Case Number: 2013-0836-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the Clinton Presidential Library Staff.

Folder Title: Biotechnology [1]				
Staff Office-Individual: International Economic Affairs-Samans, Richard				
Original OA/ID Number: 3946				
Row: 38	Section: 5	Shelf: 3	Position: 1	Stack: V

Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
~~001. note~~	~~Handwritten notes re: trade negotiations (17 pages)~~	~~n.d.~~	~~P1/b(1)~~ RL 11/26/2019

COLLECTION:
Clinton Presidential Records
National Security Council
International Economic Affairs (Samans, Richard)
OA/Box Number: 3946

FOLDER TITLE:
Biotechnology [1]

2013-0836-F
ke2999

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Whaling

Bangladesh GSP

Gene -> JEPC

Biotech Larson meeting
end of this wk or Monday

Burma mtg. + paper

* NSC POTUS Library

Wool Proclamation

AGOA Proclamation

Other Proc?

Bennett Freeman -> Rep. McDermott

Environment
-> EO guidelines issuance
-> NAFTA expropriations
-> TPSC changes
-> Leveling Up Cable

Child Poverty Event

Basic Education

→ Gene meeting

- World Bank

School lunch

→ implementation

→ legislation

Ed Barron

Colombia/Bolivia => CBTPA

Byrd amendment

Jordan FTA legislature?

Nigeria debt/OMB + Treasury

→ ready for JEFC?

Trade Compliance

~~I+E monitoring implementation~~

UK trip: development speech => Malmousk;

Gene to call Leach?

Sen. Kerry + Vietnam: any follow up?

Sidney

Dec. 4 discussions begin
- TPSC mtg. on 11/22
- Fed Reg notice approved
- ER to be done by both
- paper to be circulated today on US position

textiles
rules of origin
enforcement / transshipment
services
investment

Services
GATS list exists + would be basis

Investment
- they've resisted BIT
- FTAA basis
- national treatment
- investor - state arbitration

Jordan + on Labor + Environment
① cooperation in combating illegal trade (CFCs)
② product certifications (regional lab/hub)
③ electronic waste recycling

→ expro → differential impact → expro → MAI language

★ Investment

→ bootstrap BIT

→ expro agreement possible

→ anti-money laundering

→ Korea BIT as model

→ section 1114 language

★ Services

positive approach (list) vs.

→ NAFTA negative ⇒ positive faster but conflicts w/ NAFTA → Chile/FTAA implications

Geneva proposal on e-commerce → bootstrap in

Immigration? → limited to GATS treatment
temporary

★ – dispute settlement

★ – rules of origin

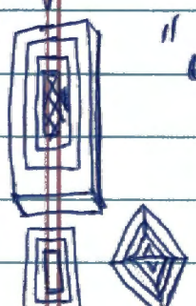
CBI rules inadequate; can't go simplest rate

– substantial transformation vs. shifting classification categories

"appropriate + commensurate ~~measures~~ action"

→ "withdrawal of benefits under the agreement"

→ fair + equitable
min std of treatment under int'l law



Fair

more procedurally detailed
→ submissions, transparency
→ what response if violation
→ amicus briefs

① trade sanctions avail WTO/NAFTA

② open Jordan

③ differentiates

Beier

-> US-Japan autos; steel 201 need to be thought about in integrated fashion w/ other priorities

Barshefsky

-> Tommy Koh lead negotiator, => environmental

Services

IPR => copyright concerns

Investment

Beier -> key issues intractable enough to make conclusion this year feasible

->transhipment

- dispute settlement => investment + services

Berger

- don't undermine legacy
- don't risk blowing up FTA under Rep. administration
- don't raise bar because could be invoked as standard for future WTO + bilateral deals, which might be unacceptable
- don't Δ bar from Jordan

Karen: stick w/ Jordan model + consolidate; don't push further now; get it passed

CB: Rule of Origin -> 2 step

- general rules
- no trade under FTA until specific rules established for pdts. sectors,

GS: POTUS wants to leave ~~footprint~~/template

SRS: development key

Need to win votes in Congress

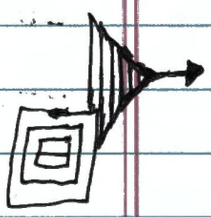
Will it be Pyrrhic (hurt further liberalization)

---

whaling

→ other collective action by IWC

- other diplomatic actions by IWC



- School feeding
- Expo
- Burma
- Biotech

Expo. mtg → Tues.

Singapore FTA

- Monday 4:30 plenary opening
- rolling tabling of proposals

- JEPC
- Oxford speech
- proclamations → AGOA

- Rules of origin mtg Monday

- Services
  - Treasury ok on posture

- "regulatory" deleted subject to — f/(other language) — Dam Ending examples

- portion of property and long-term vs. permanent
  - permanent of all or part portion ~~& to clarify~~
  - non-permanent of all property

- "only in the following circumstances" "when"

- Treasury ~~&~~ to Redraft "The Parties recognize..."
  and Lois to draft ftnote as alternative

- For purposes of expro
  Can't look behind whether measure has a public purpose.
  => (provision only applies to expro)
  Justice/USTR to draft

12/8 AFL → Burma

- new ICFTU reporting

- EU union confederation working w/ heads of state + trade ministers (Lamy as well)

- joint ownership of factories?

- ILO integrity/potency
- WTO credibility

- Military Holding Company → partnership
- forced relocations; forced labor in industrial park construction

- ICFTU report 1,000 ps. on activity since June ILO report
80% of people on border report forced labor activity

- All apparel factories are military co-or wholly owned

- Shrimp + timber use forced labor

- AFL to provide ICFTU confidential report sections

- 2 sites w/ 4 factories

Nautica, Bugle Boy, [Walmart + Jan Sport withdrew]

Unocal + Halliburton

India + US China Japan + Singapore, Fr + Germany

ILO (-) Malaysia, Japan
(+) France, UK Thai S Africa, Dominican R.

→ ILO follow mtg. 2/15
- AFL: FTA options

Biotech

→ slow progress on corn

→ consultative forum → report coming; will need to assess how we comment
- early ~~next~~ week

→ reaction to { EU Summit decision to promote precaution
potential
process to determine response

→ public diplomacy campaign
→ soy + corn animal feed dependance by EU
→ ~~release~~ distribute articles
→ Blair House unraveling? → WTO case

→ non-committal on OECD environ conference now
→ maybe 2002

→ I am to compile friends list

Research

- legal analysis
  ILO – WTO
- legal analysis => nexus
- multilateral diplomacy
- jawboning

- moral suasion
  -> what can we do (old investment / trade)
- quota call
- transhipment in SE Asia
- unilateral non-trade (diplomatic) measures => asset freeze
- multilateral diplomacy to build coalition
- roll back imports / IEEPA
  => affect

State

① Moral Suasion

- Secretary of State
- talk to import ass'n. ; parallel importers
- individual calls retailers

② raises issue of why gsi+ doesn't act
③ weak

→ precedents?
→ State EB + DRL to collaborate on a couple of PIs

⑦ Quota Call

2 categories now unrestrained
12 categories now

→ USTR believes could be defensible: drag on for a year in WTO; could cap at current levels; EB agrees; DoL believes 6 categories
→ could shift to other
→ would have to justify on import surge

⑬ Customs transhipment

→ WTO agreement
→ USTR maintains that could under WTO make case that
→ Burmese refused to show Customs around, but offered to lock it upstairs if Customs demonstrated that this was normal practice
→ not completely slammed door

Jon Rauber to Bill Schall

Call Bryan

④ - Forced labor justified
- Have Bite
  - Clearly symbolic
  - W no risks acceptable?

→ DRL total or partial restriction of imports w/ multilateral outreach

→ USTR wants broader +
  ⇒ non-trade (tourism; diplomatic representation)
  ⇒ fish + timber (where there's evidence of forced labor)
    ILO commission cited these two industries
  ⇒ equity partner sufficient nexus for ILO but not WTO?

non-trade econ: Bryan Samuel
non-economic: Eric
General trader

Non-trade measures
→ PNG sitting ambassador
→ tourism (how beyond
→ extend ban on investment to certain services
→ airlines
→ Helms-Burton style sanctions
→ asset freeze from military holds
→ Disinvestment (Jawbone UNOCAL)

Multilateral
→ visa
→ new investment ban

① Do general (w/o nexus)

② Do limited w/ nexus to mitigate risks
  add to either { non-trade economic / non-economic

International diplomacy

→ US - EU

→ POTUS - Blair mtg?

→ cable to other countries:

⇒ consult over

⇒

State
Skip;
Ed McW

Authority

- Treasury believes IEEPA a bad option → because could be abused & draw concern Congress
- Harold Koh wrote article on IEEPA use

add letter from Hill Mc

I spoke to ~~Lori~~ Karen before the meeting. She recommended going ahead w/o her. She thought that what made sense would be for us to organize a public information campaign now (consumers, companies).

link to forced labor
signal
bite
WTO rocks

Tourism
- WTO pblms w/ GATS
- organise govt. discouragement of tourism
=> follow up by Jon/Commerce/Andrew

Asset Freeze
=> follow up w/ Kohn's group
=> OFAC to research what other countries have asset freezes in place

Disinvestment
=> USG stmt.
=> inside pressure on Unocal to exert pressure on Burma
=> check on IFI lending; also private K mkts.
<=> Asian DBs

Public Education
Andrew, DRL others to work

Somalia - Moore delegate

301
- requires burden on US commerce
-

★ Develop broader and narrow options w/ respect to Texas
-> drop pretense about WTO defense
(Jon/Andrew + Harold)

NAFTA Expropriation Interpretation Proposal [12/13/00]

[Key: Areas for consideration bracketed. Differences highlighted in bold.]

The expropriation provision set forth in NAFTA Article 1110(1) is intended to reflect customary international law concerning the obligations of states with respect to expropriation of property rights and property interests that fall within the definition of investment in Article 1139. This provision addresses two situations: first, direct expropriation, where an investment is nationalized or otherwise directly expropriated through formal transfer of title or outright seizure; second, indirect expropriation, where a measure or series of measures has an effect equivalent to direct expropriation without formal transfer of title or outright seizure. The language in Article 1110(1) that reads "or take a measure tantamount to a nationalization or expropriation" explains what "indirectly" means; it does not assert or imply the existence of an additional type of nationalization or expropriation beyond that encompassed in the concepts of "direct" and "indirect" nationalization or expropriation. A measure cannot be an expropriation unless it interferes with a property interest or right cognizable under the Party's laws.

In most circumstances, nondiscriminatory [*Econ* **regulatory**] [*Reg* **Omit**] measures that are designed to protect public health, safety, the environment or other public welfare interests do not constitute expropriations; such measures may constitute expropriations [*Reg* **only in the following circumstances**:] [*Econ* **only in very limited circumstances, most notably the following**:] (1) when they eliminate or virtually eliminate the economic value of or the investor's control over property, and the measures undermine the reasonable expectations of the investor,[1/] or (2) when they result in a permanent physical occupation of all or part of the property. [*Reg* **For the purposes of Article 1110, an arbitral tribunal will not substitute its views for those of a Party as to whether a measure is designed to protect public health, safety, the environment, or other public welfare interests.** *or* **An arbitral panel will accept the Party's view of whether a measure is designed to protect public health, safety, the environment, or other public welfare interests, so long as the Party has a rational basis for its view.**] [*Econ* **Omit any language on deference.**] The determination of whether a particular measure, in a specific factual situation, rises to the level of an expropriation [*Reg* **under the principles articulated above**] [*Econ* **Omit**] requires a case-by-case, fact-based inquiry. *Reg* fn 2/ *

[1/] A Party cannot defeat a claim by asserting that a claimant had a "reasonable expectation" that the Party would, for example, fail to enforce its laws or act in violation of domestic or international law.

[2/] [*Reg* **Since each of the Party's domestic takings or expropriation law is continually evolving, if the Parties' laws change significantly, the Parties may wish to re-examine this interpretation of NAFTA Article 1110, pursuant to Articles 1131 and 1132.**][*Econ* **Omit**]

Talked to Ignacia. She's working env agencies (a) to drop fn # 2 and to drop EPA's insert (*above). Underbrush. She's been talking with our lawyers to see if all could substitute "regulatory actions" for "regulatory measures." She's worried about defn of "measures" in NAFTA; we want "regulatory." Might work. If we probably need to close loop with Ignacia

"Samuel, E Bryan" <SamuelEB@state.gov>
12/13/2000 06:08:05 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: "Miley, Stephanie A(E)" <MileySA@STATE.GOV>
Subject: Agenda for Investment Meeting

Al suggests:
(a) NAFTA expro interpretation
(b) General treatment clause ("fair and equitable')
(c) Investor-state [MAYBE]
More specificity later.

AL wants to do These

He said he wanted to discuss judicial exhaustion here but I think it's premature and want to push back. The first two will take two hours.

Message Sent To:

Richard M. Samans/OPD/EOP
"'ignacia.moreno@usdoj.gov'" <ignacia.moreno@usdoj.gov>
"'chandlermp@state.gov'" <chandlermp@state.gov>
"'brooksj@state.gov'" <brooksj@state.gov>
"Renz, David W" <RenzDW@state.gov>
"Bay, Janice F" <BayJF2@state.gov>

ENVIRONMENTALLY AND SOCIALLY SUSTAINABLE
DEVELOPMENT STUDIES AND MONOGRAPHS SERIES 23

Work in progress
for public discussion

Bioengineering of Crops

Report of the World Bank Panel on Transgenic Crops

Henry W. Kendall, Roger Beachy, Thomas Eisner, Fred Gould, Robert Herdt, Peter H. Raven, Jozef S. Schell, and M.S. Swaminathan

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

KEY BIOTECH DISCUSSION ISSUES

1. Concerted USG efforts against EU obstacles on market access for US-approved biotechnology agriculture products and for a useful report from the US-EU Biotechnology Consultative Forum.

The EU has not approved biotech products since 1998, and it has several new initiatives that are likely to have a negative impact on U.S. biotech trade. Presidents Clinton and Prodi agreed in December 1999 on a two-track biotech approach to address biotechnology issues: U.S.-EU Consultative Forum comprised of non-governmental experts; and U.S.-EU Senior Level Group (SLG) dialogue on market access and other regulatory issues. Both are moving, but in low gear. The Forum was initially slowed by a science/non-science ideological divide, but the chairs are working to bridge the gap to produce a useful report by December for Presidents Clinton and Prodi. The SLG dialogue has been hampered by serious political barriers to progress on biotech in Europe and difficulties in getting our EU interlocutors to schedule discussions on issues. Results from either track of the Clinton-Prodi process are by no means guaranteed before the US-EU Summit. We are pressing Commission DG Legras on these issues but need to determine other steps we can take before the Summit.

Issues for Decision

We would like to convey to EU authorities that absent concrete results on these fronts before the December Summit, President Clinton's and Prodi's Biotechnology Initiative will be judged a failure and that this will have consequences for our trade relations. We especially want to have the EU restart its biotech approval process and its imports of already-approved U.S. biotech corn, and take clear action against the Italian ban on approved corn imports. Not only do we need to keep the pressure on through the SLG (now scheduled for November 21) but we should consider other actions, such as encouraging developing countries to speak out more on their biotech interests and publicizing more widely the inconsistencies in Europe's official biotech position, to raise the profile internationally.

2. **USG efforts to help form, influence and coordinate with "like-minded countries" (including developing countries) on biotechnology issues to maintain a science-based, rules based approach.**

To counter EU anti-biotech challenges, foster better global understanding of biotechnology, and strengthen our diplomacy in international fora such as CODEX and WTO, we need to help establish a broader group of like-minded countries on biotech issues. Countries such as Australia, Argentina, Brazil, Canada, Chile, China, India, Japan, Kenya, Malaysia, Mexico, Nigeria, Kenya, South Africa and Singapore are among countries we might cultivate. It is especially important that we engage a broader group on the CODEX negotiating agenda, both on labeling and on precaution. We can build upon, but should not duplicate, the Miami Group that was useful on the Biosafety Protocol.

Engaging in biotech capacity building in developing countries needs to be part of our effort to build the group. This would also follow up on the G8 Okinawa communiqué calling for greater focus on agricultural capacity building in developing countries. USDA, FDA, and USAID can review their capacity building programs and the OSTP can explain its capacity building initiative. Similarly, ratcheting up our public diplomacy efforts to inform the global public of the role of biotech products can lead to a greater appreciation of biotechnology in alleviating hunger and improving living standards in the developing world, and push back on EU anti-biotech offensive.

Issues for Decision

We need interagency agreement to create this group and on what steps we can take organize it as soon as possible. We should also agree to identify and expand where possible resources for capacity building in developing countries (some members of Congress have an interest in this too) and other public diplomacy avenues we can pursue. We should also plan immediately how to organize such a group of like-minded countries to help us in CODEX, WTO, and other international fora. We should consider using the upcoming October 24-28 meeting in India of CODEX's working group drafting biotech labeling guidelines as a test case. We should start with a cleared demarche to countries on the drafting committee, and by organizing a meeting prior to the next CODEX meeting of those countries (especially developing countries) with which we might find common cause.

3. **Stronger response to emerging issues through an enhanced interagency team approach (in essence a biotech SWAT team) to engage quickly with countries and regional organizations considering highly restrictive, infeasible, and/or costly approaches to regulating biotechnology.**

The number of countries looking at or addressing biotech regulation is growing. Foreign authorities and audiences often do not understanding fully the consequences of their actions to regulate biotech products. Saudi Arabia, for example, has de facto banned biotech products with little analysis and without recognizing its implications. There are almost daily reports of the potential for similar restrictive approaches to be taken, often with little or no analysis or discussion. We are trying to respond to these developments both bilaterally and multilaterally, but need to do better. The draft FY 2001 Senate Report language underscores the need for us to more aggressively counter the EU biotech challenges. USDA, State, USTR and Commerce have been working to address these challenges and it may make sense to formalize that effort and add USAID and others to a team that communicates regularly by e-mail. This team could also pro-actively identify countries where a concerted effort by the USG could help produce a better-informed public debate on biotech.

We need to organize a USG biotech team to help us respond quickly (through demarche cables and/or letters, telephone calls, high level diplomacy and visits as needed) to foreign capitals to educate government, industry, and civic authorities. Such a team approach would require a more formalized e-mail network of interagency contacts to share information and alerts on international biotech developments, and a specific commitment to quickly draft and clear demarches to the field and identify opportunities and needs for additional diplomatic contacts and visits. The process would likely benefit from the establishment of baseline megatalkers on, for example, the science and safety of biotech, policy considerations related to biotech regulation and trade commitments/goals, points on any assistance/dialogue we might offer to further inform on biotech, and information on useful international fora where biotech issues are being discussed.

Issue for Decision

Should we formalize a US interagency team approach to reach out to foreign capitals both to preempt and tackle biotech issues?

4. Clarify biotech policy guidance related to rules governing the interface between regulatory precaution and international trade.

Labeling

The EU and over 30 countries (including Japan and Mexico) have either mandated labeling of biotech products or are considering some form of labeling. The EU specifically is likely to make mandatory labeling part of its revision of Directive 90/220. International CODEX negotiations on labeling continue in India starting October 24. Our food industry can support using a "GM-free" label for products without genetically engineered ingredients to meet market demands. We are confronted with a variety of approaches to labeling that differ from ours, and a clear need to promote approaches consistent with our own in a manner that is credible and understandable diplomatically and to the general public.

To facilitate choice and information, our policy has been to support the provision of any information that consumers wish by industry, including by labeling, provided it is truthful and not misleading. The FDA, pursuant to the Administration's May 3 biotech initiative, is developing guidelines for voluntary efforts to label products either as "GM- or biotech-free" or with something such as "may contain biotech products." We want to avoid the mistaken impression that biotech-free food has been found in any way "better" for people, and prevent any false health claims for biotech foods, yet still allow information to be provided credibly. We do require by law that food be labeled as to its nutritional composition and basic properties, including any potential for allergenicity in some people. We do not mandate or require labels for any other purpose, as we believe the costs of making such distinctions that have no known health and safety impact should be allocated by the market. For example, we support a legal standard for companies choosing to label foods as "organic" in order to serve that market, but we do not require all other foods to be labeled non-organic, which would then impose a cost on those who are comfortable buying other than organic foods.

Despite findings by some expert economists that mandatory labeling of biotech foods and treating them in the product stream as if they were toxic (via low test tolerances for non-biotech purity and extremely detailed standards of separation and traceability, etc.) may raise foods costs for everyone substantially, some (including some consumer

groups) argue for this in the international arena. Our food industry can support international standards for using a "GM-free" label for products without genetically engineered ingredients to meet consumer demands. They also argue for reasonable and consistent tolerance levels (based on both scientific safety and feasibility and consumer cost/preference considerations) and attention to ensuring that labels be truthful and not misleading. We need to give guidance to our negotiators on both strategy and tactics on these difficult issues.

Issues for Decision

Should we hold the line firmly in international negotiations on an approach more consistent with our policy? To do so, do we need to press for explicit consideration by international negotiating groups of consumer and administrative costs of heavier legal requirements for labeling? Should we also have them compare those options not only our labeling approach but as well our encouragement for a variety of initiatives (hotlines, web sites, brochures, etc.) for providing information to consumers. Could we not improve our explanation of the ways in which our approach will better protect consumer choice, welfare and income in an evolving market? For consistency, do we need to move more quickly to establish standards for a non-biotech or non-GM label here at home? Can and should we use the WTO in addition to CODEX to address this issue?

"Precautionary Principle" (PP)

We need to clarify our longstanding approach to regulatory precaution. We have repeatedly made clear to our EU interlocutors our opposition to the PP. We have not, however, yet been fully effective in dealing with the PP in international fora. It is essential that we confront and challenge what is continued EU movement to gain international acceptance of an elastic, non-science based, and inconsistent zero risk/tolerance version of the PP (contrary to the more reasonable approach originally proposed in the Commission's own White Paper) that is already having negative impacts on trade.

Already Italy and France have used the PP specifically to justify actions against biotech products, and it is unclear that the Commission will force Italy to rescind its ban on approved corn, justified using the PP. European officials (especially in member states) increasingly use the term without precision as a rationale for considering a wide

variety of highly restrictive regulations that may well be WTO-inconsistent. The European Parliament may push for an extreme version of the PP that would include provisions such as: zero risk is reasonable; proportionality and non-discrimination are not required; no risk assessment is required; and the EU should ensure that the PP is brought to bear in the implementation of SPS Agreement Article 5.7.

Application of such a standard is not only scientifically impossible, but would radically restrict consumer choice and access to new and current products. It is not a standard that Europe employs at home with regard to food, wine, or many other goods and services currently enjoyed there. Further attempts by the EU to make this a standard for others products, even if partially successful, would have direct and ultimately far broader negative impacts on consumers worldwide. It would certainly make it near impossible for developing country exports to meet SPS standards, with which they struggle already, and serve as a basis for their growth and poverty alleviation. US industry (and our scientists) is comfortable in general with our own science- based approach and efforts to incorporate caution into regulatory systems that aim to protect public safety and enhance public welfare. Our industry (and many scientists and regulators) strongly opposes the PP and EU efforts to make it an international legal principle. Our food industry also wants USG negotiators to reject discussion of the PP or the formal use of the term in all international fora, including CODEX, and urges a more effective presentation of our own strong approach. Senator Grassley has asked the GAO to investigate how the USG has handled the PP in international fora and negotiations, on the premise that the EU's approach has hurt our interests.

Issues for Decision

Whether to oppose any inclusion or discussion of the PP in CODEX, WTO, or other international bodies? If so, should we act to gain general support for an approach to regulatory precaution more in keeping with our own, and oppose EU efforts to create a simplistic one-size-fits-all standard for all instances of regulatory precaution? Can we identify additional steps to underscore with the EU our serious concern with the PP (the Summit?) and to build support elsewhere for a more balanced approach to help protect consumers everywhere.

Traceability

The EU is likely to mandate traceability of biotech products as part of its 90/220 revision. The French are pushing a more radical traceability proposal. A European version of traceability will likely compel segregation of biotech and non-biotech products throughout the food chain and substantially drive up food costs. Higher food prices will hit developing countries especially hard. We view biotech and conventional foods as substantially equivalent (a scientific concept under attack in the EU) and see no need for mandated traceability.

Our science based food safety system relies on the concept that we build upon the decades old understandings/experience we have of the genetics and microbiology of key foods/grains, and of their nutritional aspects and of human consumers reactions to them to understand the safety of varieties of these foods. In essence, scientists look at what is different in new varieties, consider the science of what the differences mean nutritionally and regarding human health and look for risks accordingly. If they assess based on the science no health risk, they judge the new variety to be "substantially equivalent" to the old one. Dispensing with that standard would imply that scientists reassess the safety of the baseline food, even if it had been in the human food chain for a very long time. Essentially, it would pose a much higher and more costly standard for biotech foods, which most scientists think would do little or nothing for human health.

Issues for Decision

Should we include a clear, cogent and analytical response to the EU traceability proposal that shows how it will increase food prices in our diplomatic outreach and negotiating efforts at CODEX and elsewhere? Should we specifically identify opportunities to raise this in our general biotech outreach? Should traceability, labeling, and the PP issues be part of the December Summit agenda since they will not be resolved by then?

Biotech Timetable

See attached biotech calendar of event.

THE WHITE HOUSE

WASHINGTON

THE PRESIDENT HAS SEEN
11-29-99

November 26, 1999

copied
Sperling
Lane
Frampton
Podesta

MEMORANDUM FOR THE PRESIDENT

FROM: LISEL LOY

Subject: Biotechnology

The attached Sperling/Lane/Frampton memo and 1-page executive summary provide background on bioengineered crops, food, and labeling and present detailed policy options developed by NEC's interagency working group on biotechnology. *Karen Tramontano asked that we forward this memo to you at Camp David.*

Gene, Neal and George recommend three policy options (please see memo for additional detail). NEC, OSTP, CEQ, DPC, NSC, and OMB, along with USDA, EPA, State, Interior, and Treasury, support all three options. **Option #1, Enhancing Public Education and Outreach**, is intended to strengthen consumer confidence in the safety of biotechnology and the soundness of our regulatory system. *It has unanimous support among your advisers and the agencies (USDA, EPA, State, Interior, Treasury, Commerce, HHS, and USTR).* **Option #2, Maintaining/ Strengthening Confidence in the U.S. Regulatory Framework,** has two parts: **a)** requiring FDA notification 90 days before products are introduced; and **b)** organizing an interagency process to examine the adequacy of federal monitoring and regulation. *Option #2 has support from all your advisers and all agencies except Commerce, which does not support 2a.* **Option #3, Facilitating Voluntary Disclosure of Consumer Product Information through Non-Biotech Labeling and other Means,** is intended to reduce uncertainty and confusion for farmers, companies, and consumers through voluntary efforts to segregate and label non-genetically modified products. It has 3 parts: **a)** a USDA process on testing, quality assurance, and tolerances for non-biotech products; **b)** an FDA process to develop guidance for non-biotech labels; and **c)** an FDA process to develop other mechanisms for providing information to consumers. *Option #3 has support from your advisers and most agencies; HHS and USTR do not support 3a) or b) because they believe even these limited steps might have the unintended effect of energizing opponents of genetically modified products and undermining public confidence in them; Commerce supports 3a) and c) but not b), for the same reasons as HHS. Agencies supporting these options counter that biotech labels are appearing already, without government action, and that these modest steps simply recognize that development and attempt to reduce uncertainty and costs.*

Option 1 (Public Education/Outreach)
Approve ✓ Disapprove ___ Discuss ___

THE PRESIDENT HAS SEEN
11-29-99

Option 2 (Confidence in U.S. Regulatory Framework)

2a (FDA advance notification)
Approve ✓ Disapprove ___ Discuss ___

2b (Interagency process on federal monitoring/regulation)
Approve ✓ Disapprove ___ Discuss ___

Option 3 (Voluntary disclosure of product information)

3a (USDA process on testing, etc.)
Approve ✓ Disapprove ___ Discuss ___

3b (FDA process for voluntary, informational non-biotech labels)
Approve ✓ Disapprove ___ Discuss ___

3c (FDA process for non-label information)
Approve ✓ Disapprove ___ Discuss ___

THE WHITE HOUSE
WASHINGTON

THE PRESIDENT HAS SEEN
11-29-99

November 24, 1999

MEMORANDUM FOR THE PRESIDENT

FROM: GENE SPERLING
NEAL LANE
GEORGE FRAMPTON

SUBJECT: Decision on Biotechnology Issues

Executive Summary:

An NEC High-Level Group on Biotechnology was created last spring to assess international and domestic biotechnology developments and consider their implications for public policy. The attached memorandum provides a discussion of the relevant issues and a set of recommended policy options.

Federal regulatory agencies remain confident that bioengineered crops and foods sold in the U.S. are safe. The U.S. Government position on labeling of genetically engineered or modified agricultural crops and products has been to oppose any mandatory labeling of such products on the grounds that they are substantially equivalent to their conventional counterparts and do not meet the FDA's current standards for product labeling. While this policy is based on sound science, it has not entirely succeeded in quieting the demands of some NGOs and consumers for labels and other information ~~about the bioengineered content of food.~~ Some US producers are moving in this direction on their ~~own, prompted in part by consumer preferences in the EU~~ and the reality that other countries, such as Japan, Korea, Australia, and New Zealand, are following the EU's lead in mandating labeling of biotech foods. ~~As some food retailers and processors have begun to demand GMO-free foods to~~ protect their brand image and avoid loss of foreign and domestic market share, this is generating uncertainty among American farmers and concern about the added segregation and testing costs.

As a result, we are recommending a package of policy options that would: 1) enhance public education and outreach about the safety of the technology and the soundness of our regulatory system; 2) take two specific steps to reinforce the strength of our food safety and environmental regulatory oversight; and 3) facilitate and lend order to emerging voluntary efforts to provide consumer product information, including through non-biotech (GMO-free) labeling. The key issue for decision relates to the third option, under which USDA would develop suggested standardized testing methods and GMO tolerance levels to substantiate GMO-free claims, and FDA would provide guidance on what would constitute a truthful and not misleading non-GMO product label. While senior White House advisers and most agencies support these steps as a potentially helpful way to reduce uncertainty and confusion on the part of farmers, companies, and consumers as the private sector tries to sort out the labeling issue, FDA, USTR, and, to a lesser extent, Commerce believe that even this limited step is inadvisable in that it might have the unintended effect of energizing those who oppose the products and call for their mandatory labeling. A fourth option, mandatory approval and labeling of biotech products, is presented for your consideration but is not recommended by any agency.

THE PRESIDENT HAS SEEN
11-24-99

THE WHITE HOUSE
WASHINGTON

November 24, 1999

MEMORANDUM FOR THE PRESIDENT

FROM: GENE SPERLING
NEAL LANE
GEORGE FRAMPTON

SUBJECT: Decision on Biotechnology Issues

Purpose: There is considerable discussion in the U.S. and around the world (particularly in Europe) about how governments should most appropriately regulate foods and crops made using biotechnology. This memorandum is intended to present the issues surrounding the current debate and provide policy options.

Background

Man has been genetically engineering crops through cross-breeding in ways that nature could not for 10,000 years. Modern biotechnology or bioengineering, which is now nearly two decades old, refers to the use of recombinant DNA and related technologies to alter the genetic makeup of living organisms. These techniques allow scientists to identify and isolate genes of interest from any organism and put them into any other organism, as well as to introduce targeted genetic changes in organisms.

The practical effect is to open up vast opportunities for developing new food crops with beneficial characteristics such as pest and drought resistance, higher yield, enhanced nutrition, better taste and vaccine delivery. With global land *per capita* available for cultivation expected to shrink by over 40% and population projected to possibly double, boosting agricultural productivity is perhaps the only way to prevent serious humanitarian crises and environmental degradation in the next century. Biotechnology has the potential to help mankind meet this challenge and, in so doing, advance our national security interests. The United States is the acknowledged world leader in the biotechnology industry. Although the use of biotechnology for producing new drugs and vaccines has been widely accepted around the world, the use of the technology in producing foods has been much less well-received in some countries. Indeed, some consumer activists have alleged that these foods are unnatural, calling them "Frankenfoods."

In 1986, an interagency group led by OSTP determined that the statutes underpinning the framework for regulating existing technologies provided appropriate authority for regulating the products of biotechnology. In publishing the "Coordinated Framework for Regulation of Biotechnology," the interagency group determined that existing health and safety laws were sufficient to provide immediate regulatory protection and certainty for industry. In light of a general scientific consensus that the

process of genetic engineering posed no inherent risk, the policy determined that regulation should continue to be based on product uses, applying the existing standards with respect to health and environmental risks of new products. Should the existing standards be found insufficient for a given class of new products, agencies would promulgate regulations under their existing authorities. For example:

- USDA promulgated regulations requiring developers of bioengineered crops to obtain a permit before planting such crops in the field. After USDA obtained significant experience with certain bioengineered crops, a more streamlined notification system was established for them. USDA regulations focus on risks that the bioengineered crops might pose to agriculture and the environment. If USDA determined from its review of the resulting data that the crop posed no unacceptable risk, it would classify the crop as a non-regulated article and allow it to be planted with no subsequent USDA involvement.

- FDA promulgated no new regulations, but did publish a statement of policy indicating that new substances bioengineered into foods would be subject to premarket approval as food additives if those substances differed significantly from substances commonly found in the diet. It went on to note, however, that most, if not all, substances that were being considered for introduction into foods through bioengineering were substantially the same as other substances found in the diet and therefore would not need premarket approval. FDA encouraged firms to consult with it on safety issues prior to marketing, which firms have been doing. This policy has been challenged in litigation that is pending in the District Court for the District of Columbia.

- EPA promulgated rules for the regulation of bioengineered microbes, as new substances, and for the regulation of pesticidal substances introduced into plants. EPA examines both environmental and human health risks of the microbes and pesticides.

Current US Government Perspective. Federal regulatory agencies remain confident that bioengineered crops and foods sold in the U.S. are safe, although some agencies believe that bioengineered species used in agriculture may pose environmental risks justifying enhanced Federal oversight. The U.S. Government (USG) position on labeling of genetically engineered or modified agricultural crops and products has been to oppose any mandatory labeling of such products. This position is based on the Food & Drug Administration's conclusion that genetically engineered foods are substantially equivalent to their conventional counterparts. However, the FDA requires labeling of food, including that which is bioengineered, whose composition has been significantly altered, whose nutritional values or intended use is different from conventional food, or which has allergenic properties. While this interpretation and policy is based on sound science, it has not entirely succeeded in quieting the demands of some NGOs and consumers for labels and other information about the bioengineered content of food .. Some other NGOs privately admit that they are not concerned about biotechnology but will not say so publicly because of the politics of the environmental community. The strength of the U.S. regulatory system is its independence from political interference in decisions affecting health, safety or environment. Indeed, the EU is seeking to replicate such a system. Steps here that appear to be undermining our regulators' independence would adversely affect public trust and provide arguments for those in Europe who want to block such a system.

International Considerations. Even though the large majority of bioengineered corn and soybeans are used for domestic purposes, the international considerations are substantial. The EU is proving increasingly problematic, in part due to recent food safety scares unrelated to biotechnology. Last June, the EU Environment Council decided to require that agri-biotech products be proven to have no environmental or health risks before being placed on the market and that the EU Directive regarding biotechnology regulation (90/220) be revised to include additional procedures for handling already-approved biotech seeds and bulk commodities. No products would be approved until the completion of this process, which the EU admits could take at least three more years. US producers are being adversely affected by this effective moratorium on regulatory approvals of bioengineered products. Corn growers are losing up to $200 million per year in exports because the EU has refused to approve seven US-approved corn varieties that are co-mingled with the sole EU-approved variety.

US producers are concerned that additional countries, such as Japan, Korea, Australia, and New Zealand, are following the EU's lead in mandating labeling of biotech foods, as foreign food retailers and processors are beginning to demand GMO-free foods to protect their brand image and avoid loss of market share without much regard to the validity of their claims and despite recognition that genetically engineered food is safe. This is generating uncertainty among American farmers and concern about the added segregation and testing costs. As a result, the Administration is working to promote fair market access for US exports and sound approaches by foreign governments to biotech issues on several fronts, including:

- Technical cooperation and information sharing in the OECD and Transatlantic Economic Partnership in projects initiated at this past June's G-8 and US-EU Summits as well as through the National Academy of Sciences and it's British counterpart, the Royal Society;

- A high-level US-EU governmental dialogue that was initiated in your recent meeting with EU Commission President Prodi for the purpose of securing more predictable regulatory approval processes in Europe and resolution of outstanding market access issues, including blocked US corn exports;

- Preparation of US negotiating objectives for the Seattle WTO Ministerial aimed at focusing any discussion about biotechnology in the new trade round on ensuring the continuing application of existing trade disciplines to biotech trade and promoting greater predictability to regulatory approvals based on sound science;

- Active participation in the 156-member CODEX Alimentarius Committee on Food Labeling Biotech Working Group, which is scheduled to report in May 2000 on guidelines and recommendations on labeling of biotech food and additives, and may reconfirm that biotech foods are equivalent to conventional foods and need not be labeled; and

- In the January 20 – 28 high-level negotiations in Montreal on the Biosafety Protocol, cooperation with our Miami Group allies to ensure that the talks do not produce an unworkable agreement that unduly restricts trade or imposes high costs without commensurate environmental benefits.

Domestic Considerations

commercial stake in how such decisions are made. Currently, farmers are receiving a modest premium for non-GMO corn and soybeans. However, growers must also self-certify that their crops are GMO-free and must retain full liability for the commodity throughout the marketing chain, even in the absence of uniform and reliable standards, segregation methods and testing capabilities.

- Environment. Finally, agricultural genetic engineering could have significant environmental impacts, both good and bad. Examples of projected benefits include reduced pressure to clear tropical rainforests for farmland (due to enhanced agricultural productivity), quicker, more effective clean-up of oil spills (with genetically engineered plants and microorganisms) and less use of harmful pesticides. Examples of potential risks include the development of "super-weeds" (if genetically modified plants hybridize with wild relatives), adverse impacts on non-target species (such as the monarch butterfly) and disruption of ecosystems (for example, by the unintended release of "super-growth" salmon into the marine environment). It is important to note that most, if not all, of these risks are not new to food production systems. In several recent cases, agencies have identified environmental risks from GMOs and responded accordingly. In 1997, EPA expressed concern about hybridization of certain genetically-modified cotton crops with wild relatives in certain parts of Florida and Hawaii, and denied approval for planting in those areas. EPA is currently considering guidelines to protect monarch butterflies in the planting of Bt corn, while the Fish and Wildlife Service is reviewing its potential effects on the Karner Blue butterfly, a species listed under the Endangered Species Act. In other cases, the regulatory authorities for addressing environmental impacts of GMOs may be less clear. FDA, for example, is currently considering applications for the approval of genetically-modified salmon that grow faster and larger than native species. Although FDA is considering the ecosystem impacts of an unintentional release of the modified salmon as part of a NEPA review, it is not clear that FDA's legal authorities would allow the agency to deny approval based on adverse ecosystem impacts if any were found.

Options

An NEC High-Level Group on Biotechnology was created last spring to assess these developments and consider their implications for public policy. Principals, Deputies and staff have met and conducted outreach with the producer and NGO communities. Following are policy options that have emerged from this process for your consideration. The first three options (enhancing public education; strengthening FDA and environmental regulatory oversight; and facilitating voluntary efforts to provide consumer product information, including voluntary labeling) have broad support among agencies. The key issue for decision relates to the third option, which recommends that USDA and FDA initiate processes to provide guidance for voluntary efforts to segregate and label non-GMO products for the purpose of reducing uncertainty and confusion for farmers, companies, and consumers as the private sector sorts out the labeling issue. USDA would develop suggested standardized testing methods and GMO tolerance levels on which to base GMO-free claims, and FDA would provide guidance on what would constitute a truthful and not misleading GMO-free product label. FDA, USTR, and, with respect to FDA's role, Commerce believe that even this limited step is inadvisable in that it might have the unintended effect of energizing those who oppose the products and call for their mandatory labeling, thereby undermining public confidence in them. The fourth option, mandatory approval and labeling of biotech products, attracted no agency's support.

- Consumers. Although US consumer perceptions of agri-biotech products remain largely positive, the situation is fluid. In its September 1999 edition, *Consumer Reports* magazine advocated labeling of bioengineered food products, while advocating that such products are safe.

And US advocacy groups are intensifying media and public education campaigns. Some contend that bioengineered foods should be subject to formal FDA safety approval before being marketed, labeled as bioengineered, and examined more thoroughly for potential environmental risks. A number of them filed a lawsuit last year against FDA, alleging that it is violating the law by not requiring such labeling and premarket approvals. Another lawsuit has been filed against EPA, alleging that its oversight of certain pesticidal substances in bioengineered crops and foods is inadequate. However, these efforts have not, so far, influenced the vast majority of U.S. consumers to demand labeling.

- Industry. Bioengineered corn, soybeans, cotton and canola are widely grown and consumed in foods here, and American consumers retain a generally benign view of the technology. Nevertheless, companies are increasingly concerned that public acceptance could erode in the face of media questions and activists' representations that the technology poses unknown long-term risks. And companies fear that international resistance to the products, especially in Europe, could eventually spill over into the US market. If this were to occur, an extremely valuable technology would be jeopardized. Industry has not reached a consensus on what direction the U.S. should take to address the problems of commodity segregation and consumer product labeling. Food processors and their trade organizations (e.g. Grocery Manufacturers Association, National Food Processors Association) are opposed to the labeling of GMOs mainly because of the increased cost. They are also concerned that efforts to facilitate or promote voluntary labeling domestically would ultimately lead to mandatory labeling and foster the perception that engineered foods are less safe than their conventionally-derived counterparts. However, some have recently begun quietly suggesting that some degree of greater engagement by the government would be desirable, including additional public education, a requirement that companies notify FDA of new bioengineered products before marketing them, and work by USDA and FDA to help farmers, companies, and consumers determine what constitutes a non-biotech product, which, so far, no country has been able to do.

- Medical and Scientific Community. The medical and scientific community, both academic and industry, is concerned that steps the Administration takes regarding bioengineered foods may have spill-over to public perceptions about the safety of pharmaceuticals and therapeutics developed through biotechnology.

- Farmers. Perhaps the most pressing aspect of the issue is the uncertainty facing farmers, who fear development of a two-tier price system with discounts for biotech crops and a shortage of conventional seeds next spring. Many of our farmers in recent years switched to bioengineered crops because of their enhanced traits, reduced costs of pest/disease control, and environmentally friendly attributes. However, growing demand for non-GMO commodities is expected to add costs due to segregation and handling, in the range of 12% to 17% more for non-GMO bulk commodities. This figure could increase substantially if very stringent thresholds were adopted by countries and companies (e.g., the EU has recently proposed that any product containing more than 1% of bioengineered product be considered bioengineered), suggesting that the US has a major

It should be noted that HHS believes that any decisions affecting FDA policy should not be made until FDA has completed three public meeting scheduled between November 18, 30, and December 13, reviewed the comments received, and reported to HHS and the White House on what it learned. In addition, none of the options in this paper would directly facilitate access for U.S. products in other countries. Countries that are requiring approval and labels, such as the EU, have their own regulations (which they have not been able to implement), and U.S. products must meet their regulations.

1. Enhancing Scientific Discussion and Public Education and Outreach to Strengthen US and Foreign Consumer Confidence

- Domestically, engage in greater outreach to emphasize the scientific basis of US regulation and convene public sessions and meetings for the purpose of soliciting broad public and scientific input on whether additional regulation (for food safety, food labeling, environmental safety) is appropriate. Panels also could be set up to provide a forum for discussing non-scientific (e.g., cultural and social) issues of public concern.

- Intensify international educational, cooperative scientific, diplomatic, and technical assistance activities to explain US regulatory policies and work toward more consistent policies.

These activities would enable the regulatory agencies to hear public concerns, receive scientific input, dispel inaccurate information, and influence regulatory decisions in foreign markets. All agencies are supportive of these steps, and many, including USDA, FDA, EPA and State, are undertaking them presently.

2. Maintaining and Strengthening Confidence in the US Regulatory Framework

a) Require Companies to Notify FDA 90 Days before Biotech Products Are Introduced into Commerce. In 1992, FDA issued a policy statement to provide industry with guidance on Federal requirements that must be met before feed and food products derived through recombinant DNA techniques can be introduced into commerce. This policy statement did not mandate pre-market notification or approval, but encouraged consultations between industry and FDA. To date, all new feed/food products have gone through this voluntary consultative process; however, critics point to the voluntary nature of this process to make the claim that FDA's oversight of GMO food is based on an honor system. In an attempt to address this criticism, FDA has launched a series of public listening sessions over the next month in part to explore what if any modifications to its policies might be warranted.

This step would provide an added level of assurance that government is aware of all products marketed and that all regulatory questions are answered prior to marketing. It would build public confidence in FDA oversight, responding to criticism that current system is an honor system in which industry voluntarily engages FDA in its safety evaluation, and possibly provide an opening to work in a more cooperative fashion with the Europeans on biotech issues. At the same time, it would not directly address the principal criticism that bioengineered foods are not subject to

mandatory premarket approval and may provide ammunition to opponents of the technology, who may portray this requirement as evidence that bioengineered foods pose special risks not associated with other foods.

All agencies are generally supportive; however, FDA has noted that going forward with mandatory premarket notification would require development of a legal rationale that does not undercut the US government's scientific assessment that foods from bioengineered plants are not inherently different from or less safe than foods from conventionally derived plants.

b) Direct CEQ/OSTP to Organize an Interagency Process to Examaine the Adequacy of Federal Environmental Monitoring Activities and Regulatory Authorities with Respect to Biotechnology. This proposed process would look at the adequacy of our environmental monitoring activities and capabilities as well as the sufficiency of the existing regulations. It would build on the the outreach processes already underway by USDA and EPA, through the creation of an independent standing committee of experts under the aegis of the National Academy of Sciences and the establishment of regional pest management centers. Analysis would begin with case studies of how the existing system applies to different transgenic organisms. Work would be designed to identify strengths and weaknesses of the current system and, in combination with scientific information, establish a foundation for future recommendations. New directions might include recommendations for additional environmental monitoring and risk assessment activities. Initial recommendations would be likely within six months. This policy option would help address questions about the environmental implications of agricultural and other biotechnology and bolster public confidence that the federal government is taking them seriously. It is supported by all agencies; however, some concern was expressed that care would have to be taken to avoid the impression the Administration did not have complete confidence in the U.S. regulatory system or had concerns about biotechnology.

3. Facilitating Voluntary Disclosure of Consumer Product Information through Non-Biotech Labeling and Other Means (i.e., defer to the private sector on product segregation, tolerance-setting, and choice of mechanism for providing consumer information, including non-biotech labeling, but engage with it in a process to reduce uncertainty and confusion for farmers, companies, and consumers).

This option would create a process of public outreach and technical research through USDA and FDA to support an orderly process of voluntary product segregation and non-biotech labeling to the extent one emerges in the private sector. USDA would develop suggested standardized testing methods and GMO tolerance levels for use in substantiating GMO-free claims, and FDA would provide guidance on what would constitute a truthful and not misleading non-GMO product label. The aim would be to reduce uncertainty and confusion on the part of farmers, companies, and consumers as the private sector sorts out the labeling issue. These steps would build on the three planned FDA hearings, the purpose of which is to share the agency's approach regarding safety evaluation and labeling of food products derived from bioengineered plant varieties, solicit views on whether FDA's policies or procedures should be modified, and gather information on appropriate means of providing information to the public about these products.

Although there is general confidence in and out of government that bioengineering *per se* does not pose unique health risks in food products that would require mandatory FDA labeling, consumer preferences abroad and, to a lesser extent, in the US are prompting some commodity firms and food companies to segregate and voluntarily label non-bioengineered crops and products. Competing producers have an interest in ensuring that any such claims are not false or misleading. Consumers have an interest in ensuring that information voluntarily disclosed on products is accurate, reliable, and comparable to information found on other products, as illustrated by the current confusion of supermarket shoppers in the UK. Finally, farmers and grain elevator operators have an interest in ensuring that steps they take to test and maintain the segregated identity of non-biotech crops will be reliable and generally recognized as valid by commodity firms. It should be noted that industry is more comfortable with negative, or "non-biotech," labeling than it is with affirmative, or "contains GMOs," labeling, which it fears could unduly raise the profile of the issue for consumers given the widespread presence of bioengineered corn, soy and other ingredients in products on US supermarket shelves.

a) USDA process on testing, quality assurance and tolerances for non-biotech products. USDA would initiate a comprehensive process of public outreach and internal research to determine the feasibility of establishing standardized testing protocols, quality assurance programs, and tolerances for voluntary non-biotech product segregation and claims. This process would take into account both consumer demands and production and handling factors such as pollen drift and commingling. It would involve public meetings, specific stakeholder group consultations, and, for development of qualify assurance procedures and tolerances, the issuance of an Advanced Notice of Proposed Rulemaking (ANPR). USDA has already begun research into standardized testing protocols, but the outreach process would most likely be initiated following next year's harvest after the industry has had more experience with segregating and testing commodities. Once a certification process were established, the GMO status of a given commodity would become a key component of industry-developed "chain of custody" programs, which might facilitate voluntary labeling of consumer products. The process could inform and support USG efforts to influence foreign regulatory decisions about where to set non-biotech tolerance levels, thereby potentially helping to preserve fair market access opportunities for US farm exports. Should domestic industry choose to use this information to develop labels, FDA would need to determine whether they were truthful and not misleading in order to ensure that no unwarranted inferences would be drawn by consumers concerning human health considerations.

b) FDA process to develop guidance for voluntary informational labels for non-biotech products. Under current Federal Food, Drug, and Cosmetics Act (FFDCA) authority, companies currently can label their products to indicate whether they contain genetically engineered ingredients. However, the labels must meet the standard of being truthful and non-misleading, as interpreted by the FDA. Such labels have already begun to appear on products, and FDA may at some point find itself compelled to issue guidance on their use and design even if you do not approve this option, particularly if companies begin to make inferences or claims about health or safety that FDA would consider misleading. Building on the current FDA hearings, this policy option would create a process by which the agency would take the affirmative step of developing guidance on the elements of a truthful and not misleading label for non-GMO food products in order to inform the design of any such claims voluntarily made

by companies. Such guidance would likely include a recommendation that GMO-free labels include a disclaimer indicating that bioengineered foods do not differ in safety or qualify from other foods. FDA recommended use of a similar disclaimer in its guidance on labeling of milk from cows not treated with rbST.

c) FDA process to develop appropriate mechanisms, other than through the food label, for providing information to consumers. Building on the current FDA hearings, and on the experience FDA gained from developing a web-site listing the Y2K compliance status of thousands of medical devices, this policy option would create a process by which the agency would develop guidance on the listing of GM and GM-free food products on Federal or company web-site or on making such information available through 800-numbers.

USDA, NEC, OSTP, DPC, CEQ and other agencies support these options, with the exception of HHS and USTR, which do not support sub-options (a) and (b) because they believe that even limited governmental involvement in activities related to biotech labeling would implicitly bless and energize the actions of those who oppose the products and call for their mandatory labeling, thereby undermining public confidence in them. HHS is also concerned that adding information on food labels on matters unrelated to the safety or fundamental characteristics of the product would undermine the function and utility of food labels, in part by adding clutter and distracting consumers from core nutritional information and by potentially inviting other demands for right-to-know labeling unrelated to safety and health considerations. USTR believes the marketplace will sort these issues out without the help of government programs. Commerce supports sub-options (a) and (c) but not (b), for the same reasons as those attributed to HHS. Agencies that are supportive of the option counter these arguments by observing that biotech-related labels are beginning to appear on products without any government action and that taking these modest steps merely recognizes this reality in a practical attempt to reduce uncertainty and costs for all involved.

4. Supporting Mandatory Pre-Market Approval and Product Labeling

The Administration could adopt the EU posture of requiring pre-market regulatory approval and labeling of products with bioengineered content above a certain threshold. It could do so by sponsoring or endorsing legislation in Congress.

a) Mandatory FDA approval. Requiring approval of new products before they are introduced into commerce (as distinguished from requiring pre-market *notification* in Option 2a above) would allow FDA itself to vouch for safety of bioengineered foods based on in-depth reviews, as it now does for food additives. This would satisfy demands of at least some consumer groups by providing an additional assurance of safety, removing the criticism that the current system depends on the good faith of biotech companies. However, such a change in policy would be opposed by industry on the grounds that it could undermine public confidence by suggesting that the federal government has serious concerns about the safety of the technology. It could also create significant period of "regulatory limbo" between the time of the proposal and enactment, delaying market entry of commercially important new foods despite the longstanding Federal view that bioengineered foods do not raise scientific or safety issues warranting such oversight.

b) Mandatory product labeling. Supporters of this policy believe that mandatory labeling of bioengineered food products may ultimately be the only way for industry and government to cease being on the defensive about bioengineered foods, in part because many consumers may end up harboring misgivings about the technology absent greater assurance that they will have control over the decision to consume foods derived from it or not. Moreover, in light of the range of bioengineered crops grown in the U.S., the scale of the processed foods that would have to be labeled might actually serve to reduce any stigma associated with labeled products. The Administration might be able to get in front of the issue in this fashion, forcing stakeholders to work with Congress to develop a solution. And by affording the maximum degree of information to consumers, mandatory labeling in the long run might well lead to lower consumer concerns regarding the technology than would otherwise be the case.

On the other hand, mandatory food labels for biotech content could undermine the function and utility of the food label, whose purpose is to provide information pertinent to characteristics and composition of the food. As such, it could distract attention from important nutritional and health information now on food labels and trigger additional calls for consumer "right to know" labeling on other issues. In addition, an abrupt policy shift of this nature could foster greater distrust of bioengineered foods by giving the impression that they must be different and riskier than other products, leading food processors to avoid their use and consumers to boycott their purchase. Since industry is currently interested most of all in having the federal government clearly and repeatedly vouch for the safety of the products, it would undoubtedly be highly critical of this policy and consider fundamentally inconsistent with long-standing government position that biotech foods are as safe as their non-engineered counterparts and, as a class, have no distinguishing characteristics that would warrant labeling. Finally, shifting away from science-based labeling could reduce the Administration's credibility with U.S. science-based societies and industries. Pharmaceutical and Genomics industries are already concerned about spill-over of anti-science sentiment from agriculture to medicine, and abandoning science-based policy in this area could reduce the Administration's ability to enlist and maintain support for science-based standards and requirements in various international fora and negotiations.

No agency supports these options, reflecting the concern, shared by industry and farmers, that such a major policy shift might alarm and confuse consumers and create a disorderly shift in their purchasing behavior that would not be warranted by our scientific understanding of the issue. The top priority of industry and farmers is for the USG to take steps to reinforce the generally strong level of consumer confidence that still prevails in the US. They perceive that these steps would work at cross purposes to this objective.

RECOMMENDATION

USDA, EPA, State, Interior, Treasury, NEC, OSTP, CEQ, DPC, NSC and OMB support Options 1, 2, and 3. Commerce supports all but Option 2(a), and HHS and USTR support all but Options 3(a) and 3(b). In addition, HHS believes strongly that implementation of Option 2(a) should follow conclusion of its current outreach process.

Option #1 -- Enhancing Public Education and Outreach to Strengthen Consumer Confidence.

Option #2 -- Maintaining and Strengthening Confidence in the US Regulatory Framework by:

a) requiring companies to notify FDA 90 days before biotech products are introduced into commerce; and
b) directing CEQ/OSTP to organize an interagency process to examaine the adequacy of federal environmental monitoring activities and regulation with respect to agricultural biotechnology.

Option #3 -- Facilitating Voluntary Disclosure of Consumer Product Information through Non-Biotech Labeling and Other Means.

a) USDA process on testing, quality assurance, and non-biotech tolerances;
b) FDA process to develop guidance for voluntary informational non-biotech labels; and
c) FDA process to develop appropriate mechanisms, other than through the food label, for providing information to consumers.

_____ Approve Recommendation

_____ Disapprove Recommendation

_____ Discuss Further

STARLINK BACKGROUND

- Corn plant bioengineered to produce Bt pesticide – Cry9C.
- All pesticide products are subject to scientific review and licensing by EPA.
- May 1998, EPA approved StarLink with strict terms and conditions.
- Use for animal feed and industrial purposes only; no export; includes grower agreements.
- EPA lacked sufficient data to conclude StarLink would not be an allergen; did not move forward with food registration.
- Summer 2000, outside scientific advice, stated there is no evidence that it is or is not an allergen; further testing methods needed.

BACKGROUND EVENTS

- *Genetic ID*, a laboratory hired by *Genetically Engineered Food Alert*, detected Cry9C DNA in Taco Bell taco shells.

- Kraft and FDA confirmed Cry9C DNA present in taco shells. Recalls instituted by Kraft, Safeway, and Mission Foods.

RECENT REGULATORY ACTIVITIES

- With strong urging by EPA, Aventis voluntary canceled registration. No StarLink will be planted in 2001 and beyond.

- USDA and Aventis have and continue to work to take custody of 2000 crop. Establishing direct control and chain of custody to ensure only directed to animal feed or industrial uses.

- USDA estimates, 88% of 2000 crop is accounted for. Leaves around 9 million bushels possibly co-mingled with corn grain.

- There is concern that some of the 1999 crop could also have been co-mingled.

CURRENT LANDSCAPE IN INDUSTRY

- Food industry is concerned that co-mingled corn has contaminated corn grain supply. High level concern -- corn milling and processing facilities are suspending operations and laying off workers because of potential of acquiring co-mingled corn.

- Concern that problem could spread further in food industry; causing further food processing facilities to suspend operations and lay off workers.

- Grain handlers also requesting permission to export corn grain, which is possibly co-mingled.

- The food industry wants more sophisticated testing methods to ensure corn grain does not contain StarLink.

CURRENT ASSESSMENT

- Cry9C DNA is not an allergen; available evidence does not provide clear answer about allergenicity of Cry9C protein.

- Cry9C protein could potentially cause allergen reaction.

- Cry9C is relatively heat stable and is not readily digested. These traits are common to food allergens, but unique among the approved Bt products.

- However, Cry9C does not resemble other known allergens; reactions to allergens occur only after period of sensitization; lack of scientific methodologies for definitive evaluation.

- FDA is investigating a relatively small number of alleged reports of allergic reactions (~12) to StarLink.

CURRENT SITUATION

- Food industry is operating on potential scenario that StarLink is co-mingled.

- Food industry is submitting information that argues Cry9C protein is not an allergen.

- Food industry is requesting EPA establish a time-limited exemption from a tolerance for food. This would allow all current food products (except corn grain under USDA control) to flow through the market without disruption or recalls.

- EPA is initiating a review of all available and <u>new</u> information to determine if science supports time-limited tolerance exemption for food.

- Any revised decision must be supported by new information, the scientific and medical community, and include a rigorous scientific consultation process with independent experts.

Vol.
Withdrawal of license
no sale of seed or planting

1997
2000 ~~4~~ 350k acres <0.5% of total corn acreage

12% of 0.5%

2000 9.6m bushels went to 267 purchasers
½ went to feedlots
½ to commingling
450,000 bushels likely

Option One

NOTICE TO EXPORTERS

This is to advise you that the corn variety StarLink is not approved for human food use, and that the prohibition on food use extends to StarLink destined for export.

U.S. Department of Agriculture
U.S. Food and Drug Administration
U.S. Environmental Protection Agency

October XX, 2000

Pros: 1) clearly states the FDA restriction on human food use; 2) most consistent with domestic policy; 3) since there are no restrictions or requirements placed on feed and industrial uses of StarLink (per U.S. Government regulation) sets no precedent for other GM-crops, (e.g. corn gluten exported to the EU)

Cons: 1) could be viewed as loose control by corn importers, like Japan, who have remained relatively calm; 2) could be viewed as dumping a problem overseas by other countries, the general public, and the press

Option Two

NOTICE TO EXPORTERS

This is to advise you that the corn variety StarLink is not approved for human food use, and that the prohibition on food use extends to StarLink destined for export.

All contracts for export should specify the intended use of the corn.

U.S. Department of Agriculture
U.S. Food and Drug Administration
U.S. Environmental Protection Agency

October XX, 2000

Pros: 1) documentation requirement would require that the corn is sold and used as intended; 2) more proactive that Option One; 3) generally consistent with reported current trade practices

Cons: 1) while relatively consistent with domestic practice, will be viewed by exporters as more onerous that what is required of domestic, commingled StarLink corn; 2) could

create the impression with the general public that export markets and consumers are of more concern that domestic markets and consumers; 3) USG reporting requirements could be precedent setting for other GM-corn

Option Three

NOTICE TO EXPORTERS

This is to advise you that the corn variety StarLink is not approved for human food use, and that the prohibition on food use extends to StarLink destined for export.

Exports for human food use should be tested for the presence of StarLink corn. Exports going to countries that are known to prohibit StarLink corn for any use should be tested for the presence of StarLink corn. Exports for human food use to any country and exports to countries prohibiting StarLink corn must not contain StarLink corn.

All contracts for export should specify the intended use of the corn.

U.S. Department of Agriculture
U.S. Food and Drug Administration
U.S. Environmental Protection Agency

Pros: 1) the most proactive stance, documentation and testing required by the USG for all corn exported for human food use

Cons: 1) much more restrictive than domestic policy, USG is not requesting testing of any corn, U.S. consumers would take note of higher export standard and export industry would be burdened; 2) EPA and FDA have stated the very low, estimated risk of the StarLink Cry9C protein to humans, this action would not seem to be commensurate with the (virtual lack of a) public health risk; 3) USG testing and contracting requirements could be precedent setting for other GM-crops, even though industry is doing this voluntarily now for StarLink

United States Department of State

Under Secretary of State
for Economic, Business, and
Agricultural Affairs

Washington, D.C. 20520–7512

October 20, 2000

Memorandum

To: OMB - Sally Katzen
OSTP - Neil Lane

From: Al Larson AL

Subject: Biotech Meeting On Monday, October 23

I am looking forward joining your discussion of the Starlink issue. I wanted to be sure to give you a heads up on the kind of questions we are getting and issues we face internationally. In that regard, we need to address the following questions, many of which undoubtedly overlaps with domestic concerns:

- Is Starlink corn likely to have gotten into the food system in Europe or elsewhere outside of the United States? If so, what can we do about it now, and into the future?
- Is there a danger to human health from exposure to the sources we are detecting? Why or why not?
- How did this happen and what are we doing to get it out of the food system?
- Does this episode justify a change in the U.S. regulatory system and/or support the view that these products cannot be handled properly?
- What are we hearing from our international contacts, and how much do we think others are likely to politicize this issue?
- What is the message we want to deliver when questions are raised with our posts overseas or by foreign officials? To the press? Do we need a message tailored by region or country?
- Can we achieve a cleared message and cable it out to posts by Monday or Tuesday?
- What impact is this likely to have on our international stance and progress on biotech, for example in the upcoming October 24 CODEX labeling meetings?

I also attach a paper that identifies broader biotech issues we see on the international scene. While these issues may go beyond the scope of your meeting on Monday, they are all likely to be affected by how we handle Starlink. We need an early opportunity to resolve them.

Attachment

cc Gene Sperling

KEY INTERNATIONAL BIOTECH DISCUSSION ISSUES

1. Concerted USG efforts against EU obstacles on market access for US-approved biotechnology agriculture products and for a useful report from the US-EU Biotechnology Consultative Forum.

The EU has approved no new biotech products since 1998, and it has several new initiatives that are likely to have a further negative impact on U.S. biotech food and feed trade. EU actions are affecting biotech markets and perceptions worldwide, and run the risk of stopping this promising technology dead in its tracks, to the detriment of developing countries and of consumers everywhere. EU actions are also provoking a backlash against rules-based trade and undermining confidence that new technology can be safely developed for the benefit of all. This feeds into anti-globalization here and abroad.

Presidents Clinton and Prodi agreed in December 1999 on a two-track biotech approach to address biotechnology issues: a U.S.-EU Consultative Forum comprised of non-governmental experts; and, a U.S.-EU Senior Level Group (SLG) dialogue on market access and other regulatory issues. Both are moving, but in very low gear. The Forum was initially slowed by a science/non-science ideological divide, but the chairs are working to bridge the gap to produce a useful report by December for Presidents Clinton and Prodi. The SLG dialogue has been hampered by serious political barriers to progress on biotech in Europe and difficulties in getting our EU interlocutors to schedule discussions on issues. The European Commission has failed to reverse the new ban by Italy on imports of already-approved U.S. corn. This comes despite a ruling by relevant EU science officials that there was absolutely no scientific basis for the ban, senior-level Commission officials' assurances to address this problem in time for the critical October to December grain season, and efforts from our side to establish testing procedures to facilitate sales of approved biotech varieties.

Results from either track of the Clinton-Prodi process are clearly not guaranteed before the US-EU Summit now planned for December 18, 2000. We are pressing Commission DG Legras on these issues but need to determine other steps we can take before the Summit.

Issues for Decision

- What additional steps can we take to encourage the EU to restart its biotech approval process and its imports of already-approved U.S. biotech corn (and to maintain access for our soybeans and feed grain), as well as to take clear action against the Italian ban on approved corn imports?

- How to convey credibly to EU authorities (including through the next US-EU Biotech SLG meeting scheduled for November 21) that absent concrete results before the December Summit, President Clinton's and Prodi's Biotechnology Initiative will be judged a failure and that this will have consequences for our trade relations and for our mutual efforts to encourage widely-shared growth worldwide.

- Should we consider other actions, such as encouraging developing countries to speak out more on their biotech interests and publicizing more widely the inconsistencies in Europe's official biotech position, to raise the profile internationally in the run up to the Summit?

2. USG efforts to help form, influence and coordinate with "like-minded countries" (including developing countries) on biotechnology issues to maintain a science-based, rules based approach.

To counter EU and other anti-biotech challenges, foster better global understanding of biotechnology, and strengthen our diplomacy in international fora such as CODEX and WTO, we need to help establish a broader group of like-minded countries on biotech issues. Countries such as Australia, Argentina, Brazil, Canada, Chile, China, India, Japan, Kenya, Malaysia, Mexico, Nigeria, Kenya, South Africa and Singapore are among countries we might cultivate. It is especially important that we engage a broader group on the CODEX negotiating agenda, both on labeling and on precaution. We can build upon, but should not duplicate, the Miami Group that was useful on the Biosafety Protocol. USTR has also begun efforts in Geneva in discussions on agricultural issues to identify possible new allies.

Engaging in biotech capacity building in developing countries must be part of our effort to build the group. This would also follow up on the G8 Okinawa communiqué

calling for greater focus on agricultural capacity building in developing countries. USDA, FDA, and USAID could review their capacity building programs and the OSTP explain its capacity building initiative. Similarly, ratcheting up our public diplomacy efforts to inform the global public of the role of biotech products can lead to a greater appreciation of biotechnology's promise for alleviating hunger and improving living standards in the developing world, and in facilitating more environmentally sustainable agriculture, and push back on anti-biotech (and anti-rules-based trade) efforts worldwide.

Issues for Decision

- Is there interagency agreement to create this group and on what steps we can take organize it as soon as possible to help us in CODEX, WTO, and other international fora?

- How can we use the upcoming October 24-28 meeting in India of CODEX's working group on biotech labeling guidelines to advance this goal in a manner that serves our policy interests and to raise biotech's positive profile in India?

- Can we organize a meeting in India prior to this next CODEX meeting of those countries (especially developing countries) with which we might find common cause? What other avenues/events are available to us?

- Can we also agree to identify and expand where possible resources for agricultural/biotech capacity-building in developing countries (some members of Congress have an interest in this too) and to step up public diplomacy with potential allies?

- What new approaches/resources are available to us?

3. **Stronger response to emerging issues through an enhanced interagency team approach (in essence a biotech SWAT team) to engage quickly with countries and regional organizations considering highly restrictive, infeasible, and/or costly approaches to regulating biotechnology.**

The number of countries looking at or addressing biotech regulation is growing. Foreign authorities and audiences often do not understanding fully the consequences of their

actions to regulate biotech products. Saudi Arabia, for example, has de facto banned biotech products with little analysis and without recognizing its implications. There are almost daily reports of the potential for similar restrictive approaches to be taken, often with little or no analysis or discussion. We are trying to respond to these developments both bilaterally and multilaterally, but need to improve our efforts. The draft FY 2001 Senate Report language underscores the need for us to more aggressively counter the EU biotech challenges. USDA, State, USTR, Commerce and others have been working to address these challenges and it may make sense to formalize that effort and to add USAID and others to a team that communicates regularly by e-mail. This team could also pro-actively identify countries where a concerted effort by the USG could help produce a better-informed public debate on biotech.

We need to organize a USG biotech team to help us respond quickly (through demarche cables and/or letters, telephone calls, high level diplomacy and visits as needed) to foreign capitals to educate government, industry, and civic authorities. Such a team approach would require a more formalized e-mail network of interagency contacts to share information and alerts on international biotech developments, and a specific commitment to quickly draft and clear demarches to the field and identify opportunities and needs for additional diplomatic contacts and visits. The process would likely benefit from the development of baseline megatalkers on, for example, the science and safety of biotech, policy considerations related to biotech regulation and trade commitments/goals, points on any assistance/dialogue we might offer to further inform on biotech, and information on useful international fora where biotech issues are being discussed.

Issue for Decision

Should we formalize a US interagency team approach to reach out to foreign capitals both to preempt and tackle biotech issues?

4. Clarify biotech policy guidance related to rules governing the interface between regulatory precaution and international trade.

Labeling

The EU and over 30 countries (including Japan and Mexico) have either mandated labeling of biotech products or are

considering some form of labeling. The EU specifically is likely to make mandatory labeling part of its revision of Directive 90/220, which the EU expects to complete by January 2001. International CODEX negotiations on labeling continue in India starting October 24. We are confronted with a variety of approaches to labeling that differ from ours, and a clear need to promote approaches consistent with our own in a manner that is credible and understandable diplomatically and to the general public.

To facilitate choice and information, our policy has been to support the provision of any information that consumers wish by industry, including by labeling, provided it is truthful and not misleading. The FDA, pursuant to the Administration's May 3 biotech initiative, is developing guidelines for voluntary efforts to label products either as "GM- or biotech-free" or with something such as "may contain biotech products." We want to avoid the mistaken impression that biotech-free food has been found in any way "better" for people, and prevent any false health claims for biotech foods, yet still allow information to be provided credibly. We do require by law that food be labeled as to its nutritional composition and basic properties, including any potential for allergenicity in some people.

We do not mandate or require labels for any other purpose, as we have tended to believe that the costs of making such distinctions that have no known health and safety impact should be allocated by the market. For example, we support a legal standard for companies choosing to label foods as "organic" in order to serve that market, but we do not require all other foods to be labeled non-organic, which would then impose a cost on those who are comfortable buying other than organic foods. A number of expert economists find that mandatory labeling of biotech foods and treating them in the product stream as if they were toxic (via low test tolerances for non-biotech purity and extremely detailed standards of separation and traceability, etc.) will likely raise overall foods costs for everyone without commensurate health/safety benefits. Nonetheless, some (including some consumer groups) argue for these approaches in the international arena, often on "consumers right to know" grounds. The merits and demerits for consumers of alternative approaches to mandatory labeling, and the implications for similar future debates on information provision, science, food costs and trade have not been carefully examined internationally.

To meet consumer demands/concerns, our food industry can support international standards for using a "GM- or biotech-free" label for products without genetically engineered ingredients. Our industry and negotiators also argue for reasonable and consistent tolerance levels (based on scientific considerations of safety and feasibility and consumer cost/preference considerations), and attention to ensuring that labels be truthful and not misleading. We need to give guidance to our negotiators on both strategy and tactics on these difficult issues.

Issues for Decision

- Should we hold the line firmly in international negotiations on an approach more consistent with our policy?

- To do so, do we need to press for explicit consideration by international negotiating groups of consumer and administrative costs of heavier legal requirements for labeling?

- Should we also have international negotiating groups compare such options not only with our labeling approach but as well with our active encouragement for a variety of initiatives (hotlines, web sites, brochures, etc.) to provide information to consumers?

- Could we seek to improve and make fuly consistent our explanation of the ways in which our approach will better protect consumer choice, welfare and income in an evolving market?

- For consistency, do we need to move more quickly to establish standards for a non-biotech or non-GM label here at home?

- Can and should we use the WTO in addition to CODEX to address labeling/regulatory issues?

"Precautionary Principle" (PP)

We need to clarify our longstanding approach to regulatory precaution. We have repeatedly made clear to our EU interlocutors our opposition to the PP. We have not, however, yet been fully effective in dealing with the PP in international fora. It is essential that we confront and challenge what is continued EU movement to gain

international acceptance of an elastic, non-science based, and inconsistent zero risk/tolerance version of the PP (which is contrary to the more reasonable approach originally proposed in the Commission's own White Paper). The EU member states approach to the precautionary principle is already having negative impacts on trade.

Italy and France have recently used the PP specifically to justify actions against biotech product. Meanwhile, it is unclear that the Commission will force Italy to rescind its ban on approved corn, justified using the PP, despite that it has been found scientifically insupportable. European officials (especially in member states) increasingly use the term without precision as a rationale for considering a wide variety of highly restrictive regulations that may well be WTO-inconsistent. The European Parliament may push for an extreme version of the PP that would include provisions such as: zero risk as a reasonable standard against which to measure traded goods and services; no requirement of proportionality and non-discrimination; no requirement for science-based risk assessment before taking trade restrictive measures; and, agreement to bring strong pressure internationally to that this version of the PP is the foundation for implementing WTO SPS (Sanitary and Phytosanitary provisions) Agreement Article 5.7.

Application of such a standard is not only scientifically impossible, but would radically restrict consumer choice and access to new and current products. It is not a standard that Europe employs at home with regard to food, wine, or many other goods and services currently enjoyed there. Further attempts by the EU to make this a standard for others products, even if partially successful, would have direct and ultimately far broader negative impacts on consumers worldwide. It would certainly make it near impossible for developing country exports to meet SPS standards, with which they struggle already, and would thereby constrict their agricultural exports, a critical basis for their growth and poverty alleviation.

US industry (and our scientists) is comfortable in general with our own science-based approach and efforts to incorporate caution and precaution into regulatory systems so as to protect public safety and enhance public welfare. Our industry (and many scientists and regulators) strongly opposes the PP and EU efforts to make it an international legal principle. Some of our consumer groups disagree and are not yet compelled by food cost concerns or the effectiveness of alternative approaches. Our food industry

also wants USG negotiators to reject discussion of the PP or the formal use of the term in all international fora, including CODEX, and urges a more effective presentation of our own strong approach. Senator Grassley has asked the GAO to investigate how the USG has handled the PP in international fora and negotiations, on the premise that the EU's approach has hurt our interests.

Issues for Decision

Whether to oppose henceforth any inclusion or discussion of the PP in CODEX, WTO, or other international bodies?

Whether to work more actively to better articulate our own approach and work harder to gain general support for an approach to regulatory precaution more similar to our own?

Whether to aggressively oppose EU efforts to create a simplistic one-size-fits-all standard for all instances of regulatory precaution?

How to identify additional steps to underscore with the EU our serious concern with the PP (the Summit?) and to build support elsewhere for a more balanced approach to help protect consumers everywhere now and into the future?

Traceability

The EU is likely to mandate traceability of biotech products as part of its 90/220 revision. The French are pushing a more radical traceability proposal. A European version of traceability will likely compel segregation of biotech and non-biotech products throughout the food chain and substantially drive up food costs. Higher food prices will hit developing countries especially hard. We view biotech and conventional foods as substantially equivalent (a scientific concept under attack in the EU) and see no need for mandated traceability.

Our science based food safety system relies on the concept that we build upon the decades old understandings/experience we have with the genetics and microbiology of key foods/grains, and of their nutritional aspects and of human consumers reactions to them, to understand the safety of varieties of these foods. In essence, scientists look at what is different in new varieties, consider the science of what the differences mean nutritionally and regarding human health, and look for risks accordingly. If they assess based on the science no new health risk, they judge the new

variety to be "substantially equivalent" to the old one. Dispensing with that standard would imply that scientists reassess the safety of the baseline food, even if it had been in the human food chain for a very long time. Essentially, it would pose a much higher and more costly standard for biotech foods, which most scientists are convinced would do little or nothing to improve human health.

Issues for Decision

- Should we include in our diplomatic outreach and negotiating efforts at CODEX and elsewhere, a clear, cogent and analytical response to the EU traceability proposal that shows how it likely will increase food prices?

- To raise awareness, should we specifically identify opportunities to raise traceability in our general biotech outreach?

- Should traceability, labeling, and the PP issues be part of the December US-EU Summit agenda since they will not be resolved by then?

Biotech Timetable

See attached biotech calendar of event.