

American Society of Plant Biologists

15501 Monona Drive, Rockville, Maryland 20855-2768 • telephone 301-251-0560 • fax 301-279-2996

February 6, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 02D-0324

Dear Sir or Madam:

The American Society of Plant Biologists (ASPB) Committee on Public Affairs appreciates this opportunity to comment on the draft Guidance for industry on drugs, biologics and medical devices derived from bioengineered plants for use in humans and animals. ASPB is a non-profit society of 6,000 plant scientists founded in 1924 under the former name, the American Society of Plant Physiologists.

The draft guidance released by the Food and Drug Administration and Department of Agriculture seeks to facilitate development of pharmaceutical crops while maintaining safeguards against cross-pollination of pharmaceutical crops with food crops.

The value to society offered by future pharmaceutical crops is substantial. Promising research on plants engineered to produce compounds for pharmaceutical products could lead to more effective and cost-effective therapies for people throughout the world. Millions of people with disabling and life-threatening illnesses could benefit from new, plant-based pharmaceutical therapies. Millions of more people could be immunized against deadly diseases with future plant-based vaccines.

At the same time, insufficient safeguards against cross-pollination of pharmaceutical crops with food crops could pose safety hazards for the food supply, consumers, food producers, and food distributors. The tremendous benefits offered by pharmaceutical crops combined with the potential hazard of cross-pollination with food crops underlie a need for stringent regulatory guidance.

Following are some of the possible approaches that have been presented by scientists in our membership that would contribute to containment of pharmaceutical crops:

- Some in the plant science community have discussed the possibility of limiting development of pharmaceutical crops to non-food crops to prevent the possibility of cross-pollination with food crops. Some other plant scientists have noted, however, that much of the knowledge and infrastructure in the plant science community is based on food crops.

0545 03 FEB -7 P1:42

02D-0324

0586

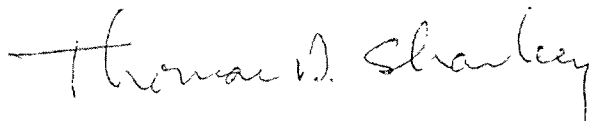
- We received further input with regard to specific proteins or gene products. Some plant scientists recommended that the specific protein or gene product engineered into a plant must be considered when deciding whether it should be allowed in food crops. Some proteins may pose sufficient risk that they should never be allowed into food crops. Each proposed modification should be evaluated for benefits and risks and whether the use of food crop species is necessary.
- We also received recommendations that genetic containment approaches should be considered for pharmaceutical crops. Use of male sterile plants for pharmaceutical crop production would contribute to containment strategies.

ASPB did not receive a consensus among recommendations from members contacted and does not have enough information at this time to formally endorse one of the above recommendations over another. These recommendations are also not submitted to replace approaches suggested in the draft guidance. These comments are submitted simply to provide insights of plant scientists we have contacted in our membership for the agencies further consideration and study.

The long-term prospects for the development of pharmaceutical crops depend upon effective containment at all times. An errant mistake by one developer of pharmaceutical plants could result in serious problems for the rest of the industry. Such a mistake could also cause severe financial losses for farmers of food crops and other interests throughout the food distribution chain.

Economic considerations notwithstanding, the overriding factor in containment questions is that the most effective approaches be put in place to protect human health and safety. We commend you in developing and seeking public comment on this important issue. Please let me know if we can provide any additional information.

Sincerely,



Thomas Sharkey
Professor, Dept. of Botany, University of Wisconsin
Chair, ASPB Committee on Public Affairs

American Society of Plant Biologists
formerly American Society of Plant Physiologists



Brian M. Hyps
Public Affairs Director

15501 Monona Drive
Rockville, Maryland 20855-2768 USA
Tel: 301-251-0560, ext. 114
Fax: 301-309-9196
bhyps@aspb.org
<http://www.aspb.org>