STATE OF NEW YORK

10095

IN ASSEMBLY

May 3, 2024

Introduced by M. of A. BORES -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to establishing minimum protocol requirements for gene synthesis providers and manufacturers of gene synthesis equipment

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Short title. This act shall be known and may be cited as the "bioterrorism prevention act".

§ 2. The public health law is amended by adding a new article 32-B to read as follows:

ARTICLE 32-B

GENE SYNTHESIS LABS

Section 3230. Minimum protocol requirements for gene synthesis providers and manufacturers of gene synthesis equipment.

§ 3230. Minimum protocol requirements for gene synthesis providers and manufacturers of gene synthesis equipment. 1. Any gene synthesis provider or manufacturer of gene synthesis equipment in the state shall operate in accordance with international gene synthesis consortium protocols.

2. Gene synthesis providers and manufacturers of gene synthesis equipment shall, at a minimum:

(a) screen synthetic gene orders to identify regulated pathogen sequences and other potentially dangerous sequences;

(b) screen the complete DNA sequence of every synthetic gene order against the DNA sequences in a common Regulated Pathogen Database (RPD) and against all entries found in one or more of the internationally coordinated sequence reference databanks (such as NCBI/GenBank, EBI/EMBL, or DDBJ). The RPD shall include data from all organisms on the federal HHS and USDA select agents and toxins list, the Australia Group list of human and animal pathogens and toxins for export control and other national lists of regulated pathogens. As a baseline, gene synthesis providers and manufacturers of gene synthesis equipment shall screen against all pathogen and toxin genes as specified in the federal select

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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agents and toxins list, the federal commerce control list, and the European Union list of dual-use items;

(c) translate all six reading frames of each synthetic gene ordered or requested into an amino acid sequence. Such sequence shall be screened against the protein sequences derived from the RPD database described in this subdivision;

(d) use automated homology screening as a filter to identify pathogen and toxin DNA sequences. When automated screening identifies a potential pathogen or toxin sequence, the order shall be reviewed by a human expert using common screening criteria and shall be either accepted, accepted with a requirement for additional customer review, or rejected;

(e) require identification data from all potential customers for synthetic genes, including at a minimum a shipping address, institution name, country, telephone number, and email address. Gene synthesis providers shall not ship to PO Boxes;

(f) screen potential customers against the federal office of foreign assets control's specially designated nationals and blocked persons list (SDN), the federal department of state's debarred list, and the federal bureau of industry and security's denied persons list, entity list, and unverified list;

(g) require additional customer screening before accepting orders for DNA sequences from regulated pathogens or toxins. Although the federal select agent regulations and the European Commission regulations do not restrict access to all select agent genes, gene synthesis providers and manufacturers of gene synthesis equipment shall supply genes from regulated pathogens only to researchers in bona fide government laboratories, universities, non-profit research institutions, or industrial laboratories demonstrably engaged in legitimate research. Customers ordering sequences unique to organisms listed in the federal select agent or the United States commerce control list that endow or enhance pathogenicity shall provide a written description of the intended use of the synthetic product. Gene synthesis providers and manufacturers of gene synthesis equipment shall verify independently: (i) the identity of the potential customer and purchasing organization; and (ii) that the described use is consistent with the activities of the purchasing organization;

(h) use the current recommendations from the federal centers for disease control and prevention or the United States department of agriculture to determine which DNA sequences are select agents as recombinant DNA fragments. Gene synthesis providers and manufacturers of gene synthesis equipment shall supply genes with such sequences only if the supplier and the customer are able to comply with all select agent regulations applicable to such gene;

(i) in general, only sell DNA or fragments of regulated pathogens to bona fide end-users. Gene synthesis providers and manufacturers of gene synthesis equipment shall not sell or ship such material to distributors or other resellers, unless such companies identify the end-user receiving the products and demonstrate their compliance with every requirement otherwise applicable to such end-user;

(j) retain records of every gene synthesized and delivered for a minimum of eight years after shipping, including at least the following: (i) the synthetic DNA sequence; (ii) the vector (if applicable); and (iii) the recipient's identity and shipping address;

(k) retain records of every gene sequence screening result for at least eight years;

(l) reserve the right to refuse to fill any order and to notify other gene synthesis providers and manufacturers of gene synthesis equipment and authorities upon identifying potentially problematic orders;

(m) establish an up-to-date contact list of national law enforcement agencies with whom to share information and report any potential misuse of synthetic genes;

(n) report any request for a gene associated with the pathogenicity of an organism received from a suspicious potential customer or potential customer failing to establish their legitimacy to law enforcement officials; and

(o) synthesize gene sequences unique to and derived from Variola (smallpox) virus DNA only in adherence with guidelines established by the World Health Organization's advisory committee for Variola virus research.

§ 2. This act shall take effect immediately.