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SCIENCE, which is now combined with THE SCIENTIFIC MONTHLY, is published each Friday by the American Association for the Advancement of Science at Business Press, Lancaster, Pa. The joint journal is published in the SCIENCE format. Entered at the Lancaster, Pa., Post Office as second class matter under the Act of 3 March 1879. SCIENCE is indexed in the *Reader's Guide to Periodical Literature*.

Editorial and personnel-placement correspondence should be addressed to SCIENCE, 1515 Massachusetts Ave., NW, Washington 5, D.C. Manuscripts should be typed with double spacing and submitted in duplicate. The AAAS assumes no responsibility for the safety of manuscripts or for the opinions expressed by contributors. For detailed suggestions on the preparation of manuscripts, book reviews, and illustrations, see *Science* 125, 16 (4 Jan. 1957).

Display-advertising correspondence should be addressed to SCIENCE, Room 740, 11 West 42 St., New York 36, N.Y.

Change of address notification should be sent to 1515 Massachusetts Ave., NW, Washington 5, D.C. 4 weeks in advance. If possible, furnish an address stencil label from a recent issue. Be sure to give both old and new addresses, including zone numbers, if any.

Annual subscriptions: \$8.50; foreign postage, \$1.50; Canadian postage, 75¢. Single copies, 35¢. Cable address: Advancesci, Washington.



Locking the Barn Door First

The Federal Food, Drug, and Cosmetic Act, passed in 1906, has been amended several times to keep it abreast of technological changes, but, until recently, it suffered from a grave and increasingly serious defect. The Act put the burden of testing new food additives for safety on the Government but had no provision for controlling the introduction of new substances. Thus manufacturers could add new compounds—enzymes, artificial flavors and coloring matter, antioxidants, preservatives, and so on—to food products without hindrance; the only recourse for the Government was to test the compounds for safety and, if it found them to be unsafe, to proceed against the producers in court. In effect, this was locking the barn door after the horse was stolen. In fairness to the food industry, it should be pointed out that almost all of the 100,000 or more firms whose products came under the provisions of the Act tested additives thoroughly before general introduction, but a few did not. Herein lay the danger to the public, a danger that increased as vast numbers of new additives were introduced at a rate much greater than that at which Government chemists could make adequate tests.

The Food Additives Amendment of 1958 (Public Law 85-929), passed on 6 September 1958 and fully effective on 6 March 1959, should do much to avoid the danger. The amendment shifts the burden of proving the safety of new additives from the Government to the producer and requires the producer to get a favorable ruling about the additive before it is introduced for public use. To do this the producer presents a petition to the Food and Drug Administration in which he gives the following information about the proposed additive: name, chemical identity if known, conditions of proposed use, relevant data about its intended effect, description of methods for making quantitative determinations, and a complete account of investigations made to test its safety. The petition will be published in the *Federal Register* in general terms as a *proposal* for a future regulation within 30 days after it is filed. Within 90 days (or 180 days if an extension is granted) the commissioner of the Food and Drug Administration will publish the final ruling on the petition. During this period those who have a substantial interest, including scientists who are expert in the effects of chemicals on the food of man and animals, may submit objections.

Scientific experts will thus have a large responsibility under the terms of the amendment. If they raise objections to a proposal, the FDA will take them into account and hold hearings or otherwise gather additional information before making a ruling. If, on the other hand, scientists do not object to a proposed favorable regulation, the FDA will assume that there is general scientific agreement and will put the regulation into effect. This procedure will put it up to the scientists to see that no potentially dangerous additives escape their vigilance, that the barn door is locked first.—G.DuS.