

House Panel Passes a Big Pesticide Bill That Environmentalists, Industry Back

By TIMOTHY NOAH

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON—The House Commerce Committee unanimously passed a bill to overhaul pesticide regulation that eliminates a strict prohibition on cancer residues in processed foods.

The vote came a day after key industry and environmental groups lent their support to the compromise measure, which also was endorsed by Reps. Tom Bliley (R., Va.) and Henry Waxman (D., Calif.). The two House members had until Tuesday been fierce opponents over how to revise the pesticide law.

Vice President Al Gore said in a written statement that the bill "meets goals President Clinton set forth early in his administration," and praised the committee "for setting aside differences to address this critical issue."

The bill seems likely to win speedy passage in the House, where it will now proceed to a floor vote, and in the Senate, which has not yet taken up the measure. Sen. Patrick Leahy (D., Vt.), a longtime ally of Mr. Waxman's on pesticide legislation, said yesterday that he would "work to move it immediately through the Senate." Sen. Richard Lugar, chairman of the Senate Agriculture Committee, said his panel will take up the bill on July 24.

The bill has the support of the Natural

Resources Defense Council, an environmental group that has been quite active on the issue, and the National Food Processors Association. But the U.S. Public Interest Research Group criticized the bill for restricting states from passing tougher pesticide standards than the federal government. To do so, under the bill, they must petition the Environmental Protection Agency.

The new pesticide bill would loosen a federal prohibition on minute traces of carcinogens in processed food that dates back to 1958, when scientists' ability to detect trace carcinogens was far less refined than it is today. In exchange for scuttling this law, known as the Delaney Clause, regulators would toughen protections for raw foods, which today are only lightly regulated with respect to pesticides. The new bill also would include new protections for children and for infants, who are especially susceptible to harm from pesticides.

With the committee's action, the pesticide bill appears likely to become the second major environmental proposal to become law in this Congress, which, until recently, seemed unlikely to pass any significant environmental bills at all. The other major bill, a rewrite of the Safe Drinking Water Act, awaits consideration by a House-Senate conference panel.

Senate Votes to Establish Commission on Gambling

WASHINGTON (AP) — The Senate voted to set up a commission to study the impact on the nation of the phenomenal growth in legal gambling.

Passage of the bill, by voice vote, came after lawmakers reached a compromise on the subpoena powers of the nine-member commission, an issue that held up action on the bill for months.

The House passed its version of the legislation last March, and President Clinton has endorsed it, promising the gambling industry the study wouldn't be a witch hunt of the industry.

"No one suggests we are going to close down Las Vegas or Atlantic City, but I think we ought to look at this problem and see what the dimensions of that problem are," said Sen. Paul Simon (D., Ill.), a sponsor of the legislation.

For two years, the commission will explore the relationship between gambling and crime and assess gambling's impact on families and the economy.

Under the compromise, the commission is authorized to subpoena documents and written answers to its questions, but public disclosures of confidential information are limited to safeguard privacy and protect trade secrets. The House version gives the commission stronger subpoena powers.

FCC Adopts Plan To Carve Up Swath Of Radio Spectrum

By a WALL STREET JOURNAL Staff Reporter

WASHINGTON — The Federal Communications Commission adopted a long-pending plan to divide a swath of radio spectrum between cellular-style wireless cable-television and satellite-communications network industries.

The action gives a big lift to the new cellular-style wireless technology, known as local multipoint distribution service, or LMDS. CellularVision of New York Inc., with investment backing from Bell Atlantic Corp. and Philips Electronics NV, sells LMDS service in New York, but had been blocked from expanding the service because of the spectrum dispute with satellite-minded firms seeking the same frequencies.

The FCC decision resolved a dispute between the two industries that the agency thought it had settled a year ago, when it issued proposed rules for carving up the disputed spectrum, in the range of 28 Ghz. Since then, as the two industries and the FCC sought to fine-tune the plan and devise ways to iron out some remaining difficulties, the July 1995 formula began to fall apart. But most companies seeking parts of the 28 Ghz spectrum recently agreed to return to the original plan, and the FCC's decision yesterday ratifies that agreement.

Among participants in the agreement were Cellular Vision and Philips, LMDS proponents, and satellite interests including AT&T Co., General Electric Co., General Motors Corp.'s Hughes Communications Galaxy unit and Teledesic, a venture created by computer magnate Bill Gates and cellular pioneer Craig McCaw.

The FCC decision still didn't meet objections of Texas Instruments Inc. and Hewlett-Packard Co. that the plan doesn't accommodate their LMDS return links. The FCC's ruling would allocate those links in the 31 Ghz area, which will mean delays in separate rulemaking and may require the two companies to redesign their systems, FCC officials said.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

LRM NO: 4738

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6/18/96

LEGISLATIVE REFERRAL MEMORANDUM

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TO: Legislative Liaison Officer - See Distribution below:

FROM: Ron PETERSON *Ron Peterson* (for) Assistant Director for Legislative Reference

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fitter_e@a1.eop.gov
Robert TUCCILLO 395-5609

SUBJECT: Environmental Protection Agency Proposed Report RE: HR1627, Pesticide Food
Safety Act of 1995

Monday, June 18, 1996
DEADLINE: 10:00 AM Thursday, June 20, 1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before
advising on its relationship to the program of the President.

Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go"
provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: This report concerns State preemption of localities

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To: E. Dwyer

*Re: Dwyer
on hold till
policy set*

FAX TRANSMITTAL

TO: <i>Pat Roberts</i>		FROM: <i>Carol M. Browner</i>	
SUBJECT: <i>Food Quality Protection Act</i>		DATE: <i>6/18/96</i>	
FAX NO. <i>303-5691</i>		FAX TO: <i>303-5691</i>	
FAX FROM: <i>303-5691</i>		FAX TO: <i>303-5691</i>	

GENERAL SERVICES ADMINISTRATION

DRAFT 6/18/96 10:30 a.m.
The Honorable Pat Roberts, Chairman
Committee on Agriculture
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The Administration would like to comment on a provision of H.R. 1627, the "Food Quality Protection Act," that would override the discretion and authority of certain localities to regulate pesticide use on behalf of their citizens.

Section 106 of H.R. 1627 would amend Section 24 (7 U.S.C. 136) of the Federal Insecticide, Fungicide, and Rodenticide Act to prohibit local governments from imposing or continuing activities to enforce local pesticide regulations when state laws do not specifically preempt local governments from doing so.

While the Administration supports strengthening the nation's pesticide and food safety laws, we do not believe that the Federal government should unduly restrict local pesticide ordinances and regulations. Given the interest for greater flexibility and discretion at the local level, state and local governments should be able to work together to find the best solutions that are protective of public health and the environment.

In fact, many localities have developed innovative solutions to unique and complex pesticide regulatory issues. ~~(For example, many local school districts have instituted Integrated Pest Management (IPM) programs to improve their pest control practices.)~~ Removing local governments from the process of regulating pesticide use may jeopardize the common sense approach to public health protection, limit local community involvement, and restrict the public's right to know about pesticides used in their communities.

*SLB
delete
not need
example*

We remain committed to working with the Congress for substantive pesticide reform that advances sound protection of public health.

The Office of Management and Budget advises that there is no objection to the presentation of these views from the standpoint of the President's program.

Sincerely,

Carol M. Browner

(Identical letter sent to Rep. de la Garza)

Put schedule Jim Schala

7/3/96

Pesticides — Dingell's staff is anxious
for an agreement —

- Waxman thinks it's a mistake
- but Dingell wants

— Can agree — probably can have
an agreement. —

(~~to~~ accomplishments —

(~~to~~ add them to the environment —

^{no} good coming out of it

— new draft today —

— starting on Monday over —

— Test July 10th markup —
not worried

— Not much —

Facts — will have markup next Wed., even if
they don't really —

→ no more statements —

Crucial point — what's in The Bill

Fixing 4/5 — CODEX

— FIFRA supremacy clause
(only act under FIFRA first)
unless it hurts people

— Prop 65 drop [but preempt
state on tolerances.] —

We were
silent

fix technical stuff. -

Benefits - estrogens (drinking water provisions
on estrogen testing in food and drug)

benefits

(ii) drop

drop take Administration's language on health-health

3rd-economic test. - Waxman stand-

↳ we would argue for phase out. -

- Drinking H₂O had right to know provision -

- want comparable in pesticides

- want "green star" type program.

Phil's head - benefits, green star -

↳

Enviros softening

- Env. working for Mark Chidress etc.

- may bring along NRC -

- Eric Olsen -

At Meserhuff firm about

May get consumers union, others -

- presumption issue -

Jin - Drinking water process is a good (regulatory) one.

- Have one end that has moved as it
discharge petition to 230+ members

Has moved through Ag Com. -

Doug Parsons - EPA Reg.

George Fizzle - CEA

- Adopts all pieces about Children in our bill

- dB - much better

In Admin - we said CBA applied only
to older - New were strictly health based

This bill recognizes time limit / phase out

12-13 yrs. (ours was 5)

- preempts Prop 65

- preempts rights of all states to set different tolerances
(which states have rarely done)

Can't act independently under PFIDCA - like to
as provision

Specificity of risk Stds. -

"endocrine" not included enough time

- Bliley wants subcommittee made 12 days from now. —
- Waxman —

Dringell has always been in favor of preempting state tolerances —

- New vs. Old pesticides. —
- Role of Benefits —
- POP 65 —
- Harmonization b/w FIFRA and FFDCA —
 - ↳ could delay action for 8 yrs.
- ↳ Clarifying "negligible" —
 - State preemption OMA / Food Processors —
 - fall on their sword
 - CA, MA, NY, FL, WI
 - 1 2

- benefits

p. 10 (i)

With Dole in the Doldrums, Worried Republicans Get Rebellious and Press Hard for a Big Tax Cut

By JACKIE CALMES

Staff Reporter of THE WALL STREET JOURNAL
WASHINGTON — The new byword for Republican candidates these days is: You're on your own.

After Bob Dole clinched the Republican presidential nomination in March, House Speaker Newt Gingrich pronounced that the GOP Congress would henceforth take its cues from the party's standard-bearer.

But with Mr. Dole still in a stall this summer, far behind President Clinton in the polls, the rank and file fret that he could drag down the first Republican Congress in 40 years. And they're angling to call their own shots.

The rebelliousness is especially evident in the increasing maneuvering to draft a "pro-growth" Republican economic program heavy with tax cuts — out of despair that Mr. Dole hasn't yet done so, and won't be bold enough when he does.

"He's got to get his party back," says Ed Rollins, a longtime Republican strategist. "My greatest fear is that Newt Gingrich and his followers begin to think that Bob Dole is a drag on their re-elections, and Gingrich rises to the bait and tries to make it a Clinton-Gingrich contest. A Clinton-Gingrich race in the fall is not going to be a pretty sight for Republicans," Mr. Rollins says.

Dole campaign aides say they still are shooting to get an economic plan completed and announced this month, regardless of the national obsession with the Olympic Games that begin this weekend in Atlanta. Increasingly, they seem to think that Mr. Dole may, in the end, decide to include some kind of across-the-board income-tax cut. Such a tax cut probably would be framed as a kind of "down payment" on a more radical revamping of the U.S. tax system into the "flatter, simpler, fairer" tax code that Mr. Dole calls for on the stump.

Campaign aides figure they can attract attention from the television networks and voters not caught up in Olympic fever, and then promote the plan again at next month's Republican convention.

But to many Republicans' chagrin, Mr. Dole hasn't made final decisions yet. Economist John Taylor of Stanford University, a former member of President Bush's Council of Economic Advisers, has spent long hours at the Dole campaign, working on lengthy memos for the candidate. One surprise has been the role of Donald Rumsfeld, the senior campaign policy adviser who, insiders say, has emerged as a proponent of an ambitious economic and tax-cut plan. Mr. Rumsfeld, a business executive and former defense secretary, was long considered a traditional GOP deficit hawk, like Mr. Dole himself. But colleagues say he has been increasingly converted to the tax arguments of economic-growth proselytizers.

All this deliberation, meanwhile, is so much fiddling as Rome burns to some

conservative Republicans in Congress. The combination this week of new poll numbers, such as a Harris Poll out today showing Mr. Dole 22 points behind Mr. Clinton, and the stock market's volatility, is fueling their impatience for an ambitious tax-cut program. Exploiting that, to the

annoyance of the Dole campaign, is former Dole rival Jack Kemp.

Mr. Kemp is pushing his former associates in Congress, such as Mr. Gingrich and Senate Majority Leader Trent Lott of Mississippi, to convene an economic summit on Capitol Hill, tentatively scheduled for July 23. After meeting last Friday with his friends in the group known as the "Amigos" — Messrs. Gingrich and Lott, and Sen. Connie Mack of Florida — Mr. Kemp announced on a weekend television appearance that there would be a news conference of the congressional leaders today to announce the summit and economic goals. A top Dole campaign adviser, former Minnesota Rep. Vin Weber, is also a member of the Amigos group.

But GOP leaders, realizing that such action would be viewed as a slap at candidate Dole, have demurred for now. Gingrich spokeswoman Lauren Sims says, "Jack Kemp would like a press conference on Wednesday, but we don't see any way that Newt's schedule would allow that." She adds that anything the congressional Republicans do would complement Mr. Dole's agenda.

Privately Expressed Views

Yet despite his fellow Republicans' recurring annoyance with Mr. Kemp's pronouncements, privately they say he reflects what other GOP leaders can't or won't say publicly about the Dole campaign. If Mr. Dole "comes up with something lame," says Bruce Bartlett, a former Treasury official and a tax-cut proponent, congressional Republicans will "come up with something on their own — even if it means running away from Dole."

A senior Dole aide counters that the Kemp idea is "only a problem to the extent that it makes it appear Jack is dictating what he wants."

Separately, Mr. Kemp and his allies have put out the word that he and Wall Street financier Felix Rohatyn, a prominent Democrat, would co-host a September forum to forge a pro-growth plan, and fill the perceived void left by the Dole and Clinton campaigns. But Mr. Rohatyn denies the reports. "I said I don't even want to discuss this in the midst of an election campaign," he recalls.

The GOP rebelliousness already showed up last week when Congress reversed course — Mr. Dole's course — on the strategy for passing welfare legislation.

GOP leaders dropped their longstanding insistence, echoed by Mr. Dole, that their bill combine changes in welfare and the Medicaid health program. Both congressional Republicans and Mr. Dole had banked on using an expected Clinton veto of a combined bill as an election issue.

But restive rank-and-file Republicans argued that the GOP Congress needs achievements as well as political issues, even if it means sharing credit with the president. Although the Dole campaign remained opposed to the new stratagem, at the last minute it produced a letter from Mr. Dole to make it appear that the GOP leaders were doing his bidding.

Republicans are still favored to hold their House and Senate majorities, though many political analysts say that if the election were held today, the Democrats could take control. A shift of just 20 seats in the House, and either three or four in the Senate, depending on who's elected president, would transfer power again to the Democrats.

Tight Congressional Races

GOP candidates in tough districts privately worry about the fallout for them should Mr. Dole fizzle. But Elizabeth Wilner, a top expert on congressional

racess, says the problem for GOP candidates in a weak Dole showing "is not so much a case of negative coattails as it is the potential for lower turnout because Republican voters aren't enthusiastic about their presidential candidate."

Neil Newhouse of Public Opinion Strategies, a Republican consulting firm that's handling more than 40 congressional races, says, "None of this group has ever depended on the top of the ticket to bring them in office or keep them there." Moreover, he adds, "this situation is a hell of a lot better" than four years ago, when Republicans shared the ballot with a doomed President Bush. "It's not Bob Dole, it's the generic political climate" that more concerns Republicans, Mr. Newhouse says, as the nation's voters have turned sour on the self-styled revolutionary GOP Congress.

Some Republicans, meanwhile, already see a potential silver lining should Mr. Dole still look like a loser by Election Day. They figure — privately, of course — that their GOP congressional candidates could be helped as voters instinctively choose a divided government — re-electing Mr. Clinton and a GOP Congress to keep a rein on each other.

—Gerald F. Seib
contributed to this article.

THE WALL STREET JOURNAL
= WEDNESDAY, JULY 17, 1996



Bob Dole

House Votes to Continue Salary Freeze For Congress Despite Some Warnings

By DAVID ROGERS
And CHRISTOPHER GEORGES

Staff Reporters of THE WALL STREET JOURNAL
WASHINGTON — The House voted to deny members of Congress their annual cost-of-living pay adjustment, marking the fourth time in as many years that lawmakers have kept salaries frozen at \$133,600.

The lopsided, 352-67 roll call reflected the political pressures going into the fall elections. Older members warned, however, that the chamber was undercutting itself by backtracking on the system set up in the late 1980s to allow orderly adjustments in pay.

"We are leaving the House to people born with a silver spoon in their mouth," complained Rep. Jerry Lewis. But the California Republican found himself matched against freshmen in his own party who pressured the GOP leadership last week for the chance to introduce the pay-freeze amendment.

Salaries for members of the Supreme Court, cabinet secretaries and Vice President Al Gore would also be frozen at their respective levels.

The action came last night as the House took up a \$23.2 billion Treasury-spending bill making deep cuts in the Internal Revenue Service's budget for the new fiscal year beginning Oct. 1. The leadership hopes to complete passage today.

The measure would be the 10th of the 13 annual spending bills to move through the House.

Progress in the Senate has been far slower. To date, only one bill has passed the chamber, which remains bogged down in a time-consuming debate over the establishment of a federal storage facility for nuclear waste in Nevada.

The Senate voted yesterday to limit initial debate, allowing the leadership to proceed to the bill last evening. But the measure is still subject to filibuster and a second debate-limiting vote July 25. Republicans will have to scramble to pack in as many spending bills as possible in the intervening days.

Senate Appropriations Committee Chairman Mark Hatfield (R., Ore.) has so

far resisted pressure to shortcut the process by simply passing a single, governmentwide stopgap bill to cover the first six months of the new fiscal year. But Mr. Hatfield warned yesterday that this option "begins to take shape as we look at the failure of the Senate as a whole."

To get home early, the leadership is prepared to simply continue spending at current levels. But the first casualties would be the scores of set-asides for home-state projects that Republicans have salted away this election year.

Two competing energy and water bills, approved within hours yesterday by the House and Senate Appropriations panels, illustrate this dilemma. The \$19.4 billion House measure favors home-state water projects by adding more than \$121 million to the administration's request for Army Corps of Engineers construction funds. By comparison, the Senate is more generous in providing for atomic-energy defense activities, which are a major priority for Sen. Pete Domenici (R., N.M.), up for re-election in a state greatly dependent on the nuclear-lab program.

Freshmen Republicans in California and Illinois are among those benefiting from new-found largesse in the House. Speaker Newt Gingrich (R., Ga.) has made no secret of his desire to use the appropriations process to help endangered Republicans. But meeting with reporters, Majority Leader Richard Armey (R., Texas) insisted he knew nothing of such a policy. "I don't know how to even spell 'pork' . . .," Mr. Armey said. "Pork is not a hot topic in Republican leadership meetings."

House Compromises on How to Regulate Cancerous Pesticides in Processed Foods

By TIMOTHY NOAH

Staff Reporter of THE WALL STREET JOURNAL
WASHINGTON — House negotiators struck a compromise on a long-simmering dispute over how to regulate cancer-causing pesticide traces in processed foods.

The compromise would eliminate the Delaney Clause, a 1950s-era law banning even minute traces of carcinogens in processed foods. It is expected to be passed by the House Commerce Committee today with the blessing of the Environmental Protection Agency, environmentalists and the processed-food industry.

The new pesticide bill, endorsed yesterday by Commerce Committee Chairman Thomas Bliley of Virginia and Democratic Rep. Henry Waxman of California — until now, bitter foes on the issue — represents the second 11th-hour compromise on an environmental issue during this Congress. A few months ago, the lawmakers weren't expected to pass any environmental bills. A Safe Drinking Water Act revision is currently awaiting consideration by a House-Senate conference committee.

The Senate hasn't yet taken up the pesticide bill, but the House's action increases the likelihood that the Senate will approve the measure.

Although the Clinton administration hasn't yet formally endorsed the pesticide proposal, an EPA official said yesterday that the agency will support the bill "if it stays the way it's going to committee."

Like a plan put forth earlier by the EPA — but resisted by Congress — the new compromise would impose a single health-based standard for both raw and processed foods. In effect, it would loosen current regulation of processed foods in exchange for strengthening current regulation of raw foods.

Instead of the Delaney Clause's strict prohibition against any trace carcinogens in processed foods, the new language would require that pesticides guarantee a "reasonable certainty of no harm" to consumers of raw and processed food. The Delaney Clause wasn't enforced to the letter until recent years, after a federal judge required the EPA to tighten its enforcement. This, in turn, caused the EPA to cancel many pesticide approvals, putting pressure on the pesticide industry to agree to new regulatory language.

The bill also would require pesticide

manufacturers to demonstrate that their products pose no harm specifically to infants and children, who are more likely to be harmed by pesticides. And the bill would drop language inserted by the House Agriculture committee that would have prevented states and localities from regulating pesticides more strictly than the federal government. Separate language, more narrowly worded, would still restrict states and localities somewhat, but the states could impose stronger standards with permission from the EPA.

"We haven't seen everything in it," said Tim Willard, a spokesman for the National Food Processing Association. But based on "what we've seen," he said, his organization will support the bill.

Erik Olson, a senior attorney for the Natural Resources Defense Council, an environmental group, said it also would support the agreement.

Senate Passes a Bill To Penalize Oil Firms Investing in Iran, Libya

Dow Jones News Services

WASHINGTON — The Senate passed by voice vote a tough version of legislation to penalize foreign energy companies that invest in or trade with Iran or Libya.

In the bill approved last evening, sanctions against companies investing in Libya's oil sector would be mandatory. In a version of the bill the House approved unanimously last month, the administration would have discretion to waive the penalties. The two bills are similar in most other respects.

The differences may be ironed out in House-Senate conference. While the House dislikes the Libya investment trigger, Republican leaders want to get a final bill to the president's desk fairly quickly, and one aide suggested the House may go along with the Senate provision to avoid a messy conference.

Many of the U.S.'s closest European allies have significant energy investments in Libya, whereas Iran's oil sector was closed to foreign investment until fairly recently.

Update on Food Safety Draft Legislation

July 16, 1996

How Does the Commerce Committee Draft Improve Current Law?

Health-based Safety Standard:

The bill establishes a single, health-based safety standard for pesticide residues on all foods. It uses the term "reasonable certainty of no harm" as the general safety standard, which is the same approach used in the Administration's 1994 bill.

- ◆ A single, health based standard eliminates the longstanding problems posed by multiple standards for pesticide residues in raw and processed foods.
- ◆ The bill also distinguishes between pesticides with 'threshold' and 'non-threshold' effects, an important distinction to strengthen health-based risk determinations.

Special Provisions for Infants and Children:

The bill incorporates language that is virtually identical to the Administration's 1994 bill to implement key recommendations of the National Academy of Sciences report "Pesticides in the Diet of Infants and Children."

- ◆ requires an explicit determination that tolerances are safe for children
- ◆ includes an additional 'safety factor' of up to ten-fold to account for uncertainty in data relative to children
- ◆ requires consideration of children's special sensitivities and exposures to pesticide chemicals
- ◆ eliminates benefit considerations when setting tolerances for children

no "special tolerances" for children

Limitations on "Benefits" Considerations:

Unlike current law, which contains an open-ended provision for the consideration of a pesticide's "benefits" when setting tolerances, the bill would place specific limits on benefits considerations.

- ◆ Benefits considerations would apply only to non-threshold effect pesticides (e.g., carcinogens), so that no benefits considerations would

be allowed when setting tolerances for all other pesticides that may have reproductive, or other effects.

- ◆ Benefits considerations would be further limited by three "backstops" on the level of risk that could be offset by benefits. The first is a limit on the acceptable risk in any one year - this limitation greatly reduces the risks. The second limitation is on the lifetime risk, which would allow EPA to remove risky tolerances after specific phase-out periods. The third limitation is that benefits could not be used to override the health-based standard for children.
- ◆ These benefit limiting provisions greatly strengthen current law to ensure our food is safe and is a key principal for the Administration.

Endocrine Disruptors:

- ◆ The bill includes language to evaluate the effects of endocrine disruptors when setting tolerances.

Data Call-in Authority:

- ◆ The draft provides EPA with new authority to require that chemical manufacturers provide data on their products, separate from the existing authority in FIFRA. Specifically included is the ability to evaluate endocrine effects of pesticides.

Enforcement:

- ◆ Includes enhanced enforcement by allowing FDA to impose civil penalties for tolerance violations.

Right to Know:

- ◆ Requires distribution of a brochure at food stores on the health effects of pesticides on how to avoid risks and which foods may contain higher pesticide residues because of benefits considerations.

National Uniformity:

- ◆ States will be unable to set tolerances except for those established using benefits considerations.

- ◆ States will have a new fast track procedure to petition EPA to set a tolerance to protect the citizens of the state.

Where Do Problems Still Exist?

The FIFRA portion of the bill includes two provisions that are of concern to the Administration:

- ◆ The bill preempts local governments from enacting regulation at the local level unless states have affirmatively granted authority to localities.
- ◆ The bill limits the rights of Native Americans to regulate pesticide use on tribal lands. This provision would limit the authority of Indian Tribes to protect their economic security, health, and welfare.

Commerce Committee Food Safety Draft

Version #2 - Current

July 16, 1996

Issue	Compared to Administration	Compared to HR 1627	Compared to Current Law
Benefits			
Phase-out of Benefits	Time limited, with cap on risk, but not a phaseout	Better	Better
Benefits Provision	Better	Better	Better
Health/Health Benefits Trade	Similar	Better	Better
Standard			
Negligible Risk Definition	Similar	Better	Better
Health Standard	Similar	Better	Better
Threshold Effects	Better	Better	Better
Risk Backstop	Better	Better	Better
Other Issues			
Kids	Similar	Better	Better
Estrogen Effects	Better	Better	Better
Right to Know	Better	Better	Better
Coordination with FIFRA	Similar	Fixed	Similar
CODEX Preemption	N/A	Fixed	N/A
Tolerance Fees	Similar	Better	Better
Tolerance Preemption	Does preempt, but has a backstop	Fixed	Does preempt, but has a backstop
Prop. 65 Preemption	Explicitly allows state warnings	Fixed	Better

Issue	Compared to Administration	Compared to HR 1627	Compared to Current Law
FDA Enforcement	Similar - civil penalties	Better	Better
Data Call-In	Similar	Better	Better

Commerce Committee Food Safety Draft

Version #2 - Current

July 16, 1996

Issue	Compared to Administration	Compared to HR 1627	Compared to Current Law
Benefits			
Phase-out of Benefits	<i>Chemical-specific</i> Time limited, with cap on risk, but not a phaseout	Better	Better
Benefits Provision	Better	Better	Better
Health/Health Benefits Trade	Similar	Better	Better
Standard			
Negligible Risk Definition	Similar	Better	Better
Health Standard	<i>single - reasonable certainty of no harm</i> Similar	<i>+ foods must be safe</i> Better	Better
Threshold Effects	Better	Better	Better
Risk Backstop	Better	Better	Better
Other Issues			
Kids	Similar	Better	Better
Estrogen Effects	Better	Better	Better
Right to Know	Better	Better	Better
Coordination with FIFRA	<i>can take independent action under this statute</i> Similar	Fixed	Similar
CODEX Preemption	N/A	Fixed	N/A
Tolerance Fees	Similar	Better	Better
Tolerance Preemption	Does preempt, but has a backstop	Fixed	Does preempt, but has a backstop
Prop. 65 Preemption	Explicitly allows state warnings	Fixed	Better

Issue	Compared to Administration	Compared to HR 1627	Compared to Current Law
FDA Enforcement	Similar - civil penalties	Better	Better
Data Call-In	Similar	Better	Better

1 Strike title IV and insert the following:

2 **TITLE IV-AMENDMENTS TO THE**
3 **FEDERAL FOOD, DRUG, AND**
4 **COSMETIC ACT**

5 **SEC 401. SHORT TITLE AND REFERENCE.**

6 (a) **SHORT TITLE.**—This title may be cited as the
7 “Food Quality Protection Act of 1996 ”.

8 (b) **REFERENCE.**—Whenever in this title an amend-
9 ment or repeal is expressed in terms of an amendment
10 to, or repeal of, a section or other provision, the reference
11 shall be considered to be made to a section or other provi-
12 sion of the Federal Food, Drug, and Cosmetic Act.

13 **SEC. 402. DEFINITIONS.**

14 (a) **SECTION 201(q).**—Section 201(q) (21 U.S.C.
15 321(q)) is amended to read as follows:

16 “(q)(1) The term ‘pesticide chemical’ means any sub-
17 stance that is a pesticide within the meaning of the Fed-
18 eral Insecticide, Fungicide, and Rodenticide Act, including
19 all active and inert ingredients of such pesticide.

20 “(2) The term ‘pesticide chemical residue’ means a
21 residue in or on raw agricultural commodity or processed
22 food of—

23 “(A) a pesticide chemical; or

24 “(B) any other added substance that is present
25 on or in the commodity or food primarily as a result

1 of the metabolism or other degradation of a pesticide
2 chemical.

3 “(3) Notwithstanding paragraphs (1) and (2), the
4 Administrator may by regulation except a substance from
5 the definition of ‘pesticide chemical’ or ‘pesticide chemical
6 residue’ if—

7 “(A) its occurrence as a residue on or in a raw
8 agricultural commodity or processed food is attrib-
9 utable primarily to natural causes or to human ac-
10 tivities not involving the use of any substances for
11 a pesticidal purpose in the production, storage, proc-
12 essing, or transportation of any raw agricultural
13 commodity or processed food; and

14 “(B) the Administrator, after consultation with
15 the Secretary, determines that the substance more
16 appropriately should be regulated under one or more
17 provisions of this Act other than sections
18 402(a)(2)(B) and 408.”.

19 (b) SECTION 201(s).—Paragraphs (1) and (2) of sec-
20 tion 201(s) (21 U.S.C. 321(s)) are amended to read as
21 follows:

22 “(1) a pesticide chemical residue in or on a raw
23 agricultural commodity or processed food; or

24 “(2) a pesticide chemical; or”.

1 (c) SECTION 201.—Section 201 (21 U.S.C. 321) is
2 amended by adding at the end the following:

3 “(gg) The term ‘processed food’ means any food
4 other than a raw agricultural commodity and includes any
5 raw agricultural commodity that has been subject to proc-
6 essing, such as canning, cooking, freezing, dehydration, or
7 milling.

8 “(hh) The term ‘Administrator’ means the Adminis-
9 trator of the United States Environmental Protection
10 Agency.”.

11 **SEC. 403. PROHIBITED ACTS.**

12 Section 301(j) (21 U.S.C. 331(j)) is amended in the
13 first sentence by inserting before the period the following:
14 “; or the violat[ing] of section 408(g)(2) or any regula-
15 tion issued under that section.”.

16 **SEC. 404. ADULTERATED FOOD.**

17 Section 402(a)(2) (21 U.S.C. 342(a)(2)) is amended
18 to read as follows:

19 “(2)(A) if it bears or contains any added poi-
20 sonous or added deleterious substance (other than a
21 substance that is a pesticide chemical residue in or
22 on a raw agricultural commodity or processed food,
23 a food additive, a color additive, or a new animal
24 drug) that is unsafe within the meaning of section
25 406;

1 “(B) if it bears or contains a pesticide chemical
2 residue that is unsafe within the meaning of section
3 408(a); or

4 “(C) if it is or if it bears or contains—

5 “(i) any food additive that is unsafe within
6 the meaning of section 409; or

7 “(ii) a new animal drug (or conversion
8 product thereof) that is unsafe within the
9 meaning of section 512; or”.

10 **SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
11 **CHEMICAL RESIDUES.**

12 Section 408 (21 U.S.C. 346a) is amended to read as
13 follows:

14 **“TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
15 **CHEMICAL RESIDUES**

16 **“SEC. 408. (a) REQUIREMENT FOR TOLERANCE OR**
17 **EXEMPTION.—**

18 **“(1) GENERAL RULE.—**Except as provided in
19 paragraph (2) or (3), any pesticide chemical residue
20 in or on a food shall be deemed unsafe for the pur-
21 pose of section 402(a)(2)(B) unless—

22 **“(A) a tolerance for such pesticide chemi-**
23 **cal residue in or on such food is in effect under**
24 **this section and the quantity of the residue is**
25 **within the limits of the tolerance; or**

1 “(B) an exemption from the requirement
2 of a tolerance is in effect under this section for
3 the pesticide chemical residue.

4 For the purposes of this section, the term ‘food,’
5 when used as a noun without modification, shall
6 mean a raw agricultural commodity or processed
7 food.

8 “(2) PROCESSED FOOD.—Notwithstanding
9 paragraph (1)—

10 “(A) if a tolerance is in effect under this
11 section for a pesticide chemical residue in or on
12 a raw agricultural commodity, a pesticide chem-
13 ical residue that is present in or on a processed
14 food because the food is made from that raw
15 agricultural commodity shall not be considered
16 unsafe within the meaning of section
17 402(a)(2)(B) despite the lack of a tolerance for
18 the pesticide chemical residue in or on the proc-
19 essed food if the pesticide chemical has been
20 used in or on a raw agricultural commodity in
21 conformity with an exemption or tolerance
22 under this section, such residue in or on the
23 raw agricultural commodity has been removed
24 to the extent possible in good manufacturing
25 practice, and the concentration of the pesticide

1 chemical residue in the processed food is not
2 greater than the tolerance prescribed for the
3 pesticide chemical residue in the raw agricul-
4 tural commodity; or

5 “(B) if an exemption for the requirement
6 for a tolerance is in effect under this section for
7 a pesticide chemical residue in or on a raw agri-
8 cultural commodity, a pesticide chemical residue
9 that is present in or on a processed food be-
10 cause the food is made from that raw agricul-
11 tural commodity shall not be considered unsafe
12 within the meaning of section 402(a)(2)(B).

13 “(3) RESIDUES OF DEGRADATION PRODUCTS.—
14 If a pesticide chemical residue is present in or on a
15 food because it is a metabolite or other degradation
16 product of a precursor substance that itself is a pes-
17 ticide chemical or pesticide chemical residue, such a
18 residue shall not be considered to be unsafe within
19 the meaning of section 402(a)(2)(B) despite the lack
20 of a tolerance or exemption from the need for a tol-
21 erance for such residue in or on such food if—

22 “(A) the Administrator has not determined
23 that the degradation product is likely to pose
24 any potential health risk from dietary exposure
25 that is of a different type than, or of a greater

1 significance than, any risk posed by dietary ex-
2 posure to the precursor substance; and

3 “(B) either—

4 “(i) a tolerance is in effect under this
5 section for residues of the precursor sub-
6 stance in or on the food, and the combined
7 level of residues of the degradation product
8 and the precursor substance in or on the
9 food is at or below the stoichiometrically
10 equivalent level that would be permitted by
11 the tolerance if the residue consisted only
12 of the precursor substance rather than the
13 degradation product; or

14 “(ii) an exemption from the need for
15 a tolerance is in effect under this section
16 for residues of the precursor substance in
17 or on the food; and

18 “(C) the tolerance or exemption for resi-
19 dues of the precursor substance does not state
20 that it applies only to particular named sub-
21 stances or states that it does not apply to resi-
22 dues of the degradation product.

23 “(4) EFFECT OF TOLERANCE OR EXEMP-
24 TION.—While a tolerance or exemption from the re-
25 quirement for a tolerance is in effect under this sec-

1 tion for a pesticide chemical residue with respect to
2 any food, the food shall not by reason of bearing or
3 containing any amount of such a residue be consid-
4 ered to be adulterated within the meaning of section
5 402(a)(1).

6 “(b) AUTHORITY AND STANDARD FOR TOLER-
7 ANCE.—

8 “(1) AUTHORITY.—The Administrator may
9 issue regulations establishing, modifying, or revoking
10 a tolerance for a pesticide chemical residue in or on
11 food—

12 “(A) in response to a petition filed under
13 subsection (d); or

14 “(B) on the Administrator’s own initiative
15 under subsection (e).

16 “(b) AUTHORITY AND STANDARD FOR TOLER-
17 ANCE.—

18 “(1) AUTHORITY.—The Administrator may
19 issue regulations establishing, modifying, or revoking
20 a tolerance for a pesticide chemical residue in or on
21 food—

22 “(A) in response to a petition filed under
23 subsection (d);

24 “(B) on the Administrator’s own initiative
25 under subsection (e).

1 “(2) STANDARD.—

2 “(A) GENERAL RULE.—

3 “(i) STANDARD.—The Administrator
4 may establish a tolerance for a pesticide
5 chemical residue in or on food only if the
6 Administrator determines that the toler-
7 ance is safe. The Administrator shall mod-
8 ify or revoke a tolerance if the Adminis-
9 trator determines it is not safe.

10 “(ii) DETERMINATION OF SAFETY.—
11 As used in this section, the term ‘safe’,
12 with respect to a tolerance for a pesticide
13 chemical residue, means that the Adminis-
14 trator has determined that there is a rea-
15 sonable certainty that no harm will result
16 from aggregate exposure to such residue,
17 including all anticipated dietary exposures
18 and all other exposures for which there is
19 reliable information.

20 “(B) TOLERANCES FOR ELIGIBLE PES-
21 TICIDE CHEMICAL RESIDUES.—

22 “(i) DEFINITION.—As used in this
23 subparagraph, the term ‘eligible pesticide
24 chemical residue’ means a pesticide chemi-
25 cal residue as to which—

1 “(I) the Administrator is not able
2 to identify a level of exposure to the
3 residue at which the residue will not
4 cause or contribute to a known or an-
5 ticipated harm to human health (re-
6 ferred to in this section as a
7 ‘nonthreshold effect’);

8 “(II) the lifetime risk of experi-
9 encing the nonthreshold effect is ap-
10 propriately assessed by quantitative
11 risk assessment; and

12 “(III) with regard to any known
13 or anticipated harm to human health
14 for which the Administrator is able to
15 identify a level at which the residue
16 will not cause such harm (referred to
17 in this section as a ‘threshold effect’),
18 the Administrator determines that the
19 level of aggregate exposure is safe.

20 “(ii) DETERMINATION OF TOLER-
21 ANCE.—Notwithstanding subparagraph
22 (A), a tolerance for an eligible pesticide
23 chemical residue may be left in effect or
24 modified under this subparagraph if—

1 “(I) at least one of the conditions
2 described in clause (iii) is met; and

3 “(II) both of the conditions de-
4 scribed in clause (iv) are met.

5 “(iii) CONDITIONS REGARDING USE.—
6 For purposes of clause (ii), the conditions
7 described in this clause with respect to a
8 tolerance for an eligible pesticide chemical
9 residue are the following:

10 “(I) Use of the pesticide chemical
11 that produces the residue protects
12 consumers from adverse effects on
13 health that would pose a greater risk
14 than the dietary risk from the residue.

15 “(II) Use of the pesticide chemi-
16 cal that produces the residue is nec-
17 essary to avoid a significant disrup-
18 tion in domestic production of an ade-
19 quate, wholesome, and economical
20 food supply.

21 “(iv) CONDITIONS REGARDING
22 RISK.—For purposes of clause (ii), the
23 conditions described in this clause with re-
24 spect to a tolerance for an eligible pesticide
25 chemical residue are the following:

1 “(I) The yearly risk associated
2 with the nonthreshold effect from ag-
3 gregate exposure to the residue does
4 not exceed 10 times the yearly risk
5 that would be allowed under subpara-
6 graph (A) for such effect.

7 “(II) The tolerance is limited so
8 as to ensure that the risk over a life-
9 time associated with the nonthreshold
10 effect from aggregate exposure to the
11 residue is not greater than twice the
12 lifetime risk that would be allowed
13 under subparagraph (A) for such ef-
14 fect.

15 “(v) REVIEW.—Five years after the
16 date on which the Administrator makes a
17 determination to leave in effect or modify
18 a tolerance under this subparagraph, and
19 thereafter as the Administrator deems ap-
20 propriate, the Administrator shall deter-
21 mine, after notice and opportunity for com-
22 ment, whether the registrant has dem-
23 onstrated that a condition described in
24 subclause (I) or (II) continues to exist with
25 respect to the tolerance and that the yearly

1 and lifetime risks from aggregate exposure
2 to such residue comply with the limits
3 specified in clause (iv). If the Adminis-
4 trator determines by such date that such
5 condition does not continue to exist, or
6 that such risks do not continue to comply
7 with such limits, the Administrator shall,
8 not later than 180 days after the date of
9 such determination, modify or revoke the
10 tolerance under subsection (e).

11 “(v) INFANTS AND CHILDREN.—Any
12 tolerance under this subparagraph shall
13 meet the requirements of subparagraph
14 (C).

15 “(C) EXPOSURE OF INFANTS AND CHIL-
16 DREN.—*[In making determinations under sub-
17 paragraph (A) and (B) regarding a tolerance
18 for a pesticide chemical residue], *[and in de-
19 termining at what level to establish or modify
20 a tolerance], the Administrator—

21 “(i) shall assess the risk of the pes-
22 ticide chemical residue based on—

23 “(I) available information about
24 consumption patterns among infants
25 and children up to age 6 that are like-

1 ly to result in disproportionately high
2 consumption of foods containing or
3 bearing such residue among infants
4 and children in comparison to the
5 general population;

6 “(II) available information con-
7 cerning the special susceptibility of in-
8 fants and children to the pesticide
9 chemical residues, including neuro-
10 logical differences between infants and
11 children and adults, and effects of in
12 utero exposure to pesticide chemicals;
13 and

14 “(III) available information con-
15 cerning the cumulative effects on in-
16 fants and children of such residues
17 and other substances that have a com-
18 mon mechanism of toxicity; and

19 “(ii) shall—

20 “(I) ensure that there is an
21 ample margin of safety for infants
22 and children and impose other re-
23 quirements necessary to ensure that
24 exposure to the pesticide chemical res-
25 idue will be safe; and

1 “(II) publish a specific deter-
2 mination regarding the safety of the
3 pesticide chemical residue for infants
4 and children.

5 The Secretary of Health and Human Services
6 and the Secretary of Agriculture, in consulta-
7 tion with the Administrator, shall conduct sur-
8 veys to document dietary exposure to pesticides
9 among infants and children. *[In the case of
10 threshold harms,] for purposes of clause (ii)(I)
11 an additional tenfold margin of safety for the
12 pesticide chemical residue and other sources of
13 exposure shall be applied for infants and chil-
14 dren to take into account potential pre- and
15 post-natal toxicity and completeness of the data
16 with respect to exposure and toxicity to infants
17 and children. Notwithstanding such require-
18 ment for an additional factor, the Adminis-
19 trator may determine that a margin of safety
20 for the pesticide chemical residue is considered
21 ample only if, on the basis of reliable data, such
22 margin will fully protect infants and children.

23 “(D) FACTORS.—In making *[each] deter-
24 mination under this paragraph, the Adminis-

1 trator shall consider, among other relevant fac-
2 tors—

3 “(i) the validity, completeness, and re-
4 liability of the available data from studies
5 of the pesticide chemical and pesticide
6 chemical residue;

7 “(ii) the nature of any toxic effect
8 shown to be caused by the pesticide chemi-
9 cal or pesticide chemical residue in such
10 studies;

11 “(iii) available information concerning
12 the relationship of the results of such stud-
13 ies to human risk;

14 “(iv) available information concerning
15 the dietary consumption patterns of con-
16 sumers (and major identifiable subgroups
17 of consumers);

18 “(v) available information concerning
19 the cumulative effects of such residues and
20 other substances that have a common
21 mechanism of toxicity;

22 “(vi) available information concerning
23 the aggregate exposure levels of consumers
24 (and major identifiable subgroups of con-
25 sumers) to the pesticide chemical residue

1 and to other related substances, including
2 dietary exposure under the tolerance and
3 all other tolerances in effect for the pes-
4 ticide chemical residue, and exposure from
5 other non-occupational sources;

6 “(vii) available information concerning
7 the variability of the sensitivities of major
8 identifiable subgroups of consumers;

9 “(viii) when assessing chronic dietary
10 risk, available data and information on the
11 percent of food actually treated with pes-
12 ticide chemical (including aggregate pes-
13 ticide use data collected by the Department
14 of Agriculture), if the Administrator—

15 “(I) finds that the data are reli-
16 able and provide a valid basis to show
17 what percentage of the food derived
18 from such crop is likely to contain
19 such pesticide chemical residue;

20 “(II) finds that the exposure esti-
21 mate does not understate exposure for
22 any significant subpopulation group;

23 “(III) finds that, if data are
24 available on pesticide use and con-
25 sumption of food in a particular area,

1 the population in such area is not
2 dietarily exposed to residues above
3 those estimated by the Administrator;
4 and

5 “(IV) provides for the periodic
6 reevaluation of the estimate of antici-
7 pated dietary exposure;

8 “(ix) such information as the Admin-
9 istrator may require on whether the pes-
10 ticide chemical may have an effect in hu-
11 mans that is similar to an effect produced
12 by a naturally occurring estrogen or other
13 endocrine effects; and

14 “(x) *[safety factors which in the
15 opinion of experts qualified by scientific
16 training and experience to evaluate the
17 safety of food additives are generally recog-
18 nized as appropriate for the use of animal
19 experimentation data].

20 “(E) DATA AND INFORMATION REGARDING
21 ANTICIPATED AND ACTUAL RESIDUE LEVELS.—

22 “(i) AUTHORITY.—In making *[a] deter-
23 mination under this paragraph, the Adminis-
24 trator may consider available data and informa-
25 tion on the anticipated residue levels of the pes-

1 ticide chemical in or on food and the actual res-
2 idue levels of the pesticide chemical that have
3 been measured in food, including residue data
4 collected by the Food and Drug Administration.

5 “(ii) REQUIREMENT.—If the Administrator
6 relies on anticipated or actual residue levels in
7 establishing or modifying a tolerance under this
8 section, the Administrator shall require the pes-
9 ticide registrant to provide data five years after
10 the date on which the tolerance is established or
11 modified, and thereafter as the Administrator
12 deems appropriate, demonstrating that such
13 residue levels are not above the levels so relied
14 on. If the registrant fails to provide such data
15 by such date, or if the data do not demonstrate
16 that the residue levels are not above the levels
17 so relied on, the Administrator shall modify or
18 revoke the tolerance under subsection (e) not
19 later than 180 days the date on which the data
20 were required to be provided.

21 “(3) DETECTION METHODS.—

22 “(A) GENERAL RULE.—A tolerance for a
23 pesticide chemical residue in or on a food shall
24 not be established by the Administrator unless
25 the Administrator determines, after consulta-

1 tion with the Secretary, that there is a practical
2 method for detecting and measuring the levels
3 of the pesticide chemical residue in or on the
4 food.

5 “(B) DETECTION LIMIT.—A tolerance for
6 a pesticide chemical residue in or on a food
7 shall not be established at a level lower than the
8 limit of detection of the method for detecting
9 and measuring the pesticide chemical residue
10 specified by the Administrator under subpara-
11 graph (A).

12 “(4) INTERNATIONAL STANDARDS.—In estab-
13 lishing a tolerance for a pesticide chemical residue in
14 or on a food, the Administrator shall determine
15 whether a maximum residue level for the chemical
16 has been established by the Codex Alimentarius
17 Commission. If a Codex maximum residue level has
18 been established for the chemical and the Adminis-
19 trator does not propose to adopt the Codex level, the
20 Administrator shall publish for public comment a
21 notice explaining the reasons for departing from the
22 Codex level.

23 “(c) AUTHORITY AND STANDARD FOR EXEMP-
24 TIONS.—

1 “(1) AUTHORITY.—The Administrator may
2 issue a regulation establishing, modifying, or revok-
3 ing an exemption from the requirement for a toler-
4 ance for a pesticide chemical residue in or on a
5 food—

6 “(A) in response to a petition filed under
7 subsection (d); or

8 “(B) on the Administrator’s initiative
9 under subsection (e).

10 “(2) STANDARD.—

11 “(A) GENERAL RULE.—

12 “(i) STANDARD.—The Administrator
13 may establish an exemption from the re-
14 quirement for a tolerance for a pesticide
15 chemical residue in or on a food only if the
16 Administrator determines that the exemp-
17 tion is safe.

18 “(ii) DETERMINATION OF SAFETY.—
19 The term ‘safe, with respect to an exemp-
20 tion for a pesticide chemical residue,
21 means that the Administrator has deter-
22 mined that there is a reasonable certainty
23 that no harm will result from aggregate ex-
24 posure to such residue, including all antici-
25 pated dietary exposures and all other expo-

1 sures for which there is reliable informa-
2 tion.

3 “(B) REVOCATION.—An exemption from
4 the requirement for a tolerance for a pesticide
5 chemical residue in or on a food shall be re-
6 voked if the Administrator, in response to a pe-
7 tition for the revocation of the exemption or at
8 the Administrator’s own initiative, determines
9 that the exemption does not satisfy the criterion
10 of subparagraph (A).

11 “(C) FACTORS.—In making a determina-
12 tion under this paragraph, the Administrator
13 shall take into account, among other relevant
14 factors, the factors set forth in subsection
15 (b)(2)(D) other than the factor set forth in
16 clause (viii) of such subsection.

17 “(3) LIMITATION.—An exemption from the re-
18 quirement for a tolerance for a pesticide chemical
19 residue in or on a food shall not be established by
20 the Administrator unless the Administrator deter-
21 mines, after consultation with the Secretary—

22 “(A) that there is a practical method for
23 detecting and measuring the levels of such pes-
24 ticide chemical residue in or on such food; or

1 “(B) that there is no need for such a
2 method, and states the reasons for such deter-
3 mination in the order issuing the regulation es-
4 tablishing or modifying the regulation.

5 “(d) PETITION FOR TOLERANCE OR EXEMPTION.—

6 “(1) PETITIONS AND PETITIONERS.—Any per-
7 son may file with the Administrator a petition pro-
8 posing the issuance of a regulation—

9 “(A) establishing, modifying, or revoking a
10 tolerance for a pesticide chemical residue in or
11 on a food; or

12 “(B) establishing, modifying, or revoking
13 an exemption from the requirement of a toler-
14 ance for such a residue.

15 “(2) PETITION CONTENTS.—

16 “(A) ESTABLISHMENT.—A petition under
17 paragraph (1) to establish a tolerance or ex-
18 emption for a pesticide chemical residue shall
19 be supported by such data and information as
20 are specified in regulations issued by the Ad-
21 ministrator, including—

22 “(i)(I) an informative summary of the
23 petition and of the data, information, and
24 arguments submitted or cited in support of
25 the petition; and

1 food, including a description of the analyt-
2 ical methods used;

3 “(vi) a practical method for detecting
4 and measuring the levels of the pesticide
5 chemical residue in or on the food, or for
6 exemptions, a statement why such a meth-
7 od is not needed;

8 “(vii) a proposed tolerance for the
9 pesticide chemical residue, if a tolerance is
10 proposed;

11 “(viii) if the petition relates to a toler-
12 ance for a processed food, reports of inves-
13 tigation conducted using the processing
14 method(s) used to produce that food;

15 “(ix) such information as the Admin-
16 istrator may require to make the deter-
17 mination under subsection (b)(2)(C);

18 “(x) such information as the Adminis-
19 trator may require on whether the pes-
20 ticide chemical may have an effect in hu-
21 mans that is similar to an effect produced
22 by a naturally occurring estrogen or other
23 endocrine effects;

24 “(xi) information regarding exposure
25 to the pesticide chemical residue due to

1 any tolerance or exemption already granted
2 for such residue; and

3 “(xii) such other data and information
4 as the Administrator requires by regulation
5 to support the petition.

6 “[xii) practical methods for removing
7 any amount of the residue that would ex-
8 ceed any proposed tolerance; and

9 “(xiii) all relevant data bearing on the
10 physical or other technical effect that the
11 pesticide chemical is intended to have and
12 the quantity of the pesticide chemical that
13 is required to produce the effect].

14 If information or data required by this subpara-
15 graph is available to the Administrator, the per-
16 son submitting the petition may cite the avail-
17 ability of the information or data in lieu of sub-
18 mitting it. The Administrator may require a pe-
19 tition to be accompanied by samples of the pes-
20 ticide chemical with respect to which the peti-
21 tion is filed.

22 “(B) MODIFICATION OR REVOCATION.—
23 The Administrator may by regulation establish
24 the requirements for information and data to
25 support a petition to modify or revoke a toler-

1 ance or to modify or revoke an exemption from
2 the requirement for a tolerance.

3 “(3) NOTICE.—A notice of the filing of a peti-
4 tion that the Administrator determines has met the
5 requirements of paragraph (2) shall be published by
6 the Administrator within 30 days after such deter-
7 mination. The notice shall announce the availability
8 of a description of the analytical methods available
9 to the Administrator for the detection and measure-
10 ment of the pesticide chemical residue with respect
11 to which the petition is filed or shall set forth the
12 petitioner’s statement of why such a method is not
13 needed. The notice shall include the summary re-
14 quired by paragraph (2)(A)(i)(I).

15 “(4) ACTIONS BY THE ADMINISTRATOR.—

16 “(A) IN GENERAL.—The Administrator
17 shall, after giving due consideration to a peti-
18 tion filed under paragraph (1) and any other
19 information available to the Administrator—

20 “(i) issue a final regulation (which
21 may vary from that sought by the petition)
22 establishing, modifying, or revoking a tol-
23 erance for the pesticide chemical residue or
24 an exemption of the pesticide chemical res-
25 idue from the requirement of a tolerance;

1 “(ii) issue a proposed regulation
2 under subsection (e), and thereafter issue
3 a final regulation under subsection (e); or

4 “(iii) issue an order denying the peti-
5 tion.

6 “(B) PRIORITIES.—The Administrator
7 shall give priority to petitions for the establish-
8 ment or modification of a tolerance *[or exemp-
9 tion] for a pesticide chemical residue that ap-
10 pears to pose a significantly lower risk to
11 human health from dietary exposure than pes-
12 ticide chemical residues that have tolerances in
13 effect for the same or similar uses.

14 “(C) EXPEDITED REVIEW OF CERTAIN
15 PETITIONS.—

16 “(i) DATE CERTAIN FOR REVIEW.—If
17 a person files a complete petition with the
18 Administrator proposing the issuance of a
19 regulation establishing a tolerance for a
20 pesticide chemical residue that presents a
21 lower risk to human health than a pes-
22 ticide chemical residue for which a toler-
23 ance has been left in effect or modified
24 under subsection (b)(2)(B), the Adminis-

1 trator shall complete action on such peti-
2 tion under this paragraph within 1 year.

3 “(ii) REQUIRED DETERMINATIONS.—

4 If the Administrator issues a final regula-
5 tion establishing a tolerance for a safer
6 pesticide chemical residue under clause (i),
7 the Administrator shall, not later than 180
8 days after the date on which the regulation
9 is issued, determine whether a condition
10 described in subclause (I) and (II) of sub-
11 section (b)(2)(B)(iii) continues to exist
12 with respect to a tolerance that has been
13 left in effect or modified under subsection
14 (b)(2)(B). If such condition does not con-
15 tinue to exist, the Administrator shall, not
16 later than 180 days after the date on
17 which the determination under the preced-
18 ing sentence is made, modify or revoke
19 under subsection (e) the tolerance left in
20 effect or modified under subsection
21 (b)(2)(B).

22 “(5) [ADMINISTRATIVE PROCEDURES.—Chap-
23 ter 5 of title 5, United States Code, shall not apply
24 with respect to this section.]

1 “(e) ACTION ON ADMINISTRATOR’S OWN INITIA-
2 TIVE.—

3 “(1) GENERAL RULE.—The Administrator may
4 issue a regulation—

5 “(A) establishing, modifying, or revoking a
6 tolerance for a pesticide chemical or a pesticide
7 chemical residue;

8 “(B) establishing, modifying, or revoking
9 an exemption of a pesticide chemical residue
10 from the requirement of a tolerance; or

11 “(C) establishing general procedures and
12 requirements to implement this section.

13 A regulation issued under this paragraph shall be-
14 come effective upon its publication.

15 “(2) NOTICE.—Before issuing a final regulation
16 under paragraph (1), the Administrator shall issue
17 a notice of proposed rulemaking and provide a pe-
18 riod of not less than 60 days for public comment on
19 the proposed regulation, except that a shorter period
20 for comment may be provided if the Administrator
21 for good cause finds that it would be contrary to the
22 public interest to do so and states the reasons for
23 the finding in the notice of proposed rulemaking.

24 “(f) SPECIAL DATA REQUIREMENTS.—

1 “(1) REQUIRING SUBMISSION OF ADDITIONAL
2 DATA.—If the Administrator determines that addi-
3 tional data or information are reasonably required to
4 support the continuation of a tolerance or exemption
5 that is in effect under this section for a pesticide
6 chemical residue on a food, the Administrator
7 shall—

8 “(A) issue a notice requiring the person
9 holding the pesticide registrations associated
10 with such tolerance or exemption to submit the
11 data or information under section 3(c)(2)(B) of
12 the Federal Insecticide, Fungicide, and
13 Rodenticide Act;

14 “(B) issue a rule requiring that testing be
15 conducted on a substance or mixture under sec-
16 tion 4 of the Toxic Substances Control Act; or

17 “(C) publish in the Federal Register, after
18 first providing notice and an opportunity for
19 comment of not less than 90 days’ duration, an
20 order—

21 “(i) requiring the submission to the
22 Administrator by one or more interested
23 persons of a notice identifying the person
24 or persons who will submit the required
25 data and information;

1 “(ii) describing the type of data and
2 information requiring to be submitted to
3 the Administrator and stating why the
4 data and information could not be obtained
5 under the authority of section 3(c)(2)(B)
6 of the Federal Insecticide, Fungicide, and
7 Rodenticide Act or section 4 of the Toxic
8 Substances Control Act;

9 “(iii) describing the reports of the Ad-
10 ministrator required to be prepared during
11 and after the collection of the data and in-
12 formation;

13 “(iv) requiring the submission to the
14 Administrator of the data, information,
15 and reports referred to in clauses (ii) and
16 (iii); and

17 “(v) establishing dates by which the
18 submissions described in clauses (i) and
19 (iv) must be made.

20 The Administrator may revise any such order
21 to correct an error. The Administrator may re-
22 quire data or information pertaining to whether
23 the pesticide chemical may have an effect in hu-
24 mans that is similar to an effect produced by

1 a naturally occurring estrogen or other endo-
2 crine effects.

3 “(2) NONCOMPLIANCE.—If a submission re-
4 quired by a notice issued in accordance with para-
5 graph (1)(A), a rule issued under paragraph (1)(B),
6 or an order issued under paragraph (1)(C) is not
7 made by the time specified in such notice or order,
8 the Administrator may by order published in the
9 Federal Register modify or revoke the tolerance or
10 exemption in question. In any review of such an
11 order under subsection (g)(2), the only material
12 issue shall be whether a submission required under
13 paragraph (1) has not been made by the time speci-
14 fied.

15 “(g) EFFECTIVE DATE, OBJECTIONS, HEARINGS,
16 AND ADMINISTRATIVE REVIEW.—

17 “(1) EFFECTIVE DATE.—A regulation issued
18 under subsection (d)(4), (e)(1), or (f)(2) shall take
19 effect upon publication unless the regulation speci-
20 fies otherwise. The Administrator may stay the ef-
21 fectiveness of the regulation if, after issuance of
22 such regulation, objections are filed with respect
23 such regulation pursuant to paragraph (2).

24 “(2) FURTHER PROCEEDINGS.—

1 “(A) Within 60 days after a regulation or
2 order is issued under subsection (d)(4), (e)(1),
3 or (f)(1), any person may file objections thereto
4 with the Administrator, specifying with particu-
5 larity the provisions of the regulation or order
6 deemed objectionable and stating reasonable
7 grounds therefor. If the regulation or order was
8 issued in response to a petition under sub-
9 section (d)(1), a copy of each objection filed by
10 a person other than the petitioner shall be
11 served by the Administrator on the petitioner.

12 “(B) An objection may include a request
13 for a public evidentiary hearing upon the objec-
14 tion. The Administrator shall, upon the initia-
15 tive of the Administrator or upon the request of
16 an interested person and after due notice, hold
17 a public evidentiary hearing if and to the extent
18 the Administrator determines that such a public
19 hearing is necessary to receive factual evidence
20 relevant to material issues of fact raised by the
21 objections. The presiding officer in such a hear-
22 ing may authorize a party to obtain discovery
23 from other persons and may upon a showing of
24 good cause made by a party issue a subpoena
25 to compel testimony or production of documents

1 from any person. The presiding officer shall be
2 governed by the Federal Rules of Civil Proce-
3 dure in making any order for the protection of
4 the witness or the content of documents pro-
5 duced and shall order the payment of a reason-
6 able fees and expenses as a condition to requir-
7 ing testimony of the witness. On contest, such
8 a subpoena may be enforced by a Federal dis-
9 trict court.

10 “(C) As soon as practicable after receiving
11 the arguments of the parties, the Administrator
12 shall issue an order stating the action taken
13 upon each such objection and setting forth any
14 revision to the regulation or prior order that the
15 Administrator has found to be warranted. If a
16 hearing was held under subparagraph (B), such
17 order and any revision to the regulation or prior
18 order shall, with respect to questions of fact at
19 issue in the hearing, be based only on substan-
20 tial evidence of record at such hearing, and
21 shall set forth in detail the findings of facts and
22 the conclusions of law or policy upon which the
23 order or regulation is based.

24 “(h) JUDICIAL REVIEW.—

1 “(1) PETITION.—In a case of actual con-
2 troversy as to the validity of any order issued under
3 subsection (f)(1)(C) or (g)(2)(C) or any regulation
4 that is the subject of such an order, any person who
5 will be adversely affected by such order or regulation
6 may obtain judicial review by filing in the United
7 States Court of Appeals for the circuit wherein that
8 person resides or has its principal place of business,
9 or in the United States Court of Appeals for the
10 District of Columbia Circuit, within 60 days after
11 publication of such order or regulation, a petition
12 praying that the order or regulation be set aside in
13 whole or in part.

14 “(2) RECORD AND JURISDICTION.—A copy of
15 the petition under paragraph (1) shall be forthwith
16 transmitted by the clerk of the court to the Adminis-
17 trator, or any officer designated by the Adminis-
18 trator for that purpose, and thereupon the Adminis-
19 trator shall file in the court the record of the pro-
20 ceedings on which the Administrator based the order
21 or regulation, as provided in section 2112 of title 28,
22 United States Code. Upon the filing of such a peti-
23 tion, the court shall have exclusive jurisdiction to af-
24 firm or set aside the order or regulation complained
25 of in whole or in part. As to orders issued following

1 a public evidentiary hearing, the findings of the Ad-
2 ministrator with respect to questions of fact shall be
3 sustained only if supported by substantial evidence
4 when considered on the record as a whole.

5 “(3) ADDITIONAL EVIDENCE.—If a party ap-
6 plies to the court for leave to adduce additional evi-
7 dence and shows to the satisfaction of the court that
8 the additional evidence is material and that there
9 were reasonable grounds for the failure to adduce
10 the evidence in the proceeding before the Adminis-
11 trator, the court may order that the additional evi-
12 dence (and evidence in rebuttal thereof) shall be
13 taken before the Administrator in the manner and
14 upon the terms and conditions the court deems
15 proper. The Administrator may modify prior find-
16 ings as to the facts by reason of the additional evi-
17 dence so taken and may modify the order or regula-
18 tion accordingly. The Administrator shall file with
19 the court any such modified finding, order, or regu-
20 lation.

21 “(4) SUPREME COURT REVIEW.—The judgment
22 of the court affirming or setting aside, in whole or
23 in part, any order and any regulation which is the
24 subject of such an order shall be final, subject to re-
25 view by the Supreme Court of the United States as

1 provided in section 1254 of title 28 of the United
2 States Code. The commencement of proceedings
3 under this paragraph shall not, unless specifically
4 ordered by the court to the contrary, operate as a
5 stay of a regulation or order.

6 “(5) APPLICATION.—Any issue as to which re-
7 view is or was obtainable under this subsection shall
8 not be the subject of judicial review under any other
9 provision of law.

10 “(i) CONFIDENTIALITY AND USE OF DATA.—

11 “(1) GENERAL RULE.—Data and information
12 that are submitted to the Administrator under this
13 section in support of a tolerance or an exemption
14 from a tolerance shall be entitled to confidential
15 treatment for reasons of business confidentiality and
16 to exclusive use and data compensation to the same
17 extent provided by sections 3 and 10 of the Federal
18 Insecticide, Fungicide, and Rodenticide Act.

19 “(2) EXCEPTIONS.—Data that are entitled to
20 confidential treatment under paragraph (1) may
21 nonetheless be disclosed to the Congress of the Unit-
22 ed States, and may be disclosed, under such security
23 requirements as the Administrator may provide by
24 regulation, to—

1 “(A) employees of the United States au-
2 thorized by the Administrator to examine such
3 data in the carrying out of their official duties
4 under this Act or other Federal statutes in-
5 tended to protect the public health; or

6 “(B) contractors with the United States
7 authorized by the Administrator to examine
8 such data in the carrying out of contracts under
9 this Act or such statutes.

10 “(3) SUMMARIES.—Notwithstanding any provi-
11 sion of this subsection or other law, the Adminis-
12 trator may publish the informative summary re-
13 quired by subsection (d)(2)(A)(i) and may, in issu-
14 ing a proposed or final regulation or order under
15 this section, publish an informative summary of the
16 data relating to the regulation or order.

17 “(j) STATUS OF PREVIOUSLY ISSUED REGULA-
18 TIONS.—

19 “(1) REGULATIONS UNDER SECTION 406.—Reg-
20 ulations affecting pesticide chemical residues in or
21 on raw agricultural commodities promulgated, in ac-
22 cordance with section 701(e), under the authority of
23 section 406(a) upon the basis of public hearings in-
24 stituted before January 1, 1953, shall be deemed to
25 be regulations issued under this section and shall be

1 subject to modification or revocation under sub-
2 sections (d) and (e).

3 “(2) REGULATIONS UNDER SECTION 409.—Reg-
4 ulations that established tolerances for substances
5 that are pesticide chemical residues in or on proc-
6 essed food, or that otherwise stated the conditions
7 under which such pesticide chemicals could be safely
8 used, and that were issued under section 409 on or
9 before the date of the enactment of this paragraph,
10 shall be deemed to be regulations issued under this
11 section and shall be subject to modification or rev-
12 ocation under subsection (d) or (e).

13 “(3) REGULATIONS UNDER SECTION 408.—Reg-
14 ulations that established tolerances or exemptions
15 under this section that were issued on or before the
16 date of the enactment of this paragraph shall remain
17 in effect unless modified or revoked under subsection
18 (d) or (e).

19 “(k) TRANSITIONAL PROVISION.—If, on the day be-
20 fore the date of the enactment of this subsection, a sub-
21 stance that is a pesticide chemical was, with respect to
22 a particular pesticidal use of the substance and any result-
23 ing pesticide chemical residue in or on a particular food—

24 “(1) regarded by the Administrator or the Sec-
25 retary as generally recognized as safe for use within

1 the meaning of the provisions of subsection (a) or
2 section 201(s) as then in effect; or

3 “(2) regarded by the Secretary as a substance
4 described by section 201(s)(4), such a pesticide
5 chemical residue shall be regarded as exempt from
6 the requirement for a tolerance, as of the date of en-
7 actment of this subsection.

8 The Administrator shall by regulation indicate which sub-
9 stances are described by this subsection. Any exemption
10 under this subsection may be modified or revoked as if
11 it had been issued under subsection (c).

12 “(I) HARMONIZATION WITH ACTION UNDER OTHER
13 LAWS.—

14 “(1) COORDINATION WITH FIFRA.—To the extent
15 practicable and consistent with the review deadlines in
16 subsection (m), in issuing a final rule under this sub-
17 section that suspends or revokes a tolerance or exemption
18 for a pesticide chemical residue in or on food, the Adminis-
19 trator shall coordinate such action with any *[such] relat-
20 ed necessary action under the Federal Insecticide, Fun-
21 gicide, and Rodenticide Act.

22 “(2) REVOCATION OF TOLERANCE OR EXEMP-
23 TION FOLLOWING CANCELLATION OF ASSOCIATED
24 REGISTRATIONS.—If the Administrator, acting under
25 the Federal Insecticide, Fungicide, and Rodenticide

1 Act, cancels the registration of each pesticide that
2 contains a particular pesticide chemical and that is
3 labeled for use on a particular food, or requires that
4 the registration of each such pesticide be modified to
5 prohibit its use in connection with the production,
6 storage, or transportation of such food, due in whole
7 or in part to dietary risks to humans posed by resi-
8 dues of that pesticide chemical on that food, the Ad-
9 ministrator shall revoke any tolerance or exemption
10 that allows the presence of the pesticide chemical, or
11 any pesticide chemical residue that results from its
12 use, in or on that food. The Administrator shall use
13 the procedures set forth in subsection (e) in taking
14 action under this paragraph. A revocation under this
15 paragraph shall become effective not later than 180
16 days after—

17 “(A) the date by which each such cancella-
18 tion of a registration has become effective; or

19 “(B) the date on which the use of the can-
20 celed pesticide becomes unlawful under the
21 terms of the cancellation, whichever is later.

22 “(3) SUSPENSION OF TOLERANCE OR EXEMP-
23 TION FOLLOWING SUSPENSION OF ASSOCIATED REG-
24 ISTRATIONS.—

1 “(A) SUSPENSION.—If the Administrator,
2 acting under the Federal Insecticide, Fungicide,
3 and Rodenticide Act, suspends the use of each
4 registered pesticide that contains a particular
5 pesticide chemical and that is labeled for use on
6 a particular food, due in whole or in part to die-
7 tary risks to humans posed by residues of that
8 pesticide chemical on that food, the Adminis-
9 trator shall suspend any tolerance or exemption
10 that allows the presence of the pesticide chemi-
11 cal, or any pesticide chemical residue that re-
12 sults from its use, in or on that food. The Ad-
13 ministrators shall use the procedures set forth in
14 subsection (e) in taking action under this para-
15 graph. A suspension under this paragraph shall
16 become effective not later than 60 days after
17 the date by which each such suspension of use
18 has become effective.

19 “(B) EFFECT OF SUSPENSION.—The sus-
20 pension of a tolerance or exemption under sub-
21 paragraph (A) shall be effective as long as the
22 use of each associated registration of a pesticide
23 is suspended under the Federal Insecticide,
24 Fungicide, and Rodenticide Act. While a sus-
25 pension of a tolerance or exemption is effective

1 the tolerance or exemption shall not be consid-
2 ered to be in effect. If the suspension of use of
3 the pesticide under that Act is terminated, leav-
4 ing the registration of the pesticide for such use
5 in effect under that Act, the Administrator
6 shall rescind any associated suspension of toler-
7 ance or exemption.

8 “(4) TOLERANCES FOR UNAVOIDABLE RESI-
9 DUES.—In connection with action taken under para-
10 graph (2) or (3), or with respect to pesticides whose
11 registrations were suspended or canceled prior to the
12 date of the enactment of this paragraph under the
13 Federal Insecticide, Fungicide, and Rodenticide Act,
14 if the Administrator determines that a residue of the
15 canceled or suspended pesticide chemical will un-
16 avoidably persist in the environment and thereby be
17 present in or on a food, the Administrator may es-
18 tablish a tolerance for the pesticide chemical residue.
19 In establishing such a tolerance, the Administrator
20 shall take into account both the factors set forth in
21 subsection (b)(2) and the unavoidability of the resi-
22 due and shall use the procedures set forth in sub-
23 section (e). The Administrator shall review any such
24 tolerance periodically and modify it as necessary so

1 that it allows no greater level of the pesticide chemi-
2 cal residue than is unavoidable.

3 “(5) PESTICIDE RESIDUES RESULTING FROM
4 LAWFUL APPLICATION OF PESTICIDE.—Notwith-
5 standing any other provision of this Act, if a toler-
6 ance or exemption for a pesticide chemical residue in
7 or on a food has been revoked, suspended, or modi-
8 fied under this section, an article of that food shall
9 not be deemed unsafe solely because of the presence
10 of such pesticide chemical residue in or on such food
11 if it is shown to the satisfaction of the Secretary
12 that—

13 “(A) the residue is present as the result of
14 an application or use of a pesticide at a time
15 and in a manner that was lawful under the
16 Federal Insecticide, Fungicide, and Rodenticide
17 Act; and

18 “(B) the residue does not exceed a level
19 that was authorized at the time of that applica-
20 tion or use to be present on the food under a
21 tolerance, exemption, food additive regulation,
22 or other sanction then in effect under this Act;
23 unless, in the case of any tolerance or exemption re-
24 voked, suspended, or modified under this subsection
25 or subsection (d) or (e), the Administrator has is-

1 sued a determination that consumption of the legally
2 treated food during the period of its likely availabil-
3 ity in commerce will pose an unreasonable dietary
4 risk.

5 “(6) TOLERANCE FOR USE OF PESTICIDES
6 UNDER AN EMERGENCY EXEMPTION.—If the Admin-
7 istrator grants an exemption under section 18 of the
8 Federal Insecticide, Fungicide, and Rodenticide Act
9 (7 U.S.C. 136p) for a pesticide chemical, the Admin-
10 istrator shall establish a tolerance or exemption from
11 a tolerance for the residue of the pesticide chemical.
12 Such a tolerance or exemption from a tolerance shall
13 have an expiration date. The Administrator may es-
14 tablish such a tolerance or exemption without pro-
15 viding notice or a period for comment on the toler-
16 ance or exemption. The Administrator shall promul-
17 gate regulations within 365 days after the date of
18 the enactment of this paragraph governing the es-
19 tablishment of tolerances and exemptions under this
20 paragraph. Such regulations shall be consistent with
21 the safety standard under subsections (b)(2) and
22 (c)(2) and with section 18 of the Federal Insecticide,
23 Fungicide, and Rodenticide Act.

24 “(m) FEES.—

1 “(1) AMOUNT.—The Administrator shall by
2 regulation require the payment of such fees as will
3 in the aggregate, in the judgment of the Adminis-
4 trator, be sufficient over a reasonable term to pro-
5 vide, equip, and maintain an adequate service for the
6 performance of the Administrator’s functions under
7 this section. Under the regulations, the performance
8 of the Administrator’s services or other functions
9 under this section, including—

10 “(A) the acceptance for filing of a petition
11 submitted under subsection (d);

12 “(B) the promulgation of a regulation es-
13 tablishing, modifying, or revoking a tolerance or
14 establishing or revoking an exemption from the
15 requirement of a tolerance under this section;

16 “(C) the acceptance for filing of objections
17 under subsection (d)(6); or

18 “(D) the certification and filing in court of
19 a transcript of the proceedings and the record
20 under subsection (d)(7);

21 may be conditioned upon the payment of such fees.

22 The regulations may further provide for waiver or
23 refund of fees in whole or in part when in the judg-
24 ment of the Administrator such a waiver or refund

1 is equitable and not contrary to the purposes of this
2 subsection.

3 “(2) DEPOSIT.—All fees collected under para-
4 graph (1) shall be deposited in the Registration and
5 Expedited Processing Fund created by section 4(k)
6 of the Federal Insecticide, Fungicide, and
7 Rodenticide Act. Such fees shall be available to the
8 Administrator, without fiscal year limitation, for the
9 performance of the Administrator’s services or func-
10 tions as specified in paragraph (1).

11 “(n) NATIONAL UNIFORMITY OF TOLERANCES.—

12 “(1) QUALIFYING PESTICIDE CHEMICAL RESI-
13 DUE.—For purposes of this subsection, the term
14 ‘qualifying pesticide chemical residue’ means a pes-
15 ticide chemical residue resulting from the use, in
16 production, processing, or storage of a food, of a
17 pesticide chemical that is an active ingredient and
18 that --

19 “(A) was first approved for such use in a
20 registration of a pesticide issued under section
21 3(c)(5) of the Federal Insecticide, Fungicide,
22 Rodenticide Act on or after April 25, 1985, on
23 the basis of data determined by the Adminis-
24 trator to meet all applicable requirements for

1 data prescribed by regulations in effect under
2 that Act on April 25, 1985; or

3 “(B) was approved for such use in a rereg-
4 istration eligibility determination issued under
5 section 4(g) of that Act on or after the date of
6 enactment of this subsection.

7 “(2) QUALIFYING FEDERAL DETERMINATION.—
8 For purposes of this subsection, the term ‘qualifying
9 Federal determination’ means a tolerance or exemp-
10 tion from the requirement for a tolerance for a
11 qualifying pesticide chemical residue that was--

12 “(A) issued under this section after the
13 date of enactment of this subsection and deter-
14 mined by the Administrator under subsection
15 (b)(2)(A); or

16 “(B) issued (or, pursuant to subsection (h)
17 or (I), deemed to have been issued) under this
18 section and determined by the Administrator to
19 meet the standard under subsection (b)(2)(A)
20 (in the case of a tolerance) or (c)(2) (in the
21 case of an exemption); and

22 “(3) LIMITATION.—The Administrator may
23 make the determination described in paragraph
24 (2)(B) only by issuing a rule in accordance with the
25 procedure set forth in subsection (d) or (e) and only

1 if the Administrator issues a proposed rule and al-
2 lows a period of not less than 30 days for comment
3 on the proposed rule. Any such rule shall be
4 reviewable in accordance with subsections (d)(6) and
5 (d) (7).

6 “(4) STATE AUTHORITY.—Except as provided
7 in paragraphs (5), (6), and (8) no State or political
8 subdivision may establish or enforce any regulatory
9 limit on a qualifying pesticide chemical residue in or
10 on any food if a qualifying Federal determination
11 applies to the presence of such pesticide chemical
12 residue in or on such food, unless such State regu-
13 latory limit is identical to such qualifying Federal
14 determination. A State or political subdivision shall
15 be deemed to establish or enforce a regulatory limit
16 on a pesticide chemical residue in or on food if it
17 purports to prohibit or penalize the production, proc-
18 essing, shipping, or other handling of a food because
19 it contains a pesticide residue (in excess of a pre-
20 scribed limit).

21 “(5) PETITION PROCEDURE.—

22 “(A) IN GENERAL.—Any State may peti-
23 tion the Administrator for authorization to es-
24 tablish in such State a regulatory limit on a
25 qualifying pesticide chemical residue in or on

1 any food that is not identical to the qualifying
2 Federal determination applicable to such quali-
3 fying pesticide chemical residue.

4 “(B) PETITION REQUIREMENTS.—Any pe-
5 tition under subparagraph (A) shall--

6 “(i) satisfy any requirements pre-
7 scribed, by rule, by the Administrator; and

8 “(ii) be supported by scientific data
9 about the pesticide chemical residue that is
10 the subject of the petition or about chemi-
11 cally related pesticide chemical residues,
12 data on the consumption within such State
13 of food bearing the pesticide chemical resi-
14 due, and data on exposure of humans with-
15 in such State to the pesticide chemical res-
16 idue.

17 “(C) AUTHORIZATION.—Subject to para-
18 graph (6), the Administrator may, by order,
19 grant the authorization described in subpara-
20 graph (A) if the Administrator determines that
21 the proposed State regulatory limit--

22 “(i) is justified by compelling local
23 conditions; and

24 “(ii) would not cause any food to be
25 a violation of Federal law.

1 “(D) TREATMENT.—In lieu of any action
2 authorized under subparagraph (C), the Admin-
3 istrator may treat a petition under this para-
4 graph as a petition under subsection (d) to
5 modify or revoke a tolerance or an exemption.
6 If the Administrator determines to treat a peti-
7 tion under this paragraph as a petition under
8 subsection (d), the Administrator shall there-
9 after act on the petition pursuant to subsection
10 (d).

11 “(E) REVIEW.—Any order of the Adminis-
12 trator granting or denying the authorization de-
13 scribed in subparagraph (A) shall be subject to
14 review in the manner described in subsections
15 (d)(6) and (d)(7).

16 “(6) URGENT PETITION PROCEDURE.—Any
17 State petition to the Administrator pursuant to sub-
18 section (5) that demonstrates that consumption of a
19 food containing such pesticide residue level during
20 the period of the food’s likely availability in the
21 State will pose a potentially significant public health
22 threat from acute exposure shall be considered an
23 urgent petition. If an order by the Administrator to
24 grant or deny the requested authorization in an ur-
25 gent petition is not made within 30 days of receipt

1 of the petition, the petitioning State may establish
2 and enforce a temporary regulatory limit on a quali-
3 fying pesticide chemical residue in or on the food.
4 The temporary regulatory limit shall be validated or
5 terminated by the Administrator's final order on the
6 petition.

7 “(7) RESIDUES FROM LAWFUL APPLICATION.—
8 No State or political subdivision may enforce any
9 regulatory limit on the level of a pesticide chemical
10 residue that may appear in or on any food if, at the
11 time of the application of the pesticide that resulted
12 in such residue, the sale of such food with such resi-
13 due level was lawful under this section and under
14 the law of such State, unless the State demonstrates
15 that consumption of the food containing such pes-
16 ticide residue level during the period of the food's
17 likely availability in the State will pose an unreason-
18 able dietary risk to the health of persons within such
19 State.

20 “(8) SAVINGS.—Nothing in this Act preempts
21 the authority of any State or political subdivision to
22 require that a food containing a pesticide chemical
23 residue bear or be the subject of a warning or other
24 statement relating to the presence of the pesticide
25 chemical residue in or on such food.

1 “(o) *[PUBLIC’S] RIGHT TO KNOW.—Not later than
2 2 years after the date of the enactment of the Food Qual-
3 ity Protection Act of 1996, and annually thereafter, the
4 Administrator shall, in consultation with the Secretary of
5 Agriculture and the Secretary of Health and Human Serv-
6 ices, publish in a format understandable to a lay person,
7 and distribute to large retail grocers for public display,
8 the following information, at a minimum:

9 “(1) A discussion of the risks and benefits of
10 pesticide *[chemicals found in or on food] purchased
11 by consumers.

12 “(2) A listing of actions taken under subpara-
13 graph (B) of subsection (b)(2) that may result in
14 pesticide chemical residues in or on food that
15 present a yearly or lifetime risk above the level al-
16 lowed under subparagraph (A) of such subsection,
17 and the crops on which *[the pesticide chemicals
18 producing the residues] are used.

19 “(3) Recommendations to consumers for reduc-
20 ing dietary exposure to pesticide chemical residues in
21 a manner consistent with maintaining a healthy diet,
22 including a list of foods that may reasonably sub-
23 stitute for *[crops] listed under paragraph (2).

1 Nothing in this subsection shall prevent retail grocers
2 from providing additional information regarding the foods
3 listed under this subsection.”.

4 “(p) ESTROGENIC SUBSTANCES SCREENING PRO-
5 GRAM.—

6 “(1) DEVELOPMENT.—Not later than 2 years
7 after the date of enactment of this section, the Ad-
8 ministrator shall develop a screening program, using
9 appropriate validated test systems and other scientif-
10 ically relevant information, to determine whether
11 certain substances may have an effect in humans
12 that is similar to an effect produced by a naturally
13 occurring estrogen, or such other endocrine effect as
14 the Administrator may designate.

15 “(2) IMPLEMENTATION.—Not later than 3
16 years after the date of enactment of this section,
17 after obtaining public comment and review of the
18 screening program described in paragraph (1) by the
19 scientific advisory panel established under section
20 25(d) of the act of June 25, 1947 (chapter 125) or
21 the science advisory board established by section 8
22 of the environmental research, development, and
23 demonstration act of 1978 (42 U.S.C. 4365), the
24 Administrator shall implement the program.

1 “(3) SUBSTANCES.—In carrying out the screen-
2 ing program described in paragraph (1), the admin-
3 istrator—

4 “(A) shall provide for the testing of all
5 pesticide chemical residues; and

6 “(B) may provide for the testing of any
7 other substance that may have an effect that is
8 cumulative to an effect of a pesticide chemical
9 residue if the Administrator determines that a
10 substantial population may be exposed to such
11 substance.

12 “(4) EXEMPTION.—Notwithstanding paragraph
13 (3), the administrator may, by order, exempt from
14 the requirements of this section a biologic substance
15 or other substance if the administrator determines
16 that the substance is anticipated not to produce any
17 effect in humans similar to an effect produced by a
18 naturally occurring estrogen.

19 “(5) COLLECTION OF INFORMATION.—

20 “(A) IN GENERAL.—The Administrator
21 shall issue an order to a person that registers,
22 manufactures, or imports a substance for which
23 testing is required under this paragraph to con-
24 duct testing in accordance with the screening
25 program described in paragraph (1), and sub-

1 mit information obtained from the testing to
2 the Administrator, within a reasonable time pe-
3 riod that the Administrator determines is suffi-
4 cient for the generation of the information.

5 “(B) PROCEDURES.—To the extent prac-
6 ticable the Administrator shall minimize dupli-
7 cative testing of the same substance for the
8 same endocrine effect, develop, as appropriate,
9 procedures for fair and equitable sharing of test
10 costs, and develop, as necessary, procedures for
11 handling of confidential business information.

12 “(C) FAILURE OF REGISTRANTS TO SUB-
13 MIT INFORMATION.—

14 “(i) SUSPENSION.—If a person re-
15 quired to register a substance referred to
16 in paragraph (3)(A) fails to comply with
17 an order under paragraph (1) of this para-
18 graph, the Administrator shall issue a no-
19 tice of intent to suspend the sale or dis-
20 tribution of the substance by the person.
21 Any suspension proposed under this para-
22 graph shall become final at the end of the
23 30-day period beginning on the date that
24 the person receives the notice of intent to
25 suspend, unless during that period a per-

1 son adversely affected by the notice re-
2 quests a hearing or the Administrator de-
3 termines that the person referred to in
4 paragraph (1) has complied fully with this
5 paragraph.

6 “(ii) HEARING.—If a person requests
7 a hearing under subparagraph (A), the
8 hearing shall be conducted in accordance
9 with section 554 of title 5, United States
10 Code. The only matter for resolution at the
11 hearing shall be whether the person has
12 failed to comply with an order under para-
13 graph (1) of this paragraph. A decision by
14 the Administrator after completion of a
15 hearing shall be considered to be a final
16 agency action.

17 “(iii) TERMINATION OF SUSPEN-
18 SIONS.—The Administrator shall terminate
19 a suspension under this paragraph issued
20 with respect to a person if the Adminis-
21 trator determines that the person has com-
22 plied fully with this paragraph.

23 “(D NONCOMPLIANCE BY OTHER PER-
24 SONS.—Any person (other than a person re-
25 ferred to in paragraph (3)) who fails to comply

1 with an order under paragraph (1) shall be lia-
2 ble for the same penalties and sanctions as are
3 provided under section 16 of the Toxic Sub-
4 stances Control Act (15 U.S.C. 2601 and fol-
5 lowing) in the case of a violation referred to in
6 that section. Such penalties and sanctions shall
7 be assessed and imposed in the same manner as
8 provided in such section 16.

9 “(6) AGENCY ACTION.—In the case of any sub-
10 stance that is found, as a result of testing and eval-
11 uation under this section, to have an endocrine ef-
12 fect on humans, the Administrator shall, as appro-
13 priate, take action under such statutory authority as
14 is available to the Administrator, including consider-
15 ation under other sections of this Act, as is nec-
16 essary to ensure the protection of public health.

17 “(7) REPORT TO CONGRESS.—Not later than 4
18 years after the date of enactment of this section, the
19 Administrator shall prepare and submit to Congress
20 a report containing—

21 “(A) the findings of the Administrator re-
22 sulting from the screening program described in
23 paragraph (1);

24 “(B) recommendations for further testing
25 needed to evaluate the impact on human health

1 of the substances tested under the screening
2 program; and

3 “(C) recommendations for any further ac-
4 tions (including any action described in para-
5 graph (6)) that the Administrator determines
6 are appropriate based on the findings.

7 “(8) SAVINGS CLAUSE.—Nothing in this section
8 shall be construed to amend or modify the provisions
9 of the Toxic Substances Control Act or the Federal
10 Insecticide, Fungicide, and Rodenticide Act.

11 “(q) SCHEDULE FOR REVIEW OF EXISTING TOLER-
12 ANCES.—

13 “(1) IN GENERAL.—The Administrator shall re-
14 view tolerances and exemptions for pesticide chemi-
15 cal residues established prior to enactment of the
16 Food Quality Protection Act of 1996, as expedi-
17 tiously as practicable, assuring that—

18 “(A) 33 percent of such tolerances and ex-
19 emptions are reviewed within 3 years of the
20 date of enactment of the Food Quality Protec-
21 tion Act of 1996;

22 “(B) 66 percent of such tolerances and ex-
23 emptions are reviewed within 6 years of the
24 date of enactment of the Food Quality Protec-
25 tion Act of 1996;

1 “(C) 100 percent of such tolerances and
2 exemptions are reviewed within 10 years of the
3 date of enactment of the Food Quality Protec-
4 tion Act of 1996.

5 In conducting a review of a tolerance or exemption,
6 the Administrator shall determine whether the toler-
7 ance or exemption meets the requirements of (b)(2)
8 or (c)(2) and shall, by the deadline for the review of
9 the tolerance or exemption, revoke or modify any tol-
10 erance or exemption that does not meet such re-
11 quirements.

12 “(2) PRIORITIES.—In determining priorities for
13 reviewing tolerances and exemptions under para-
14 graph (1), the Administrator shall give priority to
15 the review of the tolerances or exemptions that ap-
16 pear to pose the greatest risk to public health.

17 “(3) PUBLICATION OF SCHEDULE.—Not later
18 than 12 months after the date of the enactment of
19 the Food Quality Protection Act of 1996, the Ad-
20 ministrator shall publish a schedule for review of tol-
21 erances and exemptions established prior to the date
22 of the enactment of the Food Quality Protection Act
23 of 1996. The determination of priorities for the re-
24 view of tolerances and exemptions pursuant to this
25 subsection is not a rulemaking and shall not be sub-

1 ject to judicial review, except that failure to promul-
2 gate any standard pursuant to the schedule estab-
3 lished by this paragraph shall be subject to judicial
4 review.”.

5 **SEC. 406. AUTHORIZATION FOR INCREASE MONITORING.**

6 There is authorized to be appropriated an additional
7 \$12,000,000 for increased monitoring by the Secretary of
8 Health and Human Services of pesticide residues in im-
9 ported and domestic food.

10 **SEC. 407.. CIVIL MONEY PENALTIES.**

11 Section 303(g) (21 U.S.C. 333(f)) is amended—

12 (1) by redesignating paragraphs (2), (3), and
13 (4) as paragraphs (3), (4), and (5), respectively,

14 (2) by inserting after paragraph (1) the follow-
15 ing:

16 “(2)(A) Any person who introduces into interstate
17 commerce or delivers for introduction into interstate com-
18 merce an article of food that is adulterated within the
19 meaning of section 402(a)(2)(B) shall be subject to a civil
20 money penalty of not more than \$50,000 in the case of
21 an individual and \$250,000 in the case of any other person
22 for such introduction or delivery, not to exceed \$500,000
23 for all such violations adjudicated in a single proceeding.

24 “(B) This paragraph shall not apply to any person
25 who grew the article of food that is adulterated. If the

1 Secretary assesses a civil penalty against any person under
2 this paragraph, the Secretary may not use the criminal
3 authorities under this section to sanction such person for
4 the introduction or delivery for introduction into interstate
5 commerce of the article of food that is adulterated. If the
6 Secretary assesses a civil penalty against any person under
7 this paragraph, the Secretary may not use the seizure au-
8 thorities of section 304 or the injunction authorities of sec-
9 tion 302 with respect to the article of food that is adulter-
10 ated.”;

11 (3) in paragraph (3), as so redesignated, by
12 striking “paragraph (1)” each place it occurs and
13 inserting “paragraph (1) or (2)”; and

14 (4) in paragraph (5), as so redesignated, by
15 striking “(3)” each place it occurs and inserting
16 “(4)”.