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THE WHITE HOUSE

WASHINGTON

DOMESTIC POLICY COUNCIL

Thursday, November 16, 1989

2:00 P.M.

Roosevelt Room

AGENDA

Anti-Poverty Agenda

REMARKS PREPARED FOR

JACK KEMP

SECRETARY



DISCUSSING HOPE

HOMEOWNERSHIP AND OPPORTUNITY FOR PEOPLE EVERYWHERE

AT THE

NATIONAL PRESS CLUB

WASHINGTON, D.C.

NOVEMBER 15, 1989

Homeownership and Opportunity for People Everywhere

(HOPE)

Fighting a New War on Poverty

I am pleased to be here at the National Press Club to discuss President Bush's new initiatives. When it comes to the press, our timing at HUD could be a bit better. The day we released our new reform bill, a coup was attempted against Noriega in Panama. Last Friday, the same day President Bush announced our new housing and urban development agenda, the Berlin Wall was being torn down.

Every time HUD announces a new proposal, it seems another country lurches dramatically toward freedom. Maybe I should talk to Secretary Baker about making daily press announcements.

I don't want to minimize the events of the last few days. In fact, I was thrilled to be with President Bush on the occasion of his speech to the National Association of Realtors in Dallas, when he said that, "The 1980s has been the decade of American renewal ... and ... around the world, the 1990s will inevitably be the decade of democracy."

The history-making events of recent weeks remind us that the international struggle for freedom, democracy, and justice has its parallel right here in our own country. As Berliners tear down the wall that has kept them from freedom for 28 years, so too must we tear down the walls that are keeping America's poor from the blessings of freedom and democracy in our own country.

Of course, we don't literally have walls around America's

ghettos and barrios. But economic stagnation, drugs, and despair are too often insurmountable walls that separate low-income Americans from the everyday dreams and aspirations that all of us share -- to own a home, to have a good job, and to enjoy the type of boundless opportunity that is the essence of the American Dream.

Today, in the year of the 25th anniversary of the first War on Poverty, I want to recognize the good intentions of that effort and the architects who had such great hopes to help the poor. But the overall anti-poverty system they designed was not very effective in reducing poverty and only partially effective in alleviating its worst symptoms.

All too often, their noble goals were frustrated by over-reliance on government entitlements and an attitude that poor people were unwilling or unable to become entrepreneurial risk-takers, small business men and women, producers and job holders.

President Bush has introduced the most far-reaching reforms in a quarter-century to clean up and prevent future HUD scandals. We have got to change the system in our inner cities that is rewarding deficiency and self-destructive behavior while punishing individual dignity, initiative, productive work effort, and the family structure. The ultimate scandal is to treat poor people as perpetually poor.

We reject the attitude that nothing can or should be expected from poor Americans. Our new war on poverty rests on our fundamental belief that helping someone out of poverty must

be a two-way proposition: efforts by government and others to help should be matched by the commitment of recipients to take actions to become self-sufficient. Otherwise, our programs will degenerate into hand-outs that promote resentment among the giver and dependency among those we are trying to help.

In this respect, our new war on poverty shares the goals of the original one -- a hand up, not a hand out. But we have learned a lot over the past twenty five years about what works and what doesn't. With that perspective, and with the benefit of hindsight concerning what went wrong, we feel it is the right time to rededicate ourselves to a new anti-poverty campaign.

The President's strategy for combatting poverty is called HOPE -- which stands for Homeownership and Opportunity for People Everywhere. This agenda is the most dramatic, far-reaching incentive-oriented approach to fighting poverty in the last 25 years. It will tear down the walls that come between people and their self-respect ... that prevent people from exercising their talents and reaching their potential.

Now, I know it worries some people when President Bush and Jack Kemp talk about a new war on poverty. Well, we reject social engineering of people's lives and huge entitlement programs. But we equally reject the idea of social Darwinism -- the survival of the fittest ethic that says government can do nothing to alleviate poverty.

Our HOPE strategy is a comprehensive set of proposals that can lead to success against poverty and despair:

① Don't like the low income
designator
— prefer kinder, gentler
entrepreneur zone

We know what works! Radically
alter the reward structure in our most
depressed regions — taxes, education etc etc
— — —

② Induce parents to become involved
at all levels in the education system

First, The President's HOPE agenda empowers people to take control over their own lives. Our policies give people the choice of deciding where they want to live, offering them greater control over their community and future, and boosting them toward their goals.

Second, HOPE dramatically strengthens the link between individual effort and reward. Our goal is to change the incentives at work in our inner city so that going to school and staying in school, taking a job and producing on the job, raising a family and providing for that family result in greater benefits and standing in the community than drug pushing, crime, or welfare.

Third, HOPE gives poor people a stake in their neighborhoods and the entrepreneurial economic system. Homeownership is essential to the American Dream, and by giving people an equity stake in their neighborhoods, we will introduce economic incentives and help improve behavior.

Fourth, HOPE removes the barriers that prevent private entrepreneurship from doing a better job of delivering affordable housing, decent jobs, and greater opportunity. By reducing incentive-stifling tax rates, unnecessary regulatory barriers, and exclusive, no-growth policies in the inner city, HOPE initiatives will encourage more homeownership and job-creating entrepreneurship.

There is one all important fact to remember. We can't help our Nation's poor, if our Nation itself is growing poor. The

President's capital gains tax reduction measure is not a budget issue; it's the embodiment of his belief that we have to create more jobs, more income, and more entrepreneurship, that we need more economic expansion, and that we must prevent a recession.

In Dallas I was thrilled to hear the President say that not only did he want to cut the capital gains tax for the Nation to 15 percent, but he wanted to eliminate it in the ghettos and pockets of poverty by creating Enterprise Zones.

Now isn't it ironic that the same Democratic leaders who tell us that the capital gains tax cut is only for the rich have signed their names to legislation that would eliminate it in Enterprise Zones?

Some people charge us with holding the low-income housing tax credit hostage to the capital gains tax cut. They've got it all wrong. The real hostage-takers are those who want to block the President's capital gains tax cut. The Democratic leaders are the ones who are threatening to sacrifice the low-income housing tax credit in order to defeat the President for nothing more than a partisan, empty victory. Regrettably, they are gambling with the very health of our economy.

Let me set the record straight: President Bush supports four major new tax incentives -- the LIHTC, Enterprise Zones, IRA's for first time homebuyers, and the capital gains tax cut. It's time we pass them now.

Let me discuss the rest of our HOPE package of new urban economic development and housing initiatives.

Low-income Housing Homeownership -- HOPE grants

President Bush has proposed a \$2.1 billion housing grant program that will increase low-income homeownership through non-profits and by expanding resident management and urban homesteading of publicly-assisted properties.

As I go across our Nation, I see non-profits, neighborhood groups, and community housing efforts taking the boards off vacant and foreclosed property, rehabilitating that property... often through sweat equity ... and turning thousands of dilapidated houses to decent, quality housing for low-income people.

We don't need new public construction programs that are scandal-prone and generate a cycle of dependency. By energizing this new wave of non-profit housing groups, our Nation will be blessed with thousands of new responsible property owners bringing stability and self-help to low-income neighborhoods.

But as President Bush said, the centerpiece of our HOPE agenda is homeownership.

I have been excited to see the incredible renaissance brought about in our inner cities by resident empowerment and homesteading. Kimi Gray, Bertha Gilkey, Irene Johnson, Mildred Hailey -- these are the first pioneers who are busting out of the poverty trap by taking control of their own housing through resident management.

These resident leaders are debunking the myth that empowerment is attainable only by a few charismatic individuals.

I believe there's a potential Kimi Gray at every public housing development in America. And HOPE will tap their creative energies by providing the necessary training, technical assistance, and seed capital to launch their economic enterprises and rehabilitate their housing stock as a first step towards homeownership.

Resident management and homeownership, my friends, represent new declarations of independence for today's inner city heroes, and a long-denied realization of the democratic ideal in our Nation's poorest communities. HOPE will provide the funding necessary to turn their dream into reality and help convert scores of projects from public to private homeownership in Liberty City, East Los Angeles ... in some of the most troubled housing developments across the Nation.

Ask resident leaders what empowerment means to them. They will tell you it means a renewed sense of responsibility, pride and self-esteem. But it is more. To them, and to us, empowerment is the code word of the new civil rights revolution.

Service-Supported Housing for the Homeless

Our Nation's most vulnerable people are the homeless, and they must be in the forefront of our housing policy. The tragedy of so many, including tiny children living in shelters or on the streets, in parks and campsites, and on the subways weakens our faith in freedom's advantages and causes others to question America's moral commitment.

All the homeless need basic shelter, but every single

reputable study concludes that shelter alone is not enough. We must do what President Bush suggested in his speech and add care and treatment to shelter. This approach can help solve the deep-seated problems brought on by mental disorders or substance abuse.

Therefore, President Bush has recommended to Congress a new \$728 million initiative over the next three years to fund service-supported housing for homeless who are mentally ill or substance abusers. This program will match Federal funds with State and local resources, including the community mental health block grant. Homeless Americans will receive more than \$1.4 billion not only for shelter, but for the professional treatment they need to restore their chances to live a normal and dignified life.

As an additional effort, I am directing the Federal Housing Administration to set aside 10 percent of FHA foreclosed housing for lease to non-profit groups to help house the homeless. And I am also announcing that FHA will extend essential insurance to single room occupancy (SRO) housing. The loss of SRO's from many of our inner cities through gentrification has been a major reason for the disappearance of decent housing for homeless persons. Also as President Bush has repeatedly made clear, this Administration is also absolutely committed to full funding of the McKinney Act for the homeless.

Low-Income Housing Preservation

Another part of President Bush's HOPE initiative is to preserve some 350,000 rental units of low-income Federal housing at risk of being lost as a result of mortgage prepayment. HUD will offer each resident the monetary equivalent of a 10-year voucher and the right of first refusal to help them purchase their homes and apartments.

Removing Barriers to Affordable Housing

But America also has a housing affordability problem perpetuated by exclusive zoning, Mickey Mouse regulations and complex building codes, and rent controls. In Los Angeles County, for example, these regulations alone can raise the cost of housing by \$20,000 or more.

As an inducement to tear down these barriers, President Bush is recommending the creation of 50 Housing Opportunity Zones. In return for States and cities offering up plans to eliminate barriers to affordable housing, the Federal Government will offer its own package of housing and regulatory incentives.

The President has also asked me to convene a Blue Ribbon Commission to identify barriers to affordable housing. This group of experts will make recommendations to us on specific steps we can take to help eliminate those barriers.

IRA Downpayments

As home prices skyrocket, many young couples also face difficulties getting together a downpayment for their first home. Therefore, President Bush is asking Congress for legislation allowing first-time homebuyers to draw, without penalty, on IRA

savings as a down payment for their first home.

We are also reforming FHA for the Nineties to help give low- and moderate-income Americans easier access to their first homes.

Conclusion

Ladies and gentlemen, what a dramatic moment in human history. I don't believe there is any more important time to show that the entrepreneurial democratic system is the greatest anti-poverty weapon the world has ever seen. Poland, Hungary, Czechoslovakia, East Germany, the Chinese students in Tiananmen Square, even the people of Bulgaria are looking to America for ideas -- ideas to create new wealth, wide-ranging opportunity, and democratic freedoms.

Yet, how can we tell the world that democracy is the social and economic tool for them if we can't make it work for everyone in our own Nation? I can't help but feel that history has linked the cause of freedom abroad with the cause of freedom, dignity, and justice right here in America's ghettos and barrios in one great cause for good.

As President Bush said in Texas, "We must unleash the resources of the profit and non-profit sectors, of churches and synagogues, States and localities in our great national enterprise to assure safe, decent, and affordable housing for all.... Only then will we be able to complete our vision of a free and prosperous America, full of opportunity for people everywhere."

#

S E N S I T I V E

CABINET AFFAIRS STAFFING MEMORANDUM

Date: Nov. 13, 1989 **Number:** _____ **Due By:** _____

Subject: 19th Meeting of the Domestic Policy Council, Thursday, Nov. 16,
1989, 2:00 PM in the Roosevelt Room.

ALL CABINET MEMBERS	Action	FYI		Action	FYI
Vice President	☒	☐	CEA	☒	☐
State	☐	☐	CEQ	☐	☐
Treasury	☐	☐	OSTP	☐	☒
Defense	☐	☐		☐	☐
Justice	☒	☐		☐	☐
Interior	☒	☐		☐	☐
Agriculture	☒	☐		☐	☐
Commerce	☐	☒		☐	☐
Labor	☒	☐		☐	☐
HHS	☒	☐	Scowcroft	☐	☐
HUD	☒	☐	Porter	☒	☐
Transportation	☐	☐	Cicconi (For WH Staffing)	☒	☐
Energy	☒	☐		☐	☐
Education	☒	☐		☐	☐
Veterans	☒	☐		☐	☐
OMB	☒	☐		☐	☐
USTR	☐	☐		☐	☐
Chief of Staff	☒	☐	Executive Secretary for:		
UN	☐	☐	DPC	☐	☐
CIA	☐	☐	EPC		☒
National Drug Policy	☐	☐		☐	☐
EPA	☐	☒		☐	☐
GSA	☐	☐		☐	☐
NASA	☐	☐		☐	☐
OPM	☐	☐		☐	☐
SBA	☐	☐		☐	☐

REMARKS: Attached are an agenda and a paper recommending a low income opportunity strategy for the Administration to be discussed at the 19th meeting of the Domestic Policy Council on Thursday, Nov. 16, 1989 from 2:00 to 3:00 PM in the Roosevelt Room. The paper is sensitive in nature and should be treated as a close hold document.

Please note that this is a meeting for principals only, and your office should notify Justine (456-2800) by COB, Wednesday, Nov. 15 as to whether

RETURN TO: ✓ or not you will attend the meeting.

☐ **David Q. Bates**
Cabinet Secretary
456-2174
(1st Floor, West Wing)

☐ Associate Director
Office of Cabinet Affairs
456-2800
(Room 235, OEOB)

THE WHITE HOUSE
WASHINGTON

November 13, 1989

MEMORANDUM FOR THE DOMESTIC POLICY COUNCIL

FROM: KENNETH P. YALE *Ky*
Executive Secretary

SUBJECT: Nineteenth Meeting of the Domestic Policy Council,
Thursday, November 16, 1989, 2:00 P.M. in the
Roosevelt Room

The Domestic Policy Council will hold its 19th meeting, for principals only, on Thursday, November 16, 1989 from 2:00 to 3:00 PM in the Roosevelt Room. The subject of the meeting is the Administration's Anti-Poverty Agenda.

Attached are an agenda and a paper recommending a low income opportunity strategy for the Administration. William L. Roper, Chairman of the Low Income Opportunity Board, a DPC Working Group, will make a presentation. Please note that this paper is sensitive in nature and should be treated as a close hold document.

Please inform Justine D'Andrea (456-2800) by COB Wednesday, November 15, as to whether or not you plan to attend this meeting.

Attachments

THE WHITE HOUSE
WASHINGTON

DOMESTIC POLICY COUNCIL

Thursday, November 16, 1989

2:00 P.M.

Roosevelt Room

AGENDA

Anti-Poverty Agenda

*Bush Admin
should be proud
of what has been accomplished*

THE WHITE HOUSE
WASHINGTON

November 13, 1989

*has low income opportunities
rather than need for etc.*

MEMORANDUM FOR THE DOMESTIC POLICY COUNCIL

FROM: WILLIAM L. ROPER, Chairman, *WLR*
Low Income Opportunity Board

SUBJECT: A Low Income Opportunity Strategy for the Bush
Administration

Background

The Domestic Policy Council met on July 6 and July 25 to discuss the role of the Low Income Opportunity Board. It recommended to the President that the Board develop, within 90 days, the principles of a Bush Administration low income opportunity agenda, and document the Administration's progress to date. The President approved this recommendation on September 14. This memorandum outlines the Administration's efforts and a possible low income opportunity strategy.

✓ Current Administration Low Income Opportunity Efforts

Since taking office less than a year ago, President Bush has advanced and supported many new initiatives which are likely to have a significant impact on low income Americans. In crafting a low income opportunity strategy, we start with a significant number of proposals affecting children, the working poor, and the homeless and others in need of housing assistance.

For children, the President proposed a \$250 million increase in Head Start for 1990 as well as an extension of Medicaid eligibility to pregnant women and infants with incomes below 130 percent of the poverty level (with Medicaid coverage for immunizations for all children up to age five who are eligible for Food Stamps). To improve the quality of education, he has supported increased flexibility and choice, and targeting Federal dollars to help those most in need. He will soon sign legislation making positive changes in the nation's child nutrition programs. In addition, the Administration is implementing major changes in the nation's Child Support Enforcement program authorized by the Family Support Act of 1988.

For the working poor, the President has proposed tax credits for low-income families with children under age four, and a reorganization of the Job Training Partnership Act to target resources on the most economically disadvantaged. The Administration has developed regulations implementing the Job Opportunities and Basic Skills Training (JOBS) program of the Family Support Act of 1988, which establishes a major new work,

training, and education program for those on welfare. By insisting on a training wage for newly-employed teenagers, the President was the first to achieve a minimum wage increase with measures to reduce the job-loss impact on the working poor.

For the homeless, the President has proposed full funding of the Stewart B. McKinney Homeless Assistance Act and a \$50 million initiative designed to reduce homelessness that is based on local private-public partnerships. For others in need of housing assistance, the President recently announced a forward-looking plan to increase homeownership opportunities and to create jobs and entrepreneurial activity in the nation's distressed urban and rural communities.

Finally, the President reestablished the Low Income Opportunity Board to help States implement welfare reform demonstrations involving waivers of more than one program.

The Board believes the principles behind these initiatives-- assistance well-targeted to those in need, provided directly in a way which maximizes aid, rather than through bureaucracies-- should guide future efforts to allocate resources to low income families and individuals.

Elements of a Bush Administration Low Income Opportunity Agenda

The challenges in developing further a low income opportunity strategy are: 1) how to make more effective use of existing resources; and 2) how to articulate our current activities in terms of an overall strategy. The Administration has already done much for which it can take credit. The Board recommends the following:

a) **Articulate the principles behind the Administration's existing initiatives.** The one phrase which most people could associate with the President's domestic policy is "a kinder, gentler America." The Administration should more forcefully articulate those principles which tie together its initiatives as a conservative vision of a kinder, gentler America, such as carefully targeting assistance to those most in need, providing States and localities greater flexibility in the use of Federal funds, and empowering the poor themselves.

b) **Support strategies that empower local communities and the poor themselves.** The current welfare system is built upon a "top down" approach in which the Federal government develops rules and regulations for public assistance programs which are imposed upon State and local governments and welfare recipients. A "bottom up" approach, in contrast, would decentralize the decision-making process by "empowering" those institutions and individuals better able to address the needs of the poor.

Examples of such policies include: tenant management in public housing; choice in education; enhanced funding for Head

Start, a child development program designed with significant parental involvement; enterprise zones; and housing vouchers. These are all initiatives currently supported by the Administration.

Empowering the poor is consistent with conservative principles of self-help and entrepreneurship, while providing a clear alternative to traditional program expansions. In addition, empowerment strategies may be more effective because they require the direct involvement of the poor themselves, while costing the Federal government less, since better use is made of existing funding. At every opportunity, this empowerment strategy should be contrasted with similarly named empowerment strategies of the Great Society, which gave power to the providers of social services.

For these reasons, it is important for the Administration to continue to work with State and local governments and provide the necessary leadership in making empowerment strategies work. As the foundation of a broad low income opportunity agenda, the Board recommends empowerment as a critical principle to be used in shaping and assessing all program initiatives.

c) **Simplify the welfare system.** There is a need to expand the effort to reduce needless complexity among eligibility policies and procedures across the welfare system. The Board recommends that the DPC authorize an interagency review to propose ways to simplify and streamline these policies, consistent with program objectives and within a budget neutral framework, and to report back periodically to the DPC.

d) **Target assistance to people and areas that need it most.** Carefully targeting resources is a theme particularly important in periods of fiscal restraint. It also provides the high ground from which to resist alternate agendas, such as child care legislation that extends subsidies to the middle class as well as the poor. In addition to being a rhetorical strategy, the option outlined below provides an opportunity to make targeting a dramatic policy initiative.

Provide Flexibility

The President is committed to providing States and localities with the flexibility they need to make the most effective use of available low income program resources. Two recommendations address this goal.

Continue the Board's Initial Mission

Summit Encourage State and community-based demonstration proposals and seek changes to expand waiver authority across the welfare system. The amount of debate surrounding existing anti-poverty initiatives indicates that there is still a great deal of doubt about the causes and remedies of poverty and dependency; thus, an

important role of the Federal government is to encourage further State and local experimentation. Recognizing this, the Domestic Policy Council directed the Low Income Opportunity Board to develop legislative proposals to target expansions in waiver authority further to promote such experimentation. This is now in progress.

* A New Initiative: Low Income Opportunity Zones

OPTION: Propose a major new legislative initiative under which the Federal government would undertake, through a limited number of demonstrations, a comprehensive effort directed at high poverty areas.

The President has expressed his commitment to giving State and community leaders the flexibility they need to make the best use of available resources. Under this option, the designated high poverty areas would become "opportunity zones" in a real test of what maximum State and local flexibility can achieve when directed at high poverty areas.

According to the Bureau of the Census, 41 percent of Americans with cash incomes below the poverty line in 1988, or 13.1 million people, lived in high poverty areas (defined as census tracts with a poverty rate of 20 percent or more in 1979). Much attention in recent years has focused on inner city concentrations of poverty, illiteracy, limited workforce attachment, long-term welfare dependency, family instability, crime, drug abuse, and general isolation from mainstream society. Although these problems are often associated with inner city ghetto areas, they can be found in high poverty suburban and rural areas, including Native American reservations.

These concentrations of economic, social, and behavioral problems defy traditional government approaches to poverty. In particular, a fragmented welfare system provides little opportunity for addressing the problems of a community as a whole. This option would maximize State and local flexibility in areas with an exceptionally high incidence of poverty and other problems to test alternatives to the current welfare system.

The key element in this initiative is the widest possible waiver authority. A range of demonstration communities, including urban, suburban, and rural, would not only increase the amount of information on how to decrease poverty effectively, but would also allow more States to become involved. States and communities would be encouraged to submit demonstration proposals on a competitive basis, with Federal approval contingent upon the extent to which the proposal was consistent with the critical principles mentioned above: empowerment, targeted aid, and minimum bureaucracy. In addition, proposals should demonstrate local willingness to include the education and criminal justice systems in a comprehensive approach to a pervasive set of problems.

Pros

- o Targeting high poverty areas through a focused initiative would be viewed as tackling the heart of the issue.
- o Additional funding and flexibility may lead to innovative approaches otherwise not possible.
- o The Administration already has several initiatives aimed at disadvantaged areas (e.g., the drug program, tenant management in public housing, choice in education, and enterprise zones) that could be tied into this effort.
- o In a time of limited budget resources, particularly disadvantaged areas should be targeted for action.

Cons

- o Some may perceive this as too narrow a focus, because only a relatively small percentage of the poor reside in such areas.
- o Based on past experience, it is likely that a proposal for maximum flexibility for States and localities, even in a demonstration, will be viewed with suspicion by the many Congressional committees overseeing low income assistance programs.
- o Equity issues could arise by drawing lines around a specific area and providing differential services to people who fall within the boundaries.
- o Targeting narrow geographic areas may create administrative problems for State, county and local service agencies in charge of distributing program benefits, if they are forced to operate two systems simultaneously.
- o Targeting highly disadvantaged areas, particularly without much additional funding, can be risky. Poverty problems are serious and there are no quick or easy solutions.
- o Waiving program requirements raises difficult issues about evaluation and cost control.

*Where are the selection criteria?
Is this new or re-programmed money?*

Further Issues

If this initiative is to be put forward in legislation, the Administration will have to resolve the following basic questions beforehand:

1. Should this initiative be open to all geographic areas or should it be targeted to inner cities, which to many Americans are symbolic of the poverty problem?
2. How many demonstrations should be authorized?
3. What criteria should be used to select demonstration areas (e.g., the incidence of poverty, crime, drug abuse, female-headed families, illiteracy, etc.)?
4. Should additional funding be made available to demonstration areas and for what purpose (new programs, administrative costs, and/or evaluation costs)?

Recommendation

The Board recommends that the Administration pursue a low income opportunity agenda that rests on five key elements: 1) building on the 1989 proposals; 2) seeking to empower local communities and the poor themselves; 3) simplifying the welfare system; 4) targeting assistance to people and areas that need it most; and 5) encouraging State and community-based demonstrations.

In addition, the Board recommends that the Administration propose legislation to target high poverty areas for a concentrated attack on poverty and poverty-related problems.

THE WHITE HOUSE

WASHINGTON

DOMESTIC POLICY COUNCIL

Thursday, September 14, 1989

4:00 P.M.

Roosevelt Room

AGENDA

Food Safety Regulation

Briefing Notes: DPC Meeting on Food Safety Regulation

10
-6
Talked with Ken Yale (Exec. Sec. DPC) and Jay Plager -- Administrator of Office of Information and Regulatory Affairs (OIRA) within the OMB. Plager's group wrote the paper. He wants to regularize the regulatory process, eliminate unnecessary regulatory delays, and eliminate the "Delaney Clause" calling for zero risk -- replacing this clause with the more reasonable criterion of "negligible risk". Biogenetically modified plants are handled on a separate circuit -- not impacted here. The overall proposal -- a set of philosophic statements -- is, on the face of it, reasonable.

Need more notes + bullets
Main unanswered questions --to raise at meeting --concern the following:

097 } Proposal does not address the mechanics of how the risk assessment is done. What is needed is a detailed laying out of such things as: how is cancer risk determined; how is best scientific judgment to be brought to bear; how is cost-benefit to be determined, etc. Shouldn't we be getting together a group to regularize the methodology for risk assesment across the government, so that the process becomes less ad hoc?

Shouldn't we plan this process so that we have such a detailed framework in place at the same time we have legislation to submit to Congress? Legislation should be drafted in parallel with this detailed framework, perhaps by the same working group. Close coordination needed here.

EPA Sets Up Schedules For Phaseout of 'Alar'

mk/fm

Environmental Protection Agency is proposing a phased approach to revoke tolerances for residues of "Alar" (daminozide) on raw agricultural commodities and an immediate revocation of existing tolerances on processed foods and animal feed.

The proposal will discourage further domestic use of "Alar," establish termination dates for legally acceptable residues of commodities treated in the past and insure that imported foods comply with the same residue requirements as domestic foods.

The action comes almost three months after Uniroyal Chemical Company, the sole manufacturer of the pesticide, said it was suspending production and recalling all "Alar" stocks pending further studies of the chemical's safety.

The suspension and recall did not end concerns by environmentalists and some members of Congress that foods treated with "Alar" overseas might be shipped to the U.S. Uniroyal did not halt export sales of the plant growth regulator, which has been used primarily on apples to maintain firmness and coloring during storage.

Natural Resources Defense Council, the environmental litigation group which has led

the attack on "Alar," welcomed the EPA action. Lorraine Voids, an NRDC official, calls the tolerance revocation proposals "fairly significant," but says she is concerned the agency is allowing two years to phase out the amounts of "Alar" allowed in foods.

EPA's proposal calls for initially lowering the "Alar" tolerance on apples and processed apple products from the current 20 parts per million (ppm) to five ppm on November 30, 1989. A year later, the tolerance would be lowered to one ppm, and after May 31, 1991, any detectable level would be illegal. Similar actions are being proposed for the remaining food uses.

The agency says it is allowing the gradual reduction because it "continues to believe, based on available data, that the short-term risks of eating apples or other food treated with daminozide are not significant."

In first reducing and then revoking the tolerances, EPA says it does not want to force "the unnecessary seizure of commodities legally treated with daminozide." The pesticide is usually applied to apple trees in the spring and summer.

The agency says residue data on apples from crop field studies show that most apples

Continued on Page 19

EPA Sets

Continued from Page 9

treated in the spring will have residues at harvest of five ppm or below. Apples treated in the summer show residues at harvest of 10 ppm or below.

"Any such summer use could result in treated apples being over the five ppm tolerance and therefore subject to seizure. EPA believes, however, that there has been decreased use of daminozide on apples this Summer due to Uniroyal's agreement to stop sales and recall daminozide products, the recommendation by the apple growers' trade association to stop use of daminozide, and EPA announcements that it would propose to lower daminozide tolerances this Summer," the agency says in a statement.

Uniroyal has strongly denied claims that "Alar" is a carcinogen, but EPA says it has received new data that confirm its initial findings regarding the carcinogenicity of daminozide's breakdown product, UDMH (unsymmetrical dimethyl hydrazine).

EPA initiated a special review of daminozide in 1984 under the Federal Insecticide, Fungicide & Rodenticide Act after determining that this chemical and/or UDMH caused an increased incidence of cancer in laboratory animals. In May, as part of the special review process, EPA proposed to cancel all registrations for food uses of daminozide because of its potential to cause unreasonable carcinogenic risks to humans.

AGENCY'S CANCELLATION

The agency's proposed cancellation action was based in part on a 13-month interim report of a two-year study in mice using UDMH. The final report on this study along

September 11, 1989

CHEMICAL MARKETING REPORTER

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with several other relevant studies, is due to EPA by January, after which the agency plans to issue its final regulatory determination on daminozide.

In addition to apples, daminozide is currently registered for use on cherries, nectarines, peaches, pears, peanuts, grapes, tomato transplants and ornamentals.

The tolerances being proposed by EPA for the remaining food uses of daminozide are the following: peanuts, currently at 30 ppm, would be reduced to four ppm on November 30, 1989, with a total revocation on May 31, 1991; tolerances for peanut meal, peanut hay and peanut hulls would be revoked on November 30, 1989; sweet cherries currently at 30 ppm and sour cherries currently at 55 ppm would be reduced to 15 ppm on November 30, 1989, with a total revocation on May 31, 1991; grapes, currently at 10 ppm would be reduced to 2.5 ppm on November 30, 1989, with a total revocation on May 31, 1991; peaches and nectarines, currently at 30 ppm would be reduced to 7.5 on November 30, 1989, with a total revocation on May 31, 1991; pears, currently at 20 ppm would be reduced to five ppm on November 30, 1989, with a total revocation on May 31, 1991; all tolerances for tomatoes, processed tomatoes, tomato pomace, meat and meat by-products, milk and eggs would be revoked on November 30, 1989.

Even under existing tolerances, the risks associated with "Alar" residues on these crops are considered by the agency to be negligible.

Statement

News Division, Room 404-A, United States Department of Agriculture, Washington, D.C. 20250

Joint statement by the

U.S. DEPARTMENT OF AGRICULTURE,
ENVIRONMENTAL PROTECTION AGENCY and
FOOD AND DRUG ADMINISTRATION

September 11, 1989

The federal government's concern for the safety of America's food supply is unparalleled. Aggressive research results in continual policy and program reevaluation which further ensures safe, wholesome food for our consumers. Over the years, this research has led to elimination of many chemicals from agricultural application.

Today, the Consumer Pesticide Project announced that certain grocery stores and chains have pledged to stop selling food treated with certain pesticides. This group appears to attempt to put the onus for pesticide regulations inappropriately on the U.S. grocery industry. In an attempt to indict agricultural chemicals as universally harmful to consumers, this coalition ignores the evidence that many pesticides guard the food supply from plant diseases which could have serious impact on overall consumer health.

It is vital that the federal government continue to balance the benefits and risk of pesticides through scientific research. We support such research initiatives to the fullest.

Rhetoric which fuels public reaction benefits no one. The U.S. government--yesterday, today, and tomorrow--is putting maximum effort into ensuring safe, wholesome food for this nation's tables.

#

Contact: (USDA) Kelly Shipp (202) 447-4623
(EPA) Al Heier (202) 382-4355
(FDA) Chris Lacos (202) 245-1241

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FOOD SAFETY REGULATION

September 11, 1989

Issue:

What steps should the Administration take to improve the federal government's ability to protect American consumers from dangers posed by the use of pesticide chemicals on or in food products?

Background:

Federal jurisdiction over pesticide residues in food is divided among the Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA). Monitoring and enforcement responsibilities for domestically produced and imported foods are handled by USDA (meat, poultry and egg products) and FDA (all other foods). EPA is responsible for the regulation and tolerance-setting of all pesticide products sold or distributed in the United States.

*residue
amts. on
food*

Registration is a type of license for marketing that indicates a product has been reviewed by the EPA and determined to have no unreasonable adverse effects to human life or the environment under the proposed use at the time of registration. Pesticides are registered through a process provided for by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Periodically, pesticides have to be "reregistered" -- the systematic reevaluation of old pesticides. 1988 Amendments to FIFRA require EPA to accelerate the process of reregistration. In particular, EPA has been directed, within the next nine years, to complete reregistration of the 600 active ingredients appearing in approximately 20,000 different pesticide products. Since EPA may require as many as 100 different studies on an active ingredient, the Agency will be receiving a tremendous amount of new data in the next few years. Undoubtedly, some of the new studies will raise concerns about the safety of these pesticides and EPA will need to take action to modify or eliminate their use.

Before a pesticide can be registered for use on food or animal feed, a tolerance must be established. A tolerance is the maximum amount of a pesticide residue that can legally occur on or in a food or animal feed. Products with pesticide residues exceeding tolerance levels are considered adulterated and subject to legal sanctions. Tolerances are set under the Federal Food, Drug and Cosmetic Act (FFDCA), which has evolved separately from pesticide registration authorities.

Principal Problems With Current Laws:

The statutory standards for decision-making under FIFRA and FFDCA are not consistent, and in some instances actually conflict. The standard for registering or cancelling a pesticide under FIFRA requires EPA to consider both the risks and benefits of its use. Similarly, in setting most tolerances under FFDCA, EPA interprets the law to allow consideration of costs and benefits. However, the Delaney Clause, which governs one section of FFDCA applying to residues of carcinogenic pesticides in processed food (e.g., tomato paste), contains a rigid, risk-only standard. If read literally, the Delaney Clause bars EPA from setting a tolerance for any pesticide in processed food if the pesticide causes cancer in humans or animals no matter how small the risk or how large the benefits.

Dissatisfied with the difficulties in administering the incompatible statutory standards of FIFRA and FFDCA, EPA asked the National Academy of Science (NAS) to study the Delaney Clause. The NAS report concluded there was no valid scientific basis for the Delaney Clause and recommended that all pesticides be regulated under the same statutory standard. The NAS noted that a "negligible risk" standard would reduce overall risk.

The recent controversy concerning Alar in apples served to heighten public attention on food safety issues and also raised questions about EPA's ability to deal promptly with the continuing use of a cancer causing pesticide on food utilizing existing suspension and cancellation procedures. Critics have charged that existing FIFRA suspension and cancellation procedures are too lengthy to deal effectively with pesticides that raise safety concerns.

*new
use-
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pesticides*

Currently, the administrative process for removing a dangerous pesticide from the market can take four to eight years to complete. The process begins with a determination by EPA that continued use of the pesticide poses some threat to human health or the environment. If EPA decides to pursue cancellation, a formal administrative process ensues, which can include a hearing before an administrative law judge. Judicial review of the EPA's final order is also available. During this entire time, the product remains on the market unless EPA finds that it poses an "imminent hazard." Such a finding will allow immediate suspension or temporary cancellation. This finding is rarely made, however, and has been utilized only three times in eighteen years.

who? All concerned agencies of the federal government agree that this mechanism for removing pesticides from the marketplace is cumbersome and has seriously undermined public and Congressional confidence in food safety regulation.

Congressional Activity:

Efforts to solve these problems by amending FIFRA and FFDCA have been building in Congress for years. These efforts were recently spurred by the difficulty in dealing with Alar in apples.

In 1988, Representative Waxman introduced a bill to amend FFDCA and address some of the problems identified by NAS regarding risk/benefit analysis. The Waxman bill eliminated the Delaney Clause for pesticide residues that are carcinogens and adopted a single standard for all pesticide tolerances based on "negligible risk." For carcinogenic pesticides, the negligible risk standard used in the bill was an increased statistical risk of one additional cancer case in every one million people exposed to the pesticide over an entire lifetime (1×10^{-6}). No action was taken on the 1988 bill.

In the spring of 1989 Representative Waxman introduced a stricter bill. The most notable changes in the 1989 bill are a stricter negligible risk standard and a series of very tight deadlines for EPA to reevaluate all tolerances. No provision has been made to coordinate those reviews with EPA's current reregistration deadlines under FIFRA. Furthermore, although the 1989 Waxman bill still contains the one in one million standard for carcinogens, it adds additional language to tighten the standard in some cases to at least one in one hundred million for foods consumed throughout the United States. Finally, the Waxman bill does not provide for consistency or coordination between FFDCA and FIFRA.

Discussion:

The DPC Health Policy Working Group tasked the EPA, USDA, and FDA to develop a coordinated set of proposed revisions to FFDCA and FIFRA. The interagency discussion has focused on seven issues, two relating to FFDCA and five to FIFRA. The FFDCA issues focus on reformulating the risk standards for residues of carcinogenic pesticides in food and whether tolerances established for pesticide residues under the FFDCA should override tolerance setting activities by States. The FIFRA issues relate to simplifying and speeding the process for suspending and cancelling pesticides that do not meet the statutory standards, reevaluating registrations, and strengthening authority to enforce FIFRA requirements.

In order, the seven issues are:

1. Establishment of Tolerance Levels. (FFDCA)
2. National Uniformity. (FFDCA)
3. Termination of Registration. (FIFRA)
4. Definition of "Imminent Hazard." (FIFRA)

5. Simplification of the Cancellation Process. (FIFRA)
6. Consultation within the Government. (FIFRA)
7. Enforcement. (FIFRA)

There is unanimity that FFDCA and FIFRA are in need of amendment, and the affected agencies have reached agreement on the seven issues as described below.

FFDCA ISSUES: Tolerance Setting and Uniformity:

ISSUE I: Establishment of Tolerance Levels: Standards and Implementation

Current law is not consistent because the usual process of tolerance setting based on risk assessment is precluded in one particular situation, namely residues of a carcinogen in processed foods. The Delaney Clause imposes a "zero-risk" standard in this case. This means that no substance which causes cancer in humans or animals can be deemed safe for use in any amount -- no matter how insignificant the risks to health or how great the costs to society. In light of current scientific ability to measure residues in minute amounts, this poses a virtually impossible standard.

All parties agree that, for pesticide residues in food posing carcinogenic risks, FFDCA should be amended to eliminate the Delaney Clause and add a tolerance threshold at or below which the public health is not threatened. The term which sets the standard for this new threshold is "negligible risk." There is interagency consensus on the following approach:

- A. There should be a tolerance level for pesticide residues in food, below which it is deemed that the public health is not threatened, and therefore a pesticide which satisfies this requirement could continue to be used. The tolerance level for various carcinogenic chemical substances will be established based on a predicted risk level as stated below. (This de minimis risk level replaces the concept of zero risk for cancer contained in the Delaney Clause.)

how will minimum risk be determined?

Key Point

1. Standard. The level of risk below which public health is not threatened is a level that is found to be negligible. Under appropriate regulatory risk-assessment procedures, this translates into a statistical risk level at or below a range of risk of 10^{-5} to 10^{-6} based on lifetime exposure.

what is this?

how is this to be determined?

I would think that FDA should have the lead here

2. Implementation and enforcement. In implementing and enforcing this standard, EPA, in consultation with USDA and FDA, will describe through rulemaking or other formal guidance the following:

- a. The process and procedures through which the specific tolerance level determinations are to be made; and
- b. The nature and types of human carcinogens to which the standard will be applied. This could be in terms of the existing carcinogen classifications that relate to animal and human carcinogenicity, or in other terms agreed to.

B. In order to establish a tolerance in cases when the level of human health risk is greater than negligible, the EPA shall consider the following factors:

1. Whether the risk to human health or the environment is greater from the uncontrolled pest than from the dietary risk posed by the pesticide chemical residue;
2. Whether the risk to human health or the environment is greater from alternative methods of pest control than from the dietary risk posed by the pesticide chemical residue;
3. The economic costs to consumers, including effects on price, availability and quality of food;
4. The economic effects on producers, whether they be gains or losses, including changes in prices or production; and
5. Whether reasonable efforts are being made to develop either an alternative method of pest control or an alternative pesticide chemical for use on such commodity or food.

ISSUE II: National Uniformity: When Applicable

Under current law, states may set tolerances for pesticide residues in food that are lower than those established by EPA. When states have done so, it has been a source of real concern to the food distribution industry and a source of confusion to consumers. USDA believes inconsistent tolerances could have significant adverse impacts on the ability of the United States to participate in international trade of raw agricultural

commodities and processed foods. All affected agencies agree on the following approach:

The affected agencies agree that national uniformity should be provided by statute for chemical tolerances established pursuant to the reregistration process described under the 1988 amendments to FIFRA. Any state or local standards applicable to the same chemical substances must be identical to federal standards; provided that a state may enforce a more stringent standard if it has obtained a waiver from EPA pursuant to published procedures and criteria. The criteria will allow waivers only when special local circumstances warrant.

FIFRA ISSUES: Streamlining the Suspension, Cancellation, and Re-registration Process.

Since the federal government began regulating pesticides, the underlying science and the consensus on acceptable levels of risk have changed dramatically. Thus, many pesticides have not been fully evaluated for safety by current scientific standards.

Lack of complete and up-to-date scientific evaluation of "old" pesticides is the root cause of dissatisfaction with the current regulatory system, since it results in EPA needing more data to complete risk assessments, and thus delays final decisions on food safety issues. Generally, three specific criticisms are raised: (1) data to determine which old chemicals may pose unacceptable risks are not being obtained fast enough; (2) EPA's assessment procedures are too slow to make decisions about whether a pesticide poses unacceptable risks; and (3) once EPA decides how to deal with a "bad pesticide," the administrative mechanisms available to implement decisions are too slow. All of these criticisms have been prominent in the recent debate about EPA's handling of Alar and other toxic pesticides in the food supply.

Amendments to FIFRA in 1988 significantly accelerated the pace of reregistration, requiring that EPA complete the task by 1997. EPA does not believe it is possible to finish this job sooner than 1997, due to the length of many of the studies which are required and the scarcity of testing facilities and scientific reviewers.

Currently, EPA has two ways to remove a pesticide from the marketplace: 1) cancellation and 2) temporary termination, known as suspension. Cancellation can require an extraordinary amount of time, and suspension is available only in very limited situations. As EPA obtains and reviews new information on currently registered pesticides, it will identify some which may pose previously unrecognized risks to people or the environment. If an "imminent hazard" exists, EPA may immediately suspend sale

and use through a temporary termination. Historically, EPA has only made those findings three times--for EDB, 2,4,5-T, and dinoseb. EPA expects such cases to be equally rare in the future.

More often, if new data show a significant risk, EPA will use the procedures for cancellation. The current system to cancel a pesticide (remove it from the market) when new evidence of risk arises can take 4 to 8 years to complete the administrative process. Registrants submit comments and new data during EPA's risk/benefit evaluation known as Special Review (a 2 to 4 year process). They may then ask for an administrative hearing to challenge the Special Review decision (2 to 4 more years). The pesticide remains in use during both of these procedures. The final EPA ruling may then be challenged in federal court. Faced with this process, the Agency has on occasion negotiated risk reduction measures with registrants in order to achieve more timely protective results; however, this option is not always available.

There is interagency consensus to address these problems through approaches described below for Issues III through VII: //

ISSUE III: Termination of Registration: Cancellation; Failure to Establish Continued Eligibility

Under current law (and not changed by these proposals), a registered pesticide chemical may have its registration terminated either temporarily (suspension) or permanently (cancellation). EPA also has general authority to suspend registrations for failure to provide required data. In addition to current suspension authority, this proposal would specify that:

- A. Registrants shall ensure that EPA is provided with data and information necessary to permit EPA to determine, in light of the then-applicable standards for new pesticide registrations, whether a cancellation proceeding in a given instance is warranted. Data will be provided within the following time frames: Following first registration, 19 years for pre-1984 registrations, and 15 years for 1984 and later registrations. Thereafter, every 9 years.
- B. If a registrant fails to provide EPA with the data and information required by applicable regulations or guidelines within a reasonable time after it is due or requested, EPA may order temporary termination (suspension) of the registration. ?

ISSUE IV: Definition of "Imminent Hazard"

Under current law, EPA has authority to suspend a registration if it is found to pose an "imminent hazard" to health or to the environment. Current suspension authority has a very high risk threshold that can rarely be sustained, and has little practical utility regardless of the nature or immediacy of the risk. Under the new proposal, an "imminent hazard" will be redefined to exist in either of the following circumstances:

- A. Continued use of the pesticide during the period required for cancellation would pose a substantial risk to the environment or to human health based on lifetime risk, and the risk of continued pesticide use (1) exceeds the risk posed by the substitution of alternative pesticides or other available pest control methods, or (2), in the absence of alternative pest control methods, exceeds the adverse effects of any pest which would have been controlled by the pesticide during the period required for cancellation; or
- B. Continued use of the pesticide will cause a less than substantial but significant risk to health or the environment, which, in light of the reasonably available facts and circumstances, is unreasonable, taking into account the price and availability of raw agricultural commodities and processed foods.

ISSUE V: Simplification of the Cancellation Process

Under the existing cancellation process, there is first an administrative review process in which the registrant fully participates. Then, if requested, a formal adjudicatory process with a full de novo evidentiary hearing before an Administrative Law Judge may be pursued. Finally, the registrant may also seek a full judicial review. There is interagency agreement that streamlining is necessary.

To simplify the process, in lieu of the middle step (the full de novo evidentiary hearing before an ALJ), there would be a requirement for EPA to publish (in the Federal Register) notice of, and the grounds for, its intended action. The process would include an opportunity for the registrant and others to make written submissions during a specified comment period (typically 60 days).

The administrator could also hold an informal public hearing on the issue during the comment period. There would be no requirement that anyone be forced to testify or respond to cross examination.

If the registrant requests such a public hearing, the administrator shall hold the hearing unless the administrator determines the hearing is not warranted and the registrant is thereby not prejudiced.

ISSUE VI: Consultation within the Government

Current consultation among EPA, USDA and HHS primarily occurs in the form of written comment during the cancellation process. All affected agencies agree that closer consultation throughout the process would be beneficial. Accordingly, it was agreed that there should be appropriate consultation among EPA, USDA and HHS prior to issuance of cancellation and suspension orders, and at such other times as may be agreed to in a Memorandum of Understanding.

This Memorandum of Understanding will lay out the points in the process at which consultation shall occur, and will stipulate how consultation shall be accomplished. This consultation will be for the benefit of the Administration's implementation of its programs, and will be subject to oversight by the Executive Office of the President. It, therefore, should not be the subject of judicial review.

ISSUE VII: Enforcement

EPA believes existing enforcement authorities under FIFRA are inadequate to foster voluntary compliance. EPA proposes to amend FIFRA to strengthen recordkeeping requirements, provisions regarding entry onto premises for inspection and sampling, and penalties.

*bad
publicity
for
companies
works.*

Enhanced enforcement provisions are appropriate because violations of FIFRA -- which involve misuse of dangerous chemicals -- result in harms that are similar in nature to, and equally as serious as, violations of other environmental statutes. Those violations result in penalties, both civil and criminal, that are much more severe than FIFRA currently provides. Most environmental statutes (Clean Water Act, Resource Conservation and Recovery Act, Superfund, and the Safe Drinking Water Act) have been revised in recent years to strengthen civil and criminal enforcement provisions significantly. Primarily, they provide felony penalties for knowing violations of the acts, and for knowing endangerment offenses. They also have expanded civil and administrative penalty provisions.

EPA's proposed FIFRA provisions would apply to pesticide producers, testing facilities and persons who sell, distribute, or commercially apply pesticides. Private applicators, such as farmers, would be required to keep records of their use of

backyard vegetable gardens?
these should be an insert for
either production amounts or commercial
products (+ don't include the roadside
stand of some enterprising child!)

10

restricted use pesticides and could be inspected for cause. Farmers, and others, who only use general use pesticides would not be required to keep records, but could be inspected for suspected violations or when the Agency or states are seeking information as part of an inquiry into specific environmental or health problems.

Maximum allowable civil administrative penalties would be increased from \$5,000 to \$25,000 per day for violations of provisions governing sales, distribution, or commercial use. EPA will be able to take mitigating factors into account in determining whether a warning or lesser penalty is appropriate, as current law provides. Private applicators who violate FIFRA while using a restricted use pesticide would be subject to a maximum first time penalty of \$1,000. Knowing violation of the Act would be raised to a felony for most parties (e.g., registrants, distributors, pesticide testing facilities) and a new "knowing endangerment" offense would be established for all persons subject to the Act. Knowing violations by private applicators would remain misdemeanors, unless they constitute knowing endangerment.

The statutory provisions that grant primary enforcement authority to the states would not be altered.

Conclusion of the Health Policy Working Group:

Consensus has been achieved at the working group level on all the issues. The Health Policy Working Group recommends that the approach described above be favorably considered by the Domestic Policy Council.

THE WHITE HOUSE
WASHINGTON

CABINET AFFAIRS STAFFING MEMORANDUM

Date: Sept. 12, 1989 **Number:** _____ **Due By:** _____
Subject: Eighteenth Meeting of the Domestic Policy Council, Thursday,
 September 14, 1989, 3:00 P.M. in the Roosevelt Room

	Action	FYI		Action	FYI
ALL CABINET MEMBERS	☐	☐	CEA	☒	☐
Vice President	☒	☐	CEQ	☒	☐
State	☐	☐	OSTP	☐	☐
Treasury	☐	☐	_____	☐	☐
Defense	☐	☐	_____	☐	☐
Justice	☒	☐	_____	☐	☐
Interior	☒	☐	_____	☐	☐
Agriculture	☒	☐	Scowcroft	☐	☐
Commerce	☐	☐	Porter	☐	☐
Labor	☐	☐	Breeden	☐	☐
HHS	☒	☐	Cicconi (For WH Staffing)	☒	☐
HUD	☒	☐	_____	☐	☐
Transportation	☒	☐	_____	☐	☐
Energy	☒	☐	_____	☐	☐
Education	☒	☐	_____	☐	☐
Veterans	☒	☐	_____	☐	☐
OMB	☒	☐	_____	☐	☐
USTR	☐	☐	_____	☐	☐
Chief of Staff	☒	☐	Executive Secretary for:		
UN	☐	☐	DPC	☐	☐
CIA	☐	☐	EPC	☐	☒
National Drug Policy	☐	☐	_____	☐	☐
EPA	☒	☐	_____	☐	☐
GSA	☐	☐	_____	☐	☐
NASA	☐	☐	_____	☐	☐
OPM	☐	☐	_____	☐	☐
SBA	☐	☐	_____	☐	☐

REMARKS: Attached is an agenda and a paper on Food Safety Regulation which will be presented at the 18th meeting of the Domestic Policy Council on Thursday, Sept. 14, 1989 from ~~3:00~~ to ~~4:00~~ PM in the Roosevelt Room. The paper is sensitive in nature and should be treated as a close hold document.

Please note that this is a meeting for principals only, and your office should phone Justine (456-2800) by COB, Wednesday, Sept. 13, as to whether or not you will attend the meeting.

RETURN TO:

☐ David Q. Bates
 Cabinet Secretary
 456-2174
 (1st Floor, West Wing)

☐ Associate Director
 Office of Cabinet Affairs
 456-2800
 (Room 235, OE0B)

THE WHITE HOUSE

WASHINGTON

September 12, 1989

Health Policy work group.

MEMORANDUM FOR THE DOMESTIC POLICY COUNCIL

FROM: KENNETH P. YALE *KY*
Executive Secretary

SUBJECT: Eighteenth Meeting of the Domestic Policy Council,
Thursday, September 14, 1989, 3:00 PM in the
Roosevelt Room

The Domestic Policy Council will hold its eighteenth meeting, **for principals only**, on Thursday, September 14, 1989 from ~~3:00~~ to ~~4:00~~ PM in the Roosevelt Room. The purpose of the meeting will be to discuss the attached paper on Food Safety Regulation which will be presented by William L. Roper, Deputy Assistant to the President for Domestic Policy and Chairman of the Health Policy Working Group. **Please note that this paper is sensitive in nature and should be treated as a close hold document.**

Also attached for your information is an agenda for the DPC meeting.

Please phone Justine (456-2800) by C.O.B. Wednesday, September 13, 1989, as to whether or not you will attend the meeting.

Attachments

THE WHITE HOUSE
WASHINGTON

DOMESTIC POLICY COUNCIL

Thursday, September 14, 1989

~~4~~3:00 P.M.

Roosevelt Room

AGENDA

Food Safety Regulation

FOOD SAFETY REGULATION

September 11, 1989

Issue:

What steps should the Administration take to improve the federal government's ability to protect American consumers from dangers posed by the use of pesticide chemicals on or in food products?

Background:

meat poultry eggs

Federal jurisdiction over pesticide residues in food is divided among the Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA). Monitoring and enforcement responsibilities for domestically produced and imported foods are handled by USDA (meat, poultry and egg products) and FDA (all other foods). EPA is responsible for the regulation and tolerance-setting of all pesticide products sold or distributed in the United States.

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ISSUE I: Establishment of Tolerance Levels: Standards and Implementation

Current law is not consistent because the usual process of tolerance setting based on risk assessment is precluded in one particular situation, namely residues of a carcinogen in processed foods. The Delaney Clause imposes a "zero-risk" standard in this case. This means that no substance which causes cancer in humans or animals can be deemed safe for use in any amount -- no matter how insignificant the risks to health or how great the costs to society. In light of current scientific ability to measure residues in minute amounts, this poses a virtually impossible standard.

All parties agree that, for pesticide residues in food posing carcinogenic risks, FFDCA should be amended to eliminate the Delaney Clause and add a tolerance threshold at or below which the public health is not threatened. The term which sets the standard for this new threshold is "negligible risk." There is interagency consensus on the following approach:

- A. There should be a tolerance level for pesticide residues in food, below which it is deemed that the public health is not threatened, and therefore a pesticide which satisfies this requirement could continue to be used. The tolerance level for various carcinogenic chemical substances will be established based on a predicted risk level as stated below. (This de minimis risk level replaces the concept of zero risk for cancer contained in the Delaney Clause.)
 1. Standard. The level of risk below which public health is not threatened is a level that is found to be negligible. Under appropriate regulatory risk-assessment procedures, this translates into a statistical risk level at or below a range of risk of 10^{-5} to 10^{-6} based on lifetime exposure.

2. Implementation and enforcement. In implementing and enforcing this standard, EPA, in consultation with USDA and FDA, will describe through rulemaking or other formal guidance the following:
 - a. The process and procedures through which the specific tolerance level determinations are to be made; and
 - b. The nature and types of human carcinogens to which the standard will be applied. This could be in terms of the existing carcinogen classifications that relate to animal and human carcinogenicity, or in other terms agreed to.
- B. In order to establish a tolerance in cases when the level of human health risk is greater than negligible, the EPA shall consider the following factors:
 1. Whether the risk to human health or the environment is greater from the uncontrolled pest than from the dietary risk posed by the pesticide chemical residue;
 2. Whether the risk to human health or the environment is greater from alternative methods of pest control than from the dietary risk posed by the pesticide chemical residue;
 3. The economic costs to consumers, including effects on price, availability and quality of food;
 4. The economic effects on producers, whether they be gains or losses, including changes in prices or production; and
 5. Whether reasonable efforts are being made to develop either an alternative method of pest control or an alternative pesticide chemical for use on such commodity or food.

ISSUE II: National Uniformity: When Applicable

Under current law, states may set tolerances for pesticide residues in food that are lower than those established by EPA. When states have done so, it has been a source of real concern to the food distribution industry and a source of confusion to consumers. USDA believes inconsistent tolerances could have significant adverse impacts on the ability of the United States to participate in international trade of raw agricultural

commodities and processed foods. All affected agencies agree on the following approach:

The affected agencies agree that national uniformity should be provided by statute for chemical tolerances established pursuant to the reregistration process described under the 1988 amendments to FIFRA. Any state or local standards applicable to the same chemical substances must be identical to federal standards; provided that a state may enforce a more stringent standard if it has obtained a waiver from EPA pursuant to published procedures and criteria. The criteria will allow waivers only when special local circumstances warrant.

FIFRA ISSUES: Streamlining the Suspension, Cancellation, and Re-registration Process.

Since the federal government began regulating pesticides, the underlying science and the consensus on acceptable levels of risk have changed dramatically. Thus, many pesticides have not been fully evaluated for safety by current scientific standards.

Lack of complete and up-to-date scientific evaluation of "old" pesticides is the root cause of dissatisfaction with the current regulatory system, since it results in EPA needing more data to complete risk assessments, and thus delays final decisions on food safety issues. Generally, three specific criticisms are raised: (1) data to determine which old chemicals may pose unacceptable risks are not being obtained fast enough; (2) EPA's assessment procedures are too slow to make decisions about whether a pesticide poses unacceptable risks; and (3) once EPA decides how to deal with a "bad pesticide," the administrative mechanisms available to implement decisions are too slow. All of these criticisms have been prominent in the recent debate about EPA's handling of Alar and other toxic pesticides in the food supply.

Amendments to FIFRA in 1988 significantly accelerated the pace of reregistration, requiring that EPA complete the task by 1997. EPA does not believe it is possible to finish this job sooner than 1997, due to the length of many of the studies which are required and the scarcity of testing facilities and scientific reviewers.

Currently, EPA has two ways to remove a pesticide from the marketplace: 1) cancellation and 2) temporary termination, known as suspension. Cancellation can require an extraordinary amount of time, and suspension is available only in very limited situations. As EPA obtains and reviews new information on currently registered pesticides, it will identify some which may pose previously unrecognized risks to people or the environment. If an "imminent hazard" exists, EPA may immediately suspend sale

and use through a temporary termination. Historically, EPA has only made those findings three times--for EDB, 2,4,5-T, and dinoseb. EPA expects such cases to be equally rare in the future.

More often, if new data show a significant risk, EPA will use the procedures for cancellation. The current system to cancel a pesticide (remove it from the market) when new evidence of risk arises can take 4 to 8 years to complete the administrative process. Registrants submit comments and new data during EPA's risk/benefit evaluation known as Special Review (a 2 to 4 year process). They may then ask for an administrative hearing to challenge the Special Review decision (2 to 4 more years). The pesticide remains in use during both of these procedures. The final EPA ruling may then be challenged in federal court. Faced with this process, the Agency has on occasion negotiated risk reduction measures with registrants in order to achieve more timely protective results; however, this option is not always available.

There is interagency consensus to address these problems through approaches described below for Issues III through VII:

ISSUE III: Termination of Registration: Cancellation; Failure to Establish Continued Eligibility

Under current law (and not changed by these proposals), a registered pesticide chemical may have its registration terminated either temporarily (suspension) or permanently (cancellation). EPA also has general authority to suspend registrations for failure to provide required data. In addition to current suspension authority, this proposal would specify that:

- A. Registrants shall ensure that EPA is provided with data and information necessary to permit EPA to determine, in light of the then-applicable standards for new pesticide registrations, whether a cancellation proceeding in a given instance is warranted. Data will be provided within the following time frames: Following first registration, 19 years for pre-1984 registrations, and 15 years for 1984 and later registrations. Thereafter, every 9 years.
- B. If a registrant fails to provide EPA with the data and information required by applicable regulations or guidelines within a reasonable time after it is due or requested, EPA may order temporary termination (suspension) of the registration.

ISSUE IV: Definition of "Imminent Hazard"

Under current law, EPA has authority to suspend a registration if it is found to pose an "imminent hazard" to health or to the environment. Current suspension authority has a very high risk threshold that can rarely be sustained, and has little practical utility regardless of the nature or immediacy of the risk. Under the new proposal, an "imminent hazard" will be redefined to exist in either of the following circumstances:

- A. Continued use of the pesticide during the period required for cancellation would pose a substantial risk to the environment or to human health based on lifetime risk, and the risk of continued pesticide use (1) exceeds the risk posed by the substitution of alternative pesticides or other available pest control methods, or (2), in the absence of alternative pest control methods, exceeds the adverse effects of any pest which would have been controlled by the pesticide during the period required for cancellation; or
- B. Continued use of the pesticide will cause a less than substantial but significant risk to health or the environment, which, in light of the reasonably available facts and circumstances, is unreasonable, taking into account the price and availability of raw agricultural commodities and processed foods.

ISSUE V: Simplification of the Cancellation Process

Under the existing cancellation process, there is first an administrative review process in which the registrant fully participates. Then, if requested, a formal adjudicatory process with a full de novo evidentiary hearing before an Administrative Law Judge may be pursued. Finally, the registrant may also seek a full judicial review. There is interagency agreement that streamlining is necessary.

To simplify the process, in lieu of the middle step (the full de novo evidentiary hearing before an ALJ), there would be a requirement for EPA to publish (in the Federal Register) notice of, and the grounds for, its intended action. The process would include an opportunity for the registrant and others to make written submissions during a specified comment period (typically 60 days).

The administrator could also hold an informal public hearing on the issue during the comment period. There would be no requirement that anyone be forced to testify or respond to cross examination.

If the registrant requests such a public hearing, the administrator shall hold the hearing unless the administrator determines the hearing is not warranted and the registrant is thereby not prejudiced.

ISSUE VI: Consultation within the Government

Current consultation among EPA, USDA and HHS primarily occurs in the form of written comment during the cancellation process. All affected agencies agree that closer consultation throughout the process would be beneficial. Accordingly, it was agreed that there should be appropriate consultation among EPA, USDA and HHS prior to issuance of cancellation and suspension orders, and at such other times as may be agreed to in a Memorandum of Understanding.

This Memorandum of Understanding will lay out the points in the process at which consultation shall occur, and will stipulate how consultation shall be accomplished. This consultation will be for the benefit of the Administration's implementation of its programs, and will be subject to oversight by the Executive Office of the President. It, therefore, should not be the subject of judicial review.

ISSUE VII: Enforcement

EPA believes existing enforcement authorities under FIFRA are inadequate to foster voluntary compliance. EPA proposes to amend FIFRA to strengthen recordkeeping requirements, provisions regarding entry onto premises for inspection and sampling, and penalties.

Enhanced enforcement provisions are appropriate because violations of FIFRA -- which involve misuse of dangerous chemicals -- result in harms that are similar in nature to, and equally as serious as, violations of other environmental statutes. Those violations result in penalties, both civil and criminal, that are much more severe than FIFRA currently provides. Most environmental statutes (Clean Water Act, Resource Conservation and Recovery Act, Superfund, and the Safe Drinking Water Act) have been revised in recent years to strengthen civil and criminal enforcement provisions significantly. Primarily, they provide felony penalties for knowing violations of the acts, and for knowing endangerment offenses. They also have expanded civil and administrative penalty provisions.

EPA's proposed FIFRA provisions would apply to pesticide producers, testing facilities and persons who sell, distribute, or commercially apply pesticides. Private applicators, such as farmers, would be required to keep records of their use of

restricted use pesticides and could be inspected for cause. Farmers, and others, who only use general use pesticides would not be required to keep records, but could be inspected for suspected violations or when the Agency or states are seeking information as part of an inquiry into specific environmental or health problems.

Maximum allowable civil administrative penalties would be increased from \$5,000 to \$25,000 per day for violations of provisions governing sales, distribution, or commercial use. EPA will be able to take mitigating factors into account in determining whether a warning or lesser penalty is appropriate, as current law provides. Private applicators who violate FIFRA while using a restricted use pesticide would be subject to a maximum first time penalty of \$1,000. Knowing violation of the Act would be raised to a felony for most parties (e.g., registrants, distributors, pesticide testing facilities) and a new "knowing endangerment" offense would be established for all persons subject to the Act. Knowing violations by private applicators would remain misdemeanors, unless they constitute knowing endangerment.

The statutory provisions that grant primary enforcement authority to the states would not be altered.

Conclusion of the Health Policy Working Group:

Consensus has been achieved at the working group level on all the issues. The Health Policy Working Group recommends that the approach described above be favorably considered by the Domestic Policy Council.