

plants that meet the following three criteria: (1) The plants are engineered to produce compounds that are new to the plant; (2) the new compound has not been commonly used in food or feed; and (3) the new compound is being expressed for non-food, non-feed industrial uses. Industrial uses include, but are not limited to, detergent manufacturing, paper production, and mineral recovery.

Based on the expansion of the technology and the new non-food, non-feed uses of industrial plants being developed, we believe it is prudent and necessary to remove the notification option for all industrials pending the completion of our ongoing review of part 340.

With this interim rule, which will be in effect only until December 31, 2004, we amend the regulations in part 340 to remove the notification options for such plants. Therefore, for the remainder of the 2003–2004 growing seasons all introductions of plants genetically engineered to produce industrial compounds will be conducted pursuant to APHIS' rigorous permit system. We are continuing our review of this and other issues and of the regulations in part 340 generally and will announce our plans in a document published in the **Federal Register** within the next year.

Immediate Action

Immediate action is necessary to strengthen our regulations with regard to the introductions of genetically engineered plants that encode compounds intended for industrial use because of our lack of regulatory experience and scientific familiarity with the kinds of traits in current and planned introductions. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this action effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for

this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This interim rule amends the regulations regarding genetically engineered organisms to require that introductions of plants genetically engineered to encode compounds for industrial use be conducted only under permit. Prior to this interim rule, such introductions could be accomplished under notification, an expedited permitting procedure.

Since 1993, only five companies and two public sector organizations have submitted notifications or applied for permits to introduce plants producing industrial compounds. From 1993 to 2001, 10 notifications of introductions of plant-made industrials (by 2 companies and 1 public sector entity) were received by APHIS. One notification was withdrawn; nine were acknowledged. In 2003, five permit applications for introductions of plant-made industrials have been received by APHIS (by three companies and one public sector entity).

It is difficult to predict how many organizations will apply for permits to introduce genetically engineered plants producing industrial compounds under the regulations in the future. Many unknowns will affect growth of the sector, including: Scientific/technological advances, consumer acceptance, market demand, production economics, the regulatory environment, intellectual property rights, and other critical factors.

Under the current notification procedure, when APHIS receives a notification, it is usually reviewed by a biotechnologist within 10 to 30 days, is

forwarded to the State for further review, then returned to the applicant as either acknowledged or denied. Under the current permit procedures, it could take up to 3 months longer for each plant-made industrial compound introduction to be approved. When a permit application is received by APHIS, scientists review the application for deficiencies. If deficiencies are found, the applicant is required to respond to the noted deficiencies and the permit is either issued or denied within 120 days. The permit and proposed conditions are then sent to the State in which the introduction would occur. The State may concur or add conditions and concur.

Authorizations under notification require compliance with the performance standards described in § 340.3(c). For each notification, the responsible person must describe the procedures they will take to meet the performance standards. APHIS reviews those procedures and approves or denies the notification request. Authorizations under permit require compliance with standard permit conditions and supplemental conditions based on the risks involved in each case.

The requirement to introduce plants genetically engineered to produce industrial compounds under permit will result in an increased paperwork burden for applicants. Permits require the applicant to answer three more questions. The time per response is estimated to be 5 hours, so the total additional paperwork burden per permit could be somewhere in the neighborhood of 15 hours.

It is unlikely that the additional time for processing permits or the additional paperwork requirement would discourage applicants from applying for permits for the introduction of plants producing industrial compounds. Data on applications to introduce plants producing industrial compounds under the notification system (1993–2001) versus the permit system (2003) suggest that voluntary compliance with the permit system has not discouraged applicants thus far.

TABLE 1.—APPLICATIONS TO INTRODUCE PLANTS PRODUCING INDUSTRIAL COMPOUNDS

	Total applications	Applications per year
Notification system (1993–2001)	10	Slightly more than 1 per year.
Permit system (2003)	5	Five in the first 6 months.