

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:

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

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

ARTICLE 32-B

GENE SYNTHESIS LABS

5
6 Section 3230. Minimum protocol requirements for gene synthesis providers
7 and manufacturers of gene synthesis equipment.

8
9 § 3230. Minimum protocol requirements for gene synthesis providers and
10 manufacturers of gene synthesis equipment. 1. Any gene synthesis
11 provider or manufacturer of gene synthesis equipment in the state shall
12 operate in accordance with international gene synthesis consortium
13 protocols.

14 2. Gene synthesis providers and manufacturers of gene synthesis equip-
15 ment shall, at a minimum:

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

18 (b) screen the complete DNA sequence of every synthetic gene order
19 against the DNA sequences in a common Regulated Pathogen Database (RPD)
20 and against all entries found in one or more of the internationally
21 coordinated sequence reference databanks (such as NCBI/GenBank,
22 EBI/EMBL, or DDBJ). The RPD shall include data from all organisms on the
23 federal HHS and USDA select agents and toxins list, the Australia Group
24 list of human and animal pathogens and toxins for export control and
25 other national lists of regulated pathogens. As a baseline, gene synthe-
26 sis providers and manufacturers of gene synthesis equipment shall screen
27 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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1 agents and toxins list, the federal commerce control list, and the Euro-
2 pean Union list of dual-use items;

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

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

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

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

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

37 (h) use the current recommendations from the federal centers for
38 disease control and prevention or the United States department of agri-
39 culture to determine which DNA sequences are select agents as recombi-
40 nant DNA fragments. Gene synthesis providers and manufacturers of gene
41 synthesis equipment shall supply genes with such sequences only if the
42 supplier and the customer are able to comply with all select agent regu-
43 lations applicable to such gene;

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

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

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

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

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

7 (n) report any request for a gene associated with the pathogenicity of
8 an organism received from a suspicious potential customer or potential
9 customer failing to establish their legitimacy to law enforcement offi-
10 cials; and

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

15 § 2. This act shall take effect immediately.