DRAFT CRITERIA FOR IDENTIFYING DUAL USE RESEARCH OF CONCERN

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GOAL

The primary goal of identifying dual use research of concern is to initiate a process aimed at reducing the potential that the results of certain biological research could be misapplied to threaten public heath and other aspects of national security, *while minimizing any deleterious impact to the progress of science and the important benefits that it yields*.

KEY CONCEPTS

The criteria for identifying dual use research of concern are intended to delineate that subset of biological research that may provide knowledge, products, or technology that can be *directly* misapplied with sufficient *scope* so as to threaten aspects of national security.

Threats to national security arising from the misapplication of biological research are, in essence, threats to public health, agriculture, plants, animals, the environment, and/or materiel. This would include threats to farming, raising livestock, aquaculture, terrestrial and marine wildlife, companion animals, domestic and wild plants and trees, ecological systems, other natural resources, as well as man made resources.

An assessment of research for its dual use potential will require scientific expertise and a logical, sound judgment about the probability or foreseeability that research results could be misapplied by others.

KEY CONSIDERATIONS

Careful consideration should be given to particular areas of research when evaluating their dual use potential because of the likelihood that they may provide knowledge, products, or technology that can be directly misapplied to produce harmful consequences and pose a threat to public health or other aspects of national security. These areas of research include, but are not limited to, research that:

- Enhances the harmful consequences of a biological agent or toxin by augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated
- Imparts to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions, such as first or second line prevention and treatment measures against that agent or toxin
- Enables a biological agent or toxin to evade detection methodologies, thereby restricting the capacity to identify and effectively treat infection and disease
- Enhances the susceptibility of a host population to the harmful consequences of a biological agent or toxin
- Disrupts immunity or the effectiveness of an immunization, or alters the host range or tropism of a biological agent or toxin
- Generates or reconstitutes a biological agent or toxin for which there are no known or widely available prophylactic or therapeutic interventions, that could evade detection, or for which there is no known immunity

THE CRITERIA FOR IDENTIFYING DUAL USE RESEARCH OF CONCERN

Bearing in mind the considerations outlined above, the Criteria for Identifying Dual Use Research of Concern are as follows:

Dual Use Research of Concern is research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health, agriculture, plants, animals, the environment, or materiel.

Careful consideration should be given to knowledge, products, or technologies that:

a) Enhance the harmful consequences[1] of a biological agent[2] or toxin[3]
b) Disrupt immunity[4] or the effectiveness of an immunization[5] without clinical and/or agricultural justification
c) Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions[6] against that agent or toxin, or facilitate their ability to evade detection methodologies
d) Increase the stability[7], transmissibility[8], or the ability to disseminate[9] a biological agent or toxin
e) Alter the host range[10] or tropism[11] of a biological agent or toxin
f) Enhance the susceptibility of a host population[12]
g) Generate a novel pathogenic agent[13] or toxin, or reconstitute an eradicated[14] or extinct[15] biological agent

Footnotes

[1] *Harmful Consequences:* The ability of a biological agent or toxin to critically alter normal biological functions, inflict damage on public health resources, materiel, and public safety. This would include augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated.

[2] *Biological Agent:* 18 USC 178 states: The term "biological agent" means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (B) deterioration of food, water, equipment, supplies, or material of any kind; or (C) deleterious alteration of the environment.

[3] *Toxin:* 18 USC 178 states: The term "toxin" means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes (A) any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or (B) any poisonous isomer or biological product, homolog, or derivative of such a substance.

[4] *Immunity:* Encompasses all aspects of host immunity (e.g., active, adaptive, adoptive, passive, innate, and immune modulators).

[5] *Immunization:* Refers to the active or passive induction of immunity through inoculation (e.g., natural inoculation or vaccination) with an immunizing agent or with antibodies; this includes antitoxins and toxoids.

[6] *Clinically and/or agriculturally useful prophylactic or therapeutic interventions:* Includes first or second line prevention and treatment measures or alternative therapeutics used with special populations (e.g., pregnant women and pediatric patients), in the form of vaccines, antibiotics, antivirals, antiparasitics, antibodies, herbicides, fungicides, algaecides, insecticides, etc.

[7] *Stability:* The ability of a biological agent to remain viable when exposed to various environmental factors, including temperature, relative humidity, atmospheric pollution, and sunlight. Stability also includes persistence in a host.

[8] *Transmissibility:* The ease with which an agent spreads from host to host or from vector to host (e.g., via arthropod vectors).

[9] *Disseminate:* The process by which infectious diseases or toxins are dispersed. The same routes of entry pertinent to natural spread of diseases are also relevant when their etiologic agents are delivered intentionally (e.g., inhalation of biological agent disseminated as an aerosol, or ingestion of a biological agent disseminated through a water supply).

[10] *Host range*: The number of different species or populations that can become infected by a biological agent, causing disease in the host or allowing it to become a carrier.

[11] *Tropism*: The specificity of a biological agent or toxin for a particular host tissue or cell.

[12] *Host population*: A collective of organisms that constitutes a specific group or occur in a specified habitat. In the context of the criteria, the use of this phrase implies that the misapplication of the knowledge, products, or technologies derived from the research has the potential to broadly impact a population of host organisms.

[13] *Novel Agent:* A novel agent is an agent that has not existed previously and is considered unique based on biological or other properties and traits (e.g., genotype and phenotype). Novel agents of concern are those for which there is no known or widely available prophylactic or therapeutic interventions, those that could evade detection, or those for which there is no known immunity.

[14] *Eradicated agent:* A biological agent that has been exterminated through surveillance and containment resulting in the permanent reduction to zero in the worldwide incidence in the transmission of the agent and the infection/disease it causes; intervention measures are no longer needed. Eradicated agents are thought to no longer exist in circulation in plants, animals, and the environment. Note: Reconstituted eradicated agents of concern are those for which there are no known or widely available prophylactic or therapeutic interventions, those that could evade diagnostics, or those for which there is no known immunity.

[15] *Extinct agent:* These agents are thought to no longer exist in nature or in the laboratory.