

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	Bruce McNamer to Antony Blinken, re: GMO Update (6 pages)	07/15/1999	P1/b(1) v 4/3/2020
002. email	John Duncan to Stephen Sargeant, re: Prodi GMO/WTO (3 pages)	07/28/1999	P1/b(1) v 11/26/2019
003. email	Stephen Sargeant to L. June Bartlett, et al., re: Prodi GMO/WTO (3 pages)	07/28/1999	P1/b(1) v 11/26/2019
004. email	John Duncan to D. Holly Hammonds, re: Prodi GMO/WTO (3 pages)	07/28/1999	P1/b(1) v 11/26/2019
005. email	John Duncan to D. Holly Hammonds, re: Prodi GMO/WTO (3 pages)	07/28/1999	P1/b(1) v 11/26/2019
006. email	Gayle Smith to Bruce McNamer, re: NEC Deputies GMO mtg readout (3 pages)	07/30/1999	P1/b(1) KBH 8/29/2019
007. email	Richard Holtzapple to Edward Fendley, re: Biosafety: Compulsory Labeling of Genetically Modified Foods [duplicate of 008] (10 pages)	08/05/1999	P1/b(1) v 4/3/2020
008. email	Ian Bowles to Richard Holtzapple, re: Biosafety: Compulsory Labeling of Genetically Modified Foods (10 pages)	08/05/1999	P1/b(1) v 4/3/2020
009. email	Ian Bowles to Douglas Bayley, et al., re: Biosafety: Compulsory Labeling of Genetically Modified Foods [duplicate of 008] (11 pages)	08/05/1999	P1/b(1) v 4/3/2020
010. email	Ian Bowles to Elaine Mitsler, re: Biosafety: Compulsory Labeling of Genetically Modified Foods [duplicate of 008] (10 pages)	08/11/1999	P1/b(1) v 4/3/2020
011. email	Bathsheba Crocker to Matthew Schaefer, re: Read Out of This Morning's Deputies on GMOs (2 pages)	09/30/1999	P1/b(1) KBH 8/29/2019

COLLECTION:

Clinton Presidential Records
NSC Emails
Exchange - Record (Sept 97 - Jan 01) ([GMO...])
OA/Box Number: 620000

FOLDER TITLE:

[07/01/1999 - 12/15/1999]

2013-0836-F

ke3023

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]

Exchange Mail

DATE-TIME 7/1/99 5:23:33 PM
FROM Crocker, Bathsheba N.
CLASSIFICATION UNCLASSIFIED
SUBJECT NEC DC on GMO [UNCLASSIFIED]

TO Duncan, John D.
Hammonds, D. Holly (INTECON)
Hendricks, Lori A. (INTECON)
Holtzapple, Richard A.
Lee, Malcolm R.
McNamer, Bruce
Mitsler, Elaine M. (INTECON)
Russ, Judith P. (ADMIN)
Schaefer, Matthew P. (INTECON)
Shah, Sonal R.
Crocker, Bathsheba N.
Davies, Glyn T. (EXSEC)
Dejban, Donna D. (NSA)
Hachigian, Nina L. (NSA)
Kerrick, Donald L. (NSA)
Millison, Cathy L. (EXSEC)
Mitchell, Rebecca (Julie) J. (NSA)
Moretz, Sheila K. (NSA)
Rudman, Mara E. (CNSLR)
Sargeant, Stephen T. (EXSEC)
Scott-Perez, Marilyn L. (NSA)
Storey, Sharon V. (NSA)
Sutphen, Mona K. (NSA)

CARBON_COPY

TEXT_BODY Wondering whether there will be paper for the DC on GMO tomorrow?
I wasn't sure who would be working it, so sorry to send this to everyone. Thanks, Sheba

Exchange Mail

DATE-TIME 7/15/99 9:54:23 AM

FROM McNamer, Bruce

CLASSIFICATION ~~CONFIDENTIAL~~

CLASSIFICATIONREASON 1.5(d)(e)

DATECLASSIFIEDON 07/15/1999

DECLASSIFYON 07/15/2009

SUBJECT GMO update [~~CONFIDENTIAL~~]

TO Blinken, Antony J. (EUR)

CARBON_COPY Hammonds, D. Holly (INTECON)
Schaefer, Matthew P. (INTECON)

TEXT_BODY Tony
Wanted to give you an update on where we are on GMOs. The attached memo may be more information than you need. However, if you do need more background, let me know.

TRANSLATED_ATTACHMENT tb.update.doc
UPDATE ON EVOLVING USG STRATEGY/APPROACH ON
GMOS

Engaging the EU
Much of our challenge in gaining access to EU markets stems from the lack of any clear leverage points. While the regulatory regime is muddled, it does not clearly represent a non-tariff barrier to trade, and a WTO case claiming as much risks dragging on for years with an uncertain outcome. A WTO action, moreover, risks raising the temperature around what is for the Europeans a very sensitive issue in ways unlikely to advance our aims. At the same time, we want to insist with the Europeans that this issue is of utmost importance to us. With that in mind, we will for the time being attempt to engage the Europeans on the subject

DECLASSIFIED
E.O. 13526, Sec. 3.5 (b)
White House Guidelines, September 11, 2006
By VL NARA, Date 11/20/2009
2016-0520-m (3.23)

at high levels in all appropriate fora, bilateral and multilateral, continuing to press consistently for transparent, science-based approach to GMO regulation.

Other specific initiatives include:

- * USTR will approach EU with request to renegotiate compensation arrangements for corn sales to Spain and Portugal. Our claim essentially insists that EU compensate US corn producers for sales foregone to those countries (sales negotiated as part of EU accession agreements for Spain and Portugal) by ban on

GMO imports. This could be worth \$400-\$500 million.

- * We are working with USTR and State on draft of POTUS letter and more general strategy for approach to Romano Prodi on GMOs as he assumes Presidency of the EU.

POTUS will ask Prodi to designate a high level representative to meet with appropriate USG officials to consult on the point above. We will also seek

Prodi's commitment to defining an overall Commission approach to biotechnology

and, in particular, to removing the political blocks to products sown in the United States but currently stuck in the 90/220 pipeline

- * USDA will meet with the French officials in several weeks to follow up on

Secretary Glickman's June visit there. Our strategy with the French is to

continue our dialogue on tactical issues - harmonization of approval processes,

identifying steps to restore consumer confidence - on which we can continue to

make progress in the hopes of building a more constructive relationship to tackle

larger issues (e.g., precautionary principle).

- * We are working at present with the OECD to define the terms of reference for

the work by that body on biotechnology and food safety as mandated by the G8

Leaders in June. The approach we are recommending would not have the existing

OECD working groups undertake serious new work on the subject. Rather, it would

have the OECD report back to the G8 with a short paper (a "roadmap") outlining

the ongoing work in food safety (and food biotechnology) in OECD and how it

supports and complements work in other fora (OECD, UN bodies,

Academies, etc.).

* We will continue work in the TEP Pilot Process as agreed at the US-EU Summit on harmonizing regulatory processes

* We will continue to press for and offer technical assistance to the EU for establishing an EU-wide regulatory agency for food safety that can become the EU's FDA-equivalent body. This may ultimately be driven by negotiations that would include some concessions on the U.S. side on the subject of labeling (see below)

Public Outreach/Education

State is taking lead in coordinating public outreach and education efforts on biotechnology in Europe. We have already made a start on this program, with visits by US regulators to some EU member states, invitations to EU journalists under the International Visitors Program, and speeches and editorials by US officials in Europe. Ambassador Schneider in the Netherlands will host an international conference on biotechnology in January. State expects to outline a broader communications agenda within the next month.

Independent of these coordinated efforts, but as important to public awareness, we are also working with the NAS and the Royal Academy as they convene an independent "blue ribbon" panel of scientists from the US, the UK and developing countries to review food safety issues as they relate to GMOs. This group will meet for the first time this month and will issue a final report within the next eight months.

New Approaches to Labeling - U.S. industry has largely opposed any kind of labeling, based inter alia on increased costs (particularly those associated with segregating biotech products) and the risk of heightened confusion/fear by consumers. However, new EU regulations, while painfully short on details, now require that all GMOs be labeled as such. Moreover, there are

increasing calls in international and other fora for a labeling regime, either voluntary or mandatory, which gives consumers the option of an informed choice. While the ultimate decision to label or not, at least on a voluntary basis, will be that of food providers, the Administration can play a role in different fora in defining standards for labels that are used. Indeed, our willingness to engage in such a standard-setting process (such standards can ultimately be used in either mandatory or voluntary schemes) may be one negotiating lever with the Europeans as we press for regulatory reform and market access. The Administration's public support for more widespread use of voluntary labeling would, moreover, signal a greater sensitivity to consumers' concerns, and thus might improve the overall environment around the topic. Such support would undoubtedly meet with initial industry resistance, but there are already signs that many in industry are much more amenable to some labeling of GMOs than had previously been the case.

The subject of labeling of GMOs will in all likelihood receive increased attention in this country in the near future. As noted above, Consumers Union is expected to advocate for mandatory labeling of GMOs later this month. Moreover, fallout from the current European controversy is likely to reach our shores sooner rather than later. This too would argue for consultation between industry and the Administration on appropriate standards for voluntary GMO labeling, which might take as a model USDAs work to develop standards for organic food labeling.

The Deputies have not yet committed to a standards-setting role for the USG on voluntary labeling, nor to a more public advocacy role for the use of voluntary labels. Secretary Glickman's remarks this week on the subject, while considerably toned down from his initial drafts, were his own (and in

the end
amounted to public musings about the need for industry to educate consumers,
labeling being one means of doing so), and the Administration's official policy
continues to be only that we support voluntary labeling so long as it is truthful
and not misleading, without in any way advocating such labeling.

Other markets/fora

While we do have an evolving strategy for engaging with the Europeans on GMOs,
there is a sense in which much of that battle has already been lost, at least in
the short term. This is not true in other markets like, for example, Latin
America or Asia; markets where a far greater percentage of our food exports might
be put at risk. We are helped in many of these countries (e.g. Argentina, China)
by their own growing use of biotechnology in agriculture. Nevertheless, we have
seen growing efforts in Australia, New Zealand, Japan and other countries to
address more directly concerns about GMOs, with labeling schemes being the first
suggested line of defense.

The real immediate threat to our exports in these markets, however, lies in
ongoing discussions in the multilateral fora in which these countries participate
and in which the EU particularly continues to press for its own GMO agenda (e.g.,
precautionary principle, mandatory labeling). This has been most obviously
manifest in the Biosafety Protocol negotiations, but has also been evident at the
Codex, the OECD and elsewhere. Our strategy in these contexts continues to rely
on a steadfast insistence on sound science and transparent processes as a basis
for regulation of GMOs, and on building alliances - pragmatically in the
Biosafety negotiations with other large commodity exporters, and more
ideologically in other fora like the Codex and OECD whose staff and representatives are more typically from scientific or regulatory backgrounds. We
have also resisted labeling in those fora, although recently we have

indicated
greater support for standards in voluntary labeling schemes.

GMOs are likely to inform contentious parts of the agenda at APEC
and at the WTO
Ministerial. The Deputies plan to take up the question as to
appropriate
strategy for those fora within the next month.

Exchange Mail

DATE-TIME 7/15/99 11:21:45 AM

FROM McNamer, Bruce

CLASSIFICATION ~~CONFIDENTIAL~~

CLASSIFICATIONREASON 1.5(d)(e)

DATECLASSIFIEDON 07/15/1999

DECLASSIFYON 07/15/2009

SUBJECT RE: GMO update ~~[CONFIDENTIAL]~~

TO Blinken, Antony J. (EUR)

CARBON_COPY

TEXT_BODY

you got it! but you might want to add tofu or soy sauce to the mix
-- assure yourself of the maximum GMO load.

-----Original Message-----

From: Blinken,
Antony J. (EUR)

Sent: Thursday, July 15, 1999 10:05 AM

To: McNamer,
Bruce

Cc: Hammonds, D. Holly (INTECON); Schaefer, Matthew P.
(INTECON)

Subject: RE:

GMO update ~~[CONFIDENTIAL]~~

thanks Bruce. Just what i was looking
for. Looks like excellent weekend reading over a nice beef stew
with some corn and rice.

-----Original Message-----

From: McNamer,
Bruce

Sent: Thursday, July 15, 1999 9:54 AM

To: Blinken, Antony
J. (EUR)

Cc: Hammonds, D. Holly (INTECON); Schaefer, Matthew P.
(INTECON)

Subject: GMO update ~~[CONFIDENTIAL]~~

Tony
Wanted to

DECLASSIFIED E.O. 13526
White House Guidelines,
September 11, 2006

By KDE NARA, Date 3/13/15
2013-0836-F

give you an update on where we are on GMOs. The attached memo may be more information than you need. However, if you do need more background, let me know.

<< File: tb.update.doc >>

Exchange Mail

DATE-TIME 7/28/99 11:40:41 AM

FROM Duncan, John D. (INTECON/DOS)

CLASSIFICATION ~~CONFIDENTIAL~~

CLASSIFICATIONREASON 1.5(e)

DATECLASSIFIEDON 07/26/1999

DECLASSIFYON 07/26/2009

SUBJECT RE: Prodi GMO/WT0 [~~CONFIDENTIAL~~]

TO Sargeant, Stephen T. (EXSEC)

CARBON_COPY Hammonds, D. Holly (INTECON)

DECLASSIFIED
E.O. 13526
White House Guidelines, May 16, 2017
By 12 NARA, Date 11/7/09
2016-0524-m

TEXT_BODY

you bet, will keep you informed

-----Original Message-----

From: Sargeant,
Stephen T. (EXSEC)
Sent: Wednesday, July 28, 1999 11:40 AM
To: Duncan,
John D. (INTECON/DOS)
Cc: Hammonds, D. Holly (INTECON)
Subject: RE:
Prodi GMO/WT0 [~~CONFIDENTIAL~~]

Thanks John

-----Original Message-----

From: Duncan,
John D. (INTECON/DOS)
Sent: Wednesday, July 28, 1999 11:38 AM
To: Sargeant,
Stephen T. (EXSEC)
Cc: Hammonds, D. Holly (INTECON)
Subject: FW:
Prodi GMO/WT0 [~~CONFIDENTIAL~~]

Steve,
I think this is one of those
times you need to be kept in the loop. We are on hook to do a reply
to Prodi (#5222)(due date 21 July). Interim response very difficult
since it simply suggests a meeting. Probably will be folded into

a POTUS letter to Prodi being drafted by NEC on GMOs. Can't respond until we know what to say about meeting w/POTUS. I will forward you one other set of e-mails on issue. John

-----Original

Message-----

From: Duncan, John D. (INTECON/DOS)

Sent: Wednesday,

July 28, 1999 11:32 AM

To: McNamer, Bruce

Subject: FW: Prodi GMO/WTO

~~[CONFIDENTIAL]~~

Bruce,

Any forward progress? If not, any suggestions? John

-----Original

Message-----

From: Hammonds, D. Holly (INTECON)

Sent: Monday,

July 26, 1999 3:22 PM

To: Duncan, John D. (INTECON/DOS)

Subject: RE:

Prodi GMO/WTO ~~[CONFIDENTIAL]~~

Thanks very much John..

-----Original

Message-----

From: Duncan, John D. (INTECON/DOS)

Sent: Monday,

July 26, 1999 3:18 PM

To: Hammonds, D. Holly (INTECON)

Subject: FW:

Prodi GMO/WTO ~~[CONFIDENTIAL]~~

Holly,

Bruce says Lael has responded

on the unclass system and has asked if we could find out Prodi's schedule and whether it is likely he would come here to meet with POTUS. She also wanted to find out if POTUS is going to Europe for anything in near future. I told Bruce I would call Larry Butler's replacement in Europe to try to get answers. John

-----Original

Message-----

From: McNamer, Bruce

Sent: Monday, July 26, 1999

3:13 PM

To: Duncan, John D. (INTECON/DOS)

Subject: Prodi GMO/WTO

~~[CONFIDENTIAL]~~

John

Below is copy of E-mail I sent to Lael on
unclassified system (I don't believe you are on that system)

As

you know, we have ready to go a letter from POTUS to Pres. Prodi suggesting they appoint high-level reps to discuss GMOs. We have not moved this forward, however, as we need to coordinate a response to a Prodi suggestion for a meeting with POTUS on WTO.

* In a letter

to POTUS in early June (response to POTUS' congratulatory note), Prodi suggested that he would like to meet with POTUS in the run-up to WTO Ministerial to "maximize the chances of having a positive atmosphere for the launch of the new round." We have yet to respond to the Prodi suggestion.

* NSC is not seized with the importance of the issue and, given POTUS already hectic fall schedule, will not push for a POTUS meeting.

* Holly thinks it essential that we engage in some meaningful way and soon with the EU on the WTO agenda.

She thinks a POTUS/Prodi meeting would be a great way to do so.

* NEC could push for a meeting. Holly would like to talk to you about this.

* If there is no meeting, we need to find another way to engage with Prodi on WTO (e.g., series of phone calls, high level representatives)

* USTR is looking to send Prodi GMO letter/message forward... difficult to do so without acknowledging Prodi's own request to POTUS for WTO engagement.

Exchange Mail

DATE-TIME 7/28/99 11:40:43 AM
FROM Sargeant, Stephen T. (EXSEC)
CLASSIFICATION ~~CONFIDENTIAL~~
CLASSIFICATIONREASON 1.5(e)
DATECLASSIFIEDON 07/26/1999
DECLASSIFYON 07/26/2009
SUBJECT FW: Prodi GMO/WTO [~~CONFIDENTIAL~~]
TO Bartlett, L. June (EXSEC)
Dejban, Donna D. (NSA)
Hilliard, Brenda I. (EXSEC)
Joshi, M. Kay (EXSEC)
Millison, Cathy L. (EXSEC)
Snip, Sarah E. (EXSEC/INTERN)
Wasserman, Elaine P. (EXSEC)

CARBON_COPY Snip, Sarah E. (EXSEC/INTERN)

DECLASSIFIED
E.O. 13526
White House Guidelines, May 16, 2017
By VL NARA, Date 11/16/2019
2016-0529-22

TEXT_BODY

For our tracking. Thanks
Steve

-----Original Message-----

From: Duncan,
John D. (INTECON/DOS)
Sent: Wednesday, July 28, 1999 11:38 AM
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Message-----

From: Duncan, John D. (INTECON/DOS)
Sent: Wednesday,
July 28, 1999 11:32 AM
To: McNamer, Bruce
Subject: FW: Prodi GMO/WTO
[CONFIDENTIAL]

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* USTR is looking to send Prodi GMO letter/message forward... difficult to do so without acknowledging Prodi's own request to POTUS for WTO engagement.

Exchange Mail

DATE-TIME 7/28/99 11:41:46 AM
FROM Duncan, John D. (INTECON/DOS)
CLASSIFICATION ~~CONFIDENTIAL~~
CLASSIFICATIONREASON 1.5(e)
DATECLASSIFIEDON 07/26/1999
DECLASSIFYON 07/26/2009
SUBJECT FW: Prodi GMO/WTO [~~CONFIDENTIAL~~]
TO Hammonds, D. Holly (INTECON)

CARBON_COPY

TEXT_BODY

fyi

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Subject: FW:

Prodi GMO/WTO [~~CONFIDENTIAL~~]

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D. Holly (INTECON)

Sent: Monday, July 26, 1999 3:22 PM

To: Duncan,

John D. (INTECON/DOS)

Subject: RE: Prodi GMO/WTO [~~CONFIDENTIAL~~]

Thanks

very much John..

-----Original Message-----

From: Duncan, John

D. (INTECON/DOS)

Sent: Monday, July 26, 1999 3:18 PM

To: Hammonds,

DECLASSIFIED
E.O. 13526
White House Guidelines, May 16, 2017
By 12 NARA, Date 11/16/2014
2014-0574-14

D. Holly (INTECON)
Subject: FW: Prodi GMO/WTO ~~[CONFIDENTIAL]~~

Holly,
Bruce

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~~[CONFIDENTIAL]~~

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Exchange Mail

DATE-TIME 7/28/99 3:50:05 PM
FROM Duncan, John D. (INTECON/DOS)
CLASSIFICATION ~~CONFIDENTIAL~~
CLASSIFICATIONREASON 1.5(e)
DATECLASSIFIEDON 07/26/1999
DECLASSIFYON 07/26/2009
SUBJECT FW: Prodi GMO/WTO [~~CONFIDENTIAL~~]
TO Hammonds, D. Holly (INTECON)

CARBON_COPY

TEXT_BODY

fyi

-----Original Message-----

From: McNamer, Bruce
Sent: Wednesday,
July 28, 1999 3:46 PM
To: Duncan, John D. (INTECON/DOS)
Subject: RE:
Prodi GMO/WTO [~~CONFIDENTIAL~~]

Nope

I will see Lael at 5:00. Will
ask then

-----Original Message-----

From: Duncan, John D. (INTECON/DOS)

Sent: Wednesday, July 28, 1999 11:32 AM
To: McNamer, Bruce
Subject: FW:
Prodi GMO/WTO [~~CONFIDENTIAL~~]

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-----Original Message-----

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D. Holly (INTECON)
Sent: Monday, July 26, 1999 3:22 PM

DECLASSIFIED
E.O. 13526
White House Guidelines, May 16, 2017
By VL NARA, Date 11/26/2019
2016-0524-m

To: Duncan,
John D. (INTECON/DOS)
Subject: RE: Prodi GMO/WTO ~~[CONFIDENTIAL]~~

Thanks
very much John..

-----Original Message-----

From: Duncan, John
D. (INTECON/DOS)
Sent: Monday, July 26, 1999 3:18 PM
To: Hammonds,
D. Holly (INTECON)
Subject: FW: Prodi GMO/WTO ~~[CONFIDENTIAL]~~

Holly,
Bruce

says Lael has responded on the unclass system and has asked if we could find out Prodi's schedule and whether it is likely he would come here to meet with POTUS. She also wanted to find out if POTUS is going to Europe for anything in near future. I told Bruce I would call Larry Butler's replacement in Europe to try to get answers. John

-----Original
Message-----

From: McNamer, Bruce
Sent: Monday, July 26, 1999
3:13 PM
To: Duncan, John D. (INTECON/DOS)
Subject: Prodi GMO/WTO
~~[CONFIDENTIAL]~~

John
Below is copy of E-mail I sent to Lael on
unclassified system (I don't believe you are on that system)

As

you know, we have ready to go a letter from POTUS to Pres. Prodi suggesting they appoint high-level reps to discuss GMOs. We have not moved this forward, however, as we need to coordinate a response to a Prodi suggestion for a meeting with POTUS on WTO.

* In a letter

to POTUS in early June (response to POTUS' congratulatory note), Prodi suggested that he would like to meet with POTUS in the run-up to WTO Ministerial to "maximize the chances of having a positive atmosphere for the launch of the new round." We have yet to respond to the Prodi suggestion.

* NSC is not seized with the importance
of the issue and, given POTUS already hectic fall schedule, will

not push for a POTUS meeting.

* Holly thinks it essential that we engage in some meaningful way and soon with the EU on the WTO agenda.

She thinks a POTUS/Prodi meeting would be a great way to do so.

* NEC could push for a meeting. Holly would like to talk to you about this.

* If there is no meeting, we need to find another way to engage with Prodi on WTO (e.g., series of phone calls, high level representatives)

* USTR is looking to send Prodi GMO letter/message forward... difficult to do so without acknowledging Prodi's own request to POTUS for WTO engagement.

Exchange Mail

DATE-TIME 7/30/99 4:30:41 PM
FROM Smith, Gayle E. (AF)
CLASSIFICATION ~~CONFIDENTIAL~~
CLASSIFICATIONREASON 1.5(e)
DATECLASSIFIEDON 07/30/1999
DECLASSIFYON 07/30/2009
SUBJECT RE: NEC Deputies GMO mtg - readout [~~CONFIDENTIAL~~]
TO McNamer, Bruce

DECLASSIFIED
PER E.O. 13526
2016-0529-m (3.24)
3/6/2019 KBH

CARBON_COPY

TEXT_BODY

thanks

-----Original Message-----

From: McNamer, Bruce
Sent: Friday,
July 30, 1999 3:58 PM
To: @AFRICA - African Affairs
Subject: FW:
NEC Deputies GMO mtg - readout [~~CONFIDENTIAL~~]

-----Original
Message-----

From: Holtzapple, Richard A.
Sent: Friday, July 30,
1999 3:47 PM
To: McNamer, Bruce
Subject: RE: NEC Deputies GMO mtg
- readout [~~CONFIDENTIAL~~]

Bruce - Do you want to cc: @Africa on
this as well?

-----Original Message-----

From: McNamer, Bruce

Sent: Friday, July 30, 1999 3:46 PM
To: Steinberg, James; Hammonds,
D. Holly (INTECON); Blinken, Antony J. (EUR)

Cc: Holtzapple, Richard
A.; @INTECON - Economic Affairs
Subject: NEC Deputies GMO mtg -
readout [~~CONFIDENTIAL~~]

Deputies met (July 30) to discuss GMO strategy for multilateral trade fora (APEC, FTAA, and WTO) and for the Biosafety Protocol.

In general, our strategy as we approach these talks is largely defensive. In each fora, we have already achieved some commitment to a science-based, transparent approach to the regulation of GMOs. Given the present surge in negative publicity around the topic, and the aggressiveness of the EU in pursuing its own GMO agenda, we should be cautious not to initiate any actions (such as a re-opening of the SPS in the WTO) which might result in our losing control of the issue and ultimately put us in a worse position than we are in now. That said, we might achieve some small gains:

- * APEC - The 1997 Ministerial issued a statement endorsing a science-based approach to GMOs, and encouraged the further technical work on the topic. For this year's Ministerial, we will push for a statement noting the technical work done to date and re-committing APEC to a science-based approach to GMOs.

- * Deputies discussed raising the profile of the issue at APEC, but want to be sensitive to domestic political pressures on member countries, particularly New Zealand, host for this year's Ministerial

- * FTAA - There has not been sufficient groundwork laid to permit including biotech in FTAA Ministerial in early November. Nevertheless, USTR plans to use the Ministerial to shore up bilateral support for our GMO position in advance of the WTO.

- * WTO - Will seek a commitment to address GMOs in a transparent, science-based way. However, we will not in all likelihood seek to re-open the SPS, for fear of opening a Pandora's box which we could not shut.

As we approach the next round of negotiations at the Biosafety Protocol in September, we are anticipating the best outcome at this point would be a failure of those talks, as most of the participants at present line up on the side of an agreement extremely inimical to our interests. We will continue to work to keep the so-called "Miami Group" (U.S., Canada, Argentina, Australia, Chile and Uruguay) together as a blocking coalition to the Protocol as currently proposed.

In the context of the Biosafety Protocol, and in the larger context of our overall international strategy on GMOs, we are exploring ways to better inform and assist developing countries as they formulate their own approaches to the subject. Over the next several weeks, an inter-agency group led out of State will develop proposals for outreach in particular to African countries, both in the form of information exchange and in technical assistance. The goal of this effort would be to better inform these countries as to the potential benefits to them of biotechnology, and to help them to develop the regulatory and scientific infrastructure to oversee the introduction and wider use of GMOs - both as producers and consumers.

Exchange Mail

DATE-TIME 8/4/99 11:22:55 AM
FROM Crocker, Bathsheba N. (NSA)
CLASSIFICATION UNCLASSIFIED
SUBJECT RE: GMO's --Sandy's interest [UNCLASSIFIED]
TO Bernard, Kenneth W. (HEALTH)
Sutphen, Mona K. (NSA)
Hammonds, D. Holly (INTECON)

CARBON_COPY**TEXT_BODY**

Ken: fyi, I'm covering for Mona this week and next. I don't have a copy of the discussion paper any more. Hope Intecon/NEC can get you a copy.

Thanks, Sheba

-----Original Message-----

From: Bernard,
Kenneth W. (HEALTH)
Sent: Wednesday, August 04, 1999 10:55 AM
To: Sutphen,
Mona K. (NSA); Hammonds, D. Holly (INTECON)
Cc: Crocker, Bathsheba
N. (NSA)
Subject: RE: GMO's --Sandy's interest [UNCLASSIFIED]

Mona:

Back today. Do you have a copy of the DC discussion paper I could see?

Holly: Do you have anything drafted on this? --Ken

-----Original
Message-----

From: Sutphen, Mona K. (NSA)
Sent: Monday, July
19, 1999 5:06 PM
To: Bernard, Kenneth W. (HEALTH)
Cc: @INTECON
- Economic Affairs
Subject: RE: GMO's --Sandy's interest [UNCLASSIFIED]

fyi:

as you all work, you should be aware that js gave sandy a copy of the dc discussion paper. your comments should assume he's at least skimmed that paper. m

-----Original Message-----

From: Bernard,
Kenneth W. (HEALTH)
Sent: Sunday, July 18, 1999 12:37 PM
To: Sutphen,
Mona K. (NSA)
Cc: @INTECON - Economic Affairs
Subject: GMO's --Sandy's
interest [UNCLASSIFIED]

At the Friday Senior Staff meeting, Sandy said he wanted a briefing on Genetically Modified Organisms (GMOs). This is an extremely complex trade/political/health issue that shares a stew pot with the likes of "hormones in meat," "pesticides residues on vegetables," and "pharmaceutical IPR issues." Each has a scientific component, but trade and politics are the ruling features. As was noted in Cologne, food safety (and trade) is a hot issue - just ask Coca Cola, the Belgian chicken producers or the (former) British Beef industry. My guess is that food/trade will be a defining US/EU/Asia debate over the next few years.

Holly tells me her staff will be taking an initial stab at the GMO issue for Sandy. I'll be in Florida for a speech on July 19, and in California after that (cell phone 202-395-3809) until August 3. As I will be back here for most of August, I would like to sit down sometime then with Holly and others to perhaps think broadly how to deal with GMOs and some of the other related issues noted above.

Pls pass this to Sandy if
you think necessary. --Cheers, ---Ken Bernard

Exchange Mail

DATE-TIME 8/4/99 12:58:42 PM
FROM Hammonds, D. Holly (INTECON)
CLASSIFICATION UNCLASSIFIED
SUBJECT RE: GMO's --Sandy's interest [UNCLASSIFIED]
TO Bernard, Kenneth W. (HEALTH)

CARBON_COPY**TEXT_BODY**

great. Pls feel free to call lael about your interest.

-----Original

Message-----

From: Bernard, Kenneth W. (HEALTH)

Sent: Wednesday,

August 04, 1999 12:38 PM

To: Hammonds, D. Holly (INTECON)

Subject: RE:

GMO's --Sandy's interest [UNCLASSIFIED]

Thanks - Next week is

OK by me.... I should probably talk to Lael about sitting in on discussions, if appropriate.

-----Original Message-----

From: Hammonds,

D. Holly (INTECON)

Sent: Wednesday, August 04, 1999 11:35 AM

To: Bernard,

Kenneth W. (HEALTH); Sutphen, Mona K. (NSA)

Cc: Crocker, Bathsheba

N. (NSA); Schaefer, Matthew P. (INTECON)

Subject: RE: GMO's --Sandy's
interest [UNCLASSIFIED]

Ken: In addition to the discussion paper,
NEC (Brainard) sent Sandy a paper on this issue and a description
of a process she is running. Bruce McNamer who has these docs is
out on vacation.

If Sandy's office can't locate either/both, Matt
(who is also out) and I will try to do so ...but tomorrow!

-----Original

Message-----

From: Bernard, Kenneth W. (HEALTH)
Sent: Wednesday,
August 04, 1999 10:55 AM
To: Sutphen, Mona K. (NSA); Hammonds,
D. Holly (INTECON)
Cc: Crocker, Bathsheba N. (NSA)
Subject: RE:
GMO's --Sandy's interest [UNCLASSIFIED]

Mona: Back today. Do
you have a copy of the DC discussion paper I could see?
Holly:
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Mona K. (NSA)
Sent: Monday, July 19, 1999 5:06 PM
To: Bernard,
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Cc: @INTECON - Economic Affairs
Subject: RE:
GMO's --Sandy's interest [UNCLASSIFIED]

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or the (former) British Beef industry. My guess is that food/trade
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Pls pass this

to Sandy if you think necessary. --Cheers, ---Ken Bernard

Exchange Mail

DATE-TIME 8/5/99 1:40:09 PM

FROM Holtzapple, Richard A.

CLASSIFICATION ~~CONFIDENTIAL~~

CLASSIFICATIONREASON 1.5(b)

DATECLASSIFIEDON 08/05/1999

DECLASSIFYON 08/05/2009

SUBJECT BIOSAFETY: COMPULSORY LABELING OF GENETICALLY MODIFIED FOODS [~~CONFIDENTIAL~~]

TO Fendley, Edward J. (ADMIN)

CARBON_COPY

TEXT_BODY

DECLASSIFIED
E.O. 13526, Sec. 3.5 (b)
White House Guidelines, September 11, 2006
By VL NARA, Date 11/26/2019
2016-0529-2 (3.25)

-----Original Message-----

From: WHSR
Sent: Wednesday, August 04, 1999 5:55 AM
To: Hammonds, D. Holly (INTECON); Hill, John J. (ASIA/INTERN);
Holtzapple, Richard A.; Huso, Ravic R. (ASIA); Keith, James R. (ASIA);
Lee, Malcolm R.; Lieberthal, Kenneth G. (ASIA);
Osius, Theodore G. (VP);
Pritchard, Charles (Jack) L. (ASIA); Schaefer, Matthew P. (INTECON);
Shah, Sonal R.
Subject: BIOSAFETY: COMPULSORY LABELING OF GENETICALLY MODIFIED FOODS

~~CONFIDENT~~

I A L SECTION 01 OF 03 CANBERRA 002584

DEPARTMENT FOR EAP/ANP,
OES/ETC
DEPARTMENT PASS USTR
DEPARTMENT PASS USDA
USDA ALSO FOR
FAS

USDA FOR OFFICE OF SECRETARY (SIDDIQUI)
FAS FOR ADMINISTRATOR
TGALVIN
FAS ALSO FOR ITP/PSHEIKH/BSIMMONS/BSLUTSKY
GENEVA PASS
USTR
AUCKLAND, MELBOURNE, PERTH AND SYDNEY ALSO FOR FCS
USDOC FOR
4530/IEP/EAP/OPB/GPAINE/AMAYEDA
USDOC FOR 3132/USFCS/OIO/EAP/TFALCO
USDOC
FOR 6132/ITA/BI/EARAKAKI

E.O. 12958: DECL: 08/04/09
TAGS: SENV,
EAGR, TBIO, ETRD, BEXP, AS, NZ
SUBJECT: BIOSAFETY: COMPULSORY LABELING
OF GENETICALLY
MODIFIED FOODS

REF: (A) CANBERRA 2490 (B) CANBERRA
718 (C) WELLINGTON 254
(NOTAL); (D) 98 SYDNEY 2296 (NOTAL)

(U)
CLASSIFIED BY ECONOMIC OFFICER BRIAN SILER FOR
REASON
1.5 (B).

1.
(U) SUMMARY FOODS SOLD IN AUSTRALIA OR NEW ZEALAND
AFTER
OCTOBER
2000 MUST CARRY A MANDATORY LABEL IF THEY CONTAIN
GENETICALLY MODIFIED
(GM) INGREDIENTS. THE AUSTRALIA NEW
ZEALAND FOOD STANDARDS COUNCIL
(ANZFSC) VOTED TO REQUIRE
LABELING AT AN AUGUST 3 MEETING IN CANBERRA.
COUNCIL
MEMBERS REJECTED AN INDUSTRY-FAVORED OPTION OF
VOLUNTARY
LABELING
UNDER A CODE OF PRACTICE. ANZFSC ORDERED ITS
REGULATORY BODY, THE
AUSTRALIA-NEW ZEALAND FOOD AUTHORITY
(ANZFA), TO DRAFT THE REQUIRED
FOOD SAFETY STANDARD IN TIME
FOR CONSIDERATION AT AN OCTOBER ANZFSC
MEETING. THE

STANDARD WOULD LIKELY TAKE EFFECT ONE YEAR LATER.
THE
COUNCIL SIGNALLED ITS INTENTION TO ASK ANZFA TO
ESTABLISH
THRESHOLDS
FOR THE PRESENCE OF GM MATERIAL IN FOODS BELOW
WHICH LABELING WOULD
NOT BE REQUIRED. THE THRESHOLD
PROPOSAL IMMEDIATELY DREW CRITICISM
FROM CONSUMER AND OTHER
GROUPS THAT HAD SOUGHT LABELING OF ALL GM
FOODS. END
SUMMARY.

2. (U) THE HEALTH MINISTERS OF AUSTRALIA,
NEW ZEALAND, AND
THE SIX STATES AND TWO TERRITORIES OF AUSTRALIA,
WHO
TOGETHER COMPRISE ANZFSC, DEBATED MORE THAN SEVEN
HOURS
AUGUST
3 BEFORE REACHING A CONSENSUS DECISION TO REQUIRE
MANDATORY LABELING
OF ALL FOODS EITHER PRODUCED USING
RECOMBINANT DNA TECHNOLOGY OR
CONTAINING GM INGREDIENTS.
THE DECISION EFFECTIVELY EXTENDED A BLANKET
LABELING
REQUIREMENT TO ALL GM FOOD TO BE SOLD IN THE TWO
COUNTRIES,
REGARDLESS
OF HOW OR WHETHER THE PRODUCT DIFFERED FROM ITS
NON-GM EQUIVALENT.

3.
(U) THE COUNCIL HAD PREVIOUSLY APPROVED A FOOD
STANDARD
(A18) IN
AUGUST 1998 THAT REQUIRED GM FOODS THAT WERE
SUBSTANTIALLY DIFFERENT
FROM THE TRADITIONAL FORM OF THAT
FOOD TO BE LABELED. THEN IN DECEMBER
1998, UNDER PRESSURE
FROM ANTI-GM TECHNOLOGY ACTIVISTS AND CONSUMER
GROUPS, THE
COUNCIL CALLED FOR A FURTHER STANDARD TO ALSO
REQUIRE
THE
LABELING OF GM FOOD SUBSTANTIALLY EQUIVALENT TO
THE

TRADITIONAL
FORM (REF B). ANZFA PRESENTED THE COUNCIL WITH
SEVERAL OPTIONS
(REF A), INCLUDING COMPULSORY LABELING,
WHICH WAS ADOPTED TUESDAY.
UNDER THE PROPOSED STANDARD,
LABELS WOULD STATE THAT FOODS DO,
MAY, OR DO NOT CONTAIN GM
INGREDIENTS. THE COUNCIL SPECIFICALLY
NOTED THAT LABELS MAY
ALSO STATE THAT FOODS "CONTAIN GENETICALLY
MODIFIED
INGREDIENTS APPROVED BY HEALTH AUTHORITIES."

4. (U)
ANZFA MUST STILL ADDRESS AN EXTENSIVE LIST OF THORNY
IMPLEMENTATION
ISSUES IN PREPARING ITS AMENDED STANDARD, TO
BE CONSIDERED BY THE
COUNCIL IN OCTOBER. THESE INCLUDE:
METHODS OF LABELING, INCLUDING
AUTHORIZED SYMBOLS;
SUPPLEMENTARY MEANS OF PROVIDING RELEVANT
INFORMATION
TO
CONSUMERS; IMPLEMENTATION COSTS TO INDUSTRY AND
GOVERNMENT;
A
POSSIBLE INDUSTRY CODE OF PRACTICE; COMPLIANCE WITH
WORLD
TRADE
ORGANIZATION (WTO) AND CODEX ALIMENTARIUS RULES;
COMPLIANCE TESTING
OF FOOD; COMPLIANCE STANDARDS FOR
MANUFACTURERS RELATED TO FOOD
ORIGINS; TREATMENT OF FOODS
CONTAINING NO GM INGREDIENTS; THRESHOLD
LEVELS FOR REQUIRING
LABELING; AND THE TIMING OF IMPLEMENTATION.

5.
(U) IN ITS MEDIA RELEASE FOLLOWING THE DECISION (FAXED
TO
OES/ETC/CENRIGHT),
THE COUNCIL NOTED THAT SAFETY ASSESSMENTS

~~CONFIDENTIAL~~

~~1~~ SECTION 02 OF 03 CANBERRA 002584

DEPARTMENT FOR EAP/ANP, OES/ETC
DEPARTMENT

PASS USTR
DEPARTMENT PASS USDA
USDA ALSO FOR FAS
USDA FOR OFFICE
OF SECRETARY (SIDDIQUI)
FAS FOR ADMINISTRATOR T GALVIN
FAS ALSO
FOR ITP/PSHEIKH/BSIMMONS/BSLUTSKY
GENEVA PASS USTR
AUCKLAND, MELBOURNE,
PERTH AND SYDNEY ALSO FOR FCS
USDOC FOR 4530/IEP/EAP/OPB/GPAINE/AMAYEDA
USDOC
FOR 3132/USFCS/OIO/EAP/TFALCO
USDOC FOR 6132/ITA/BI/EARAKAKI

E.O.
12958: DECL: 08/04/09
TAGS: SENV, EAGR, TBIO, ETRD, BEXP, AS, NZ
SUBJECT:
BIOSAFETY: COMPULSORY LABELING OF GENETICALLY
MODIFIED FOODS

OF
GM PRODUCTS (MANDATED UNDER STANDARD A18) WOULD
CONTINUE
AND THAT
"NO SAFETY CONCERNS HAVE BEEN SHOWN TOWARDS ANY
OF
THE FOODS ASSESSED
AT THIS STAGE." THE MESSAGE THAT THE
COUNCIL WAS NOT ADDRESSING
SAFETY CONCERNS PER SE WAS ECHOED
BY THE AUSTRALIAN PARLIAMENTARY
SECRETARY FOR HEALTH,
SENATOR GRANT TAMBLING, WHO CHAIRED THE COUNCIL
MEETING.
"IN DEALING WITH THE ISSUE OF GENETICALLY MODIFIED
FOODS,"
HE
SAID, "THE COUNCIL WAS VERY MINDFUL THAT IT IS
ESSENTIALLY, AND
PRIMARILY, A PUBLIC INFORMATION AND RIGHT-
TO-KNOW ISSUE THAT IS
THE MOST IMPORTANT FACTOR."

6. ~~(C)~~ IN A CHANGE OF VIEW, INDUSTRY
TOO SAW THE ISSUE
BEFORE THE COUNCIL AS PRIMARILY THAT OF ADDRESSING
CONSUMER

ANXIETY OVER THE NEW TECHNOLOGY. THE EXECUTIVE DIRECTOR OF THE NATIONAL ASSOCIATION OF CROP PRODUCTION AND ANIMAL HEALTH, AN OPPONENT OF MANDATORY LABELING JUST MONTHS AGO, TOLD ESTOFF THAT THE ASSOCIATION SUPPORTED THE COUNCIL DECISION. IN THE PAST MONTHS, HE SAID, THERE HAD BEEN A "CHANGE IN TIDES," AND THE COUNCIL HAD TO RESPECT CONSUMER DEMANDS THAT THEY HAD A RIGHT TO KNOW. HE INDICATED THAT THE DECISION TO REQUIRE LABELING WOULD HELP PLACATE CRITICS OF GM TECHNOLOGY AND HELP CREATE AN ATMOSPHERE WHERE EXISTING PRODUCTS, CURRENTLY EFFECTIVELY BARRED FROM RELEASE INTO THE MARKET, COULD BE INTRODUCED. THE REAL AND BIGGER GAME, HE SAID, WAS THE GOVERNMENT'S NASCENT REGULATORY SYSTEM FOR THE ENTIRE BIOTECHNOLOGY SECTOR, WHICH IS CRUCIAL TO ITS FUTURE. THE REGULATORY FRAMEWORK COULD NOW BE ADVANCED WITHOUT THE DISTRACTION OF CONSUMER ANGST AND FRUSTRATION ABOUT GM FOOD, HE SAID.

7. (U) THERE WAS LESS ENTHUSIASM FOR THE COUNCIL DECISION ELSEWHERE IN THE BUSINESS SECTOR. MITCH HOOKE, THE EXECUTIVE DIRECTOR OF THE AUSTRALIAN FOOD AND GROCERY COUNCIL (AFGC) AND AN OUTSPOKEN OPPONENT OF MANDATORY LABELING, ARGUED THAT THE LABELING REQUIREMENT AS PROPOSED BY THE COUNCIL WAS UNWORKABLE. IT WOULD, HE SAID IN A MEDIA RELEASE, "MISLEAD AND CONFUSE CONSUMERS, AND ADD

CONSIDERABLE RECURRENT COSTS ON INDUSTRY AND
ULTIMATELY
CONSUMERS,
WITH LITTLE TANGIBLE BENEFIT." THE AFGC'S
SCIENTIFIC AND TECHNICAL
DIRECTOR TOLD ESTOFF THAT THE
COUNCIL'S DECISION HAD PLACED A STILL
GREATER RESPONSIBILITY
ON THE FOOD INDUSTRY TO EXPLAIN TO CONSUMERS
WHAT THEY WERE
EATING. IT WOULD NOW HAVE TO HELP EXPLAIN WHAT THE
LABELS
REALLY MEANT, ESPECIALLY, HE NOTED, IN THE CASE OF
"NON-GMO"
FOOD
CLAIMS BASED ON THRESHOLD EXEMPTIONS.

8. (U) CONSUMER GROUPS AND
THE AUSTRALIAN MEDICAL
ASSOCIATION, WHICH BACKED A LABELING REQUIREMENT,
WELCOMED
THE COUNCIL'S DECISION AS A MAJOR STEP FORWARD FOR
THEIR
CAUSE.
HOWEVER, THEY WERE QUICK TO RAISE OBJECTIONS TO
ANZFSC'S CALL FOR
ESTABLISHING THRESHOLD LEVELS THAT WOULD
PROVIDE A LABELING EXEMPTION
TO PRODUCTS WITH MINIMAL
AMOUNTS OF GM MATERIAL. A SPOKESMAN FOR
THE AUSTRALIAN
CONSUMERS' ASSOCIATION TOLD MELBOURNE'S NEWSPAPER
THE AGE
THAT "IT WOULD BE COUNTERPRODUCTIVE TO CONTINUE TO
DEBATE
ON
WHEN YOU DO AND DON'T NEED TO HAVE TO SAY A FOOD
CONTAINS
GENETICALLY
MODIFIED INGREDIENTS. IT EITHER DOES OR IT DOES
NOT IN THE EYES
OF CONSUMERS."

9. ~~(C)~~ AN EMBASSY CONTACT IN ANZFA SAID THAT
ALTHOUGH
NORMALLY
SUCH A STANDARD WOULD BECOME EFFECTIVE 12 MONTHS
AFTER ITS APPROVAL
BY ANZFSC (I.E. OCTOBER 2000), THE
COUNCIL HAD SPECIFICALLY DIRECTED

ANZFA TO ADDRESS THIS
ISSUE IN ITS RECOMMENDATIONS FOR THE PLANNED
ANZFSC MEETING
IN OCTOBER. NONETHELESS, SHE SAID THAT DESPITE LIKELY
CALLS

~~CONFIDENTIAL~~ SECTION 03 OF 03 CANBERRA 002584

DEPARTMENT
FOR EAP/ANP, OES/ETC
DEPARTMENT PASS USTR
DEPARTMENT PASS USDA
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ALSO FOR FAS
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USDOC FOR 3132/USFCS/OIO/EAP/TFALCO
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FOR 6132/ITA/BI/EARAKAKI

E.O. 12958: DECL: 08/04/09
TAGS: SENV,
EAGR, TBIO, ETRD, BEXP, AS, NZ
SUBJECT: BIOSAFETY: COMPULSORY LABELING
OF GENETICALLY
MODIFIED FOODS

FROM GM OPPONENTS FOR A QUICK IMPLEMENTATION
OF LABELING,
ANZFA WOULD PROBABLY RECOMMEND THE OCTOBER 2000
DATE.
WITH
MANY DIFFICULT ISSUES SURROUNDING THE LABELING
REQUIREMENTS
STILL
TO BE ADDRESSED IN DETAIL, TIME WOULD BE NEEDED BY
BOTH GOVERNMENT,
REGULATORS AND BUSINESS.

10. ~~(C)~~ PROVIDING THE COUNCIL WITH RECOMMENDATIONS
ON WHERE
TO SET THRESHOLD LEVELS WOULD BE PARTICULARLY
DIFFICULT,
SHE

SAID. IN THE RUN-UP TO TUESDAY'S MEETING, SHE SAID, MINISTERS HAD REJECTED ANZFA RECOMMENDATIONS TO EXCLUDE ALTOGETHER FROM THE LABELING REQUIREMENT THOSE HIGHLY REFINED GM FOOD INGREDIENTS SUCH AS SUGARS, OILS AND STARCHES WHOSE MINUTE, RESIDUAL TRACES OF DNA WERE DEEMED BY ANZFA AS MEANINGLESS. SHE OBSERVED THAT THE COUNCIL

OPTED INSTEAD FOR A DECISION THAT FOCUSED ON BEING SEEN TO ADDRESS CONSUMER CONCERNS FIRST AND FOREMOST. ANZFA WILL NOW REVISIT BOTH THIS THRESHOLD QUESTION AND THAT OF WHAT PERCENTAGE OF GM INGREDIENT IN A FOOD WOULD TRIGGER THE NEED FOR LABELING. COMPLICATING THINGS, SHE ADDED, WAS THAT FACT THAT "THE MINISTERS WANT LABELING THAT'S CHEAP, PRACTICAL AND EASY TO ENFORCE."

11. ~~(C)~~ COMMENT: THE PAGE-LONG LIST OF STILL-TO-BE-RESOLVED ISSUES HANDED TO ANZFA BY THE COUNCIL IS A STRONG INDICATOR THAT THERE IS STILL MUCH TO BE RESOLVED ON THE LABELING FRONT. FOR ALL ITS COMPELLING EMPIRICAL LOGIC, THE THRESHOLD APPROACH IS CERTAIN TO BE ATTACKED BY DOCTRINAIRE GM OPPONENTS. STILL, THE COUNCIL'S VERY PUBLIC CONCESSION TO CONSUMER CONCERNS MAY WELL TAKE SOME OF THE STEAM OUT OF ANTI-GM CRUSADERS' ALL OR NOTHING CHAMPAIGN FOR THE HEARTS AND MINDS OF THOSE SAME CONSUMERS. THIS WILL BE HELPED IF THE SEA CHANGE IN INDUSTRY'S VIEWS ON LABELING CAN BE FOLLOWED BY SOME

EFFECTIVE PUBLIC EDUCATION EFFORTS BY
GOVERNMENT AND PRO-GM BUSINESS.
SHORT OF RUNNING AFOUL OF
THE WTO OR CODEX, IT WOULD APPEAR THAT
MANDATORY LABELING,
AND ALL IT ENTAILS, HAS NOW MADE A BRIDGEHEAD
DOWN UNDER.
END COMMENT.

HOLMES

Exchange Mail

DATE-TIME 8/5/99 7:02:01 PM
 FROM Bowles, Ian A. (ENV)
 CLASSIFICATION ~~CONFIDENTIAL~~
 CLASSIFICATIONREASON 1.5(b)
 DATECLASSIFIEDON 08/05/1999
 DECLASSIFYON 08/05/2009
 SUBJECT BIOSAFETY: COMPULSORY LABELING OF GENETICALLY MODIFIED FOODS [~~CONFIDENTIAL~~]
 TO Holtzapple, Richard A.

CARBON_COPY

TEXT_BODY

Thanks. Will get on distro list. Just got on this system 2 weeks ago. Think this would be of interest to Lael and to Rick Samans from our recent conversations on the subject if you know a way to get it to them in Bruce's absense Thanks, Ian

-----Original Message-----

From:
 Holtzapple, Richard A.
 Sent: Thursday, August 05, 1999 1:43 PM
 To:
 Bowles, Ian A. (ENV); McNamer, Bruce; Sandalow, David B. (ENV)
 Subject:
 BIOSAFETY: COMPULSORY LABELING OF GENETICALLY MODIFIED FOODS
 [~~CONFIDENTIAL~~]

Shouldn't
 WHSR be including you on distro of this stuff?

-----Original Message-----

From:
 WHSR
 Sent: Wednesday, August 04, 1999 5:55 AM
 To: Hammonds, D.
 Holly (INTECON); Hill, John J. (ASIA/INTERN);
 Holtzapple, Richard
 A.; Huso, Ravic R. (ASIA); Keith, James R. (ASIA);
 Lee, Malcolm

DECLASSIFIED
 E.O. 13526, Sec. 3.5 (b)
 White House Guidelines, September 11, 2006
 By ✓ NARA, Date 11/26/2014
2016-0524-22 (3.26)

R.; Lieberthal, Kenneth G. (ASIA); Osius, Theodore G. (VP);
Pritchard,
Charles (Jack) L. (ASIA); Schaefer, Matthew P. (INTECON);
Shah,
Sonal R.
Subject: BIOSAFETY: COMPULSORY LABELING OF
GENETICALLY
MODIFIED FOODS

~~CONFIDENTIAL~~ SECTION 01 OF 03 CANBERRA
002584

DEPARTMENT FOR EAP/ANP, OES/ETC
DEPARTMENT PASS USTR
DEPARTMENT
PASS USDA
USDA ALSO FOR FAS
USDA FOR OFFICE OF SECRETARY (SIDDIQUI)
FAS
FOR ADMINISTRATOR T GALVIN
FAS ALSO FOR ITP/PSHEIKH/BSIMMONS/BSLUTSKY
GENEVA
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USDOC FOR 3132/USFCS/OIO/EAP/TFALCO
USDOC
FOR 6132/ITA/BI/EARAKAKI

E.O. 12958: DECL: 08/04/09
TAGS: SENV,
EAGR, TBIO, ETRD, BEXP, AS, NZ
SUBJECT: BIOSAFETY: COMPULSORY LABELING
OF GENETICALLY
MODIFIED FOODS

REF: (A) CANBERRA 2490 (B) CANBERRA
718 (C) WELLINGTON 254
(NOTAL); (D) 98 SYDNEY 2296 (NOTAL)

(U)
CLASSIFIED BY ECONOMIC OFFICER BRIAN SILER FOR
REASON
1.5 (B).

1.
(U) SUMMARY FOODS SOLD IN AUSTRALIA OR NEW ZEALAND

AFTER
OCTOBER
2000 MUST CARRY A MANDATORY LABEL IF THEY CONTAIN
GENETICALLY MODIFIED
(GM) INGREDIENTS. THE AUSTRALIA NEW
ZEALAND FOOD STANDARDS COUNCIL
(ANZFSC) VOTED TO REQUIRE
LABELING AT AN AUGUST 3 MEETING IN CANBERRA.
COUNCIL
MEMBERS REJECTED AN INDUSTRY-FAVORED OPTION OF
VOLUNTARY
LABELING
UNDER A CODE OF PRACTICE. ANZFSC ORDERED ITS
REGULATORY BODY, THE
AUSTRALIA-NEW ZEALAND FOOD AUTHORITY
(ANZFA), TO DRAFT THE REQUIRED
FOOD SAFETY STANDARD IN TIME
FOR CONSIDERATION AT AN OCTOBER ANZFSC
MEETING. THE
STANDARD WOULD LIKELY TAKE EFFECT ONE YEAR LATER.
THE
COUNCIL SIGNALLED ITS INTENTION TO ASK ANZFA TO
ESTABLISH
THRESHOLDS
FOR THE PRESENCE OF GM MATERIAL IN FOODS BELOW
WHICH LABELING WOULD
NOT BE REQUIRED. THE THRESHOLD
PROPOSAL IMMEDIATELY DREW CRITICISM
FROM CONSUMER AND OTHER
GROUPS THAT HAD SOUGHT LABELING OF ALL GM
FOODS. END
SUMMARY.

2. (U) THE HEALTH MINISTERS OF AUSTRALIA,
NEW ZEALAND, AND
THE SIX STATES AND TWO TERRITORIES OF AUSTRALIA,
WHO
TOGETHER COMPRISE ANZFSC, DEBATED MORE THAN SEVEN
HOURS
AUGUST
3 BEFORE REACHING A CONSENSUS DECISION TO REQUIRE
MANDATORY LABELING
OF ALL FOODS EITHER PRODUCED USING
RECOMBINANT DNA TECHNOLOGY OR
CONTAINING GM INGREDIENTS.
THE DECISION EFFECTIVELY EXTENDED A BLANKET
LABELING
REQUIREMENT TO ALL GM FOOD TO BE SOLD IN THE TWO
COUNTRIES,
REGARDLESS

OF HOW OR WHETHER THE PRODUCT DIFFERED FROM ITS
NON-GM EQUIVALENT.

3.

(U) THE COUNCIL HAD PREVIOUSLY APPROVED A FOOD
STANDARD

(A18) IN

AUGUST 1998 THAT REQUIRED GM FOODS THAT WERE
SUBSTANTIALLY DIFFERENT

FROM THE TRADITIONAL FORM OF THAT

FOOD TO BE LABELED. THEN IN DECEMBER

1998, UNDER PRESSURE

FROM ANTI-GM TECHNOLOGY ACTIVISTS AND CONSUMER
GROUPS, THE

COUNCIL CALLED FOR A FURTHER STANDARD TO ALSO
REQUIRE

THE

LABELING OF GM FOOD SUBSTANTIALLY EQUIVALENT TO
THE

TRADITIONAL

FORM (REF B). ANZFA PRESENTED THE COUNCIL WITH
SEVERAL OPTIONS

(REF A), INCLUDING COMPULSORY LABELING,
WHICH WAS ADOPTED TUESDAY.

UNDER THE PROPOSED STANDARD,

LABELS WOULD STATE THAT FOODS DO,

MAY, OR DO NOT CONTAIN GM

INGREDIENTS. THE COUNCIL SPECIFICALLY

NOTED THAT LABELS MAY

ALSO STATE THAT FOODS "CONTAIN GENETICALLY
MODIFIED

INGREDIENTS APPROVED BY HEALTH AUTHORITIES."

4. (U)

ANZFA MUST STILL ADDRESS AN EXTENSIVE LIST OF THORNY
IMPLEMENTATION

ISSUES IN PREPARING ITS AMENDED STANDARD, TO
BE CONSIDERED BY THE

COUNCIL IN OCTOBER. THESE INCLUDE:

METHODS OF LABELING, INCLUDING

AUTHORIZED SYMBOLS;

SUPPLEMENTARY MEANS OF PROVIDING RELEVANT
INFORMATION

TO

CONSUMERS; IMPLEMENTATION COSTS TO INDUSTRY AND
GOVERNMENT;

A

POSSIBLE INDUSTRY CODE OF PRACTICE; COMPLIANCE WITH
WORLD

TRADE

ORGANIZATION (WTO) AND CODEX ALIMENTARIUS RULES;
COMPLIANCE TESTING
OF FOOD; COMPLIANCE STANDARDS FOR
MANUFACTURERS RELATED TO FOOD
ORIGINS; TREATMENT OF FOODS
CONTAINING NO GM INGREDIENTS; THRESHOLD
LEVELS FOR REQUIRING
LABELING; AND THE TIMING OF IMPLEMENTATION.

5.

(U) IN ITS MEDIA RELEASE FOLLOWING THE DECISION (FAXED
TO

OES/ETC/CENRIGHT),

THE COUNCIL NOTED THAT SAFETY ASSESSMENTS

~~CONFIDENTIAL~~

→ SECTION 02 OF 03 CANBERRA 002584

DEPARTMENT FOR EAP/ANP, OES/ETC

DEPARTMENT

PASS USTR

DEPARTMENT PASS USDA

USDA ALSO FOR FAS

USDA FOR OFFICE

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USDOC FOR 6132/ITA/BI/EARAKAKI

E.O.

12958: DECL: 08/04/09

TAGS: SENV, EAGR, TBIO, ETRD, BEXP, AS, NZ

SUBJECT:

BIOSAFETY: COMPULSORY LABELING OF GENETICALLY
MODIFIED FOODS

OF

GM PRODUCTS (MANDATED UNDER STANDARD A18) WOULD
CONTINUE

AND THAT

"NO SAFETY CONCERNS HAVE BEEN SHOWN TOWARDS ANY
OF

THE FOODS ASSESSED

AT THIS STAGE." THE MESSAGE THAT THE

COUNCIL WAS NOT ADDRESSING
SAFETY CONCERNS PER SE WAS ECHOED
BY THE AUSTRALIAN PARLIAMENTARY
SECRETARY FOR HEALTH,
SENATOR GRANT TAMBLING, WHO CHAIRED THE COUNCIL
MEETING.

"IN DEALING WITH THE ISSUE OF GENETICALLY MODIFIED
FOODS,"

HE

SAID, "THE COUNCIL WAS VERY MINDFUL THAT IT IS
ESSENTIALLY, AND
PRIMARILY, A PUBLIC INFORMATION AND RIGHT-
TO-KNOW ISSUE THAT IS
THE MOST IMPORTANT FACTOR."

6. ~~(C)~~ IN A CHANGE OF VIEW, INDUSTRY
TOO SAW THE ISSUE
BEFORE THE COUNCIL AS PRIMARILY THAT OF ADDRESSING
CONSUMER
ANXIETY OVER THE NEW TECHNOLOGY. THE EXECUTIVE
DIRECTOR
OF
THE NATIONAL ASSOCIATION OF CROP PRODUCTION AND
ANIMAL
HEALTH,
AN OPPONENT OF MANDATORY LABELING JUST MONTHS
AGO,
TOLD ESTOFF THAT
THE ASSOCIATION SUPPORTED THE COUNCIL
DECISION. IN THE PAST MONTHS,
HE SAID, THERE HAD BEEN A
"CHANGE IN TIDES," AND THE COUNCIL HAD
TO RESPECT CONSUMER
DEMANDS THAT THEY HAD A RIGHT TO KNOW. HE
INDICATED
THAT
THE DECISION TO REQUIRE LABELING WOULD HELP PLACATE
CRITICS
OF
GM TECHNOLOGY AND HELP CREATE AN ATMOSPHERE
WHERE
EXISTING PRODUCTS,
CURRENTLY EFFECTIVELY BARRED FROM RELEASE
INTO THE MARKET, COULD
BE INTRODUCED. THE REAL AND BIGGER
GAME, HE SAID, WAS THE GOVERNMENT'S
NASCENT REGULATORY
SYSTEM FOR THE ENTIRE BIOTECHNOLOGY SECTOR, WHICH
IS CRUCIAL
TO ITS FUTURE. THE REGULATORY FRAMEWORK COULD NOW

BE
ADVANCED
WITHOUT THE DISTRACTION OF CONSUMER ANGST AND
FRUSTRATION ABOUT
GM FOOD, HE SAID.

7. (U) THERE WAS LESS ENTHUSIASM FOR THE COUNCIL
DECISION
ELSEWHERE IN THE BUSINESS SECTOR. MITCH HOOKE, THE
EXECUTIVE
DIRECTOR OF THE AUSTRALIAN FOOD AND GROCERY
COUNCIL (AFGC) AND AN
OUTSPOKEN OPPONENT OF MANDATORY
LABELING, ARGUED THAT THE LABELING
REQUIREMENT AS PROPOSED
BY THE COUNCIL WAS UNWORKABLE. IT WOULD,
HE SAID IN A MEDIA
RELEASE, "MISLEAD AND CONFUSE CONSUMERS, AND
ADD
CONSIDERABLE RECURRENT COSTS ON INDUSTRY AND
ULTIMATELY
CONSUMERS,
WITH LITTLE TANGIBLE BENEFIT." THE AFGC'S
SCIENTIFIC AND TECHNICAL
DIRECTOR TOLD ESTOFF THAT THE
COUNCIL'S DECISION HAD PLACED A STILL
GREATER RESPONSIBILITY
ON THE FOOD INDUSTRY TO EXPLAIN TO CONSUMERS
WHAT THEY WERE
EATING. IT WOULD NOW HAVE TO HELP EXPLAIN WHAT THE
LABELS
REALLY MEANT, ESPECIALLY, HE NOTED, IN THE CASE OF
"NON-GMO"
FOOD
CLAIMS BASED ON THRESHOLD EXEMPTIONS.

8. (U) CONSUMER GROUPS AND
THE AUSTRALIAN MEDICAL
ASSOCIATION, WHICH BACKED A LABELING REQUIREMENT,
WELCOMED
THE COUNCIL'S DECISION AS A MAJOR STEP FORWARD FOR
THEIR
CAUSE.
HOWEVER, THEY WERE QUICK TO RAISE OBJECTIONS TO
ANZFSC'S CALL FOR
ESTABLISHING THRESHOLD LEVELS THAT WOULD
PROVIDE A LABELING EXEMPTION
TO PRODUCTS WITH MINIMAL
AMOUNTS OF GM MATERIAL. A SPOKESMAN FOR
THE AUSTRALIAN

CONSUMERS' ASSOCIATION TOLD MELBOURNE'S NEWSPAPER
THE AGE
THAT "IT WOULD BE COUNTERPRODUCTIVE TO CONTINUE TO
DEBATE
ON
WHEN YOU DO AND DON'T NEED TO HAVE TO SAY A FOOD
CONTAINS
GENETICALLY
MODIFIED INGREDIENTS. IT EITHER DOES OR IT DOES
NOT IN THE EYES
OF CONSUMERS."

9. ~~(C)~~ AN EMBASSY CONTACT IN ANZFA SAID THAT
ALTHOUGH
NORMALLY
SUCH A STANDARD WOULD BECOME EFFECTIVE 12 MONTHS
AFTER ITS APPROVAL
BY ANZFSC (I.E. OCTOBER 2000), THE
COUNCIL HAD SPECIFICALLY DIRECTED
ANZFA TO ADDRESS THIS
ISSUE IN ITS RECOMMENDATIONS FOR THE PLANNED
ANZFSC MEETING
IN OCTOBER. NONETHELESS, SHE SAID THAT DESPITE LIKELY
CALLS

~~CONFIDENTIAL~~ SECTION 03 OF 03 CANBERRA 002584

DEPARTMENT
FOR EAP/ANP, OES/ETC
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E.O. 12958: DECL: 08/04/09
TAGS: SENV,
EAGR, TBIO, ETRD, BEXP, AS, NZ
SUBJECT: BIOSAFETY: COMPULSORY LABELING
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FROM GM OPPONENTS FOR A QUICK IMPLEMENTATION OF LABELING, ANZFA WOULD PROBABLY RECOMMEND THE OCTOBER 2000 DATE. WITH MANY DIFFICULT ISSUES SURROUNDING THE LABELING REQUIREMENTS STILL TO BE ADDRESSED IN DETAIL, TIME WOULD BE NEEDED BY BOTH GOVERNMENT, REGULATORS AND BUSINESS.

10. ~~(C)~~ PROVIDING THE COUNCIL WITH RECOMMENDATIONS ON WHERE TO SET THRESHOLD LEVELS WOULD BE PARTICULARLY DIFFICULT, SHE SAID. IN THE RUN-UP TO TUESDAY'S MEETING, SHE SAID, MINISTERS HAD REJECTED ANZFA RECOMMENDATIONS TO EXCLUDE ALTOGETHER FROM THE LABELING REQUIREMENT THOSE HIGHLY REFINED GM FOOD INGREDIENTS SUCH AS SUGARS, OILS AND STARCHES WHOSE MINUTE, RESIDUAL TRACES OF DNA WERE DEEMED BY ANZFA AS MEANINGLESS. SHE OBSERVED THAT THE COUNCIL OPTED INSTEAD FOR A DECISION THAT FOCUSED ON BEING SEEN TO ADDRESS CONSUMER CONCERNS FIRST AND FOREMOST. ANZFA WILL NOW REVISIT BOTH THIS THRESHOLD QUESTION AND THAT OF WHAT PERCENTAGE OF GM INGREDIENT IN A FOOD WOULD TRIGGER THE NEED FOR LABELING. COMPLICATING THINGS, SHE ADDED, WAS THAT FACT THAT "THE MINISTERS WANT LABELING THAT'S CHEAP, PRACTICAL AND EASY TO ENFORCE."

11. ~~(C)~~ COMMENT: THE PAGE-LONG LIST OF STILL-TO-BE-RESOLVED ISSUES HANDED TO ANZFA BY THE COUNCIL IS A STRONG

INDICATOR
THAT THERE
IS STILL MUCH TO BE RESOLVED ON THE LABELING
FRONT. FOR ALL ITS
COMPELLING EMPIRICAL LOGIC, THE
THRESHOLD APPROACH IS CERTAIN TO
BE ATTACKED BY DOCTRINAIRE
GM OPPONENTS. STILL, THE COUNCIL'S VERY
PUBLIC CONCESSION
TO CONSUMER CONCERNS MAY WELL TAKE SOME OF THE
STEAM OUT OF
ANTI-GM CRUSADERS' ALL OR NOTHING CHAMPAIGN FOR
THE
HEARTS
AND MINDS OF THOSE SAME CONSUMERS. THIS WILL BE
HELPED IF
THE
SEA CHANGE IN INDUSTRY'S VIEWS ON LABELING CAN BE
FOLLOWED BY SOME
EFFECTIVE PUBLIC EDUCATION EFFORTS BY
GOVERNMENT AND PRO-GM BUSINESS.
SHORT OF RUNNING AFOUL OF
THE WTO OR CODEX, IT WOULD APPEAR THAT
MANDATORY LABELING,
AND ALL IT ENTAILS, HAS NOW MADE A BRIDGEHEAD
DOWN UNDER.
END COMMENT.

HOLMES

Exchange Mail

DATE-TIME 8/5/99 7:05:25 PM
FROM Bowles, Ian A. (ENV)
CLASSIFICATION ~~CONFIDENTIAL~~
CLASSIFICATIONREASON 1.5(b)
DATECLASSIFIEDON 08/05/1999
DECLASSIFYON 08/05/2009
SUBJECT BIOSAFETY: COMPULSORY LABELING OF GENETICALLY MODIFIED FOODS [~~CONFIDENTIAL~~]
TO Bayley, Douglas C. (WHSR)
 Blackburn, John (WHSR)
 Bresnahan, Gary E. (WHSR/STP)
 Broadwick, Bonnie . (WHSR)
 Cheramie, Don E. (WHSR)
 Crowder, Stevan D. (WHSR)
 Ehrendreich, Joel (WHSR)
 Erdahl, Douglas M. (WHSR)
 Ford, Robert G. (WHSR)
 Fuchs, Joachim D. (WHSR)
 Jansen, Christian P. (WHSR)
 Jarosinski, Frank J. (WHSR)
 Laskowski, Gregory J. (WHSR)
 Manning, Michael T. (WHSR)
 McGee, Jenny A. (WHSR)
 Merletti, Roger D. (WHSR)
 Payne, Raymond H. (WHSR/STP)
 Porterfield Patrick C. (WHSR)
 Powell, Elliott (WHSR/EXSEC)
 Rickard, Robin S. (WHSR)
 Rogers, Elizabeth B. (WHSR)
 Schrader, Joel M. (WHSR)
 Sibley, Matthew W. (WHSR)
 Sigler, Ralph H. (WHSR)
 Smith, James A. (WHSR)
 Sutliff, Deana R. (WHSR)
 Swarm, Amy L. (WHSR)
 Tarver, J. Sean (WHSR)
 Williams, Robert S. (WHSR)

DECLASSIFIED
 E.O. 13526, Sec. 3.5 (b)
 White House Guidelines, September 11, 2006
 By VL NARA, Date 11/26/2009
2016-0524-m (3.27)

CARBON_COPY

TEXT_BODY

Pls slug me with traffic on biosafety and genetically modified organisms

(GMOs) as well as trade/environment and WTO/environment. Thx. Ian

-----Original

Message-----

From: Holtzapple, Richard A.

Sent: Thursday, August

05, 1999 1:43 PM

To: Bowles, Ian A. (ENV); McNamer, Bruce; Sandalow,
David B. (ENV)

Subject: BIOSAFETY: COMPULSORY LABELING OF
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REF: (A) CANBERRA 2490 (B) CANBERRA
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CLASSIFIED BY ECONOMIC OFFICER BRIAN SILER FOR
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FOR THE PRESENCE OF GM MATERIAL IN FOODS BELOW WHICH LABELING WOULD NOT BE REQUIRED. THE THRESHOLD PROPOSAL IMMEDIATELY DREW CRITICISM FROM CONSUMER AND OTHER GROUPS THAT HAD SOUGHT LABELING OF ALL GM FOODS. END SUMMARY.

2. (U) THE HEALTH MINISTERS OF AUSTRALIA, NEW ZEALAND, AND THE SIX STATES AND TWO TERRITORIES OF AUSTRALIA, WHO TOGETHER COMPRISE ANZFSC, DEBATED MORE THAN SEVEN HOURS AUGUST 3 BEFORE REACHING A CONSENSUS DECISION TO REQUIRE MANDATORY LABELING OF ALL FOODS EITHER PRODUCED USING RECOMBINANT DNA TECHNOLOGY OR CONTAINING GM INGREDIENTS. THE DECISION EFFECTIVELY EXTENDED A BLANKET LABELING REQUIREMENT TO ALL GM FOOD TO BE SOLD IN THE TWO COUNTRIES, REGARDLESS OF HOW OR WHETHER THE PRODUCT DIFFERED FROM ITS NON-GM EQUIVALENT.

3.

(U) THE COUNCIL HAD PREVIOUSLY APPROVED A FOOD STANDARD (A18) IN AUGUST 1998 THAT REQUIRED GM FOODS THAT WERE SUBSTANTIALLY DIFFERENT FROM THE TRADITIONAL FORM OF THAT FOOD TO BE LABELED. THEN IN DECEMBER 1998, UNDER PRESSURE FROM ANTI-GM TECHNOLOGY ACTIVISTS AND CONSUMER GROUPS, THE COUNCIL CALLED FOR A FURTHER STANDARD TO ALSO REQUIRE THE LABELING OF GM FOOD SUBSTANTIALLY EQUIVALENT TO THE TRADITIONAL FORM (REF B). ANZFA PRESENTED THE COUNCIL WITH SEVERAL OPTIONS (REF A), INCLUDING COMPULSORY LABELING,

WHICH WAS ADOPTED TUESDAY.
UNDER THE PROPOSED STANDARD,
LABELS WOULD STATE THAT FOODS DO,
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E.O.

12958: DECL: 08/04/09

TAGS: SENV, EAGR, TBIO, ETRD, BEXP, AS, NZ

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CALLS

~~CONFIDENTIAL~~ SECTION 03 OF 03 CANBERRA 002584

DEPARTMENT

FOR EAP/ANP, OES/ETC

DEPARTMENT PASS USTR

DEPARTMENT PASS USDA

USDA

ALSO FOR FAS

USDA FOR OFFICE OF SECRETARY (SIDDIQUI)

FAS FOR ADMINISTRATOR

TGALVIN

FAS ALSO FOR ITP/PSHEIKH/BSIMMONS/BSLUTSKY

GENEVA PASS

USTR

AUCKLAND, MELBOURNE, PERTH AND SYDNEY ALSO FOR FCS

USDOC FOR

4530/IEP/EAP/OPB/GPAINE/AMAYEDA

USDOC FOR 3132/USFCS/OIO/EAP/TFALCO

USDOC

FOR 6132/ITA/BI/EARAKAKI

E.O. 12958: DECL: 08/04/09

TAGS: SENV,

EAGR, TBIO, ETRD, BEXP, AS, NZ

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WITH

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HOLMES

Exchange Mail

DATE-TIME 8/11/99 7:27:18 PM
FROM Bowles, Ian A. (ENV)
CLASSIFICATION ~~CONFIDENTIAL~~
CLASSIFICATIONREASON 1.5(b)
DATECLASSIFIEDON 08/11/1999
DECLASSIFYON 08/11/2009
SUBJECT BIOSAFETY: COMPULSORY LABELING OF GENETICALLY
MODIFIED FOODS [~~CONFIDENTIAL~~]
TO Mitsler, Elaine M. (INTECON)
CARBON_COPY
TEXT_BODY

DECLASSIFIED
E.O. 13526, Sec. 3.5 (b)
White House Guidelines, September 11, 2006
By 172 NARA, Date 11/16/2006
7016-0524-00 (3.28)

please pass to Rick Samans. Many thanks, Ian

-----Original Message-----

From:
Holtzapple, Richard A.
Sent: Thursday, August 05, 1999 1:43 PM
To:
Bowles, Ian A. (ENV); McNamer, Bruce; Sandalow, David B. (ENV)
Subject:
BIOSAFETY: COMPULSORY LABELING OF GENETICALLY
MODIFIED FOODS
[~~CONFIDENTIAL~~]

Shouldn't
WHSR be including you on distro of this stuff?

-----Original Message-----

From:
WHSR
Sent: Wednesday, August 04, 1999 5:55 AM
To: Hammonds, D.
Holly (INTECON); Hill, John J. (ASIA/INTERN);
Holtzapple, Richard
A.; Huso, Ravic R. (ASIA); Keith, James R. (ASIA);
Lee, Malcolm
R.; Lieberthal, Kenneth G. (ASIA); Osius, Theodore G. (VP);
Pritchard,
Charles (Jack) L. (ASIA); Schaefer, Matthew P. (INTECON);

Shah,
Sonal R.
Subject: BIOSAFETY: COMPULSORY LABELING OF
GENETICALLY
MODIFIED FOODS

~~CONFIDENTIAL~~ SECTION 01 OF 03 CANBERRA
002584

DEPARTMENT FOR EAP/ANP, OES/ETC
DEPARTMENT PASS USTR
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E.O. 12958: DECL: 08/04/09
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SUBJECT: BIOSAFETY: COMPULSORY LABELING
OF GENETICALLY
MODIFIED FOODS

REF: (A) CANBERRA 2490 (B) CANBERRA
718 (C) WELLINGTON 254
(NOTAL); (D) 98 SYDNEY 2296 (NOTAL)

(U)
CLASSIFIED BY ECONOMIC OFFICER BRIAN SILER FOR
REASON
1.5 (B).

1.
(U) SUMMARY FOODS SOLD IN AUSTRALIA OR NEW ZEALAND
AFTER
OCTOBER
2000 MUST CARRY A MANDATORY LABEL IF THEY CONTAIN

GENETICALLY MODIFIED
(GM) INGREDIENTS. THE AUSTRALIA NEW
ZEALAND FOOD STANDARDS COUNCIL
(ANZFSC) VOTED TO REQUIRE
LABELING AT AN AUGUST 3 MEETING IN CANBERRA.
COUNCIL
MEMBERS REJECTED AN INDUSTRY-FAVORED OPTION OF
VOLUNTARY
LABELING
UNDER A CODE OF PRACTICE. ANZFSC ORDERED ITS
REGULATORY BODY, THE
AUSTRALIA-NEW ZEALAND FOOD AUTHORITY
(ANZFA), TO DRAFT THE REQUIRED
FOOD SAFETY STANDARD IN TIME
FOR CONSIDERATION AT AN OCTOBER ANZFSC
MEETING. THE
STANDARD WOULD LIKELY TAKE EFFECT ONE YEAR LATER.
THE
COUNCIL SIGNALLED ITS INTENTION TO ASK ANZFA TO
ESTABLISH
THRESHOLDS
FOR THE PRESENCE OF GM MATERIAL IN FOODS BELOW
WHICH LABELING WOULD
NOT BE REQUIRED. THE THRESHOLD
PROPOSAL IMMEDIATELY DREW CRITICISM
FROM CONSUMER AND OTHER
GROUPS THAT HAD SOUGHT LABELING OF ALL GM
FOODS. END
SUMMARY.

2. (U) THE HEALTH MINISTERS OF AUSTRALIA,
NEW ZEALAND, AND
THE SIX STATES AND TWO TERRITORIES OF AUSTRALIA,
WHO
TOGETHER COMPRISE ANZFSC, DEBATED MORE THAN SEVEN
HOURS
AUGUST
3 BEFORE REACHING A CONSENSUS DECISION TO REQUIRE
MANDATORY LABELING
OF ALL FOODS EITHER PRODUCED USING
RECOMBINANT DNA TECHNOLOGY OR
CONTAINING GM INGREDIENTS.
THE DECISION EFFECTIVELY EXTENDED A BLANKET
LABELING
REQUIREMENT TO ALL GM FOOD TO BE SOLD IN THE TWO
COUNTRIES,
REGARDLESS
OF HOW OR WHETHER THE PRODUCT DIFFERED FROM ITS
NON-GM EQUIVALENT.

3.

(U) THE COUNCIL HAD PREVIOUSLY APPROVED A FOOD STANDARD (A18) IN AUGUST 1998 THAT REQUIRED GM FOODS THAT WERE SUBSTANTIALLY DIFFERENT FROM THE TRADITIONAL FORM OF THAT FOOD TO BE LABELED. THEN IN DECEMBER 1998, UNDER PRESSURE FROM ANTI-GM TECHNOLOGY ACTIVISTS AND CONSUMER GROUPS, THE COUNCIL CALLED FOR A FURTHER STANDARD TO ALSO REQUIRE THE LABELING OF GM FOOD SUBSTANTIALLY EQUIVALENT TO THE TRADITIONAL FORM (REF B). ANZFA PRESENTED THE COUNCIL WITH SEVERAL OPTIONS (REF A), INCLUDING COMPULSORY LABELING, WHICH WAS ADOPTED TUESDAY. UNDER THE PROPOSED STANDARD, LABELS WOULD STATE THAT FOODS DO, MAY, OR DO NOT CONTAIN GM INGREDIENTS. THE COUNCIL SPECIFICALLY NOTED THAT LABELS MAY ALSO STATE THAT FOODS "CONTAIN GENETICALLY MODIFIED INGREDIENTS APPROVED BY HEALTH AUTHORITIES."

4. (U)

ANZFA MUST STILL ADDRESS AN EXTENSIVE LIST OF THORNY IMPLEMENTATION ISSUES IN PREPARING ITS AMENDED STANDARD, TO BE CONSIDERED BY THE COUNCIL IN OCTOBER. THESE INCLUDE: METHODS OF LABELING, INCLUDING AUTHORIZED SYMBOLS; SUPPLEMENTARY MEANS OF PROVIDING RELEVANT INFORMATION TO CONSUMERS; IMPLEMENTATION COSTS TO INDUSTRY AND GOVERNMENT; A POSSIBLE INDUSTRY CODE OF PRACTICE; COMPLIANCE WITH WORLD TRADE ORGANIZATION (WTO) AND CODEX ALIMENTARIUS RULES; COMPLIANCE TESTING OF FOOD; COMPLIANCE STANDARDS FOR

MANUFACTURERS RELATED TO FOOD
ORIGINS; TREATMENT OF FOODS
CONTAINING NO GM INGREDIENTS; THRESHOLD
LEVELS FOR REQUIRING
LABELING; AND THE TIMING OF IMPLEMENTATION.

5.
(U) IN ITS MEDIA RELEASE FOLLOWING THE DECISION (FAXED
TO
OES/ETC/CENRIGHT),
THE COUNCIL NOTED THAT SAFETY ASSESSMENTS
~~CONFIDENTIAL~~
SECTION 02 OF 03 CANBERRA 002584

DEPARTMENT FOR EAP/ANP, OES/ETC
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E.O.
12958: DECL: 08/04/09
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BIOSAFETY: COMPULSORY LABELING OF GENETICALLY
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GM PRODUCTS (MANDATED UNDER STANDARD A18) WOULD
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"NO SAFETY CONCERNS HAVE BEEN SHOWN TOWARDS ANY
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"IN DEALING WITH THE ISSUE OF GENETICALLY MODIFIED
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HOLMES

Exchange Mail

DATE-TIME 8/18/99 6:44:00 PM

FROM Bowles, Ian A. (ENV)

CLASSIFICATION UNCLASSIFIED

SUBJECT gmo cable [UNCLASSIFIED]

TO Bernard, Kenneth W. (HEALTH)

CARBON_COPY

TEXT_BODY can you forward the opus II cable on biotech that you mentioned to me. looks like i did not get it. if you send it on, i'll ask WHSR to forward similar such cable on to me. thanks, ian

Exchange Mail

DATE-TIME 8/19/99 8:33:26 AM
FROM Bernard, Kenneth W. (HEALTH)
CLASSIFICATION UNCLASSIFIED
SUBJECT RE: gmo cable [UNCLASSIFIED]
TO Bowles, Ian A. (ENV)

CARBON_COPY**TEXT_BODY**

Here it is. I didn't get it either. When I heard about it, I found it on the search engine. When you talk to the sitroom, ask them to include me as well. Thanks. --Ken

PREC: IMMEDIATE
CLASS: UNCLASSIFIED SSN: 1442 DOCID: M4000099

OAAUZYUW
RUEHCAA1442 2242141-UUUU--RHEHNSC.
ZNR UUUUU ZZH
O 122138Z AUG
99
FM SECSTATE WASHDC

FM: SECSTATE WASHDC
TO: ALL DIPLOMATIC
AND CONSULAR POSTS IMMEDIATE

INFO: RUEHBS/USEU BRUSSELS IMMEDIATE
RUEHGV/USMISSION
GENEVA IMMEDIATE 8439
RUEAIIA/CIA WASHDC 6483
RUEKJCS/SECDEF WASHDC
6981
RHEHNSC/NSC WASHDC 8095
RUEAEPA/EPA WASHDC
RUETIAA/DIRNSA
FT GEO G MEADE MD
RHFJUSC/US CUSTOMS SERVICE WASHDC
RULSDMK/DEPT
OF TRANSPORTATION WASHDC
RHEBAAA/USDOE WASHDC 0750

UNCLAS
SECTION 01 OF 11 STATE 151442

PASS ECONCOUNSELOR, AGCOUNSELOR,
AND USIA

E.O. 12958: N/A
TAGS: ETRD EAGR, TBIO, SENV, ECON, KSCA
SUBJECT:
BIOTECHNOLOGY - OPUS II

REF: STATE 113313

GENEVA FOR USTR,
ALSO AGRICULTURE
BRUSSELS ALSO FOR USEU
PARIS ALSO FOR OECD

1.
THIS IS AN ACTION REQUEST. SEE PARA 2.

2. SUMMARY AND ACTION
REQUEST. BIOTECHNOLOGY IS AN ISSUE
THAT IS FLUID AND REQUIRES A
QUICK-RESPONSE MECHANISM IN
ORDER TO ADDRESS UNFOLDING EVENTS. WASHINGTON
AGENCIES
ARE LAUNCHING A PUBLIC DIPLOMACY INITIATIVE TO PROVIDE
SUCH
A MECHANISM (PARA 3). EMBASSIES' COOPERATION WILL BE
CRITICAL TO
THE SUCCESS OF THIS EFFORT. POSTS MAY
DISTRIBUTE THE UPDATED BACKGROUNDER
(PARA 4), AND LIST OF
SOME BENEFITS OF BIOTECHNOLOGY (PARA 5) AS
NEEDED.
WASHINGTON REMAINS INTERESTED IN RECEIVING INFORMATION ON
THE
STATUS OF PRODUCTS DERIVED FROM BIO-ENGINEERED PLANTS
IN HOST COUNTRIES
AND IDEAS ON HOW TO ADDRESS NEGATIVE
CONSUMER CONCERNS OR RESTRICTIVE

REGULATORY PRACTICES.

POSTS IN ASIA, LATIN AMERICA, AND EUROPE
ARE ASKED TO
DEVELOP A LIST OF CONTACT POINTS IN GOVERNMENT, INDUSTRY,

ACADEMIA, NON-GOVERNMENT ORGANIZATIONS (NGOS), AND THE
PRESS WHO

MAY BE APPROPRIATE TO ATTEND WORLD NET
VIDEOCONFERENCES BEING SCHEDULED
FOR AUGUST AND SEPTEMBER.

WE APPRECIATE RECEIVING UPDATES TO OUR
CALENDAR OF BIOTECH
EVENTS (PARA 6), WHICH WE WILL USE TO PREPARE
ADDITIONAL
PUBLIC DIPLOMACY MATERIAL AS NEEDED. PLEASE SLUG
RESPONSES

TO EB/TPP/ATT/ATP MARILYN BRUNO 202-647-2062;

FAX: 202-647-1894;

E-MAIL: BRUNOMJ#STATE.GOV. END SUMMARY
AND ACTION REQUEST.

PUBLIC DIPLOMACY CAMPAIGN

3. AGENCIES ARE WORKING TO DEVELOP
MATERIALS FOR

INTERNATIONAL DISSEMINATION. USIA WILL BE ORGANIZING
WORLD

NET INTERACTIVE VIDEOCONFERENCES WITH SELECTED POSTS
(ASIAN COUNTRIES

WILL BE TARGETED FOR AUGUST; LATIN
AMERICAN AND EUROPEAN POSTS IN
SEPTEMBER) AND DEVELOPING

VIDEO TAPES FOR SHOWING AT SEMINARS, PRESS
CONFERENCES, OR

ROUND TABLES ORGANIZED BY INTERESTED POSTS. SEPTTEL
WILL

REQUEST SUGGESTIONS ON HOW TO ENHANCE USIA'S INTERNATIONAL
VISITORS

PROGRAMS AND WHAT ACADEMIC AND PRESS PRODUCTS
SHOULD BE AVAILABLE

ON A BIOTECH WEBSITE, SCHEDULED FOR
COMPLETION IN SEPTEMBER. THE

WEBSITE WILL INCLUDE FACT

SHEETS, A GLOSSARY OF TERMINOLOGY, SPEECHES
AND OP ED S ON

BIOTECHNOLOGY, AS WELL AS REFERENCES/LINKS TO OTHER

WEBSITES,
INCLUDING THE FOLLOWING:

U.S. BIOTECH REGULATIONS
WWW.APHIS.USDA.GOV/BIOTECH/OECD/USREGS.HTM#USDALAW
WWW.FDA.GOV
WWW.EPA.GOV
WWW.FAS.USDA.GOV

ED
WWW.EUROPA.EU-INT/COMM/DGO1/DGL.HTM
WWW.EUROPA.EU.INT/COMM/DGL2/BIOTECH/BIOT2.HTM

ARGENTINA

WWW.FOARBI.ORG.AR/

BRAZIL
WWW.FIOCRUZ.BR/CICT/OQUEE/ESTRUT/DECT/BIS/BIS.HTM1

WWW.EMBRAPA.BR/ENGLISH/INDEX.HTM

FAO/CODEX ALIMENTARIUS COMMISSION

FTP.FAO.ORG/WAICENT/FAOINFO/ECONOMIC/ESN/CODEX/DEFAULT.HTM

U.S.
CODEX
UNCLAS SECTION 02 OF 11 STATE 151442

PASS ECONCOUNSELOR,
AGCOUNSELOR, AND USIA

E.O. 12958: N/A
TAGS: ETRD EAGR, TBIO,
SENV, ECON, KSCA
SUBJECT: BIOTECHNOLOGY - OPUS II

WWW.FSIS.USDA.GOV/OA/CODEX/

OECD DATABASES
WWW.OLIS.OECD.ORG/BIOTRAK.NSF
WWW.O1IS.OECD.ORG/BIOPROD.NSF

WWW.OECD.ORG/EHS/PROJECTS.HTM
WWW.OECD.ORG/EHS/EXPERTS.HTM
WWW.OECD.ORG/EHS/SERVICE.HTM
WWW.OECD.ORG/EHS/COUNTRY.HTM

WWW.OECD.ORG/EHS/ICGB/

OECD/UNIDO

DATABASE

WWW.OECD.ORG/EHS/BIOBIN

BINAS.UNIDO.ORG/BINAS/REGULATIONS.HTML

BIOTECH

INDUSTRY

WWW.BIO.ORG

WWW.MONSANTO.COM

WWW.GMABRANDS.COM

WWW.NCGA.COM

WWW.IFICINFO.HEALTH.ORG

WWW.EUROPA-BIO.BE/NEWS

ACADEMIA:

GEORGETOWN CENTER FOR FOOD & NUTRITION POLICY

WWW.CERESNET.ORG

SCIENCE:

INTERNATIONAL LIFE SCIENCES INSTITUTE

WWW.ILSI.ORG/INDEX.HTML

USIA:

WWW.USIA.GOV/USIS.HTML

4. BACKGROUNDER

I - INTRODUCTION

"GENETICALLY-MODIFIED ORGANISMS" (GMOS) IS THE TERM USED BY SOME COUNTRIES TO IDENTIFY PRODUCTS PRODUCED THROUGH MODERN BIOTECHNOLOGY. SINCE ANIMAL AND PLANT HYBRIDIZATION AND FERMENTATION HAVE INVOLVED GENETIC MODIFICATION FOR OVER A CENTURY, U.S. REGULATORS PREFER THE TERM "BIOTECH" PRODUCTS.

SOME OF THE GOALS OF MODERN BIOTECHNOLOGY INCLUDE ENDOWING A CONVENTIONAL PRODUCT WITH A TRAIT THAT ENHANCES ITS

NUTRITIONAL COMPOSITION
OR A HOST PLANT OR ANIMAL WITH A
DESIRABLE TRAIT (SUCH AS PEST
OR DROUGHT RESISTANCE THAT
ENHANCES A PLANT'S YIELD, OR A FASTER
GROWTH RATE FOR
ANIMALS). FOR EXAMPLE, GENES FROM A COMMON MICROBE
FOUND
IN THE SOIL AND WIDELY-USED BY ORGANIC FARMERS AS A
PESTICIDE,
BACILLUS THURINGIENSIS (BT), CAN BE INSERTED
INTO THE DNA OF CORN
OR OTHER PLANTS, TO MAKE THE PLANT
NOXIOUS TO SPECIFIC INSECT PESTS.

TODAY,
MODERN BIOTECHNOLOGY IS USED TO PRODUCE ENHANCED
SEEDS, GRAINS,
FRUITS, VEGETABLES, FISH, SUGARS, CHEESES,
TREES, PAPER PRODUCTS,
COTTON, MICROORGANISMS FOR
BIOREMEDIATION, PLASTICS, DETERGENTS,
AND PHARMACEUTICALS.
THE U.S. DEPARTMENT OF AGRICULTURE (USDA) REVIEWS
BIOTECH
SEEDS, CROPS IN THE FIELD, AND ANIMALS FOR SLAUGHTER. THE
ENVIRONMENTAL
PROTECTION AGENCY (EPA) REVIEWS THE SAFETY
OF PESTICIDAL PROTEINS
IN BIOTECH PRODUCTS. THE FOOD AND
DRUG ADMINISTRATION (FDA) REVIEWS
FOODS PRODUCED FROM
BIOTECH CROPS, ANIMALS, FISH AND PROCESSES.
BIOTECH FOODS
ARE NOT COMMERCIALIZED UNLESS THEY MEET THE SAME RIGOROUS
SAFETY
STANDARDS AS THEIR TRADITIONAL COUNTERPARTS.

IN 1998, 25 PERCENT
OF U.S. CORN ACREAGE, 38 PERCENT OF
SOYBEAN ACREAGE, AND 45 PERCENT
OF COTTON ACREAGE WERE
PLANTED WITH BIOTECH VARIETIES TOTALING OVER
45 MILLION
ACRES, UP 250 PERCENT FROM 1997 LEVELS. WORLDWIDE, OVER
69
MILLION ACRES OF BIOTECH CROPS WERE PLANTED IN 1998 (OF
WHICH
15 PERCENT WERE IN DEVELOPING COUNTRIES), AND THE

TOTAL PLANTED
ACREAGE IS EXPECTED TO RISE AGAIN IN 1999.
FIELD TESTS ARE BEING
CONDUCTED ON OVER 50 NEW FOOD,
FIBER, AND FEED CROPS. THE U.S. DOES
NOT SEGREGATE
BIOTECH FROM NON-BIOTECH VARIETIES DESTINED FOR
CONSUMPTION
OR PROCESSING. HOWEVER, BIOTECH VARIETIES CAN
BE "IDENTITY-PRESERVED"
FOR COMMERCIAL REASONS, SUCH AS
THOSE WITH A "VALUE ADDED" TRAIT
(E.G., SOYBEANS WITH HIGH
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LEVELS
OF OLEIC ACID, OR THE FLAVR SAVR TOMATO).

II. U.S. SAFETY AND LABELING REGULATIONS FOR BIOTECH PRODUCTS

FOR OVER A DECADE,
U.S. BIOTECH SEED DEVELOPERS HAVE
SUBMITTED NEW SEED VARIETIES TO
USDA AND EPA FOR REVIEW
AND COOPERATED WITH THESE AGENCIES TO MONITOR
ENVIRONMENTAL
IMPACTS IN FIELD TESTS. THE U.S. REVIEW
PROCESS USES A SCIENCE-BASED
APPROACH TO RISK ASSESSMENT.
ONCE THEY HAVE SUCCESSFULLY PASSED
THE REVIEW, ALL SEEDS
(BIOTECH AND NON-BIOTECH) ARE SOLD DOMESTICALLY
AND
INTERNATIONALLY WITH IDENTIFYING TRANSPORTATION AND
HANDLING
DOCUMENTATION FOR PLANTING AND/OR CROSSBREEDING
(WITH PREVIOUSLY-APPROVED

BIOTECH AND NON-BIOTECH VARIETIES). BIOTECH SEEDS IMPORTED INTO THE U.S. FOR PURPOSES OF PLANTING ARE SUBJECT TO PRE-IMPORT REVIEW AND APPROVAL BY USDA AND, SOMETIMES, BY EPA. SEEDS INTENDED FOR CROP PRODUCTION FOR PROCESSING AND CONSUMPTION ARE REVIEWED ON A CASE-BY-CASE BASIS.

-- MOST AGRICULTURAL GRAINS AND OILSEEDS DERIVED FROM BIOTECH PLANTS, AS WELL AS ALL BULK COMMODITIES FOR CONSUMPTION OR PROCESSING, ARE HARVESTED AND CO-MINGLED WITH NON-BIOTECH GRAINS AND OILSEEDS WITHOUT SPECIAL LABELING OR TRANSPORT DOCUMENTATION IN THE U.S.

-- ALL FOODS AND PROCESSED FOODS, INCLUDING FOODS FROM BIOENGINEERED PLANTS, HAVE TO COMPLY WITH ALL THE PROVISIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA), INCLUDING THE PROVISIONS COVERING SAFETY AND LABELING. THE FFDCA DOES NOT GENERALLY REQUIRE THAT

FOODS, WHETHER FROM BIOTECH PROCESSES OR NOT, UNDERGO PRE-MARKET REVIEW AND APPROVAL BY FDA. HOWEVER, ALL FOOD ADDITIVES, INCLUDING THOSE INTRODUCED INTO FOODS BY WAY OF BIOENGINEERING, ARE REQUIRED TO BE APPROVED BY FDA BEFORE COMMERCIALIZATION.

--
IN ADDITION, FDA HAS ESTABLISHED A PROCESS BY WHICH COMPANIES CAN CONSULT WITH THE FDA ON FOOD SAFETY AND LABELING ISSUES ON NEW PRODUCTS BEFORE BRINGING THEM TO MARKET. TO DATE, COMPANIES HAVE CONSULTED WITH FDA ON ALL BIOTECH FOODS THAT HAVE BEEN BROUGHT TO MARKET.

--

TEN YEARS OF EXPERIENCE WITH COMMERCIALIZATION OF BIOTECH FOOD PRODUCTS, AND RELATED NUMEROUS AND ON-GOING FINDINGS, SHOW THAT BIOTECH FOODS DEVELOPED TO DATE PRESENT NO UNIQUE FOOD SAFETY RISKS.

-- THE

U.S. REQUIRES MANDATORY LABELING OF FOOD, INCLUDING BIOTECH FOOD, WHOSE COMPOSITION HAS BEEN SIGNIFICANTLY ALTERED OR WHOSE NUTRITIONAL VALUE, INTENDED USE, STORAGE OR PROCESSING CHARACTERISTICS ARE DIFFERENT FROM ITS CONVENTIONAL FOOD COUNTERPARTS OR WHEN IT CONTAINS AN UNEXPECTED ALLERGEN. FOOD LABELING MUST BE TRUTHFUL AND NOT BE MISLEADING. SOME BIOTECH FOOD PRODUCTS IN THE COMMERCIAL STREAM ARE "IDENTITY PRESERVED" AND SOMETIMES SO LABELED FOR COMMERCIAL REASONS.

III

- PROBLEM: RESTRICTED MARKET ACCESS

PROBLEMS PERTAINING TO THE REGULATION AND ACCEPTANCE OVERSEAS OF BIOTECH FOODS HAVE ARISEN IN A NUMBER OF INTERNATIONAL FORA. THIS REFLECTS IN PART THE PRESSURES TO ALLAY CONSUMER FEARS IN CERTAIN COUNTRIES REGARDING BIOTECH FOOD SAFETY AND, POSSIBLY, PROTECTIONIST INTERESTS TO REQUIRE PRE-IMPORT APPROVALS, DOCUMENTATION, SEGREGATION, AND LABELING OF IMPORTED BIOTECH FOODS.

SINCE MARCH 1998, WITH THE EXCEPTION OF THREE BIOTECH CARNATION VARIETIES, THE EU HAS NEITHER APPROVED NOR REJECTED ANY BIOTECH PRODUCTS. (PRIOR TO THIS DATE, THE EU APPROVED, AMONG OTHERS, ONE

U.S. BIOTECH SOYBEAN

VARIETY AND FOUR U.S. BIOTECH CORN VARIETIES.)
EUROPEAN
MEMBER STATES AND THE EUROPEAN COMMISSION APPARENTLY
FEAR
GOING
AGAINST PUBLIC OPPOSITION BY APPROVING THE PRODUCTS.
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- OPUS II

IN FRANCE, FOR EXAMPLE, THE GOVERNMENT HAS DECLARED
NO
FURTHER BIOTECH APPROVALS UNTIL 2000, PENDING AN EU COURT
OF
JUSTICE REVIEW OF WHETHER THE GOVERNMENT HAS USED
APPROPRIATE REGULATORY
MECHANISMS IN BIOTECH APPROVALS.
IN THE U.K., ONE U.S. PRODUCT FAVORABLY
REVIEWED BY U.K.
SCIENTISTS IN 1998 (ROUND-UP READY CORN) IS STALLED
IN A
NEWLY-REQUIRED INTER-MINISTERIAL REVIEW PROCESS WHICH MUST
BE
COMPLETED BEFORE AN APPROVAL CAN BE FORWARDED INTO THE
COMMISSION'S
APPROVAL PROCEDURES. SEVERAL U.K.
SUPERMARKET CHAINS HAVE BANNED
BIOTECH INPUTS FROM THEIR
BRAND NAME PRODUCTS, AND ARE ADVERTISING
THEIR GROCERY
LINE AS "GMO-FREE." IT APPEARS NOW THAT THE U.S.
AFFILIATE
OF A SWISS BABY FOOD MANUFACTURER IS MOVING IN
THE SAME DIRECTION.

THERE
ARE NOW AT LEAST SEVEN VARIETIES OF BIOTECH CORN
PLANTED AND HARVESTED
IN THE U.S. THAT HAVE YET TO BE
APPROVED IN THE EU. ALTHOUGH PRODUCERS
SIGNED GROWER

AGREEMENTS TO MARKET THEIR NEW CORN VARIETIES FOR DOMESTIC USE ONLY, EXPORTERS ARE UNWILLING TO SHIP ANY U.S. CORN TO THE EU (AND IMPORTERS ARE UNWILLING TO RECEIVE IT) BECAUSE OF THE RISK THAT SHIPMENTS MAY BE BLOCKED. THE U.S. LOST \$200 MILLION DUE TO CANCELLED CORN EXPORTS TO THE EU BECAUSE OF EU DELAYS IN GRANTING MARKETING APPROVAL TO TWO U.S. CORN VARIETIES IN 1998, AND WE FACE SIMILAR LOSSES THIS YEAR.

THE IMPACT OF THIS PROBLEM IS AFFECTING U.S. PLANTING DECISIONS. IN 1999, A GERMAN COMPANY DECIDED NOT TO MARKET ITS NEW BIOTECH SOYBEAN TO U.S. FARMERS, CONCERNED THAT THE VARIETY HAD NOT BEEN APPROVED IN THE EU, AND THAT THE OUTPUT, ONCE CO-MINGLED, COULD CAUSE THE EU TO REJECT ALL U.S. SOYBEANS AND DERIVATIVE PRODUCTS. SOME EUROPEAN FOOD PROCESSORS AND DISTRIBUTORS HAVE INDICATED THAT THEY ARE ATTEMPTING TO USE SUBSTITUTE SOURCES FOR SOY OR CORN BECAUSE THEY DO NOT WANT ANY BIOTECH COMPONENTS IN THEIR PRODUCTS.

THE PROBLEM MAY HAVE BEEN EXACERBATED BY A MAY 1999 LABORATORY STUDY CONDUCTED BY CORNELL UNIVERSITY THAT FOUND THAT NEARLY HALF OF MONARCH BUTTERFLY CATERPILLARS DIED WHEN FED ON MILKWEED DUSTED WITH BIOTECH BT CORN POLLEN. THE RESULTS OF THE CORNELL STUDY ARE NOT SURPRISING, SINCE BT IS DESIGNED TO BE NOXIOUS TO THE EUROPEAN CORN BORER AND ITS RELATIVES, INCLUDING MONARCH CATERPILLARS (WHICH DO NOT FEED ON CORN PLANTS, BUT ONLY ON MILKWEED PLANTS). HOWEVER, THE EU CITED THIS STUDY AS

ITS REASON
FOR PLACING A MORATORIUM ON THE APPROVAL OF ONE
U.S. BT CORN VARIETY,
EVEN THOUGH THE STUDY AUTHORS HAD
CHARACTERIZED THE RESULTS OBTAINED
IN THE LABORATORY AS
:PRELIMINARY." IMPORTANT STUDIES IN THE FIELD
OF BT
POLLEN ON "NON-TARGET" ORGANISMS AND PESTS HAVE NOT BEEN
COMPLETED.
YET EVEN IF FIELD STUDIES SHOW SOME MONARCH
CATERPILLARS ARE AFFECTED
BY BT CORN POLLEN, THESE RESULTS
MUST BE CONSIDERED IN THE CONTEXT
OF THE IMPACT ON THE
CATEPILLARS OF TRADITIONAL PESTICIDES WHICH
ARE SPRAYED ON
OR NEAR CORN FIELDS.

THE EU'S DIRECTIVE 90/220
REGULATES THE ENVIRONMENTAL
RELEASE OF BIOTECH SEEDS AND ESTABLISHES
SAFETY AND
APPROVAL PROCESSES FOR ALL BIOTECH FOODS PLACED ON THE
MARKET.
THIS DIRECTIVE HAS A HISTORY OF NON-TRANSPARENCY
AND UNPREDICTABILITY,
AND THE EU IS IN THE PROCESS OF
DETERMINING HOW TO REVISE IT. THE
MOST RECENT DRAFT
REVISION, PROPOSED ON JUNE 25 BY THE EU ENVIRONMENT
COUNCIL,
INCLUDES A TEN-YEAR LIMIT ON APPROVALS,
ADDITIONAL PROCEDURES FOR
HANDLING BIOTECH PRODUCTS
ALREADY APPROVED, MANDATORY PUBLIC CONSULTATIONS,
LABELING
AND TRACKING BIOTECH PRODUCTS THROUGHOUT THE COMMERCIAL
STREAM,
AND STRICTER USE OF THE "PRECAUTIONARY PRINCIPLE"
(SEE BELOW). THE
REVISED VERSION IS NOT EXPECTED TO BE
APPROVED UNTIL 2000, WITH
AN IMPLEMENTATION DATE OF 2002.
U.S. REGULATORY OFFICIALS HAVE COMMENTED
ON THE PROPOSED
LEGISLATION.

THE EU ADOPTED ADDITIONAL LEGISLATION
(REGULATION 1813/97)

IN JANUARY 1997, WHICH SET UP MANDATORY LABELING OF "NOVEL FOODS" AND "NOVEL FOOD PRODUCTS," WHICH INCLUDE ANY FOOD THAT IS "NO LONGER EQUIVALENT" TO AN EXISTING FOOD OR FOOD INGREDIENT.
IN MAY 1998, THE E.U. ADOPTED REGULATION

1139/98 THAT CLARIFIED THE "EQUIVALENCY" STANDARD TRIGGERING THE MANDATORY LABELING REQUIREMENT FOR FOOD AND UNCLAS SECTION 05 OF 11 STATE 151442

PASS ECONCOUNSELOR, AGCOUNSELOR, AND USIA

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TAGS: ETRD, EAGR, TBIO, SENV, ECON, KSCA
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FOOD INGREDIENTS PRODUCED FROM TWO SPECIFIC BIOTECH VARIETIES (ROUND-UP-READY SOYBEANS AND THE FIRST GENETICALLY-ENGINEERED CORN APPROVED IN THE EU) THAT WERE APPROVED PRIOR TO THE NOVEL FOODS REGULATION. THE EU STATED IN THE REGULATION THAT FOODS OR FOOD PRODUCTS DERIVED FROM THESE TWO GENETICALLY-ENGINEERED VARIETIES ARE "NOT EQUIVALENT" TO THEIR CONVENTIONAL COUNTERPARTS IF THEY DISPLAY THE PRESENCE OF DNA OR PROTEIN RESULTING FROM GENETIC MODIFICATION. SUCH "NON-EQUIVALENT" FOODS OR FOOD INGREDIENTS REQUIRE A LABEL STATING "DERIVED FROM GENETICALLY-MODIFIED MAIZE/SOYA," AND INDICATING THE CHARACTERISTICS OR PROPERTIES THAT WERE GENETICALLY MODIFIED.

HOWEVER, THE EU HAS NOT YET CLARIFIED THE DETAILS ON HOW TO IMPLEMENT THE LAW. THIS HAS CREATED PROBLEMS FOR U.S.

PRODUCERS OF NON-BIOTECH AGRICULTURAL PRODUCTS AS WELL.
FOR
EXAMPLE, A U.S. NON-BIOTECH SOY PROTEIN EXPORTER IS
FACING A \$60
MILLION LOSS IN 1999, SINCE MANY EU IMPORTERS
ARE REQUIRING "GMO-FREE"
CERTIFICATION OF ITS NON-BIOTECH
SOY PRODUCT. MARKET LOSS HAS RESULTED
SINCE NO EU "GMO-
FREE" CERTIFICATION, TESTING METHODOLOGY TO DETECT
THE
PRESENCE OF BIOTECH PRODUCTS, NOR MINIMUM THRESHOLDS TO
ACCOMMODATE
"ADVENTITIOUS CONTAMINATION" AND FALSE
POSITIVES HAVE BEEN ESTABLISHED.

THE
QUESTION WHETHER TO MAKE BIOTECH FOOD LABELING
MANDATORY IS STILL
BEING DEBATED IN AUSTRALIA, NEW
ZEALAND, JAPAN, BRAZIL AND KOREA.
THROUGH THEIR JOINT
FOOD AUTHORITY, AUSTRALIA AND NEW ZEALAND HAVE
INDICATED
THAT THEY WILL LIKELY REQUIRE SOME SORT OF MANDATORY
LABELING,
BUT ARE STILL DISCUSSING THE PRACTICAL
IMPLICATIONS OF HOW SUCH
LABELING WOULD BE IMPLEMENTED.

IV - PRECAUTIONARY APPROACH

THE
U.S. HAS BEEN A WORLD LEADER IN THE DEVELOPMENT OF
RIGOROUS AND
EFFECTIVE REGULATIONS AND, IN REGULATING FOOD
AND ENVIRONMENTAL
SAFETY, THE U.S. ADOPTS A PRECAUTIONARY

APPROACH. SEVERAL U.S.
DOMESTIC STATUTES EMBODY
PRECAUTION, INCLUDING THE FEDERAL FOOD
DRUG AND COSMETICS
ACT, THE TOXIC SUBSTANCES CONTROL ACT AND THE
FEDERAL
FUNGICIDE, INSECTICIDE AND RODENTICIDE ACT. IN
INTERNATIONAL
ENVIRONMENTAL INSTRUMENTS, THE U.S. HAS
ACCEPTED REFERENCES TO

"A PRECAUTIONARY APPROACH" IN A NUMBER OF DIFFERENT CONTEXTS, INCLUDING IN PRINCIPLE 15 OF THE 1992 RIO DECLARATION: "IN ORDER TO PROTECT THE ENVIRONMENT, THE PRECAUTIONARY APPROACH SHALL BE WIDELY APPLIED BY STATES ACCORDING TO THEIR CAPABILITIES. WHERE THERE ARE THREATS OF SERIOUS OR IRREVERSIBLE DAMAGE, LACK OF FULL SCIENTIFIC CERTAINTY SHALL NOT BE USED AS A REASON FOR POSTPONING COST-EFFECTIVE MEASURES TO PREVENT ENVIRONMENTAL DEGRADATION." THE U.S. ALSO SUPPORTS ARTICLE 5.7 OF THE WTO SANITARY AND PHYTOSANITARY (SPS) AGREEMENT (AND A SIMILAR PROVISION IN THE NAFTA) WHICH PERMITS THE ADOPTION OF PROVISIONAL MEASURES TO BE TAKEN TO ENSURE SAFETY ON THE BASIS OF AVAILABLE PERTINENT INFORMATION IN CASES WHERE SCIENTIFIC EVIDENCE IS INSUFFICIENT.

THE EU HAS FREQUENTLY REFERRED TO "THE PRECAUTIONARY PRINCIPLE," BUT HAS NOT DEFINED WHAT IT IS, OR HAS DEFINED IT DIFFERENTLY IN DIFFERENT CONTEXTS. FOR EXAMPLE, IN THE RECENT WTO TRADE DISPUTE KNOWN AS THE BEEF HORMONES CASE, THE EU UNSUCCESSFULLY ARGUED THAT THE "PRECAUTIONARY PRINCIPLE" MUST BE READ INTO THE WTO SPS AGREEMENT TO JUSTIFY ITS DECISION TO BAN IMPORTS OF U.S. BEEF TREATED GROWTH HORMONES. (FOR FURTHER BACKGROUND ON THIS CASE, SEE SECTION ON CODEX, BELOW.) THE EU ALSO RECENTLY ATTEMPTED TO INTRODUCE THE "PRECAUTIONARY PRINCIPLE" AS A FACTOR FOR ASSESSING FOOD SAFETY IN THE CODEX ALIMENTARIUS, THE INTERNATIONAL BODY THAT DEVELOPS THE FOOD SAFETY STANDARDS THAT ARE RELIED ON IN SPS DISPUTE

SETTLEMENT DECISIONS. AT THE BIOSAFETY
PROTOCOL
NEGOTIATIONS, THE EU ATTEMPTED TO ELEVATE THE
"PRECAUTIONARY
PRINCIPLE" TO A NEW PRINCIPLE OF CUSTOMARY
PUBLIC INTERNATIONAL
LAW, WHICH WOULD SERVE AS A LENS
THROUGH WHICH THE ENTIRE AGREEMENT
WOULD BE IMPLEMENTED.
THE EU ARGUED THAT, BASED ON THE "PRECAUTIONARY
PRINCIPLE,"
THE MOST STRINGENT REGULATORY MEASURES, EVEN
TRADE BANS, COULD BE
IMPOSED UNTIL IT IS AFFIRMATIVELY
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151442

PASS ECONCOUNSELOR, AGCOUNSELOR, AND USIA

E.O. 12958:

N/A

TAGS: ETRD EAGR, TBIO, SENV, ECON, KSCA

SUBJECT: BIOTECHNOLOGY

- OPUS II

DEMONSTRATED BY THE PRODUCER THAT EACH BIOTECH PRODUCT

DOES NOT HAVE AND COULD NEVER HAVE AN ADVERSE
ENVIRONMENTAL OR
HEALTH EFFECT.

THE U.S. HAS CONCERNS THAT THE EU IS FUNDAMENTALLY

MISINTERPRETING THE "PRECAUTIONARY PRINCIPLE/APPROACH" BY
ATTEMPTING
TO APPLY IT TO JUSTIFY BANNING AN ENTIRE
TECHNOLOGY, RATHER THAN
CONSIDERING EACH BIOTECH PRODUCT
ON ITS SCIENTIFIC MERITS.

V

- FORA WHERE BIOTECHNOLOGY IS BEING DISCUSSED

BIOTECHNOLOGY IS
ON THE AGENDA IN OVER 15 FORA, THE MOST
IMPORTANT OF WHICH ARE THE
CODEX ALIMENTARIUS COMMISSION
(CODEX), THE ORGANIZATION FOR ECONOMIC
COOPERATION AND

DEVELOPMENT (OECD), THE BIOSAFETY PROTOCOL TO THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD), AND THE TRANSATLANTIC ECONOMIC PARTNERSHIP (TEP) BIOTECHNOLOGY WORKING GROUP. BIOTECH HAS ALREADY BEEN RAISED IN THE G8 SUMMIT PROCESS, AND HAVE BEEN FEATURED IN THE U.S.-EU SUMMIT.

THE
CODEX ALIMENTARIUS COMMISSION (CODEX)

THE CODEX ALIMENTARIUS HAS BECOME THE SEMINAL GLOBAL REFERENCE POINT FOR FOOD SAFETY ISSUES RELATED TO PUBLIC HEALTH AND FAIR PRACTICES IN FOOD TRADE. CREATED UNDER THE UN'S WORLD HEALTH ORGANIZATION (WHO) AND FOOD AND AGRICULTURE ORGANIZATION (FAO) IN 1961, THE CODEX SYSTEM PRESENTS AN OPPORTUNITY FOR THE 165 MEMBER COUNTRIES TO ENABLE THE INTERNATIONAL COMMUNITY TO FORMULATE AND HARMONIZE FOOD SAFETY STANDARDS AND ENSURE THEIR GLOBAL IMPLEMENTATION.

CODEX STANDARDS, CODES OF PRACTICE, GUIDELINES AND RECOMMENDATIONS ARE DEVELOPED BY SPECIALIZED COMMITTEES OF SCIENTIFIC EXPERTS AND APPROVED BY THE CODEX ALIMENTARIUS COMMISSION (CAC). CODEX STANDARDS ARE ACKNOWLEDGED IN THE WTO SANITARY AND PHYTOSANITARY (SPS) AGREEMENT AND RELIED ON AS BENCHMARKS AGAINST WHICH NATIONAL FOOD MEASURES AND

REGULATIONS ARE EVALUATED WITHIN THE CONTEXT OF WTO SPS DISPUTES.

FOR EXAMPLE, THE EU HAD BANNED IMPORTING U.S. BEEF,

CLAIMING THAT IT WAS TREATED WITH HORMONES AND UNSAFE.

WHEN THE U.S. DISPUTED THIS BAN AS A VIOLATION OF THE SPS AGREEMENT
IN THE WTO, THE DISPUTE SETTLEMENT PANEL
CONSIDERED THE RISK ASSESSMENTS
OF CODEX SCIENTISTS, AND
HELD IN FAVOR OF THE U.S. THAT THE BEEF
FROM HORMONE-
TREATED CATTLE WAS SAFE. THE EU APPEALED THE WTO
DECISION, CLAIMING THAT THE "PRECAUTIONARY PRINCIPLE" AND
"OTHER
FACTORS" BESIDES SCIENTIFIC EVIDENCE, SHOULD BE
TAKEN INTO ACCOUNT.
THE EU LOST THE APPEAL WHEN THE WTO
APPELLATE BODY CONFIRMED THAT
SPS DECISIONS WOULD BE MADE
ONLY ON THE BASIS OF "SOUND SCIENCE."

NOTE:
ALTHOUGH THE BEEF HORMONE CASE HAS NOTHING TO DO
WITH BIOTECHNOLOGY,
HORMONE-TREATED BEEF, AND BST
(HORMONES GIVEN TO DAIRY COWS TO
BOOST MILK PRODUCTION)
ARE OFTEN ILLOGICALLY CITED TOGETHER WITH
BIOTECH FOODS.
(ALL THREE CASES ARE ALSO OFTEN ILLOGICALLY CITED
TOGETHER
WITH BSE -- MAD COW DISEASE -- CREATING FURTHER
CONFUSION).

ON
JULY 3, THE CAC ESTABLISHED AN AD HOC INTER-
GOVERNMENTAL TASK FORCE
TO ELABORATE STANDARDS OR
RECOMMENDATIONS FOR BIOTECH FOODS, COORDINATE
CLOSELY WITH
APPROPRIATE CODEX COMMITTEES, AND TO TAKE FULL ACCOUNT
OF
WORK CARRIED OUT BY NATIONAL AUTHORITIES, FAO, WHO, AND
OTHER
INTERNATIONAL ORGANIZATIONS AND FORA. THE TASK
FORCE, CHAIRED BY
JAPAN, IS SCHEDULED TO MEET IN THE FIRST
HALF OF 2000, ISSUE A PRELIMINARY
REPORT IN 2001, AND
PRESENT STANDARDS FOR FINAL ADOPTION IN JUNE
2003.

THE TASK FORCE WILL LIKELY CONSULT WITH TWO CODEX COMMITTEES ALREADY ADDRESSING BIOTECH ISSUES: THE CODEX COMMITTEE ON FOOD LABELING, WHICH ESTABLISHED A WORKING GROUP OF 23 COUNTRIES IN APRIL 1999 TO DEVELOP GUIDELINES FOR BIOTECH FOOD LABELING BY MAY 2000; AND THE CODEX
UNCLAS SECTION 07 OF 11 STATE 151442

PASS ECONCOUNSELOR,
AGCOUNSELOR, AND USIA

E.O. 12958: N/A
TAGS: ETRD EAGR, TBIO,
SENV, ECON, KSCA
SUBJECT: BIOTECHNOLOGY - OPUS II

COMMITTEE ON
GENERAL PRINCIPLES, WHICH IS CONTINUING
DEBATE ON THE NEED TO INTRODUCE
"OTHER FACTORS" (SOCIO-
ECONOMIC, ENVIRONMENTAL, CONSUMER CHOICE,
ANIMAL RIGHTS)

AND "THE PRECAUTIONARY PRINCIPLE" INTO THE CODEX
RISK
ASSESSMENT PROCESS. OTHER CODEX ACTIVITIES POTENTIALLY
ADDRESSING
BIOTECH INCLUDE THE WORK OF THE AD HOC
INTERGOVERNMENTAL TASK FORCE
ON ANIMAL FEEDING, AND
PROPOSED HORIZONTAL SCIENCE-BASED WORK ON
FOOD ADDITIVES,
CONTAMINANTS, PESTICIDE AND VETERINARY DRUG RESIDUES,
FOOD
HYGIENE, FOOD LABELING AND NUTRITION AMONG THE CODEX
COMMITTEES.

OECD

SCIENTISTS FROM TWO SUB-GROUPS OF THE OECD'S ENVIRONMENTAL
POLICY
COMMITTEE WERE IDENTIFIED BY THE G8 HEADS IN JUNE
1999 AS EXPERTS

IN BIOTECHNOLOGY AND ASKED TO REPORT BACK
TO THE G8 BY MAY 2000
ON THE "IMPLICATIONS OF
BIOTECHNOLOGY AND OTHER ASPECTS OF FOOD
SAFETY." THE
OECD WORKING GROUP FOR THE HARMONIZATION OF REGULATORY
OVERSIGHT
IN BIOTECHNOLOGY, WHICH WAS ESTABLISHED IN 1995,
WAS RECOGNIZED
FOR ITS WORK ON THE ENVIRONMENTAL ASPECTS
OF BIOTECH PLANTINGS,
HAVING PRODUCED CONSENSUS DOCUMENTS
ON TRAITS AND ON CROPS, AND
HARMONIZATION OF MOLECULAR
GENETIC CHARACTERIZATION FOR ASSESSING
PLANTING APPROVALS
AND ENVIRONMENTAL IMPACTS. THE OECD TASK FORCE
ON NOVEL
FOODS AND FEEDS, WHICH WILL NEXT MEET IN SEPTEMBER 1999,
WAS
RECOGNIZED FOR ITS WORK ON BIOTECH FOOD SAFETY. THE
OECD HAS ALSO
DEVELOPED AND MAINTAINED BIOTRACK, WHICH
PROVIDES ONLINE INFORMATION
ABOUT BIOTECH FIELD TESTS,
COMMERCIAL PRODUCTS, AND REGULATORY DEVELOPMENTS
OF OECD
MEMBER COUNTRIES AND CONSENSUS DOCUMENTS. TO ADVANCE
INFORMATION-SHARING
WITH DEVELOPING COUNTRIES, BIOTRACK
ONLINE IS "LINKED" WITH THE
UNIDO BIOSAFETY INFORMATION
NETWORK AND ADVISORY SERVICE (BINAS),
AND THE SECRETARIAT
OF THE CONVENTION ON BIODIVERSITY (CBD).

IN
ORDER TO RESPOND TO THE G8 REQUEST AND CONDUCT A
TRANSPARENT WORK
PROGRAM, THE OECD MAY SPONSOR A
CONFERENCE WITH SCIENTISTS, ACADEMICIANS,
CONSUMERS, AND
NGOS.

-
BIOSAFETY PROTOCOL

THE ORIGINAL
NEGOTIATING MANDATE FOR THE BIOSAFETY
PROTOCOL TO THE CONVENTION

ON BIODIVERSITY (CBD) WAS TO
REGULATE THE TRANSBOUNDARY MOVEMENT
OF LIVING MODIFIED
ORGANISMS (LMOS) INTENDED FOR DELIBERATE RELEASE
INTO THE
ENVIRONMENT (SEEDS FOR PLANTING, FISH FOR PROPAGATION,
MICROBES
FOR BIOREMEDIATION). OVER THE THREE-YEAR COURSE
OF NEGOTIATIONS,
HOWEVER, THE ISSUES OF BIOTECH FOOD AND
FEED COMMODITIES FOR CONSUMPTION
OR PROCESSING, FOOD
SAFETY, AND LABELING WERE INTRODUCED. THE USG
BELIEVES
THAT THESE ISSUES RELATE DIRECTLY TO HUMAN AND ANIMAL
HEALTH,
AND ARE BEYOND THE PROTOCOL'S NEGOTIATING MANDATE.
THESE ISSUES
ARE MORE APPROPRIATELY LEFT TO THE CODEX
ALIMENTARIUS, WHICH HAS
RECOGNIZED AUTHORITY IN SUCH FOOD
SAFETY ISSUES AND WHICH HAS ESTABLISHED
WORKING GROUPS TO
ADDRESS THEM.

IN ADDITION TO THE ISSUE OF FOOD
SAFETY, AN INFORMAL,
FRIENDS OF THE CHAIR MEETING TENTATIVELY SCHEDULED
FOR
SEPTEMBER, WILL ATTEMPT TO BRIDGE THE DIFFERENCES ON
SEVERAL
KEY PROTOCOL PROVISIONS: THE PROPOSED REQUIREMENT
THAT BULK BIOTECH
AGRICULTURAL COMMODITIES (E.G. CORN,
SOYBEANS) RECEIVE AN IMPORTING
GOVERNMENT'S APPROVAL PRIOR
TO SHIPMENT; THE PROPOSED REQUIREMENT
THAT BIOTECH
COMMODITIES BE SHIPPED, HANDLED, PROCESSED AND PACKAGED
WITH
SPECIAL DOCUMENTATION AND TRACKING THROUGHOUT THE
COMMERCIAL STREAM;
AND THE PROPOSITION NOT TO INCLUDE A
"SAVINGS" CLAUSE, WHICH CLARIFIES
THAT THE PROTOCOL WILL
NOT AFFECT EXISTING RIGHTS AND OBLIGATIONS
OF THE PARTIES
UNDER EXISTING INTERNATIONAL AGREEMENTS, INCLUDING
THE
WTO.

TEP

THE TRANSATLANTIC ECONOMIC PARTNERSHIP (TEP)
BIOTECHNOLOGY
UNCLAS SECTION 08 OF 11 STATE 151442

PASS ECONCOUNSELOR,
AGCOUNSELOR, AND USIA

E.O. 12958: N/A
TAGS: ETRD, EAGR, TBIO,
SENV, ECON, KSCA
SUBJECT: BIOTECHNOLOGY - OPUS II

WORKING GROUP
WAS INITIATED IN 1998 TO EXCHANGE
INFORMATION ON THE TECHNICAL AND
SCIENTIFIC ISSUES WHICH
ARE PART OF THE REGULATORY APPROVAL PROCESS
FOR BIOTECH
PRODUCTS. THE TEP "PILOT PROJECT" WAS ESTABLISHED TO
ENABLE
A COMPARISON OF CERTAIN U.S. AND EU ENVIRONMENTAL
REVIEW PROCESSES
FOR BIOTECH PRODUCTS PRIOR TO

COMMERCIALIZATION. UNDER ONE ACTIVITY
OF THE PROJECT,
U.S. AND EU REGULATORS (USDA/APHIS AND DG-XI RESPECTIVELY)

WILL COMPARE CERTAIN ASPECTS OF THEIR SCIENTIFIC REVIEW OF
BIOTECH
PRODUCT APPLICATIONS. UNDER THE SECOND ACTIVITY,
REGULATORS WILL
MONITOR EACH OTHER'S PROCESSING OF AN
APPLICATION FILED SIMULTANEOUSLY
IN THE U.S. AND AN EU
MEMBER STATE BY AN INDUSTRY PARTICIPANT.

THE BIOTECH WORKING GROUP IS SUPPORTED BY DIALOGUES WITH
INDUSTRY,
CONSUMERS, ENVIRONMENTALISTS, AND LEGISLATORS,
WHICH MEET REGULARLY
TO PROVIDE RECOMMENDATIONS AND
GUIDANCE FOR THE TEP PILOT PROJECT.

SEVERAL

OTHER FORA HAVE ESTABLISHED BIOTECH WORKING GROUPS OR COMMITTEES, INCLUDING THE UN (UNEP, UNECE, UNCTAD, UNCSTD, UNIDO), INTERNATIONAL PLANT PROTECTION CONVENTION (IPPC), AND THE FRAMEWORK CONVENTION ON CLIMATE CHANGE (FCCC). THE ASIAN PACIFIC ECONOMIC COOPERATION (APEC) INITIATIVE HAS ADDRESSED BIOTECH IN SEVERAL COMMITTEES AND WORKSHOPS.

VI - CONCLUSION

U.S. POLICIES ARE BASED ON PRECAUTION AND SUPPORTED BY SCIENCE, RIGOROUS YET WORKABLE FOOD AND ENVIRONMENTAL SAFETY STANDARDS, A HISTORY OF OPEN DIALOGUE WITH ENVIRONMENTAL AND CONSUMER NON-GOVERNMENT ORGANIZATIONS (NGOS) AND INDUSTRY GROUPS, AND AN AWARENESS OF THE POTENTIAL ENVIRONMENTAL AND HEALTH BENEFITS OF BIOTECHNOLOGY.

OVER THE NEXT FEW YEARS -- ABSENT INCREASED INTERNATIONAL PUBLIC BACKLASH -- WE MIGHT EXPECT A WIDE ARRAY OF NEW BIOTECH-RELATED FOOD, DETERGENT, TEXTILE, PAPER, PHARMACEUTICAL, AND OTHER PRODUCTS TO BE DEVELOPED AND COMMERCIALIZED WORLDWIDE. (NOTABLY, BIOTECH PHARMACEUTICALS AND NON-FOOD BIOTECH PRODUCTS HAVE RAISED LITTLE CONTROVERSY COMPARED WITH BIOTECH FOODS.)

THEREFORE, THIS PROBLEM IS NOT OURS ALONE. OTHER COUNTRIES WITH A STAKE IN THIS TECHNOLOGY MUST BE ENGAGED

TO FIND SOLUTIONS. THE NEGOTIATING STANCE OF OTHER GOVERNMENTS AND PRIVATE GROUPS WILL PLAY AN ENORMOUS ROLE

IN THE OUTCOME. MANY
SCIENTISTS WORLDWIDE RECOGNIZE THAT
THERE COULD BE NUMEROUS POTENTIAL
BENEFITS, INCLUDING
ENVIRONMENTAL BENEFITS, FROM BIOTECHNOLOGY.
HOWEVER, MANY
COUNTRIES THAT HAVE AGRICULTURAL PRODUCTS IN THEIR
BIOTECH
DEVELOPMENT PIPELINE HAVE EXPRESSED OPPOSITION TO
BIOTECHNOLOGY
DEVELOPMENT IN VARIOUS FORA.

WE WILL BE SEEKING A WAY FOR THE
U.S. AND OTHER
GOVERNMENTS TO COME TOGETHER TO MORE EFFECTIVELY
ADDRESS
THE CONCERNS SURROUNDING BIOTECH PRODUCTS AND ENCOURAGE
TRANSPARENT
REGULATORY PROCEDURES TO ADDRESS THE SAFETY OF
FUTURE PRODUCTS.
WE WISH TO AVOID ACCESS RESTRICTIONS
AND CONSEQUENT TRADE DISPUTES
(UNDER THE WTO TECHNICAL
BARRIERS TO TRADE, SANITARY/PHYTOSANITARY
AGREEMENTS, THE
TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS
AGREEMENT),
A BIOSAFETY PROTOCOL REQUIRING PROCEDURES AND
CONTAINING OBLIGATIONS
WITH WHICH THE U.S. CANNOT COMPLY,
INTRODUCTION OF NON-SCIENTIFIC
CRITERIA IN THE CODEX FOOD
SAFETY STANDARD-SETTING PROCESS, AND
MANDATORY
COUNTRY-BY-COUNTRY OR INTERNATIONAL BIOTECH PRODUCT
RESTRICTIONS
NOT COMMENSURATE WITH THE POTENTIAL RISKS
SUCH PRODUCTS MAY POSE.

5.
SOME POTENTIAL BENEFITS OF BIOTECHNOLOGY

THE WORLD POPULATION
IS EXPECTED TO DOUBLE TO MORE THAN 10
BILLION PEOPLE BY 2030. BY
INCREASING CROP YIELDS FOR
LAND CURRENTLY IN AGRICULTURAL USE, WE
CAN ENSURE A MORE

SECURE AND SUSTAINABLE AGRICULTURAL FUTURE, PARTICULARLY
UNCLAS
SECTION 09 OF 11 STATE 151442

PASS ECONCOUNSELOR, AGCOUNSELOR,
AND USIA

E.O. 12958: N/A
TAGS: ETRD, EAGR, TBIO, SENV, ECON,
KSCA
SUBJECT: BIOTECHNOLOGY - OPUS II

FOR DEVELOPING NATIONS,
WITHOUT THE NEED TO RECLAIM MORE
NATURAL HABITATS FOR AGRICULTURE.
BIOTECHNOLOGY IS
EXPECTED TO INCREASE CROP YIELDS BY 20% FOR SMALL-HOLDER
FARMERS
PROFITABLY AND WITHOUT DEGRADING NATURAL
RESOURCES.

AS FORMER
PRESIDENT JIMMY CARTER STATED: "RESPONSIBLE
BIOTECHNOLOGY IS NOT
THE ENEMY; STARVATION IS. WITHOUT

ADEQUATE FOOD SUPPLIES AT AFFORDABLE
PRICES, WE CANNOT
EXPECT WORLD HEALTH OR PEACE."

ENVIRONMENTAL
BENEFITS
-- ENVIRONMENTAL STRESSES FROM INSECTS, AND PLANT
DISEASES
REQUIRE AN ALTERNATIVE TO CHEMICAL TREATMENTS
THAT ARE LESS HARMFUL
TO NATURAL RESOURCES. BIOTECH CROPS
CAN POTENTIALLY DECREASE THE
NEED FOR PESTICIDES AND
HERBICIDES TO CONTROL PESTS, WEEDS, AND
PLANT DISEASES AND
ALLOW MORE SELECTIVE APPLICATION OF AGRICULTURAL
CHEMICALS.
FOR EXAMPLE:

-BIOTECH POTATO, CORN, AND COTTON PLANTS HAVE
BEEN
ENGINEERED TO PRODUCE A BACTERIAL TOXIN (BACILLUS
THURINGIENSIS OR "BT" DELTA ENDOTOXIN) TO WARD OFF

DESTRUCTIVE
INSECTS ON THEIR OWN, REDUCING THE NEED
FOR EXTERNALLY-APPLIED
CHEMICALS;

-BIOTECH HERBICIDE-TOLERANT COTTON, CORN, AND

SOYBEANS HAVE GIVEN FARMERS A CHOICE TO MAKE FEWER
APPLICATIONS
OF HERBICIDES AND TO USE MORE
ENVIRONMENTALLY-FRIENDLY HERBICIDES;

--

ENVIRONMENTAL STRESSES FROM FROST AND DROUGHT OR
FLOODING CAN DEVASTATE
YIELDS. BIOTECHNOLOGY CAN
POTENTIALLY PROVIDE ENHANCED RESISTANCE
TO NATURAL
CLIMACTIC VARIATIONS AND LESSEN RELIANCE ON WATER SOURCE
MANAGEMENT.
FOR EXAMPLE:

-PLANTS CAN POTENTIALLY BE ENHANCED TO WITHSTAND
A
DROP IN TEMPERATURE AND FROST BY MODIFYING THEIR
PRODUCTION
OF LINOLEIC ACID.

-- BIOTECH CAN POTENTIALLY DECREASE THE NEED
TO RECLAIM
NEW LAND FOR AGRICULTURE, AS SOILS CONSIDERED UNACCEPTABLE
(DUE
TO SALTS, METALS, ACIDS) CAN BE MADE PRODUCTIVE AND
MARGINAL LANDS
CAN BE CULTIVATED.

-- BIOTECH CROPS CAN POTENTIALLY PRESERVE THE
LAND'S
ABILITY TO SUPPORT CONTINUED FARMING BY REDUCING THE NEED
FOR
TILLAGE, WHICH CAUSES BOTH SOIL AND WATER RUNOFF AND
SOIL NUTRIENT
DEPLETION.

FARMER BENEFITS
-- BIOTECH CAN POTENTIALLY INCREASE
PROFITABILITY FOR
FARMERS. FOR EXAMPLE:

-BIOTECHNOLOGY HAS

IMPROVED THE QUALITY OF SEED
GRAINS AND THE ABILITY TO PRODUCE
BIGGER HARVESTS
FROM CURRENTLY CULTIVATED LAND.

-INCREASED
YIELDS AND REDUCED CHEMICAL AND LABOR
COSTS CAN REPRESENT INCREASED
INCOME FOR THE FARMER.

-U.S. FARMERS SPEND \$12 BILLION YEARLY
ON FERTILIZER,
ALMOST HALF OF WHICH EVAPORATES OR WASHES AWAY.
SOME
PLANTS, SUCH AS CORN, MIGHT BE MODIFIED TO DRAW

NITROGEN FROM THE SOIL AND AIR, DRAMATICALLY REDUCING
THE NEED
FOR FERTILIZER.

-- BIOTECH CROPS CAN BE SAFER TO PRODUCE. FOR
EXAMPLE,
FARM WORKERS WOULD BE LESS EXPOSED TO TOXIC AGRICULTURAL
CHEMICALS
WHEN USE OF PESTICIDES AND HERBICIDES IS
REDUCED.

-- FARMERS
RECEIVE CAPACITY BUILDING IN NEW FARMING
TECHNOLOGIES AND CAN PRODUCE
CROPS THAT REQUIRE LESS
HANDLING, EASIER STORAGE, NO REFRIGERATION,
LONGER SHELF-
LIFE.

HUMAN HEALTH
-- BENEFICIAL TRAITS CAN POTENTIALLY
BE ADDED TO PLANTS.
FOR EXAMPLE:

UNCLAS SECTION 10 OF 11 STATE
151442

PASS ECONCOUNSELOR, AGCOUNSELOR, AND USIA

E.O. 12958:

N/A

TAGS: ETRD EAGR, TBIO, SENV, ECON, KSCA

SUBJECT: BIOTECHNOLOGY

- OPUS II

-CORN, SOYBEANS, CANOLA, AND OTHER PLANTS ARE BEING

MODIFIED TO REDUCE THE SATURATED FAT CONTENT OF COOKING

OILS DERIVED FROM THESE PLANTS;

-POTATOES ARE BEING MODIFIED

TO ABSORB LESS FAT WHILE

FRYING;

-"NUTRICEUTICALS" ARE

BEING DEVELOPED, INCLUDING

FRUITS AND VEGETABLES CONTAINING

HIGHER LEVELS OF

CERTAIN NUTRIENTS SUCH AS VITAMINS C AND E,

AND BETA

CAROTENE, TO HELP REDUCE RISK OF CHRONIC DISEASES

SUCH AS SOME CANCERS AND HEART DISEASE;

-RICE IS BEING

PRODUCED WITH AN IMPROVED PROTEIN

PROFILE TO INCLUDE HIGHER

LEVELS OF THE ESSENTIAL

AMINO ACID, LYSINE.

-- TRAITS HARMFUL

TO HUMAN HEALTH CAN BE ELIMINATED. FOR

EXAMPLE, ALLERGEN-CAUSING

PROTEINS CAN BE REMOVED FROM

FOODS, INCLUDING RICE.

--EDIBLE

VACCINES ARE UNDER DEVELOPMENT. FOR EXAMPLE:

-THE MAY 1998

NATURE MEDICINE MAGAZINE REPORTED ON

THE CLINICAL TRIAL OF

THE FIRST EDIBLE VACCINE.

RESEARCHERS WERE SUCCESSFUL INTRODUCING

ANTIGENS IN

POTATOES AND "ARE HOPING TO ENGINEER BANANAS TO

PRODUCE ANTIGENS." THE RESULTS SHOWED PROMISE FOR THE DEVELOPMENT

OF LESS COSTLY, SAFE, AND EFFECTIVE

MEDICINE FOR INTESTINAL

DISEASES IN DEVELOPING

NATIONS (CURRENTLY THOUSANDS OF INFANT

DEATHS ARE

CAUSED BY E. COLI).

-BIOTECHNOLOGY MAY BE
ABLE TO REDUCE THE HIGH COSTS,
TRANSPORTATION LOGISTICS AND
THE NEED FOR
REFRIGERATION FOR VACCINES IN DEVELOPING COUNTRIES.

ANIMAL HEALTH

--BIOTECH CAN PROVIDE FORAGE CROPS WITH INCREASED LEVELS
OF
PROTEINS, OTHER NUTRIENTS, AND POSSIBLY DISEASE-
FIGHTING VACCINES.

CONSUMER BENEFITS

-- ENHANCED FLAVORS AND PRODUCT UNIFORMITY OF FRUITS AND
VEGETABLES
HAVE BEEN DEVELOPED THROUGH MODERN
BIOTECHNOLOGY.

-- BIOTECH
CAN HELP KEEP FOOD PRICES LOW THROUGH FUTURE
ADVANCES THAT CAN ENHANCE
THE PRODUCTION, DISTRIBUTION,
PACKAGING, AND HANDLING OF BIOTECH
FOOD PRODUCTS.

SCIENTIFIC ADVANCES

-- BIOTECH IS PROVIDING NEW
TECHNOLOGIES FOR TRADITIONAL
PRODUCTION, SUCH AS BREWING, BAKING
AND CHEESE-MAKING.
BIOTECH HAS ALREADY IMPROVED PRODUCTS VITAL TO
FOOD

PRODUCTION, SUCH AS ENZYMES, PROTEINS, AND VITAMINS. FOR
EXAMPLE:

-RENNIN, AN ENZYME USED TO MAKE CHEESE, IS
TRADITIONALLY
TAKEN FROM THE LINING OF CALVES'
STOMACHS AFTER SLAUGHTER.
BIOTECH RESEARCHERS HAVE
ISOLATED AND COPIED THE SPECIFIC GENE
THAT PRODUCES
RENNIN AND REPRODUCED IT IN BACTERIA. THIS ALLOWS

THE PRODUCTION OF RENNIN BY BACTERIA. TODAY, NEARLY

50

PERCENT OF RENNIN IS PRODUCED THROUGH BIOTECH,
PROVIDING A
MORE SOURCE OF THE ENZYME THAT IS MORE
CONSISTENT AND PURE.

--

R&D WILL CONTINUE TO ADVANCE BETTER METHODS TO IDENTIFY
AND LOCATE
TOXINS, PATHOGENS, OR CONTAMINANTS IN FOOD.

-- LICENSING AGREEMENTS
WITH SEED PRODUCERS CAN ALLOW FOR
BENEFIT-SHARING IN PATENT RIGHTS.

--

CAPACITY-BUILDING AND INFORMATION SHARING WILL SUPPORT
WORLD TRADE
IN BIOTECH PRODUCTS.

6. CALENDAR OF EVENTS

AUGUST
11-13
APEC SENIOR OFFICIALS MEETING
17 WORLD NET - ASIA
UNCLAS SECTION
11 OF 11 STATE 151442

PASS ECONCOUNSELOR, AGCOUNSELOR, AND USIA

E.O.
12958: N/A
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SUBJECT: BIOTECHNOLOGY
- OPUS II

17 DOS MEETING WITH BIOTECH INDUSTRIES - WASHINGTON

SEPTEMBER
1-2
ASEAN SEOM - JAKARTA
2-3 HARVARD U. - CONFERENCE ON BIOTECH
2-3
UN COMMISSION ON SCIENCE AND TECHNOLOGY WORKSHOP
13 CORN GROWERS'
ASSN. BIOTECH CONFERENCE - WASHINGTON

14 OECD JOINT BUREAU MEETING
15-17
OECD NOVEL FOODS AND FEEDS TASK FORCE
27 ASEAN ECONOMIC MINISTERIAL

TBD
APEC LEADERS MEETING - WELLINGTON
TBD BIOSAFETY PROTOCOL TALKS RESUME
TBD
WORLD NET - LATIN AMERICA
TBD WORLD NET - EUROPE

TBD ELECTRONIC
JOURNAL ON BIOTECH PUBLISHED - USIA
TBD BIOTECH WEBSITE UP AND RUNNING
- USIA

OCTOBER
03-06 COUNCIL FOR RESPONSIBLE NUTRITION - PALM
SPRINGS
11-15 FAO - INT'L FOOD TRADE BEYONE 2000 - MELBOURNE

NOVEMBER
18-19
BIOTECHNOLOGY LAW CONFERENCE - WASHINGTON

JANUARY
TBD USIA VISITORS
PROGRAM
TBD ROUNDTABLE ON BIOTECH - EMBASSY HAGUE

FEBRUARY
TBD
BIOSAFETY PROTOCOL - FINAL NEGOTIATIONS

MARCH
TBD USIA VISITORS
PROGRAM

MAY
TBD OECD REPORTS TO G8
TBD CODEX BIOTECH TASK FORCE
MEETS
TBD CODEX COMMITTEE ON FOOD LABELING

JUNE
TBD CONVENTION
ON BIODIVERSITY - NAIROBI
TBD G8 SUMMIT
ALBRIGHT

DIST:
SIT:
HAMMONDS HOLTZAPPLE LEE SCHAEFER SHAH SIT: NSC

-----Original Message-----

From: Bowles,
Ian A. (ENV)
Sent: Wednesday, August 18, 1999 6:44 PM
To: Bernard,
Kenneth W. (HEALTH)
Subject: gmo cable [UNCLASSIFIED]

can you
forward the opus II cable on biotech that you mentioned to me. looks
like i did not get it. if you send it on, i'll ask WHSR to forward
similar such cable on to me. thanks, ian

Exchange Mail

DATE-TIME 8/27/99 9:19:09 AM

FROM Millison, Cathy L. (EXSEC)

CLASSIFICATION UNCLASSIFIED

SUBJECT GLICKMAN/ROHATYN MTG RE GMO [UNCLASSIFIED]

TO Crocker, Bathsheba N. (NSA)
Scott-Perez, Marilyn L. (NSA)
Moretz, Sheila K. (NSA)

CARBON_COPY Bartlett, L. June (EXSEC)
Dejban, Donna D. (NSA)
Hilliard, Brenda I. (EXSEC)
Joshi, M. Kay (EXSEC)
Millison, Cathy L. (EXSEC)
Wasserman, Elaine P. (EXSEC)

TEXT_BODY Ladies:

I see there's a meeting tentatively scheduled for Monday
with Glickman & Rohatyn re GMO. Do you need briefing material and
if so, who should I ask to prepare it?

Thanks.

Exchange Mail

DATE-TIME 9/21/99 9:36:11 AM

FROM Bowles, Ian A. (ENV)

CLASSIFICATION UNCLASSIFIED

SUBJECT CANADA: GMO LABELING PROJECT ANNOUNCED [UNCLASSIFIED]

TO Duncan, John D. (INTECON/DOS)
Hammonds, D. Holly (INTECON)
Hendricks, Lori A. (INTECON)
Lee, Malcolm R. (NEC)
Mitsler, Elaine M. (INTECON)
Samans, Richard (NEC)
Schaefer, Matthew P. (INTECON)
Shah, Sonal R.
Epstein, Gerald L. (OSTP)
Hane, Gerald J. (OSTP)
MacDonald, Bruce W. (OSTP)
Rinaldi, Steven M. (OSTP)
Ward, JoAnn (OSTP)

CARBON_COPY Sandalow, David B. (ENV)

TEXT_BODY @Intecon -- Please pass to Rick Samans and Lael B.
@OSTP -- please
pass to Cliff Gabriel.

Thanks, Ian

-----Original Message-----

From:

WHSR

Sent: Monday, September 20, 1999 5:26 PM

To: Bowles, Ian

A. (ENV); Sandalow, David B. (ENV)

Subject: CANADA: GMO LABELING
PROJECT ANNOUNCED

UNCLAS OTTAWA 003413

DEPARTMENT FOR
G, E, EB, OES, WHA/CAN

DEPARTMENT PASS USTR FOR DEPUTY USTR ESSERMAN
AND MARY
RYCKMAN

E.O. 12958: N/A

TAGS: TBIO, EAGR, ETRD, GM

SUBJ:

CANADA: GMO LABELING PROJECT ANNOUNCED

REF: OTTAWA 3353

1.
AS ANTICIPATED IN OUR REFTTEL, LATE ON SEPTEMBER 17, 1999
THE CANADIAN
COUNCIL OF GROCERY DISTRIBUTORS (CCGD) AND THE
CANADIAN GENERAL
STANDARDS BOARD (CGSB) ANNOUNCED A PROJECT
TO DEVELOP A "CANADIAN
STANDARD FOR THE VOLUNTARY LABELING
OF FOODS DERIVED FROM BIOTECHNOLOGY".
THE CANADIAN
MINISTER OF AGRICULTURE, LYLE VAN CLIEF, MADE THE
ANNOUNCEMENT
ON BEHALF OF THE CCGD AND CGSB AND HAS
PROMISED FINANCIAL SUPPORT
TO THE LABELING PROJECT THROUGH
HIS DEPARTMENT'S AGRI-FOOD TRADE
2000 PROGRAM.
2. AS A COROLLARY, A REPORTER WHO INTERVIEWED THE
MINISTER
ON SEPTEMBER 17 TOLD EMBOFF THAT THE MINISTER HAS NOT
RULED
OUT
MANDATORY LABELING STANDARDS AS A FUTURE DEVELOPMENT,
ALTHOUGH THE
MINISTER (WITHOUT BEING PROMPTED) OBSERVED
THAT BRITAIN HAS FOUND
MANDATORY STANDARDS IMPOSSIBLE TO
ENFORCE.
3. THE CGSB WILL MANAGE
THE DEVELOPMENT OF THE NEW STANDARD
ON BEHALF OF THE CCGD. THE
STANDARD WILL BE DEVELOPED WITH
PARTICIPATION FROM CONSUMER GROUPS,
FOOD COMPANIES,
PRODUCERS (I.E., FARMERS), INTEREST GROUPS, AND
GOVERNMENT
REGULATORS THROUGH THE FORMATION OF A STANDARDS

COMMITTEE
WHICH
IS EXPECTED TO BEGIN MEETING IN OCTOBER 1999. NO
TIMELINE HAS BEEN
PROVIDED FOR COMPLETION OF THE PROJECT.

4. THE CCGD REPRESENTS
ABOUT 80% OF MAJOR FOOD RETAILERS IN
CANADA AND IS INVOLVED IN PUBLIC
AWARENESS AND EDUCATION
ACTIVITIES FOR BIOTECHNOLOGY. OTHER MAJOR
INDUSTRY
STAKEHOLDERS HAVE INDICATED THEIR FULL ENDORSEMENT OF
THE
INITIATIVE
INCLUDING THE FOOD AND CONSUMER PRODUCTS
MANUFACTURERS ASSOCIATION
OF CANADA (WHOSE MEMBERS PROVIDE
ABOUT 75% OF THE FOOD AND BEVERAGES
AVAILABLE TO CANADIAN
CONSUMERS) AND THE CANADIAN FEDERATION OF
INDEPENDENT
GROCERS (WHICH REPRESENTS SMALL, OFTEN RURAL, GROCERY
RETAILERS).

5.
THE CGSB IS AN "ACCREDITED STANDARDS DEVELOPMENT
ORGANIZATION" WITHIN
THE DEPARTMENT OF PUBLIC WORKS AND
GOVERNMENT SERVICES OF THE GOVERNMENT
OF CANADA. THE CGSB
"DEVELOPS VOLUNTARY STANDARDS THROUGH CONSENSUS",
AND DOES
HAVE SOME EXPERIENCE IN THE REALM OF AGRICULTURAL
PRODUCTS

-
IN JUNE 1999 THE CGSB COMPLETED A NATIONAL STANDARD FOR
ORGANIC
AGRICULTURE WHICH CLARIFIES JUST WHAT ORGANIC
MEANS. THE NEW ORGANIC
AGRICULTURE STANDARD PROHIBITS THE
USE OF GENETICALLY ENGINEERED
OR MODIFIED ORGANISMS.

6. MEANWHILE, IN RESPONSE TO THE PROJECT
ANNOUNCEMENT,
GREENPEACE'S GENETIC ENGINEERING CAMPAIGN COORDINATOR,
MICHEAL
KHOO, DECLARED THAT "LABELING IS NOT A SOLUTION.
IF THE FOOD IS

NOT SAFE, IT SHOULD BE TAKEN OFF THE SHELF."
KHOO TOLD EMBOFF THAT
GREENPEACE (AND ITS SISTER NGOS WITH
WHOM IT HAS TEAMED UP ON THIS
ISSUE) WILL LIKELY NOT TAKE
PART IN THE DEVELOPMENT OF THE VOLUNTARY
STANDARD - BUT IF
THE TERMS OF REFERENCE WERE ACCEPTABLE MIGHT CONSIDER
PLAYING
A ROLE. KHOO NOTED ALSO THAT THE ANTI-GMO PUBLIC
EDUCATION CAMPAIGN
IN CANADA WILL BEGIN IN EARNEST IN EARLY
OCTOBER 1999.

GIFFIN

Exchange Mail

DATE-TIME 9/23/99 6:21:53 PM
FROM Osius, Theodore G. (VP)
CLASSIFICATION UNCLASSIFIED
SUBJECT GMO tps for leon [UNCLASSIFIED]
TO Davidson, Leslie K. (VP)

CARBON_COPY

TEXT_BODY

TRANSLATED_ATTACHMENT gmo tps for ec commissioner patten.doc
You may wish to reinforce Berger's message on genetically-modified foods as follows:

* We look forward to establishing a serious dialogue with the EC on the issue of genetically-modified foods.

* While European consumers appear comfortable with bioengineered medicines, they are clearly uncomfortable with bioengineered food. In order to restore confidence, the EC may want to consider changes in the food regulatory system

* I hope the Commission will help manage this in a responsible way.

Exchange Mail

DATE-TIME 9/30/99 1:53:06 PM
FROM Crocker, Bathsheba N. (NSA)
CLASSIFICATION ~~CONFIDENTIAL~~
CLASSIFICATIONREASON 1.5(d)
DATECLASSIFIEDON 09/30/1999
DECLASSIFYON 09/30/2009
SUBJECT RE: Read-Out of This Morning's Deputies on GMO's [~~CONFIDENTIAL~~]
TO Schaefer, Matthew P. (INTECON)

DECLASSIFIED
PER E.O. 13526
2016-0529-M (3.29)
3/6/2019 KBH

CARBON_COPY

TEXT_BODY

thanks matt.

-----Original Message-----

From: Schaefer, Matthew
P. (INTECON)

Sent: Thursday, September 30, 1999 1:28 PM

To: Crocker,
Bathsheba N. (NSA); @NSA - Natl Security Advisor
Cc: @HAMMONDS

Subject: Read-Out
of This Morning's Deputies on GMO's [~~CONFIDENTIAL~~]

Please pass
to Jim

Read-Out of Deputies Meeting on Environmental Effects of
GMOs (September 30th 9AM)

* Deputies agreed on the need to have
comprehensive GMOs policy on all three aspects (environment, consumer

safety, and trade) in place in advance of Seattle WTO Ministerial
(Nov. 30- Dec.3). Doing so will also assist in preparations for
Ministerial negotiations on the biosafety protocol that begin early
next year.

* Accordingly, deputies agree to meet again in 2-3
weeks once final paper on all three aspects is prepared. Agencies
will also work on draft press guidance on environmental effects of
GMOs.

* EPA discussed two regulatory actions it is in the process of considering concerning the environmental effects of Bt Corn:

1)

EPA is considering an increase in required "refugia" (areas where some portion of the pest population can live without exposure to pesticide so as to avoid resistance developing over time) for Bt Corn from the current varied rate of 7-20% to a uniform minimum of 20%. All manufacturers agree with this change. EPA is also considering increasing the percentage to up to 40% if the pesticide is also sprayed by the grower but there is no agreement among manufacturers on this step and USDA also has concerns. EPA would like to finalize this issue in the next week or two. Farmers will begin buying from manufacturers in late November and this condition needs to be worked into sales contracts.

2) EPA is considering requiring buffer zones of 20-30

ft. so as to prevent possible impact on non-targeted species (such as the monarch butterfly). OSTP and others believe that there is not a sufficient scientific basis for buffer zones at this point. They note that the study on monarch butterflies contained flaws (e.g., no evidence that Bt pollen in real life travels in such a manner/distance as to be found on the milkweed that monarchs eat and no evidence that Bt pollen would affect monarchs outside laboratory since they could choose non-Bt tainted milkweed). Additionally, OSTP is concerned that a buffer requirement will raise illegitimate concerns in the public (and give an unjustified appearance of credibility to the EU's positions) since there is not sufficient scientific evidence. CEQ questioned whether EPA would have sufficient "jurisdictional hook" to regulate GMOs in this fashion when they did not serve a pesticide purpose. Industry has asked EPA to hold off on a decision on buffer requirements until after an industry has further time to consider the issue.

Exchange Mail

DATE-TIME 10/13/99 11:52:51 AM
FROM Holtzapple, Richard A.
CLASSIFICATION UNCLASSIFIED
SUBJECT Biotech/GMO papers [UNCLASSIFIED]
TO Bowles, Ian A. (ENV)
Sandalow, David B. (ENV)

CARBON_COPY

TEXT_BODY

The first paper deals most broadly with all Biotech issues, the second is specific to doings at the OECD (and most likely to be effected by the papers in Ann's fax-which I thought I had a copy of, but cannot find on my pig sty of a desk), and the third paper is related just to the BSP/Cartagena process.

TRANSLATED_ATTACHMENT

Biotech - 10-04-99 - G8 Sherpa Jim Steinberg 10-13.doc
BIOTECHNOLOGY/FOOD SAFETY

Key Issues:

--Using the G8 mandate to the OECD to help address consumers' food safety concerns while protecting against any further erosion of our agricultural market access in the EU and elsewhere.
--Preventing the G8 process from excessive politicization, and maintaining the focus of the G8 mandate on food safety and regulation -- where the experts can reach consensus -- and leave broader, longer-term work by the OECD to go forward without a "hard link" to the G8.
--Supporting the UK's idea of a fully inclusive conference on biotech (including the agricultural sector), but again with no hard link to the Cologne G8 mandate; useful as input.
--Working with like-minded G8 partners (Canada) to appeal to the broader interests at stake in the UK, Germany and Japan -- all of which have strong biotech potential -- against the shorter term political interests driving a

hard-line French position.

--Continuing pressure for clear, reliable science-based regulation of biotech, consideration of cost-effectiveness, and sound public information; pressing to

avoid additional regulations and unworkable thresholds.

--Efforts to broaden engagement in the Biosafety Protocol talks beyond

environment Ministries, and negotiate a Protocol that protects the environment

without stifling trade and raising global food costs.

Talking Points:

* The report by the OECD experts on the safety and regulation of biotech foods

should be a valuable contribution to further refining the degree of science-based regulatory oversight needed.

* We should encourage the OECD and its experts to focus on the food safety

implications of biotechnology, rather than be drawn into social and environmental

debates that will render impossible our May 2000 timetable.

* An independent OECD assessment is critical to being able to educate the public

and de-politicize the discussions.

* We understand European consumers' food safety concerns, given recent

experiences with mad cow, dioxin and dried blood in wine, but we are concerned

that attention has been inappropriately diverted away from those very real food

safety problems towards biotech foods.

* Scientists find no evidence that the process of genetic modification makes

biotech foods any less safe than foods produced by more traditional means. Even

so, the EU has yet to put a workable, science-based regulatory system in place.

Meanwhile, the U.S. farm community - some of the world's strongest supporters of

open markets - are losing hundreds of millions of dollars per year in legitimate

sales.

* The OECD exercise should help us all, by making more clear to the public the scientific evidence on these issues and by pointing to effective biotech food safety assessment and regulatory approaches. We should guard its integrity if we really want to serve our leaders and our people.

* We should also work to ensure that the Biosafety Protocol negotiations, which restart in January 2000 in Montreal, have a manageable outcome that protects the environment without stifling trade or imposing potentially heavy costs on global food supplies.

* While there was no blow up at the recent Biosafety talks in Vienna, no solutions were found to the need to ensure the integrity of the WTO through an effective safety clause. There was no real coming together around practical solutions on bulk commodities despite new suggestions by some participants.

* Moreover, it is irresponsible for some in the Biosafety talks to play on the vulnerabilities felt by the developing countries by supporting the notion that they should simply avoid biotech agriculture.

* Developing country farmers deserve the same crop choices our farmers must make based on productivity, safety and consumer appeal. We should encourage them to see that there are clearly ways to manage the environmental aspects of biotech, and to help them do so as much as we can.

* We should not allow politics to undermine our longstanding rules-based, science-based approach to agricultural trade.

Background:

At the Cologne Summit, the G8 tasked two OECD groups with recognized expertise to report by May 2000 on biotechnology and various aspects of food safety, including regulatory good practices. With this report, Sherpas will be in a

position to
better assess the need for a new international regulatory framework to
deal with
biotech foods.

President Chirac pressed OECD SYG Johnston directly, in the interest
of
"transparency," to expand the scope of the OECD report to include
consumer and
environmental concerns. Chirac reiterated his notion of an
international body of
eminent scientists to weigh in on biotech issues. The French continued
this push
at the October 7 OECD Council meeting, but we had strong support
from Canada, and
some from the UK and Germany, in opposing the French. Johnston
wants to have the
OECD take up these broader issues through the creation of a new Ad
Hoc Group on
Food Safety, arguing the OECD Ministerial results allow him to do so
and that
members want it. The issue will be decided at the OECD Council
meeting October
14. Meanwhile, the UK is willing to fund a major biotech conference
in March,
more or less jointly with the OECD, with some link to the G8.

Our challenge continues to be to maintain the integrity of the G8
mandate, which
specifically focused on food safety. We and the Canadians also need
to push back
hard to combat suggestions the report of the two expert groups be
vetted or
transmitted to Sherpas by another, higher-level body in the OECD.

In general, the EU is attempting to impose its burdensome and non-
science-based
biotech regulatory regime internationally through the Biosafety
Protocol,
concurrently pushing to reopen the WTO agreements on agricultural
trade and
phytosanitary standards, and proposing to impose even more
burdensome regulations
domestically. (We are preparing to comment on the recent EU
announcement, for
example, of a 1% EU threshold for "GMO-free" products, which has
no basis in
scientific necessity nor economic feasibility. Our preliminary analysis
shows
such thresholds impose prohibitively high costs on food prices.)

While not breaking ranks from the EU, Germany and the UK are divided on the issue. (German Greens have recently lost some political ground as industry and agricultural interests are consolidating their positions.) EU President Prodi indicated in his October 5 address to Parliament that food safety would be a priority, including the possible creation of an EU-wide regulatory authority (such as the FDA). The Japanese government announced a strong pro-biotech policy, and has funded a considerable number of research and development facilities throughout Japan. Canada is committed to agricultural biotech and fully supports our position.

Biotech - 10-04-99 - Bonn 10-13 G8 Sherpa Jim Steinberg

Drafted: EB/TPP/ATT/ATP - M Bruno (7-2062)

Cleared: EB/TPP/ATT - M Baas (ok)

OES - C Enright (ok)

EUR/ERA - G Burton (ok)

EAP/J - T Vajda (ok)

E - A Pence (ok)

G - D Graham

D - K Doherty (ok)

C - C Munter (ok)

S/P - H Smith (ok)

NEC - R Samans (info)

USDOC - N Bhagat (ok)

USTR - J Payne (ok)

OSTP - C Gabriel (ok)

CEQ - D Sandalow (info)

USDA/FAS - B Slutsky (ok)

USDA/APHIS - S McCammon (info)

USDA/CODEX - E Scarbrough (info)

OVP - D Beier (info)

EPA - P Fuller (info)

USAID - J Lewis (info)

TRANSLATED_ATTACHMENT G8 - Biotech at OECD.doc

ADVANCING THE OECD'S G8 MANDATED WORK ON BIOTECH

* We need to break the logjam in the OECD Council and get the Task Force for the

Safety of Novel Foods and Feeds and the Working Group on Harmonization of Regulatory Oversight of Biotechnology to work on the report that we want for the G8 Summit.

* I think our leadership is needed to allow the OECD to move forward so we have useful results to consider before Okinawa.

* Based on reports I have had on the discussions at the OECD on October 7, I think that there is a way forward that will allow us to get this important work done, and allow the OECD to proceed on other issues.

* We can do this by letting the terms of reference of the Task Force go forward without inclusion of work on the precautionary principle, which is complex and not likely to be resolved by May, and by agreeing to allow the new Ad Hoc Group on Food Safety proposed by the SYG to deal with some of the broader issues.

* The compendium of current and planned international, regional, and national food safety systems and activities would add value and could highlight useful work on the issue in other organizations.

* We should agree together that the analytical elements of the compendium should be accepted at the October 14 OECD Council Meeting.

* We do not think that it is a good idea, however, to suggest that the compendium be the venue for recommendations on further actions for governments. Such determinations are more appropriate for the G8 itself and for national governments. We also want to avoid a competition between the work of the new Ad Hoc Group and the work underway in Codex.

* Given the need for us to help bring down the temperature on biotechnology, and to balance various aspects carefully, we should be clear that the G8 Sherpas should be the only channel for political consideration of the work we asked for.

-- The report of the Task Force and Working Group should be sent to the SYG for direct transmission to G8 Sherpas. Results of the public conference in London might be conveyed to the G8, separately from the report of the two working groups, and/or provided as input, which the Task Force could draw upon in the preparation of its report.

-- The results of the SYG's fall consultation should be made available to the Task Force and Working Group for possible consideration in preparing their report.

* We all have an interest in seeing the biotechnology issue resolved in a balanced and careful manner, by addressing concerns dispassionately and without precipitating further trade tensions. Can we agree on this approach?

* If so, we will need to so instruct our representatives who will be attending the October 14 OECD Council meeting so as to try to avoid another failure there to reach an agreement that would allow the work of the two expert groups we identified to go forward.

NOTE: U.S. Mission to OECD DCM Rich Behrend can be reached by your assistant at the following numbers to pass him a read out of your October 13 discussions before the October 14 Council Meeting in Paris: (o) 33-145-24-7417, H: 33-145-04-7585.

Drafted: EUR-GBurton/E-CAPence

Cleared:

E-ALarson

USDA-SMcCammon (OECD US Del Head)

EB/ATT-Mbaas

OES/ETC-CEnright (Subst)

NEC: RSamans (Subst, full clearance pending)

CEQ: IBowles (pending)

TRANSLATED_ATTACHMENT G8 Biosafety Protocol.doc
Biosafety Protocol

KEY US OBJECTIVES

* To reaffirm our commitment to achieving a workable Protocol, but, in the light of all the key issues left outstanding, to convey our concern regarding expectations for conclusion of the Protocol in January.

* To identify the 'must-haves' in a Protocol acceptable to the EU.

TALKING POINTS

* We feel Vienna was a constructive step toward the culmination of a useful Biosafety Protocol.

* In the face of key issues still left outstanding, we have concerns about reaching satisfactory conclusion of the Protocol in January.

* In the lead up to the January meeting, considerable flexibility will be required from all parties.

* We would like to better understand EU priorities and any areas of flexibility.

* We note that the Protocol is being negotiated largely by environment ministries, but has become an agreement with significant potential trade and agriculture impacts. Do you think it would be worthwhile to engage trade and agricultural ministries in this process?

* Issues are significant, but arriving at an agreement in January would be an enormous challenge .

* Willing to work with the EU to create Biosafety Protocol that protects biodiversity without unnecessarily inhibiting trade.

BACKGROUND

Consultation in Vienna
Representatives from the major participating blocs in the Biosafety Protocol negotiations met in Vienna, September 15-19, to determine whether differences, which resulted in suspension of the negotiations in Cartagena in February 1999, could be narrowed.

Little actual progress was made as only two major issues were discussed in detail^{3/4}

- * how to address trade in bulk agricultural commodities and
- * whether the Protocol should include language to clarify the relationship between it and existing international agreements such as the WTO.

No consensus was reached.

Nonetheless, negotiations will resume in January 2000 with the expectation that

the sessions will be followed immediately by adoption of the Protocol by high level officials.

While the atmosphere in Vienna was more constructive than in Cartagena, all key issues must still be resolved and much of the text must be amended before an acceptable Protocol is concluded. The outcome in January remains uncertain.

Like-Minded Group Proposal for Scope
Toward the end of the consultation in Vienna, the Like-Minded Group of developing countries surprised all others by proposing to broaden the scope of the Protocol to include all LMOs, allowing only for limited exceptions from the Protocol's AIA procedure. The intent of this proposal is unclear, but it appeared to set back the negotiation considerably, as LMO categories thought to be excluded from the Protocol (such as pharmaceuticals) or from the AIA (such as LMOs in transit), would now be fully captured by the Protocol.

The EU appeared very uncomfortable with the new proposal as it thought it had an agreement with the Like-Minded Group for a pharmaceutical exclusion from the Protocol, and it, like the U.S., will not accept an AIA for LMOs in transit. There was no substantive discussion on the Like-Minded proposal in Vienna.

We should determine what status the EU will afford the Like-Minded Group proposal in January.

KEY ISSUES OUTSTANDING

Commodities
Some progress was made in Vienna on how the Protocol should deal with bulk agricultural LMO commodities intended for food, feed or processing (FFP). The Miami Group's proposal to ensure very early notification of domestic LMO approvals in order to provide importing countries sufficient time to make

domestic decisions regarding imports of such LMOs, served as the foundation for a Compromise Group proposal aimed at moving the commodities discussion forward.

We were encouraged by the willingness of the Like-Minded Group to consider an alternative to the AIA for commodities. However, in attempting to address Like-Minded Group requirements for a mechanism for commodities in the Protocol that recognized the rights of countries to make domestic decisions, and that ensure respect of those decisions, the Compromise Group proposal appeared too similar to an AIA. Hence, no consensus on the commodities issue was achieved.

We should determine how the EU suggests moving forward on this issue and how important inclusion of commodities in the AIA is to the current EU position.

We, in turn, can express our intention to consider ways to move the Compromise Group proposal forward in January, but should reiterate that an AIA for commodities remains unacceptable to the Miami Group.

Savings Clause

The Miami Group's position is that a savings clause is needed to define the relationship between the Protocol and other international agreements, especially the WTO.

The EU Cartagena "compromise" proposed to remain silent with respect to the relationship between the Protocol and other international agreements. The proposal also adds language to the preamble which indicates that the Parties shall implement the Protocol in a manner "mutually supportive" of their international obligations.

While the different groups have not moved substantially from their stated positions in Cartagena, there is some indication that groups, or subsets of the

larger groups, may have more flexibility in the future. The Like-Minded Group made no definitive statements but indicated potential flexibility in their position with respect to the savings clause. Mexico, a member of the Compromise Group, has also stated their support for a savings clause. There were also some indication that Brazil's position may turn more favorable.

OTHER ISSUES

In addition to the lack of concrete progress on the commodity and savings clause issues, there was no discussion or progress in Vienna on any of the remaining outstanding key issues including documentation, precautionary approach, socio-economic considerations, illegal traffic, and trade with non-parties. The EU may raise the issues of documentation and precautionary approach.

Documentation

In Vienna, the Miami Group expressed its willingness to work from the framework for documentation proposed by the EU in Cartagena. This framework set out different documentation requirements for the different categories of LMOs such as LMOs subject to the AIA, those LMOs destined for contained use, and LMO commodities intended for food, feed, and processing.

Because there was no substantive discussion of documentation in Vienna, however, Miami Group flexibility on this issue was largely overlooked.

We should revisit documentation with the EC, reiterating our willingness to work from its proposal and identifying, if possible, what the EU must have with regard to documentation for commodities.

Precautionary Approach

The EU Proposal in Cartagena called for the retention of the Chairman's language which stated that the Objective of the Protocol is to be viewed by the Parties as being in accordance with the precautionary approach contained in Rio Principle

15.

Our opposition to this reference has been interpreted as opposition to precaution. The U.S. has developed its environmental regime with caution and due care in the absence of sufficient scientific evidence.

We do not however recognize the existence of a generally accepted principle of customary international law. We do not believe that this so-called principle can be reduced to a single formulation applicable to all environmental contexts.

(FYI: "The Precautionary approach" referred to in Rio Principle 15 provides, where there are threats of serious or irreversible damage, for cost-effective measures to be taken to prevent environmental degradation in the absence of full scientific certainty. This concept has been turned on its head by those in the biosafety debate who argue for the imposition of the most stringent measures, even trade bans, until the last scientific doubt as to the environmental effects of a product has been affirmatively erased.)

Expectations for January
The EU recognizes the task at hand in January but it is determined to finalize the Protocol prior to any substantive dialogue to revise the WTO Agriculture Agreement, which gets underway next month in Seattle.

We should convey our concern, given all the key issues outstanding, regarding expectations for conclusion of the Protocol in January.

We should determine how the EU thinks we should proceed in January, what its expectations for conclusion are, and what it believes are the implications should agreement not be reached.

Drafted: DOS/OES/ETC: PPhifer 736-7113

Cleared: DOS/OES/E: BYeager
DOS/E: APence

DOS/EB/TPP/ATT: MBruno
DOS/EUR:GBurton
DOS/EUR: NNyman
DOS/L: SSafrin
DOS/L: Dvan Hoogstraten
DOS/G: NPurvis
DOS/PCI: LDando
USDA: MSchechtman
USDA: BSlutsky
EPA: LCeleste
EPA: PAlmeida
FDA: EFlamm
USTR: Dshark
USTR: KMason
USAID: JLewis
DOC: EArakaki

H/OES/Biosafety/Biosafety-Paul/Oct99 Hleb

1

6

Exchange Mail

DATE-TIME 10/13/99 12:03:14 PM
FROM Bowles, Ian A. (ENV)
CLASSIFICATION UNCLASSIFIED
SUBJECT RE: Biotech/GMO papers [UNCLASSIFIED]
TO Holtzapple, Richard A.
Bowles, Ian A. (ENV)
Sandalow, David B. (ENV)

CARBON_COPY

TEXT_BODY thanks. ok -- these are the same ones we saw before.

-----Original

Message-----

From: Holtzapple, Richard A.

Sent: Wednesday, October

13, 1999 11:53 AM

To: @ENVIRON - Environmental

Subject: Biotech/GMO

papers [UNCLASSIFIED]

<< File: Biotech - 10-04-99 - G8 Sherpa

Jim Steinberg 10-13.doc >> << File: G8 - Biotech at OECD.doc >>

<< File: G8 Biosafety Protocol.doc >>

The first paper deals

most broadly with all Biotech issues, the second is specific to doings at the OECD (and most likely to be effected by the papers in Ann's fax-which I thought I had a copy of, but cannot find on my pig sty of a desk), and the third paper is related just to the BSP/Cartagena process.

Exchange Mail

DATE-TIME 12/15/1999 1:31:21 PM
FROM Bowles, Ian A. (ENV)
CLASSIFICATION UNCLASSIFIED
SUBJECT gmo labelling [UNCLASSIFIED]
TO Bernard, Kenneth W. (HEALTH)

CARBON_COPY

TEXT_BODY

TRANSLATED_ATTACHMENT

labeling.doc
December 15, 1999

MEMORANDUM FOR JAMES B. STEINBERG

FROM: IAN A. BOWLES

RE: GMO/FOOD SAFETY/ECO LABELING

This memo provides you with background and an update on labeling issues for biotech products from both the domestic and international sides.

Domestic

The fundamental FDA test for any voluntary food labeling is that labeling must be "truthful and not misleading." As applied in cases such as the labeling of bovine growth hormone-free ice cream by Ben & Jerry's, FDA required a disclaimer

on the label that there is not scientific evidence that this product is substantially different from one that does not use the hormone in question and that there is no scientific evidence that the hormone presents health risks.

With regard to food products with biotech inputs, FDA made the fundamental judgment that these products are "not substantially different" from non-GMO products and that mandatory labeling was not required. However, FDA policy does call for mandatory labeling if the product does differ substantially in terms of allergenicity or nutritional content.

The policy process on biotech has led us to the conclusion that USG should become proactively engaged in helping to organize tolerance levels for what might constitute "non-biotech" products. Our motivation for this action relates to market access overseas and the concern of a proliferation of different standards and labeling regimes. This step has not been announced publicly.

We are seeing trends toward segregation of GMO and non-GMO products and the beginning of private labeling efforts. Our regulatory system allows this proceed on a voluntary basis, but we can reasonably expect that FDA may need to intervene in the future to assure that labels are not misleading.

International

These issues play out in a variety of venues. At the WTO, the SPS agreement lists Codex as the international standard setting organization related to food safety. In the Beef/Hormones case, the dispute panel turned to Codex for reference on labeling. Codex uses a science-based risk assessment process and has set the standard that any food that is "compositionally or nutritionally different from its conventional counterpart or presents a health risk such as an allergen" must be labeled.

In the Biosafety Protocol negotiations, our core goal has been to ensure that the Protocol does not become unnecessarily trade restrictive and stays focused on its core environmental objective which is to regulate intentional release of living modified organisms (LMOs) into the environment. The debate has turned on the question of approaches to notifying countries of the shipment of agricultural

biotech products. This debate has not gone per se to the question of labeling at the consumer/food product level.

The Protocol envisions a "advance informed agreement" mechanism to regulate trade/movement of LMOs. We envision this mechanism to cover products such as seeds and fish that are intended for deliberate introduction into the environment. Other countries are seeking broader application of that procedure that would result in essence in a global product approval procedure.

At the WTO, additional questions have been raised about whether and how existing rules accommodate ecolabels. WTO rules broadly accommodate private ecolabeling regimes and our environmental NGOs opposed the idea of creating a "safe harbor" for ecolabels and any elaboration of disciplines on ecolabels. In our policy statement on trade and environment, we outlined the following position:

"Market-based approaches to environmental challenges, such as environmental labeling programs (ecolabels), are important and effective policy tools but should not be misused as hidden forms of trade protectionism.

Consumers have a legitimate interest in the environmental impacts of the products that they buy. Providing accurate information to consumers is an important market-based means of engaging consumers in and achieving health and environmental objectives. We will promote a domestic and international environment that is supportive of such approaches.

We believe and will defend our position that WTO rules provide sufficient flexibility to permit all forms of ecolabeling, including those involving criteria based on processes and production methods and those developed and maintained by private bodies, subject to the relevant disciplines of the multilateral trading system, including transparency and non-discrimination."

With regard to other countries labeling regimes, we have seen some movement by Japan, Australia, New Zealand and Korea to follow the EU toward mandatory labeling of GMO foods; however Australia and New Zealand are showing signs of backing away in the wake of a private sector study that highlighted the 6% marginal cost to food products of mandatory labeling.

Summary

Our essential posture is that labeling in other countries should be combined with assurance that procedures behind a labeling requirement be transparent, timely, and non-discriminatory. At a strategic level, we are trying to promote these goals, but you are aware of the complexities and complications related to trying to keep the different related issues in the boxes where they belong.

Please let me know if you have additional questions.

3

3

Exchange Mail

DATE-TIME 12/15/1999 1:44:28 PM
FROM Bernard, Kenneth W. (HEALTH)
CLASSIFICATION UNCLASSIFIED
SUBJECT RE: gmo labelling [UNCLASSIFIED]
TO Bowles, Ian A. (ENV)

CARBON_COPY

TEXT_BODY The 2 paras on "tolerance" and "voluntary labeling" were somewhat opaque to me - perhaps Jim will already know the issues well. If not, it may be worth adding a sentence or two as to our positions. I thought there was evolving consensus (excluding HHS) that voluntary labeling of food for "no GMOs" would be encouraged, or at least not discouraged. What ever happened to the Presidential decision on that? --Ken
-----Original Message-----
From: Bowles, Ian A. (ENV)

Sent: Wednesday, December 15, 1999 1:31 PM
To: Bernard, Kenneth
W. (HEALTH)
Subject: gmo labelling [UNCLASSIFIED]

<< File:
labeling.doc >>