

AMENDMENT TO RULES COMMITTEE PRINT

119–22

OFFERED BY MS. HOULAHAN OF PENNSYLVANIA

At the end of part II of subtitle C of title X, add the following:

1 **SEC. ____ . OVERSIGHT BASED ON PLAUSIBLE RISKS.**

2 (a) **RULEMAKING.**—Within 180 days from the date
3 of enactment of this Act, the Secretary shall publish a no-
4 tice of proposed rulemaking in the Federal Register to re-
5 place the existing “plant pest risk” regulatory framework
6 for genetically engineered microorganisms and plants pro-
7 duced using biotechnology with a tiered, risk-based frame-
8 work based on plausible risks to plant health, public
9 health, and the environment.

10 (b) **FRAMEWORK CONTENTS.**—The oversight frame-
11 work under subsection (a) shall reserve the highest scru-
12 tinity for novel products as follows:

13 (1) For genetically engineered microorganisms,
14 the initial categories of novel products subjected to
15 higher scrutiny shall include—

16 (A) synthetic genomes; and

1 (B) multi-species groups of genetically en-
2 gineered microorganisms that are intended for
3 release into the environment together.

4 (2) For plants produced using biotechnology,
5 the initial categories of novel products subjected to
6 higher scrutiny shall include—

7 (A) plants that produce pharmaceuticals;
8 and

9 (B) plants that produce industrial en-
10 zymes.

11 (c) EXEMPTIONS AND FAST-TRACK REVIEW.—The
12 oversight framework under subsection (a) shall exempt
13 from review or use a fast-track review for well-understood
14 genetically engineered microorganisms and plants pro-
15 duced using biotechnology as follows:

16 (1) For genetically engineered microorganisms,
17 the initial categories of products eligible for such an
18 exemption or fast-track review shall include—

19 (A) microorganisms that do not replicate
20 in the environment; and

21 (B) microorganisms that are closely related
22 to well-characterized strains.

23 (2) For plants produced using biotechnology,
24 the initial categories of products eligible for such an
25 exemption or fast-track review shall include—

1 (A) plants with changes achievable through
2 conventional breeding; and

3 (B) plants that are similar to previously-
4 approved plants.

5 (d) CLASSIFICATION.—The oversight framework
6 under subsection (a) shall contain a procedure by which
7 the Secretary may regularly evaluate which products or
8 product categories the Secretary determines should be—

9 (1) classified under subsection (b) as requiring
10 highest scrutiny; or

11 (2) reclassified as eligible for an exemption or
12 fast-track review under subsection (c).

13 (e) REPORT.—Not later than 90 days after the date
14 of the enactment of this Act, the Secretary shall submit
15 to the Committee on Agriculture, Nutrition, and Forestry
16 of the Senate and the Committee on Agriculture of the
17 House of Representatives a report detailing how imple-
18 menting the new regulatory framework described in sub-
19 section (a) may change the Department’s technical staff-
20 ing needs and what additional resources would facilitate
21 the framework’s implementation.

