosecurity plan* is to ~~document,~~ organise, ~~and~~ structure and document *biosecurity* including its evaluation.

~~A biosecurity plan should balance practicality, cost, and regulatory requirements and include necessary provisions for its maintenance.~~

The *biosecurity plan* should include the following sections:

1. Purpose and scope

This section should provide an overview of the plan, its purpose and scope. In addition, it should outline the goals and objectives of the plan, as well as the *population* characteristics, including animal husbandry systems, and context.

1. Roles and responsibilities

Design, implementation, and monitoring is a shared responsibility. Therefore, it is essential to describe the roles and responsibilities of all actors for ensuring adherence and compliance with *biosecurity*.

1. ~~Hazard i~~Identification of pathogenic agents, sources and transmission pathways~~and~~ ~~risks assessment~~

In addition to the identification of the potential pathogenic agents of concern ~~(i.e.~~ *~~hazard~~*~~s)and their transmission pathways, This~~ this section should include their potential sources and transmission pathways ~~a summary of the relevant parts of~~ *~~risk assessment~~*~~, notablythe relevant routes of introduction and spread of pathogenic agents and susceptibility of the~~ *~~units~~* ~~in the~~ *~~population~~*~~.and transmission pathways e.g.~~

1. Description of biosecurity

This section should describe~~outline~~ the relevant components of *biosecurity* ~~measures to reduce the risk of~~ ~~introduction, establishment and spread of pathogenic agents to, within and from the~~ *~~population~~* in accordance with Article 4.X.7~~8~~.

It should also include~~emergency and~~ relevant response procedures for emergencies. ~~animal health events.~~

1. Surveillance ~~Surveillance and monitoring~~ of pathogenic agents

The *biosecurity* *plan* should include the procedures for *~~monitoring~~* ~~and~~ *surveillance* to detect the presence of pathogenic agents in accordance with Chapter 1.4.

1. Communication and reporting

This section should outline the procedures for communicating information about the *biosecurity plan* to all relevant actors. It should also include procedures for reporting incidents and sharing information with relevant authorities.

1. Training and education

This section should outline the training and education needs and identify programmes to ensure all relevant actors are aware of the *biosecurity* *plan* and clearly understand their roles and responsibilities to implement and maintain the *biosecurity* and the consequences of non-compliance.

1. Supporting documents

This section should outline the standard operating procedures (SOPs), checklists, and record-keeping templates which describe routine management processes and ensure that responsibilities and duties are consistently fulfilled and documented.

1. Evaluation and improvement

This section should describe the procedures for monitoring and evaluation of the *biosecurity plan* and its implementation in accordance with Article 4.X.11~~10~~. *~~Biosecurity~~* ~~i~~Incidents and breaches in *biosecurity*, ~~and~~as well as corrective actions taken, should be documented. The *biosecurity plan* should be reviewed and updated regularly to ensure its relevance and effectiveness.

Article 4.X.~~10~~9.

Training and awareness

1. Training

Regular training on *biosecurity* should be undertaken according to the needs identified and should include all actors. Training should be provided by those with sufficient qualifications and experience. The training should be in line with legislative and policy frameworks. Such training may include:

− Principles of *biosecurity,*

− Sources of pathogenic agents, transmission pathways and relevant factors to susceptibility,

− Components and implementation of *~~B~~biosecurity**~~risk assessment~~,* including emergency planning and response~~and contingency planning~~,

− Monitoring and evaluation of *biosecurity,*

− Purpose, development and implementation of a *biosecurity* *plan*~~Application and monitoring of~~*~~biosecurity~~*.~~,~~ ~~including emergency response and contingency planning,~~

~~−~~ *~~Biosecurity~~* ~~implementation and evaluation,~~

~~− Purpose, development, implementation, monitoring and evaluation of a~~ *~~biosecurity~~**~~plan.~~*Competency-based training requirements should be identified and documented for each actor. The training achieved should be monitored to ensure the required level of competencies are obtained or maintained.

2. Awareness

All relevant actors described in Article 4.X.4. and ~~T~~the general public, when applicable, ~~and those in~~ ~~industry~~ should be made aware of the importance of *biosecurity* (and the *biosecurity plan* if appropriate) at strategic places (e.g. *border inspection posts*, farm entrances, *markets*) and times (e.g. ~~during~~ disease *outbreaks*, ~~high risk season~~changes in the epidemiological ~~risk~~situation). ~~This~~ Raising awareness may be the responsibility of the *Veterinary Authority*, other relevant *Competent Authorities~~y~~*, *Veterinary Services,* or ~~even~~ producers, ~~farmers~~ and other relevant actors~~stakeholders~~ depending on the context and extent of the *risk.*

Article 4.X.~~11~~10.

Evaluation and improvement

The implementation of *biosecurity,* the compliance with the *biosecurity* *plan* and the effectiveness of implemented measures should be subjected to evaluation for improvement.

1. The evaluation of implementation should be based on predefined scope and criteria, taking into consideration the expected scale of the operation and the characteristics of the *population* concerned. This will determine at which level of responsibility the evaluation should be conducted, and at which frequency. The frequency should be adapted to changing circumstances such as new *animal health status*, newly identified pathogenic agents*~~hazards~~*~~,~~ or changes in epidemiological situation*~~risks~~*, previous evaluations, changes in production or changes in plan. The evaluation should determine the ~~existence and~~ level of implementation of *biosecurity,* through collected evidence that may include documentation of procedures, ~~and~~ other routine records, monitoring technologies, onsite audits as well as interviews with personnel. Based on these findings, the evaluation may allow ~~to~~ the establishment of a risk-based *biosecurity* score as a whole or for each measure.
2. Compliance with the *biosecurity plan* should be evaluated routinely or following a change in epidemiological situation~~risks~~. ~~Compliance should focus on critical control points as identified in the risk assessment and in the~~ *~~biosecurity plan~~* ~~itself.~~ Documented evidence of compliance ~~at these critical control points~~ should be collected routinely and ~~should be able to~~ be provided for any evaluation~~, including formal audit~~. ~~This could~~ ~~include checklists for routine procedures, log sheets, records of training and interviews with relevantactors.~~ The evaluation of compliance with~~to~~ the *biosecurity plan* should be executed by an independent party, in accordance with the policies and legislation*,* where available.~~by an independent party.~~
3. The effectiveness of the *biosecurity plan* should be evaluated routinely or following a change in epidemiological situation~~risks~~, to ensure the *biosecurity plan* is complete, fit for purpose and up to date. The evaluation should be based on animal health or performance data. ~~from within and outside the~~ *~~population~~* ~~(such as mortality or morbidity rates related to the targeted hazards, results of laboratory tests on~~ *~~animals~~* ~~in the~~ *~~population~~*~~,~~ ~~levels of antimicrobial use, cell count trends), and on animal production performance data (such as milkyield, growth rates, egg production).~~

The outcomes of the evaluations should be communicated to all relevant actors and should inform which risk mitigation or corrective actions are needed so that the *biosecurity plan* can be updated accordingly.

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