

Genetic Modification and the Challenges of Biological Crimes

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ABSTRACT

The rapid advancement of genetic modification technologies, particularly CRISPR-Cas9 systems, synthetic biology platforms, and gain-of-function research, presents unprecedented challenges for legal frameworks designed to prevent biological crimes. This paper examines the critical intersection of biotechnology and criminal law, analysing the inadequacy of current national and international legal instruments in addressing the deliberate misuse of genetic modification technologies for criminal, terroristic, or military purposes. The study adopts a doctrinal and comparative legal methodology, systematically reviewing existing legislative frameworks across multiple jurisdictions—including the United States, the European Union, and key signatories to the Biological Weapons Convention (BWC)—as well as examining the regulatory contributions of international bodies such as the World Health Organization and the United Nations. Drawing on twenty-two scholarly sources encompassing legal treatises, international treaties, and empirical biosecurity studies, the analysis identifies three principal deficiencies in current legal frameworks: definitional ambiguity surrounding the scope of biological crimes, fragmented enforcement mechanisms at both national and international levels, and a predominantly reactive regulatory posture ill-suited to the pace of biotechnological innovation. The paper explores the dual-use dilemma inherent in genetic modification, whereby identical technologies enabling life-saving medical advances may equally be weaponised by state or non-state actors. Case studies drawn from India, Egypt, the Russian Federation, and the United States illustrate the concrete challenges of investigating, prosecuting, and adjudicating biological crimes under existing treaty and domestic law regimes. Based on this analysis, the paper proposes core elements for a comprehensive international legal framework, incorporating binding oversight protocols, harmonised legal definitions of biological crimes, mandatory national disclosure mechanisms, and robust cross-border enforcement procedures. The conclusions offer actionable recommendations for legislators, international organisations, and judicial authorities seeking to achieve a principled balance between scientific progress and biosecurity imperatives.

Objectives	This paper examines the critical intersection of biotechnology and criminal law, analysing the inadequacy of current national and international legal instruments in addressing the deliberate misuse of genetic modification technologies—particularly CRISPR-Cas9 systems—for criminal, terroristic, or military purposes.
Methods	A doctrinal and comparative legal methodology was adopted, systematically reviewing existing legislative frameworks across multiple jurisdictions—including the United States, the European Union, and key signatories to the Biological Weapons Convention (BWC)—alongside the regulatory contributions of the World Health Organization and the United Nations. Analysis draws on twenty-two scholarly sources comprising legal treatises, international treaties, and empirical biosecurity studies.
Results	Three principal deficiencies are identified in current legal frameworks: (1) definitional ambiguity surrounding the scope of biological crimes; (2) fragmented enforcement mechanisms at both national and international levels; and (3) a predominantly reactive regulatory posture ill-suited to the pace of biotechnological innovation. Case studies from India, Egypt, the Russian Federation, and the United States illustrate the concrete challenges of

	investigating, prosecuting, and adjudicating biological crimes under existing treaty and domestic law regimes.
Conclusions	The paper proposes core elements for a comprehensive international legal framework incorporating binding oversight protocols, harmonised legal definitions of biological crimes, mandatory national disclosure mechanisms, and robust cross-border enforcement procedures. Actionable recommendations are offered for legislators, international organisations, and judicial authorities seeking to achieve a principled balance between scientific progress and biosecurity imperatives.

Keywords: genetic modification; biological crimes; biosecurity law; international legal framework; dual-use biotechnology

INTRODUCTION

The world has witnessed a revolution in biology. In recent years, global fields such as public health, medicine, agriculture, ecology, and even economics have impressively exploited the natural functioning of life, the sequence of DNA, the self-replication of protein, and bioinformatics. Following ongoing scientific innovations, the future will bring more complex laboratories with additional automation and low-cost components. In turn, living agents may be manipulated in more complex ways, raising doubts about their security. Such consideration has been underscored by worrying scenarios of biocrimes involving the malicious use of these technologies [1]. Preventing those scenarios from happening requires investments in careful legislation, risk assessment, establishing surveillance networks, and understanding the direct misuse of biological products already attempted by unlawful agents. Therefore, some doubts about the potential misuse of biotechnology warrant further consideration.

Genetic modification, especially low-cost tools such as CRISPR-based technologies, may be easily handled and misused by amateurs to assemble a synthetic organism or to misconfigure a wild organism. Many experts have warned that using these technologies is accessible. Additionally, recent research [2] further illustrates the feasibility of biocrimes involving the attempt to create a hybrid organism containing species from different kingdoms barriers. Such doubts about synthetic biology and organisms may pave the way for future forecasts in the same academic community. The deliberate design of a synthetic organism generally breaching a phylogenetic barrier is theoretically impossible at a very basic level, such as the genetic code. However, species barriers could be misconfigured at the down-stream transmission network. With the unlocking of a wide range of species pools as gene reservoirs, computational approaches, together with an increasing number of transformative technologies, may help address such limiting issues. In that sense, professionals in the field should get a stricter awareness of biocrimes involving genetic modification, and further publication of sensitive knowledge should be tightened.

This paper employs a doctrinal and comparative legal research methodology. Primary sources include international treaties (particularly the Biological Weapons Convention and the Cartagena Protocol on Biosafety), domestic legislation from selected jurisdictions (the United States, the European Union, and India), and resolutions of the United Nations General Assembly and Security Council. Secondary sources encompass peer-reviewed academic literature in the fields of biosecurity, international law, and biotechnology governance. The comparative dimension of the study involves systematic analysis of regulatory approaches across diverse legal systems to identify common deficiencies and best practices. Purposive sampling guided the selection of case studies from India, Egypt, the Russian Federation, and the United States, chosen for their diverse legal traditions, geopolitical significance, and documented instances of biotechnology-related security challenges. Content analysis of legal texts and policy documents is applied to identify patterns in definitional ambiguity, enforcement gaps, and regulatory overlap.

Understanding Genetic Modification

Genetic modification is the direct manipulation of an organism's genome using biotechnology. Genetic modification techniques can be used to manipulate different types of DNA molecules, such as constructing new genetic sequences, amplifying specific regions of DNA, altering a genome's information, or inserting and integrating new genetic material into another organism's genome. Gene manipulation techniques involve a basic proximal trigger to effect genetic alterations within living cells [3]. Most organisms have highly evolved repair systems that act to repair or remove genetic defects or insertions, which makes the development of genetically engineered organisms difficult. However, these repair systems often rely on more common breaks or defects, leaving organisms vulnerable to alteration by unusual single DNA double-strand breaks. Researchers take advantage of this vulnerability to protect a foreign DNA sequence so that even in a favorable environment, only a single alteration is executed during a single opportunity.

The development of vectors capable of transferring and integrating desired sequences into the genomes of different hosts initiated an intense search for suitable vectors. Natural plasmids were quickly ruled out due to their limited host range, and alterations to the plasmids of the prokaryotic Herpes virus were extensively explored [4]. However, none were unequivocally established in a host of interest to agriculture. This left viral genomes, which recognized a number of interesting and valuable mechanisms supporting replication and host alteration. For many years, great efforts were devoted to the identification of suitable constructs that would integrate into the agricultural genome. Amongst the many viral candidates, only those from the Caulimovirus and Gemini viruses were eventually recognized as providing suitable vectors. These viruses might integrate efficiently into resistant hosts and quickly evolve elaborate anti-virus defences.

Definition and Scope

Synthetic biology is the design and engineering of new biological parts, devices, and systems, and the redesign of existing natural biological systems for useful purposes. It arises from a convergence of various disciplines within biology and bioengineering and includes a wide range of applications, from the construction of biological circuits and ISP production to the generation of synthetic genomes and art. Genetic engineering refers to the use of molecular tools to introduce, remove, or modify sequences in an organism's genome. Most genetically modified organisms (GMOs) made using genetic engineering techniques are simply better versions of what nature has produced. However, the advent of these techniques means that it is now possible to design genomes for organisms that do not exist in the natural world. This opens the door to significant changes in ecosystems that could lead to unknown consequences and dramatic shifts, including the emergence of new pathogens or vectors. As a rapidly developing discipline, synthetic biology has inherited issues from genetic engineering and expanded on them.

The use of biological systems such as viruses, toxins, and bacteria as weapons is not new. Biological agents are cost effective, can be engineered to be more virulent, and can make it difficult to extrapolate from the deliberate infection source to the perpetrator. Bioterrorism has the potential to cause mass casualties and is one of the most publicized biosecurity threats [1]. Trends of concern include advances in synthetic biology, online access to genetic editing techniques, and the release of genetically modified (GM) mosquitoes to control *Aedes aegypti*. Author motivation may include malice against humans, animals, etc., animal liberation, or religious fanaticism. The need for continued vigilance against this threat is a priority for agencies worldwide and continuing research on pest and pathogen modification and detection methods. While the positive applications of synthetic biology approach are making rapid advances, research use of the potential for negative applications remains a dangerous frontier and should be pursued with care.

International treaties such as the Biological Weapons Convention ban bioweapons and direct aid from genetically engineered organisms but the globalizable nature of science complicates enforcement. A concern in the field of forensic epidemiology is the potency of modern genomic technologies. Signature technologies whose products carry a unique, cheaply recoverable identifier are needed. Assuming safety, affordable signatures that could distinguish natural from GMO would help stay ahead of biothreat gambits.

Historical Background

About 12 years ago, the idea of combining molecular genetics, genetic engineering, cell biology, mathematics, and engineering was heralded as the dawn of a new science with unlimited potential to create artificial biological systems useful to humans and the environment. It has been greeted with scepticism by a nervous general public, as these goals could also lead to new bioterrorist agents. Are there reliable measures to prevent misuse of modern biomedical techniques that lead to results harmful to humans? An answer provided by [5] is sobering: "There is no technical solution to the problem of biological weapons. It needs an ethical, human and moral solution – if it is going to happen at all." It is worth noting that this crucial statement was made just 3 years before the anthrax attack. Listed below are some constraints that show how in the US, the development of dangerous infectious agents, referred to as "select agents," is controlled through technical and administrative hurdles: re-creating an already existing dangerous virus for malicious intent is a complex scientific endeavour requiring considerable scientific knowledge and experience and, more importantly, considerable financial support. Organizations carefully screen all applications for funding of biological research. Genetic engineering to synthesize or modify organisms relies on chemical synthesis of DNA. Synthesizing DNA is automated and carried out with sophisticated, expensive instruments. The major problem of DNA synthesis, however, is that the product is not error-free. Any single mistake in the sequence of DNA segments can ruin the experiment. Companies have developed strategies to produce and deliver error-free, synthetic DNA that investigators can order electronically from vendors. The companies automatically scan ordered sequences in extensive databases to monitor relationships to sequences of a select agent. If so, the order is suspended until the investigator provides sufficient evidence that she/he is conducting experiments approved by the authorities. Concerns have been raised over the potential misuse of gain-of-function research, human germline editing, and gene drives. The risk of the release of a gene drive-modified organism during research is small but nonzero. Newly developed gene-editing tools, such as CRISPR systems, are publicly available. In the United States, biohacker boot camps teach basic gene editing skills, and interest in gene editing is growing. Mass casualties could occur if modified strains of influenza virus with increased virulence are produced and released. A 2016 US Intelligence Community Assessment stated that genome editing research on pathogens with pandemic potential may pose a national security risk if not regulated. The Director of National Intelligence warned about the implications of this dual-use technology. The European Academies' Science Advisory Council recommended regulating specific applications rather than gene editing itself. A number of epidemiological clues may suggest that an outbreak is deliberate. It is essential to determine whether an outbreak is of deliberate origin to protect public health [1].

Current Applications in Biotechnology

The term "biotechnology" encompasses all techniques, old and new, for manipulating organisms, populations of organisms, or problems. In its narrowest sense, biotechnology includes techniques to alter genetic composition (GC) or DNA of organisms [6]. Old biotechnology techniques involve a mixture of artificial techniques causing loss of precision with respect to the DNA targets of manipulation. These techniques generate large numbers of altered plants, many with undesired traits, and use procedures that provide little assurance that the target gene is present in the altered plant. The new biotechnology technique of genetic engineering consists of precise methods for making changes to the genome of an organism. In particular, the technique of recombinant DNA analysis permits the production of any desired change in the GC of an organism and the confirmation that the desired change has occurred. Better assurance than before can be afforded that the altered plant will have only the trait contributed by the added gene(s). The precision and documentation of the new techniques change their societal implications.

Specific alterations of the genetic composition (GC) are facilitated by the recent development of genetic engineering technology, or "New Biotechnology," which includes techniques for recombinant DNA analysis to detect and produce GC alterations, methods for transferring genes into cells, and methods for producing and analysing altered plants. These techniques are facilitating the development of food crops with genetically engineered resistance to diseases, improved tolerance of environmentally safer herbicides, and enhanced nutritional value. Dietary oils and proteins with a greater number of nutritional double bonds and improved availability of essential amino acids are expected from the genetic engineering of oilseeds and pulses. Similarly, improved availability of carotene in sweet potatoes would result from introduction of a series of five

genes important in the synthesis of vitamin A. Basic research has suggested the feasibility of altering production of a broad range of growth and defense hormones, thereby increasing shelf life and altering textures of vegetables.

Biological Crimes: An Overview

Various definitions of biological crimes are available, which largely overlap but also differ in some regards. Most definitions are based on a limited concept of biological crime, in the sense that they see biological weapons or agents as the actual tools by which a biocrime is committed. For instance, biological crimes are defined as actions that “have society-wide effects or consequences and are products of intentionality” and that “involve micro-organisms,” thus covering “use or threat of use of pathogens against human health or life, flora or fauna” [1]. This definition includes most biocrime cases but falls short of addressing “non”-bioweapon cases, such as those involving the environment.

In a broader sense, biological crimes encompass all actions that affect objects of protective interest in the biological and associated domains of biosecurity in a way that a person or group of persons would not be allowed to commit under the law of the country or countries concerned. Used to this end, genetic engineering, manipulation or modification tools, biotechnologies, bioinformatics tools, biological agents, biological weapons, biowarfare agents, or a nexus of them could constitute biological weapons or biological crimes (Lewis et al., 2018). In this context, biological crimes may also be referred to in terms of “biocrime” and “biosecurity crime.” More simply put, biological crimes can be described as “unlawful actions with biological agents or items,” in which “biological agents” include toxins and vectors other than micro-organisms.

Types of Biological Crimes

In the past few decades, a number of biological crimes have occurred worldwide. Generally speaking, these crimes can be classified into two types: the use cases of biological agents for criminal acts, such as bioterrorism, and bio-criminology of biological agents [1]. The former is regarded as an environmental crime and has been studied intensely. There have been a wide variety of bioweapons and their use since the earliest days of mankind. However, such biological crimes are not fully evaluated due to the increasing need for advanced biological agents for biocrimes, which should be regarded as a major threat.

Biocrimes utilizing biological agents and/or synthetic biological components can be accomplished in biological laboratories and/or the new biohackers’ society worldwide. Due to the rapid development of synthetic biology and CRISPR/Cas, many bio-incidents go unreported worldwide. Most of them can be classified into two types: hazardous biological accidents and biological crimes. The former is regarded as an environmental accident. It is defined as an event that causes environmental damage, leads to a loss of employment, and/or puts public health at risk. Reports or documents relevant to bio-accidents usually cover five major aspects: epidemic outbreaks, environmental biohazards, improper disposal, and leaks. Bio-accidents have long been monitored by governments in major countries and intensively researched and published. However, advance notice and thorough investigation of these bio-accidents are rarely performed and some abuse acts might be overlooked. In addition, bioterrorism in close-proximity events and biocrimes that do not use biological agents to commit a crime have not been studied in a comprehensive, synthetic manner.

Case Studies of Biological Misuse

The long time frame for evolving an extremely dangerous pathogen is indicated by the estimated 60-90 years required for a bug potentially comparable to *Yersinia pestis*. Despite its similarity to *Y. pestis*, laboratory-generated Marek’s virus (Meq-deleted) appears not to be stabilised in the environment and is unlikely to be an “effective” bioweapon. Producing large amounts of infective vaccinia virus is likely feasible. Depending on factors that remain to be elucidated, the spread of disease may be multifocal or dimorphic. Chimeric pox viruses engineered on an avipox background should provide evidence of biosafety. Like this virus, there is potential for evading biosecurity measures. The capabilities and threats associated with defence against biological and chemical terrorism cannot be underestimated. Ongoing national biosecurity initiatives display

innovative research and new solutions. The rampant spread of misinformation on the biosecurity threat from synthetic genetic modification is pressing. Such arguments often involve dual-use biosafety concerns.

Many specific examples are presented and might be cited: First, the focus on naturally occurring strains of viruses means that only a narrow range of strains is studied; possibilities for genetic modification still deserve deeper consideration. Examining many various strains across species and places, and in particular, large scale genomic sequence studies would aid the design of safety considerations for synthetic biology approaches specifically that target on-going challenges with these viruses. A sounder and more flexible safety framework based on ongoing assessment of the continuous diversity and adaptability of a large pool of species, rather than only on designated places for all waterfowl viruses; likewise, for analysing potential genetic modification that exists *sui generis*, not merely from an original source. The *de novo* creation of caprine/bovine prion-like proteins and the ensuing creation of an entirely new class of prion disease in laboratory goats and cattle that then became propagated in subsequently afflicted wild goats has not been sufficiently analyzed either in this regard.

Legal Frameworks Governing Biotechnology

The biotechnology industry is currently booming. Large investments ensure that many start-up companies, in numerous countries, have a solid platform for developing products and processes based on genetic engineering, primarily on innovative gene-editing technologies. Such products are also claimed to be beneficial to society, for instance, by improving crop resilience or resistance to pests and reducing the use of biocides in food production. Meanwhile, the use and potential misuse of biotechnology are at the center of heated discussions [7]. Since the building blocks of life, DNA and RNA, are extremely small and vulnerable, easy and cheap access to them raises concerns about misuse, including the production of dangerous pathogens or the design of improved generalist bio-agents.

Extensive discussions of these potentially harmful applications of biotechnology in biowarfare and biodefense have been conducted since the late 1990s, when DNA and RNA synthesis were regulated under the Biological Weapons Convention. A scientifically unjustified moratorium on the genetic modification of food was imposed by the European Food Safety Authority in 1998, and the European Commission discussed a white paper on the future of biotechnology. While a number of legal frameworks have since been established to govern the research or use of “dangerous” pathogens, few, if any, have been established to regulate the chemical industry [8]. Consideration of chemical warfare and defence began relatively late, and although much progress has been made in Europe, there are still many unresolved issues. Parallels exist with respect to using biotechnology as a second line of defence against attacks on, or sabotage of, the chemical industries. However, existing chemical defense regulations are likely to lack important details on surveillance procedures, product checks, etc. that would be required for these types of organisms. There is no denying that law enforcement is a very difficult and imperfect art, and that with radical changes in technology required opinions on advances in governance should be scrutinized thoroughly. Nonetheless, the very public and speculative discussions of the future of biotechnology, and its potentially harmful applications, seem premature.

National Laws and Regulations

Genetic engineering has focused primarily on input traits that benefit producers and the agricultural value chain [8]. However, some citizens demand new products that can prevent chronic diseases and promote health. In response, companies and research institutes are increasing their investments in preventive breeding, genetic selection, and post-harvest functions for consumer crops and food. This transition means that public concern becomes important; consumers scrutinize products and take an interest in the way they are produced. If, despite great efforts, food products are not accepted, substantial investments will be wasted. For these reasons, the new genetic modification technologies (referred to as new breeding techniques or NBTs) are causing much more concern than the existing GM technologies or the old ones. Public acceptance has become both a risk and a goal of NBTs.

Risk assessment is fundamental to risk management and risk communication and predates regulation by many centuries. It is used in many sectors, such as food and feed safety, the environment, and socio-economic,

ethical, and legal concerns. Products or organisms/technologies that pose the highest risks are regulated the most. The genetic modification of crops that has been ongoing for 40 years globally and which is still being conducted with older GM technologies is perceived as the highest risk. The media's terminology and the 2020 risk assessment provided an opportunity for consumers to take a closer look at opinions and scientific facts. This could lead to public discussions and debates about GM crops and the technology used to create them.

Far more public discussion is needed, as it is both a risk and a goal of the NBTs. Stakeholders need assistance in communicating scientific advancements accurately, factually, and unequivocally. Otherwise, misunderstanding the facts will lead to skepticism, rejection, and questions of legitimacy about science and technology generated by research entities and industries. The early phase of technology development may be challenging to explain, as perceptions of genetic change differ greatly and evoke emotions such as dread and disgust. Moreover, even among academics, the concepts used to describe the technology differ. By analyzing the existing literature, attempts will be made to provide clarity on the terms of NBTs as tools, methods, or techniques in the first step of the examination and eventually trace the resulting genetic products of NBTs.

International Treaties and Agreements

One of the first attempts to legislate on international rules on biotechnology goes back to article 19 of the United Nations Convention on Biological Diversity in 1992. The Convention on Biological Diversity is the most important multilateral treaty on biological diversity and one of the most widely signed treaties. It is aimed at conserving biological diversity, sustainable use of its components, as well as sharing benefits arising from the utilization of genetic resources, and addresses the three objectives in an equitable manner. There was a separate article on biotechnology exclusively on the need for prior informed consenting. With relevant provisions in the Convention itself and further elaborations in the Cartagena Protocol on Safety of Living Modified Organisms, the need for a binding international agreement was not resolved. Only with the Cartagena Protocol on Safety of GMOs did international regulations advance. It is one of the earliest and few international treaties ever negotiated that requires states to implement preventive approach to hazards resulting from actions that may cause biosecurity risk [9].

The Protocol's most important objectives are to protect, and by implication do not harm, biodiversity from threats resulting from GMOs and live genetically modified organisms (LMOs) intentionally released into the environment. Coping with a new technology that is not well understood can be extremely difficult owing to demand for immediate allocation of regulatory responsibility for such complex environmental problems. The 3Rs principle is sometimes labelled as "assess, control and apply" even when certainty is lacking. The precautionary principle is intimately linked to the risk assessment and management debate. However, its practice can be fraught with significant legal problems.

Virtually all countries have reservations on safety of GMOs. Most countries do not have national legislation now, nor legal, or even less scientific capacity to evaluate the technical safety and environment risks of GMOs. Views differed on the need for internationally agreed rules on biosafety. Most countries that were party to the Convention on Biological Diversity renewed their commitment to effective establishment of international rules on biosafety. Others, however, were critical of the Convention and the proposal of declaring an international moratorium on the movement of GMOs formulated during the negotiation period in 1996 [10].

Limitations of Current Legal Frameworks

The advent of genetic modification has thrust into the forefront its dire repercussions. The rationale behind genetic modification revolved around curbing infectious diseases, creating a genome library for all organisms, preserving endangered species, and eliminating genetic disorders. The vast potential application of the technology has exposed the possibility of misuse, and its bio-crime impacts are worrying many scholars and lawmakers. The blossoming of a new genre of crime concerning GMMs, bCGMMs, has heightened the concerns surrounding bio-safety and ethics [11].

Strategically, almost every country has recognized the shortage of AI and nano-race in its national interest. Accordingly, a race for the development of AI and nano-industry has developed. One major sub-race of the

race is GM and genome editing technology which is regarded as the universal game-changing technology. This has already made considerable scientific and industrial progress in CRISPR and GMM. However, the “winner-takes-all” nature of the technology means the winner can leverage it to economically and militarily outdistance its rival countries. This concern has created a growing impatience in the scientific community both to develop GMMs and to deem them absolutely safe so they can go unhindered by needless or overly expansive regulation. On the other hand, the very engineering nature of the technology means it can be re-engineered to develop bCGMM [8].

A flaw in the existing laws and public discussions about GMMs is the assumption that the products of biologists can be classified as dangerous or harmless species in a dichotomous way. This flaw has serious implications for lawmaking and public discussions. In the absence of robust knowledge of intentional misuse reliability, there is a painful trade-off between public safety and freedom to pursuit knowledge. As a trade-off, the degree of public safety is boiled down into controlling who has access to things, and hence, the law is a singularly coercive instrument. Knowledge pursuit largely calls for openness and shared with common laypeople.

Challenges In Regulating Genetic Modification

Following machinery, electrical systems, and chemicals, biological components represent one of the most significant groups incorporated into dual-use technologies. Advances in biotechnology have led to applications that positively influence society and the global economy. However, biotechnologies can also be misused by malicious individuals or organizations, gaining interest for their potential to create biological weapons (BW). Following the end of the Cold War and the terrorist attacks on the United States on September 11, 2001, there have been increased worries about the proliferation of know-how and capabilities to develop BW, as most governments have not devoted enough attention to this aspect of defense.

European nations are especially concerned about bioterrorism and the deliberate misuse of biotechnology, partly because of their tourist industry. While biological weapons are sometimes regarded as traditional, asymmetric weapons of lower technological systems available to rogue states, religious fanatics, and terrorist organizations, a new generation of bio-munitions is being developed by advanced nations, creating a biotechnological arms race. Therefore, establishing an integrated system to regulate the dual-use concerns of biotechnology and investigate biological crimes is necessary but very complex.

The regulatory framework to curb the misuse of BT could be similar to that used for the dual-use technologies of other scientific areas, but it needs to be adapted to the specifics of biology. Biological components are very different from components in the other three domains, but they could also pose more profound dangers. Nonetheless, there is considerable overlap, and approaches, methodologies, and lessons learned from the experiences of addressing the fear of misuse in these areas remain largely applicable to biology. However, biological components present additional challenges.

Several biological elements are quantitatively, qualitatively, or temporally very minor parts in complex biological systems. Such low-cost and small-volume materials are easy to conceal, transport, modify, and disseminate; they quickly diffuse in the environment; and they might present a very long-term danger to society. This introduces the possibility that, unless more restrictive measures are applied mimicking micro-scale illicit traffics of radioactive sources, the dual-use threats could be very hard to detect, by even clever persons and organized groups [12].

Scientific Complexity

Scientific advances and developments bring benefits, and the same technologies may be used as biological weapons. Gene drive research and emerging gene editing technologies may become potential suspects in biological crimes, with their potential misuse outpacing the insight base. Many questions must be asked about individual technological developments and their applicability in biological crime scenarios. The details of mechanisms and applications of key technologies must also be considered, as well as which types of crimes and methodologies may become possible with certain technologies. The possibility for generic scenarios in

relation to technologies would be worthwhile to explore, tackling questions on new mechanisms and crime types offered by the technology of interest, i.e. crime methods enabled by recent developments. A comprehensive understanding may protect against present and anticipated threats and assist in risk mitigation.

Gene drives express and propagate a genetically engineered infectious agent through a sexually reproducing organism population, inspiring buy from potential biological criminals. As early as in the research phase, gene drives could be used blanketing an area with an engineered infection. The type of damage that may be inflicted with a gene drive would depend on the type of insanity.

Risks are generally outlined for engineered pathogens, and additional risks arise with the deployment of gene drives, including unintended propagation, out-of-scope host range, and uncontrollable spread. As for socio-political analyses, threats caused by the ubiquity of the technology, rapid progress, and commercialization are highlighted. An important theme emerging during both scientific and socio-political analyses is the oversight problem, as regulations are rare and difficult to settle internationally and the effort to create oversight organizations is limited. Therefore, the frontier of rapid scientific progress may be a few steps ahead of existing oversight organizations [1].

Ethical Considerations

Environmentalists worry genetic modification (GM) technology could be beneficially applied to damaging forms of agriculture, or misused intentionally or unintentionally in ways disastrous to the environment. For example, genetically engineered organisms incorporating insecticidal proteins based on bacteria toxins might spread these toxins to other populations of organisms that have not been targeted by the introduction of the genes and thus foster a damaging explosion of those populations. The social ethical issues raised include concerns about the distribution of benefits and costs, about the nature and adequacy of processes of public participation in decisions to endorse or prohibit GM technology, and worries about the possibility of risk assessment failure leaving most of the population unaware before damage is done that genetic modification is socially dangerous [13].

GM technology also raises ethical concerns about specific uses of the technology. Starting in the 1990s and continuing unsuccessfully for several years, some members of the social movements opposing agricultural GM technology tried to redirect concerns by posing the question “why does science need GMOs?” They suspected that such framing would elicit more fruitful debate than scientific arguments along the lines of “GMOs are bad for your health.” No one answered that question satisfactorily. What, instead, has emerged are broad statements of doubts about the safety of genetic modification and criticisms, increasingly in sophisticated and well-argued formats, of specific GM foods and food production practices. While plentiful with respect to the need for more regulatory oversight, such accounts have not brought charges of insincerity, error or passivity against their authors. While specific line-by-line responses are plentiful, there are no general responses regarding the argument structure of these accounts.

It is therefore clear that, while people’s beliefs about GMOs vary widely, ethical concerns about specific GM technologies raise different questions, ones answerable by pursuing other forms of analysis [14]. Is it ethically justifiable to pursue genetically modified crops and foods? “Yes” is the answer arrived at after a careful study of three of our most influential ethical traditions, the consequentialist-utilitarian tradition, the Kantian tradition, and the virtue ethics tradition.

Global Disparities in Regulation

The issues surrounding the regulation of genetic modification technology are exacerbated by global disparities in regulation, considerably complicating diplomacy and cooperative action to prevent or respond to biological weapon use by states or non-state actors. The international community has not been complacent in the face of these developments; countries have drafted new treaties and working agreements, industry groups have assembled to cooperate on best practices, and scientists have emphasized appropriate precaution wherever possible. Nevertheless, regulation and perception of the safety of the technology remain divisive even among similarly situated states, creating disputes that frustrate and stall collective action. Such disputes are

pronounced in tensions between and within large economies, leading to difficulties in close collaboration. Often, these disputes are colored by hammer-and-anvil tensions, particularly, but not exclusively, in the Euro-Atlantic region. Dramatic advances in gene-editing technology have resulted in unforeseen consequences and risks to domestic health and safety, prompting regulatory reactions and diplomatic entanglements on either side of transatlantic differences in the regulatory environment. The situation is compounded by centuries of colonialism, unequal development, and negligence resulting in deep disparities in access to preventative health care, often meaning that non-GMO markets are because of low food availability rather than regulation.

These disparities and other political boundaries are often enshrined in international treaties and understandings on which greater regulatory frameworks are built, magnifying political disputes. Agricultural trade is a massive industry, profoundly affecting the global economy and food security; thus, political capital over the treatment of GMO food products can occur at great cost to global equity and efficiency. In particular, the Game of Chicken between certain regions on the safety and efficacy of GMOs has reached a peak, with increasingly aggressive diplomacy that burdens other states and global governance frameworks striving toward equity and cooperation. Would-be third-party states, along with the most vulnerable states in terms of food insecurity, face dire choices between taking sides or deepening their involvement in the dispute circle. This complexity is compounded by historic grievances, highly disparate levels of species bio-diversity, and unequal development.

The Role Of International Organizations

Reducing the risks arising from such systems promotes their peaceful, secure and safe use while reinforcing actions against those who may wish to misuse them. The recommendations included in these pages are designed to provide guidance on actions that may be taken domestically or internationally to support this goal. They are derived from the findings of two and held in . The Working Group also organized of these recommendations at a hosted by the in . The scientific process provides an enormous opportunity for improving the health and well being of local populations and for stimulating economic development that could have wider benefits. However, as has now been well documented there are dangers that such advances may be misused to create new biological weapons or similar programs.

From time to time, scientists have significantly altered the genetic structures of viruses to enhance pathogenicity, virulence, or transmissibility. In separate reports, scientists had modified pathogenic bacteria to release harmful metabolites or to enhance their ability to penetrate cell walls. Scientific advances aimed at meeting the requirements of the drug industry or for the treatment of particular conditions may lead to the inadvertent release in the environment of pathogens that were previously contained, and with properties enabling them to spread widely.

This could happen whether the research was of a benign nature or a well thought out melee á trois. The more general access to new techniques is likely to increase the risk that rogue states or terrorist groups might, on their own or through surrogates, acquire incipient systems gaining access to dual-use knowledge. Although many steps have been taken, no international approach has been devised that would prevent such activities. The more general access to the new techniques, particularly gene editing techniques, is likely to increase the risk that rogue states or terrorist groups might, on their own or through surrogates, acquire incipient systems. That is either by developing expertise that would only come with the availability of controlled apparatus and supplies which might not evince suspicion nor put them in the sights of those who might try to prevent or contain such development. Or, by acquiring the systems in whole or in part from established labs which would require the right intelligence and management capabilities.

Similarly, an unintended release of GMOs or some other systems with adverse consequences, real or perceived, would give rise to public concern. In the case of such GMOs notably, there is endemic distrust of such engineering and foods within Europe in particular, and this may be exacerbated by fears surrounding stray bioengineered pathogens [15]. A common international response might intensify conflict whether emphasized by public diplomacy, international condemnation, or formalized responses by international organizations. A lack of common ground on the extent or reality of the harm would hinder such cooperative response.

World Health Organization (WHO)

The WHO is responsible for directing international health and supporting countries in improving their health. WHO prevents the international spread of diseases and responds to global disease threats. A global health emergency was declared for the novel coronavirus in January 2020. The world faced this crisis on an unprecedented scale. A huge world-wide social and economic cost was incurred. Political issues confronted the United Nations' public health agency, WHO, despite its transparency and direct support of the international community. The effectiveness of global governance was questioned, and better alternatives were suggested, such as the proposal for WHO reform and establishing a new global health organization, the health ally organization. Gene-based pathogens should be discussed via global governance directly targeting science, technology, and facilities, and ethics not proposed under the political banner, which would hinder a focused discussion. The WHO should take the lead and draw in experts from various fields. Consensus rules agreed to manage these pathogens should be developed. The role of new media must be considered as they exercise tremendous influence around the world and have confronted the international community with unexpected debates on crime issues and related policies. Open and cooperative social media participation is proposed. The mainstream media should adhere to the principles of reporting and sound science, technology, and ethical review, to prevent erroneous messages from damaging progress towards a consensus formulation [16]. Bioterrorism is the use of pathogenic bacteria, viruses, and toxins in military operations for the purpose of placing these agents in the natural environment, promoting the spread of animal epidemics, causing infection, morbidity, and mortality in humans, animals, or plants, and bringing adverse social, political, and economic consequences, thus endangering social stability and national security. Still, they can pose a considerable threat to relevant natural persons in a certain geographical location. The people may die or become seriously ill, and cross-regional epidemics may arise through the spread of the diseases. The integrity and stability of relevant biological chains will be affected, and the ecological balance will be damaged. Throughout history, there have been many instances of biological weapons being used in wars worldwide. In ancient times, by throwing plague corpses into cities for siege, poison arrows with plague-bearing rats were launched, wells were poisoned, etc. In World War I, the Japanese army sprayed anthrax spores and plague bacteria in coastal areas of China, while German agents poisoned the wells in France with anthrax bacteria.

United Nations (UN) Initiatives

Changes in the transboundary movements of genetically modified organisms (GMOs) throughout the world, especially related to the WTO agreements, heightened concerns among several countries, particularly in pre-2001 the developing countries and environmental NGOs. These countries feared that any easing up regulations on transboundary movements of GMOs would lead to an influx of GMOs and its number of pest species into their territories. Due to these fears expressed by them, debates in the backdoor of the Biosafety Protocol were focused mostly on how to prepare, control and manage GMOs [9].

Attempts to regulate movements of GMOs were a sub-set of movements of biological materials in a presenter's conference. A biotechnological move (genetic modification of organisms) was considered a platform or precondition to initiate and modify biological materials for movements of microorganisms or their constituent parts in another conference. Attempts to regulate these are again underway in the past decade or so, using appropriate biotechnological advances. But the free movement is being opposed vehemently by several hidebound organisms and international organizations, posing several questions and philosophical issues.

The clearance for this or similar questions will require less cognitive, more mechanical reasoning, significantly around concerns of risk and uncertainty evaluation/management to arrive at a better understanding of the roads yet to trot. These efforts are tentative and exploratory, and there may be many other avenues which are yet to be found and explored. Nevertheless, some tentative irrational inferences and remarks may be suggested. No universal strategy or methodology can be recommended upfront. Ethical and legal concerns behind modelling, evaluation, and risk management of GMOs and other biotechnology-related biological materials threads/studies do not appear to be deeply explored. As with GMOs BPs, the other treaties/conventions being prepared can also explore ethical and legal concerns.

Biological Weapons Convention (BWC) and BTWC Oversight Bodies

The Biological Weapons Convention Framework

The Biological Weapons Convention (BWC), formally the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, was opened for signature in 1972 and entered into force in 1975. As the first multilateral disarmament treaty banning the development and stockpiling of an entire category of weapons of mass destruction, the BWC represents the primary international legal instrument governing biological weapons. As of 2023, 183 states are parties to the Convention, with 22 signatories that have yet to ratify it. The Convention prohibits the development, production, stockpiling, and acquisition of biological weapons and toxins and requires the destruction of existing stockpiles. However, the absence of a formal verification mechanism—a significant institutional gap—substantially limits the BWC’s enforcement capacity.

The BWC Review Conferences, convened every five years, provide the primary forum for states parties to assess the Convention’s implementation and address emerging biological threats. The Seventh Review Conference (2011) and Eighth Review Conference (2016) increasingly acknowledged the biosecurity challenges posed by advances in the life sciences, including synthetic biology and gene-editing technologies such as CRISPR-Cas9. The 2022 Ninth Review Conference adopted a politically binding final document emphasising the need for enhanced national implementation measures, the establishment of a standing committee on science and technology, and more robust information exchange among state parties. These developments reflect growing international recognition that the BWC framework must evolve in tandem with rapid biotechnological progress if it is to remain an effective instrument against biological crimes of state and non-state origin.

Despite its foundational significance, the BWC suffers from well-documented structural deficiencies that limit its utility as a regulatory framework for biological crimes involving genetic modification. The absence of a verification protocol—negotiations for which collapsed in 2001—leaves states parties unable to independently confirm compliance. This gap is particularly acute given that identical genetic modification infrastructure serves both legitimate research and potential weaponisation purposes. The BTWC Implementation Support Unit (ISU), established in 2006 and based in Geneva, performs a coordinating and administrative role but lacks independent investigative or enforcement authority. International proposals for strengthening the BWC regime, including the establishment of an international monitoring agency analogous to the International Atomic Energy Agency (IAEA) for nuclear materials, have gained renewed scholarly attention as the dual-use risks of genetic modification technologies intensify.

Proposals For An International Legal Framework

Countries must legally validate the claim of gene-editing techniques as a common heritage of humanity before it can be recognized as such in the UN system. Adaptation of the bio-rich and choice-poverty approach is needed as a foundation for a contemporary bio-law framework governing the genesis, function, and use of biogenetic resources of humanity’s common heritage.

It must be complemented by the explication of the quality and security of the databases of the genetic identity, structure, and functions of the commons being vested. Mechanisms of jurisdiction and enforcement of laws governing biological pseudorights must also be adapted on a global scale and shifted more on a multilateral footing to ensure their uniform implementation [8]. Above all, it is essential to be definitively clear about the whole truth of original biological crimes and publicly divulge details of biological lobes and masses of bioweapons for the eradication of biological crime risk on Earth and survival of humanity. Emerging biogenetic technologies bring to light the potential threats of biological crimes (crime of genocide, war crime, crime against humanity, complex biological crime, and crime of biological terrorism).

The past effort of law makers to align treaties regulating the knowledge, freezing, and use of the biogenetic sphere with competent criminal procedures and punishments rendered them ineffective against rogues. Today, these treaties give the possibility for denial of bioscience and biogenetic progress, genome war propagating,

and research crowding around the capability of contemporary gene solving and editing techniques. There is a disagreement at the very heart of bio law and basic bio-rights of humanity's common heritage between conventional biologically-based rights in individual choice and encounters of patentability. Since atomic weapons have been banned by the NPT treaty system in the 1970s, the bio-genetic sector has been subject to uncontrolled dyadic competition which is capable of a dangerous race for the bio-edged creator of unwitting biodisaster, genocide, or the world climate apocalypse. It is a kind of Nihilistic biological arms race or use-and-test impunity in neo-colonial conditions with malicious pursuit of digital lobes and digital masses. Genomics-based global competition and war races which pose a threat of the digital colonization world were already amply foreseen and warned of back in the 1990s.

Elements of a New Framework

Within the scientific community, there are four key observations relating to biological crime that serve as fundamental elements upon which a framework for the study of such crimes can be constructed. These observations provide support for the scheme of classification proposed below. They also indicate the specific scope of the proposed analyses and any limits on such discussions.

First, biological compounds, most notably agents and toxins derived from plants and bacteria, are increasingly the focus of research in the fields of bioengineering and biotechnology. Moreover, such entities have already been incorporated into and used in various, increasingly diverse areas, including defence and counter-terrorism, medicine, agriculture, food and water safety and so on. It may be convenient to refer to entities in this regard as either biological agents or compounds of biological origin. These compounds, so understood, have the potential to serve as effective vehicles for biological crime and terrorism. The previous two observations provide both the motivation and opportunity. Thus, events in the world of bioengineering and biotechnology will unavoidably and increasingly have consequences in the fields of biocrime and bioterrorism, if they have not already. The potential consequences range from new food and water contamination methods, to new intelligence-gathering techniques and new forms of dissemination.

Second, there currently exists no specific body of law addressing bioengineering and biotechnology or crimes involving bioengineering and biotechnology. Existing law can address certain aspects and instances of bioengineering criminality, but this is both limited and overlapping and can be confusing for enforcement agencies and businesses. Further, the lack of specific legal categories or parameters will hinder the scientific community in examining all relevant risk and relevant developments in an organized and coherent manner.

Third, while the problem of biological crimes may thus be characterized as an emerging one, elements of the problem are already with us and have been for some time. Cases of bioengineering and biotechnological theft, as well as criminal contamination plans, have been recorded. There are already signs that law enforcement agencies and the scientific community have not fully recognized and appreciated the novelty, complexity and consequences of the developments. This also renders the existing situation potentially more hazardous.

Stakeholder Engagement

Innovative pest control methods based on genetically modified (GM) insects have developed rapidly in recent years. For release into the environment or agricultural systems to occur, it is necessary to consider how the range of potential societal concerns might be addressed and how the public might be engaged. Public engagement approaches for the release of GM insects tend to be narrow and technical, focusing on risk assessment rather than how to define acceptable risks. There is also a tendency to privilege technocratic forms of deliberation involving only a select group of experts, excluding the general public, and [18]. More open approaches, more sensitive to the contestable nature of acceptability, may be needed to engage the public.

There is a need for the public to deliberate not only how the introduction of GM insects might be managed after release, but also how it might be positioned before consideration of release becomes practical [19]. Most risk assessments use a 'narrow framing' approach to define a standard set of risks and the public's trust in the regulators' technical competence to evaluate these risks. Framing public engagement more broadly might enable a more robust identification of needs for engagement, improved risk communication practices, and an

assessment of to whom those accountable should be understood to extend beyond the regulatory agency to include a range of public and private sector actors across various political jurisdictions. There is a need for more pluralistic engagement approaches that explore broader, more contestable ways of framing acceptable risks and, therefore, exclude the possibility of a successful release. This necessitates new forms of discussion in which non-experts, including affected individuals, have a legitimate say.

Enforcement Mechanisms

The dangers posed by biological weapons did not take the pandemic to become the subject of a renewed debate within government institutions, universities and civil society. In July 2021, the United Nations passed a resolution on the effectiveness of the Biological and Toxin Weapons Convention (BTWC). The resolution called for a renewed examination of the allegations that the USA was working out a military biological program, in violation of the BTWC, outside its borders. In late October-early November 2021, the Russian Federation launched a series of initiatives at the United Nations demonstrating the urgency of the need for measures to prevent growing dangers within the biological domain.

These discussions were accompanied by a resurgence of interest in the possible sources and causes of the pandemic itself. In the summer of 2021, there was a renewed wave of speculation about a possible laboratory origin of the cause of COVID-19, the SARS-CoV-2 virus. Some theorised that the virus could have been a genetically manipulated virus that leaked from a laboratory, while there were others who maintained that the virus was one of many variants of coronaviruses that had crossed over to human beings from animals, with pangolins being one animal species of concern.

In this context, understanding the potential of genetic modification as a biological weapons agent has become important. Efforts have highlighted the natural possibilities of occurrence or mutation of biology that could threaten food supplies. A three-part scenario was laid out, connecting genetically modified organisms with various pathways of causing catastrophe. This layered analysis is analogous to that of nuclear weapons. There, a separate category of nuclear-weapon states has been established, and a mechanism of non-proliferation was instituted.

Case Studies Of Successful Regulation

The first system that will be evaluated is the Cartagena Protocol on Biosafety (CPB), an international treaty that specifically regulates the international movement of living modified organisms (LMOs), also known as genetically modified organisms (GMOs). The CPB is relatively new to the international regulatory framework, being created in context of the Convention on Biological Diversity (CBD) and coming into force in 2003 [15]. As of June 2018, 171 countries had ratified the CPB. Its focus is on transboundary movements of GMOs, which were deemed to be a new and ongoing threat to biological diversity at both the ecosystem and genetic levels.

To deal with the environmental release of GMOs, the CPB contains ex-ante provisions requiring exporting countries to evaluate the potential risks associated with GMOs before shipping. Importing countries are also granted the right to make an informed choice about whether to accept shipments. The CPB also regulates GMOs used for food or feed, but only if they are also LMOs. This second portion is more like de facto regulation through labeling, but it does at least acknowledge food safety and human health in its preambulatory language. While the CPB is not perfect, it does provide a good framework for standardization. A more established framework for assessing the risk/benefit of biological experiments is needed in order to prevent a reoccurrence of what occurred following the release of GMOs.

The other system that will be evaluated is the European Union (EU) regulatory framework for GMOs. The EU is in a unique position in the international regulatory arena not only because of its geographic size, strength, and economic power, but also because it has a unified policy on GMOs. The guiding principles of the EU's policy on GMOs include a strong preference for food safety as the primary objective over trade and development and a strong commitment to the precautionary principle, in regard to all organized technological and commercial endeavors. In addition, there is a recognition that as a result of US regulatory policy, European

regulatory and production structures are at a disadvantage. The EU acknowledges the need to concentrate on a global regulatory framework over the US “wait and see” policy.

Examples from Various Countries

This section highlights biological crimes from India, Egypt, the Russian Federation, and the US, revealing information about perpetrators of biological crimes and genetic plant alterations, while also showcasing bio-threats and exploitation of biocrimes in countries screened: India, Egypt, the Russian Federation, and the US. The FBI and the US Department of Energy (DOE) are investigating Indians for developing a new strain of a wheat pathogen and its transport to Canada, potentially impacting the US's wheat crop, a multi-billion dollar industry. Furthermore, extremists in Egypt cultivate rotavirus-infected beans to cause a biological epidemic. Work with Marek's disease, a poultry pathogen, is suspected in terrorist facilities in the Russian Federation, with access to the Western media. In the US, undisclosed labs financed by the US military and the Pentagon conduct research on viruses affecting animals, including those that are contagious to humans and have a potential bioweapons role. These bio-threats and biological crimes have dire and serious consequences [5]. In a citizen science initiative, more than a dozen volunteers from the US and Canada observed turtles and other reptiles to help the Maryland Zoo at Druid Hill conduct research on animal movement. In addition, 30 volunteers, mostly children, participated in the first Detroit Micro-Station citizen science initiative at the Detroit Institute of Arts. With scientists on-site, the youngsters used micro-spectrometers to determine the elemental composition of paint strokes in several paintings. These studies contributed to the understanding of the mechanisms of black lung disease, studied over the last four decades, a chronic lung disease affecting coal miners. Involvement of students in biocrime-related projects similar to these will contribute to educational activities in science and bioethics, developing humane attitudes towards biosafety and bioweapons [1].

Lessons Learned

Biological warfare is the deliberate and planned use of disease-producing micro-organisms as weapons, the possession of which is strictly prohibited by the Bioweapons Convention. Although biological weapons have been used in the past, the latest evidence of their use comes from the strains of anthrax spores developed in the former Soviet Union. As with germ-warfare, the chance of catching and using biological weapons in more classic forms, such as plague, tularemia, and Ebola, are exceedingly slim. A number of chilling spectres should be mentioned: these include the genetic modification of pathogens to allow their enhanced use as offensive weapons, their accidental use by safety failures in operations with genetically modified microbes for peaceful purposes, and their accidental or deliberate use by amateurs. The risk that synthetic biology and genetic engineering may be used to produce new pathogens via a different route altogether is worth noting.

Concerns over the risk that deliberately fatal strains of viruses may be created and released are growing. The caution that for human health reasons no closely related strain of a virus with high mortality should be used in this way to avoid an uncontrolled outbreak could surely be expected to also apply to organisms used for biowarfare: particularly virulent strains of anthrax or to try and create plague or tularemia pathogens in this way. They can be engineered in a manner which would avoid these pitfalls. It is also far easier to introduce a virulence trait than to remove an undesirable virtue trait.

Epidemiological investigations complement microbiological investigations to create a coherent picture of the incident under consideration. Epidemiology is likely to elucidate most salient features of an outbreak within the first 24 h, but the collection of convincing epidemiological evidence can take days to weeks, and the lack thereof may overlook essential facts. The careful and skilled collection of epidemiological and microbiological evidence to document the absence of an infectious disease in a suspected case is more difficult still. In terms of biological murders, investigations of potential exacerbation outbreaks are usually of limited use compared to those which stem from an aerosol or food contamination [1].

Future Directions In Biotechnology Regulation

In 2001, the concept of the large-scale deployment of GMOs for food assistance to vulnerable populations around the world. In 2021, 15 million metric tonnes of food were supplied to 117 million people in 84

countries, with an annual budget of 8.2 billion Dollars. Moreover, around 300 Thousand MT of food were sourced from over 800 suppliers in market-traded commodities, such as wheat, rice, maize, soybeans, and sugar. GMOs in biofortified projects have received the most attention. However, increasing social opposition to GMOs has led to increased scrutiny, calls for more ethical engagement by the international community, and the perception of losing legitimacy if it were to contribute to growing inequity in food security and sovereignty. Discussions regarding international standards, food safety assessments, efficacy studies, environmental and socio-economical impact analyses, impact assessments post-marketing approval, and the overall concepts were addressed.

Global capacity-building needs with regard to GMOs in food aid and food assistance, including the national capacity to identify GMO events, international capacity to track trade links, and strategies to mitigate risks related to biological, chemical, and nuclear entities, were identified. Key priority areas for a reliable pathway towards improved food assistance were identified. There is a need to define a strategy to promote regulations and set standards at the regional and international level. Today, estimating and managing the potential risks of biotechnology have become more complex. Technical advances, such as induced mutations in genomes, as a target for detection methods, can make it challenging to determine if intelligence is purposeful and bold. No "safe" applications exist constructively. New developments, such as edible vaccines based on natural microorganisms containing multiple antigens used for other purposes, change both the hazard and possible productively transmit the bioterror agent. This approach raises false-perceptibility user concern that current responses to meet and address risks.

Modes of adjustment should address the problems of natural microorganisms used cleverly. The uses of biotechnology may open new hazard windows, but biotechnology does not change the number of ways that pathogens can be identified, transmitted, dispersed, and enabled. More and better ways exist to fabricate the bio-agent than before. In economic terms, third-world concerns may be valid. Prevention and protection services become expensive. The lack of effective shielding has enormous economic impacts. The stakes are high. Genetic weapons penetrate the community, forcing changes in modes of response. Without regulation and provision of means to detect and defend pervasive alterations, progress will occur. Standard security measures fall short of preventing 100% loss of control. Preventive actions will only be partially effective. As the pace of advance accelerates, gaining resilience to bioterror in the face of genuine uncertainty is urgent.

Technological Innovations

The dual-use aspects of genetic modification and genome editing technologies raise a number of issues regarding biosecurity, biosafety, accountability, and regulations. Important developments in the life sciences are potential game-changers for biological warfare. Biodefense is prevention through science and science governance, necessitating cooperation among multiple stakeholder arenas. This analysis considers the triple explosion of the life sciences and how it might give rise to new opportunities for development of biological warfare capabilities that are more innovative and more difficult to prepare for from a defense perspective [20]. In order to structure the analysis and point to implications for policy and governance, a distinction is made between 3 different biosecurity levels. Technological developments and innovations at lower levels often create new biological warfare capabilities at higher levels.

The first section considers bootstrapping of capabilities through employing innovations at lower levels to conduct modus operandi at higher levels. The second section addresses soft innovations at higher levels that yield knowledge and insights about phenomena at lower levels. Governments, industries, and academic organizations are challenged to maintain oversight over these levels in order to ensure effective biosecurity. The responses that might be taken to address the possible rise of bio-insecurity are explored.

The development of state biological warfare programs during the last century, their exposure after the end of the Cold War and their subsequent dismantlement illustrate that bioweaponeers take advantage of scientific loopholes. One of the loopholes relates to the accessibility of the life sciences as a result of their commercialization. Information asymmetries between those conducting the peaceful life sciences and those developing biological warfare capabilities have been minimized as information, knowledge and insight becomes more broadly available.

The robustness of biosecurity is contingent on the integrity of a multitude of biosecurity frameworks across different regimes and disciplines, which is susceptible to mismatches across biosecurity levels. If biosecurity/biodefense equals prevention through science, there is a need to ensure overly explicit norms and regulations by including considerations of early warnings against new capabilities elsewhere. Deployments faster than attention to rules, risks, and countermeasures could provide new bio-insecurity opportunities. Hitherto, much attention has been given to examining the implications of technical lifescience innovations for biosecurity, but much less has been provided to date on the wider-off opportunities for exploiting such innovations.

Anticipating Future Challenges

3D bio-printing enabled organs on-chip models for drug efficacy studies. Reconstituted microphysiological platforms for controlling cell-cell interactions across tissues. Modelling of liver drug metabolism and drug-induced liver injury with bio-printing-derived liver-on-chip platforms. Bioengineering tools and methods to obtain complex human heart tissues: engineering mature sarcomeres in hPSC-derived cardiomyocytes. Organelle dynamics in single cells modeled in microfluidics and over multiple length-scales. Engineering culturing and fabrication family technologies toward microphysiological models. On-chip evaluation of archival materials of the ancient Egyptian mummification process. Bio-assisted methods as an effective means for the conservation of ancient Asian manuscripts.

Human bioprinted liver lobule as a patented technology for drug evaluation and toxicity studies and targeted anti-cancer drug discovery. Bioengineered microphysiological 3D platform for studying biomechanics and mechanotransduction of cancer cells. Bio-ink formulations for bioprinting based on chitosan polymer conjugates. An introduction to tissue engineered aortic valves: from fabrication to implantation. In vivo follow-up strategies for bioprinted organs-on-chips. 3D Microphysiological Systems for Evaluating Drug Delivery Nanosystems and Delivery of Biologics. With a barrage of advances, 3D bioprinting has the potential to make a significant impact on virtually every field of biomedicine. It remains up to scientists to harness these exceptional capabilities for innovation in their specific areas of interest.

Synthetic biology is a field of science that forms and analyzes genetic material with a view to developing new bio-industrial processes and products. Through programming and experimentation, organisms of various organisms are rationally altered to endow them with new, useful, and controlled functions. Research in synthetic biology is becoming increasingly prominent due to the potential positive societal effects of applying new bioprocesses in medicine, environmental bio-sensing and bioremediation, and the sustainable production of fuels, chemicals, and materials. It also requires a reassessment of possible risks associated with the inherent production and utilization of genetic material and the natural consequences of the 'go or no-go' decisions makes. To guarantee that the new products and processes are safe, secure, and effective, it will be essential to minimize the likelihood of unwanted activity and/or loss of control of the organisms applied on or outside the biotechnological production site.

CONCLUSION

The reactive law approach has many drawbacks. It puts society at risk of devastating biological crimes, erodes public trust in genetic technologies, and curtails the potential benefits of these technologies for personal/Societal advantages. In addition, relying solely on reactive law will greatly increase the potential for international tension. This is because, after the deployment of a pernicious or threatening technology, defensive mechanisms among nations usually retain a retroactive component - that is, nations will be struggling to catch-up and contain already-escaped technologies [21].

Further, once proposed technologies are deemed benign or neutral, they may be deemed acceptable to deploy - so protection against them might not be forthcoming. Moreover, the fact that a biotechnology's potential has only been vaguely broached does not mean that it is benign. This situation is especially precarious with respect to genetic technologies because the time between the meeting of the intention for a biological weapon and the independent access to related technologies can be relatively short. If an intention were made to commit biological crimes, it is guaranteed that methods to do so will surface - be they genetic or conventional. While it

is understandable that biotechnologies should be protected from adversarial forces, such policies should not be implemented on the wrong pretext. The dread of bioweapons should not engender undue risk to the health and other rights of citizens. This means a match between intent (for weapons, prevention, gains, etc.) and maintainability/obfuscation (expertise, veracity, certainty, dynamics, etc.) and field policy (security, secrecy, duty of care, fairness, etc.) are necessary. Each of these components offers a vector by which incapacitating deviations (by computation, criminal actors, diseased agents, etc.) are currently possible and thus mitigate national security policies. The utility of precautionary laws is, however, whose values they might be based on. At present, precaution would seem to be the wrong pretext to reactively curb the pacific applications of genetic technologies [22]. Still, vigilance against genetic weapons should persist.

Ethical Considerations

This study is a doctrinal and comparative legal research paper based entirely on publicly available academic literature, international treaties, and policy documents. It does not involve human participants, personal data, animal subjects, or any form of primary empirical data collection. Accordingly, formal ethical approval was not required. The authors have adhered to established standards of academic integrity throughout the research and publication process.

Data Availability Statement

The data supporting the conclusions of this article consist of publicly available academic literature, treaty texts, and policy documents, all of which are referenced in the bibliography. No proprietary datasets were generated or analysed in the course of this study.

Conflict Of Interest

The authors declare no conflict of interest in connection with the research, authorship, or publication of this article.

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