

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 and genetically modified plants
7 and plants produced using biotechnology with a tiered,
8 risk-based framework based on plausible risks to plant
9 health and the environment.

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

13 (1) For genetically engineered or genetically
14 modified plants, the initial categories of novel prod-
15 ucts subjected to higher scrutiny shall include—

16 (A) synthetic genomes; and

17 (B) multi-species groups of genetically en-
18 gineered or genetically modified plants that are

1 intended for release into the environment to-
2 gether.

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

6 (A) plants that produce pharmaceuticals;
7 and

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

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

15 (1) For genetically engineered or genetically
16 modified plants, the initial categories of products eli-
17 gible for such an exemption or fast-track review
18 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 ex-
25 emption 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 should be classified under subsection
9 (b) or reclassified as eligible for exemptions or fast-track
10 review under subsection (c).

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

