To: Parrott, Patricia[parrott.patricia@epa.gov]
Cc: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Vogel, Dana
Sent: Fri 1/29/2016 3:50:04 PM
Subject: Fwd: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
EPA commnets BRA TBT 648 pesticides 12-8-15 d_JD.doc
ATT00001.htm

Dana Vogel
Sent from my iPhone

Begin forwarded message:

From: "Dawson, Jeffrey" <Dawson.Jeff@epa.gov>
Date: January 28, 2016 at 3:38:12 PM EST
To: "Vogel, Dana" <Vogel.Dana@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Thanks

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Vogel, Dana

Sent: Thursday, January 28, 2016 3:27 PM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

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Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

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From: Vogel, Dana
Sent: Thursday, January 28, 2016 3:23 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Middleton, Karlyn <Middleton.Karlyn@epa.gov>; Mendez, Elizabeth <Mendez.Elizabeth@epa.gov>
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

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On Jan 28, 2016, at 2:19 PM, Lowit, Anna <Lowit.Anna@epa.gov> wrote:

Ex. 5 - Deliberative Process

Anna B. Lowit, Ph.D.

Senior Scientist

Health Effects Division

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Vogel, Dana
Sent: Wednesday, January 27, 2016 11:27 AM
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Ex. 5 - Deliberative Process

Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

parrott.patricia@epa.gov

From: Sanchez, Becxi - FAS [mailto:Becxi.Sanchez@fas.usda.gov]
Sent: Wednesday, January 27, 2016 10:48 AM
To: Avila, Marielsie - FAS <Marielsie.Avila@fas.usda.gov>; Parrott, Patricia <parrott.patricia@epa.gov>; Taveau, Daniella <Taveau.Daniella@epa.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
Importance: High

Ex. 5 - Deliberative Process

Cheers,

Becxi

From: Avila, Marielsie - FAS
Sent: Wednesday, January 27, 2016 8:27 AM
To: Parrott, Patricia; Taveau, Daniella; Sanchez, Becxi - FAS
Cc: Keigwin, Richard; Wise, Louise
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Patricia,

Ex. 5 - Deliberative Process

Thanks,

Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

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Sent: Wednesday, January 27, 2016 8:24 AM
To: Avila, Marielsie - FAS; Taveau, Daniella; Sanchez, Becxi - FAS
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Washington, DC 20460

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Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

+Becxi Sanchez

Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

From: Taveau, Daniella [mailto:Taveau.Daniella@epa.gov]
Sent: Tuesday, January 26, 2016 5:11 PM
To: Parrott, Patricia
Cc: Keigwin, Richard; Avila, Marielsie - FAS; Wise, Louise

Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Daniella

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Patty,

Ex. 5 - Deliberative Process

Daniella

On Jan 26, 2016, at 1:40 PM, Parrott, Patricia <parrott.patricia@epa.gov> wrote:

Ex. 5 - Deliberative Process

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Begin forwarded message:

From: "Jordan, William" <Jordan.William@epa.gov>
Date: November 9, 2015 at 3:36:35 PM EST
To: "Parrott, Patricia" <parrott.patricia@epa.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Bill

William Jordan

Deputy Director, Programs

Office of Pesticide Programs

U. S. Environmental Protection Agency

Phone: 703-305-1049

Fax: 703-308-4776

Mailing Address:

USEPA Headquarters
Clinton Building
1200 Pennsylvania Ave., NW
Mail Code (7501P)
Washington, DC 20460

Courier Address:

Potomac Yards South
2777 Crystal Drive
Room 12-235
Arlington, VA

From: Taveau, Daniella
Sent: Monday, November 09, 2015 2:53 PM
To: Jordan, William <Jordan.William@epa.gov>
Cc: Wise, Louise <Wise.Louise@epa.gov>; Lewis, Susan <Lewis.Susan@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Herndon, George <Herndon.George@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Helfgott, Daniel <Helfgott.Daniel@epa.gov>
Subject: Fwd: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Bill,

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Daniella

Begin forwarded message:

From: "Ray McAllister" <RMcAllister@croplifeamerica.org>
To: "Taveau, Daniella" <Taveau.Daniella@epa.gov>
Cc: "Janet Collins" <jcollins@croplifeamerica.org>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

I've also attached the translation of the Brazilian proposed regulation that we have been working from. I still haven't figured out who did the translation (industry or Brazilian government). I need to do a bit more ch3ecking before sharing the CropLife draft comments to Brazil with you.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Friday, October 30, 2015 11:35 AM
To: 'Lance, Jennifer - FAS' <Jennifer.Lance@fas.usda.gov>; Rasmussen, Mark - FAS <Mark.Rasmussen@fas.usda.gov>;

Allen, Maurice - FAS
<Maurice.Allen@fas.usda.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Jennifer:

This is the notification that was received by our European colleagues.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Benjamin.MUSALL@ec.europa.eu [mailto:Benjamin.MUSALL@ec.europa.eu]
Sent: 20 October 2015 15:45
To: Euros Jones; Joan Scott
Cc: Martin.PILSER@ec.europa.eu
Subject: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Dear Euros and Joan,

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This Resolution establishes the requirements and criteria to toxicological evaluation and classification, risk evaluation, the toxicological information in labels and leaflets, besides the procedures of pesticides' post-register alteration, its components and wood preservers in ANVISA's regulation.

Have you been alerted by some of your members about this? In any case, don't hesitate to share your concerns with us, if any.

Kind regards,

Benjamin

Benjamin MUSALL
Policy Co-ordinator

European Commission
DG TRADE
Unit G.3 - Market Access, Industry, Energy and Raw Materials

CHAR 05/23
B-1049 Brussels/Belgium
+32 2 295 60 12
benjamin.musall@ec.europa.eu

More on EU trade policy

Follow the EU's Trade Policy Team on Twitter

More on the TTIP

Follow the EU's TTIP Negotiating Team on Twitter

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<BRA648_EN.doc>

<CP_87_-_2015_English_Version - Oct 13.doc>

<Comments on Brazil Anvisa tox requirements_draft_compiled.docx>

To: Parrott, Patricia[parrott.patricia@epa.gov]
Cc: Lowit, Anna[Lowit.Anna@epa.gov]; Dawson, Jeffrey[Dawson.Jeff@epa.gov]
From: Vogel, Dana
Sent: Fri 1/29/2016 2:51:04 PM
Subject: Fwd: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
Comments on Brazil Anvisa tox requirements_draft_compiled.docx
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Ex. 5 - Deliberative Process

Dana

Dana Vogel
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From: "Lowit, Anna" <Lowit.Anna@epa.gov>
Date: January 28, 2016 at 2:19:24 PM EST
To: "Vogel, Dana" <Vogel.Dana@epa.gov>
Cc: "Dawson, Jeffrey" <Dawson.Jeff@epa.gov>, "Middleton, Karlyn" <Middleton.Karlyn@epa.gov>, "Mendez, Elizabeth" <Mendez.Elizabeth@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Anna B. Lowit, Ph.D.

Senior Scientist

Health Effects Division

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

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Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

parrott.patricia@epa.gov

From: Sanchez, Becxi - FAS [mailto:Becxi.Sanchez@fas.usda.gov]
Sent: Wednesday, January 27, 2016 10:48 AM
To: Avila, Marielsie - FAS <Marielsie.Avila@fas.usda.gov>; Parrott, Patricia <parrott.patricia@epa.gov>; Taveau, Daniella <Taveau.Daniella@epa.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
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Ex. 5 - Deliberative Process

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Cheers,

Becxi

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To: Parrott, Patricia; Taveau, Daniella; Sanchez, Becxi - FAS
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Ex. 5 - Deliberative Process

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Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

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+Becxi Sanchez

Marielsie Avila

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Ex. 5 - Deliberative Process

Bill

William Jordan

Deputy Director, Programs

Office of Pesticide Programs

U. S. Environmental Protection Agency

Phone: 703-305-1049

Fax: 703-308-4776

Mailing Address:

USEPA Headquarters

Clinton Building

1200 Pennsylvania Ave., NW

Mail Code (7501P)

Washington, DC 20460

Courier Address:

Potomac Yards South

2777 Crystal Drive

Room 12-235

Arlington, VA

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Bill,

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Daniella

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From: "Ray McAllister" <RMcAllister@croplifeamerica.org>
To: "Taveau, Daniella" <Taveau.Daniella@epa.gov>
Cc: "Janet Collins" <jcollins@croplifeamerica.org>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

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CropLife America

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202-577-6657 (cell)

ray@croplife.us

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To: 'Lance, Jennifer - FAS' <Jennifer.Lance@fas.usda.gov>; Rasmussen, Mark - FAS <Mark.Rasmussen@fas.usda.gov>; Allen, Maurice - FAS <Maurice.Allen@fas.usda.gov>
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Kind regards,

Benjamin

Benjamin MUSALL
Policy Co-ordinator

European Commission
DG TRADE
Unit G.3 - Market Access, Industry, Energy and Raw Materials

CHAR 05/23
B-1049 Brussels/Belgium
+32 2 295 60 12
benjamin.musall@ec.europa.eu

More on EU trade policy

Follow the EU's Trade Policy Team on Twitter

More on the TTIP

Follow the EU's TTIP Negotiating Team on Twitter

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http://www.symanteccloud.com

<BRA648_EN.doc>

<CP_87_-_2015_English_Version - Oct 13.doc>

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Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

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Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Middleton, Karlyn <Middleton.Karlyn@epa.gov>; Mendez, Elizabeth <Mendez.Elizabeth@epa.gov>
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Health Effects Division

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Sent: Wednesday, January 27, 2016 10:48 AM
To: Avila, Marielsie - FAS <Marielsie.Avila@fas.usda.gov>; Parrott, Patricia <parrott.patricia@epa.gov>; Taveau, Daniella <Taveau.Daniella@epa.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
Importance: High

Ex. 5 - Deliberative Process

Cheers,

Becxi

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Sent: Wednesday, January 27, 2016 8:27 AM
To: Parrott, Patricia; Taveau, Daniella; Sanchez, Becxi - FAS
Cc: Keigwin, Richard; Wise, Louise
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Patricia,

Ex. 5 - Deliberative Process

Thanks,

Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

From: Parrott, Patricia [mailto:parrott.patricia@epa.gov]
Sent: Wednesday, January 27, 2016 8:24 AM
To: Avila, Marielsie - FAS; Taveau, Daniella; Sanchez, Becxi - FAS
Cc: Keigwin, Richard; Wise, Louise
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

parrott.patricia@epa.gov

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+Becxi Sanchez

Marielsie Avila

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Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

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Daniella

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Patty,

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Daniella

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From: "Jordan, William" <Jordan.William@epa.gov>
Date: November 9, 2015 at 3:36:35 PM EST
To: "Parrott, Patricia" <parrott.patricia@epa.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Bill

William Jordan

Deputy Director, Programs

Office of Pesticide Programs

U. S. Environmental Protection Agency

Phone: 703-305-1049

Fax: 703-308-4776

Mailing Address:

USEPA Headquarters
Clinton Building
1200 Pennsylvania Ave., NW
Mail Code (7501P)
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Courier Address:

Potomac Yards South
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From: "Ray McAllister" <RMcAllister@croplifeamerica.org>
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Cc: "Janet Collins" <jcollins@croplifeamerica.org>
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Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

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To: 'Lance, Jennifer - FAS' <Jennifer.Lance@fas.usda.gov>; Rasmussen, Mark - FAS <Mark.Rasmussen@fas.usda.gov>; Allen, Maurice - FAS <Maurice.Allen@fas.usda.gov>
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Sent: 20 October 2015 15:45
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Cc: Martin.PILSER@ec.europa.eu
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Kind regards,

Benjamin

Benjamin MUSALL
Policy Co-ordinator

European Commission
DG TRADE
Unit G.3 - Market Access, Industry, Energy and Raw Materials

CHAR 05/23
B-1049 Brussels/Belgium
+32 2 295 60 12

benjamin.musall@ec.europa.eu

More on EU trade policy

Follow the EU's Trade Policy Team on Twitter

More on the TTIP

Follow the EU's TTIP Negotiating Team on Twitter

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For more information please visit http://www.symanteccloud.com

<BRA648_EN.doc>

<CP_87_-_2015_English_Version - Oct 13.doc>

<Comments on Brazil Anvisa tox requirements_draft_compiled.docx>

To: Vogel, Dana[Vogel.Dana@epa.gov]
Cc: Dawson, Jeffrey[Dawson.Jeff@epa.gov]; Middleton, Karlyn[Middleton.Karlyn@epa.gov]; Mendez, Elizabeth[Mendez.Elizabeth@epa.gov]
From: Lowit, Anna
Sent: Thur 1/28/2016 7:19:24 PM
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
Comments on Brazil Anvisa tox requirements_draft_compiled.docx

Ex. 5 - Deliberative Process

Anna B. Lowit, Ph.D.

Senior Scientist

Health Effects Division

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Vogel, Dana
Sent: Wednesday, January 27, 2016 11:27 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Subject: Fwd: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

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Dana Vogel

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Ex. 5 - Deliberative Process

Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

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Importance: High

Thank you, Marielsie, Patricia et al,

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+Becxi Sanchez

Marielsie Avila

International Trade Specialist

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To: "Parrott, Patricia" <parrott.patricia@epa.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Bill

William Jordan

Deputy Director, Programs

Office of Pesticide Programs

U. S. Environmental Protection Agency

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Fax: 703-308-4776

Mailing Address:

USEPA Headquarters

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Courier Address:

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Arlington, VA

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Bill,

Ex. 5 - Deliberative Process

Daniella

Begin forwarded message:

From: "Ray McAllister" <RMcAllister@croplifeamerica.org>
To: "Taveau, Daniella" <Taveau.Daniella@epa.gov>
Cc: "Janet Collins" <jcollins@croplifeamerica.org>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

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Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

Ex. 6 - Personal Privacy

ray@croplife.us

From: Ray McAllister
Sent: Friday, October 30, 2015 11:35 AM
To: 'Lance, Jennifer - FAS' <Jennifer.Lance@fas.usda.gov>; Rasmussen, Mark - FAS <Mark.Rasmussen@fas.usda.gov>; Allen, Maurice - FAS <Maurice.Allen@fas.usda.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Jennifer:

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Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

Ex. 6 - Personal Privacy

ray@croplife.us

From: Benjamin.MUSALL@ec.europa.eu [mailto:Benjamin.MUSALL@ec.europa.eu]
Sent: 20 October 2015 15:45
To: Euros Jones; Joan Scott
Cc: Martin.PILSER@ec.europa.eu

Subject: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

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Kind regards,

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Benjamin MUSALL
Policy Co-ordinator

European Commission
DG TRADE
Unit G.3 - Market Access, Industry, Energy and Raw Materials

CHAR 05/23
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benjamin.musall@ec.europa.eu

More on EU trade policy

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More on the TTIP

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---

<BRA648_EN.doc>

<CP_87_-_2015_English_Version - Oct 13.doc>

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Cc: Dawson, Jeffrey[Dawson.Jeff@epa.gov]
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BRA TBT 648 pesticides 12-8-15 d.doc
ATT00001.htm
Brazil CP_87_-_2015_English_Version - Oct 13.doc
ATT00002.htm

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Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

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William Jordan

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Sent: 20 October 2015 15:45
To: Euros Jones; Joan Scott
Cc: Martin.PILSER@ec.europa.eu
Subject: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Dear Euros and Joan,

We have just received a new WTO TBT notification from Brazil (see enclosed). According to the short content description, this concerns the following:

Draft Technical Resolution nº 87, 2 October 2015, regarding the pesticides' toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration.

This Resolution establishes the requirements and criteria to toxicological evaluation and classification, risk evaluation, the toxicological information in labels and leaflets, besides the procedures of pesticides' post-register alteration, its components and wood preservers in ANVISA's regulation.

Have you been alerted by some of your members about this? In any case, don't hesitate to share your concerns with us, if any.

Kind regards,

Benjamin

Benjamin MUSALL
Policy Co-ordinator

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Brazilian Health Surveillance Agency

www.anvisa.gov.br

Public Consultation No. 87, October 2nd, 2015

Federal Official Gazette of Brazil from 10/5/15

The Brazilian Health Surveillance Agency's Executive Board according to the attributions of clauses III and IV of article 15 of Law number 9,782 from January 26th, 1999, and according to clause III and paragraphs 1, 3, and 4 of article 58 of Internal Rule approved according to Annex I of the Executive Board Resolution (*RDC*) number 29 of Anvisa from July 21st, 2015, published in DOU of July 23rd, 2015, and according to clause III of article 2, III and IV of article 7 of Law number 9,782 from 1999, article 35 of Decree number 3,029 from April 16th, 1999, the Agency's Regulation Process Improvement Program, established by Regulation number 422 from April 16th, 2008, decides to subject the attached regulatory act proposal to public consultation for comments and suggestions from the general public according to the meeting from September 17th, 2015, and adopts the following Public Consultation and I Managing Director determine its publishing:

Art. 1. It is determined the period of sixty (60) days from the publishing of this Public Consultation for presentation of any reviews and suggestions in relation to the attached Resolution proposal that describes the criteria and requirements for agrochemical, compounds, and related items toxicological evaluation.

Sole Paragraph. The period related to this article will start seven (7) days after the publishing date of the Public Consultation in the Federal Official Gazette of Brazil.

Art. 2. The regulatory act proposal will be available in its entirety at the Anvisa Web portal and suggestions should be sent by completing the specific form available at: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=22736.

Paragraph 1 The received contributions will be considered public and will be available to the interested parties by means of tools included in menu "results" of the electronic form also during the consultation process.

Paragraph 2 After completing the electronic form the registration protocol number will be available to the interested party. The postal issuing nor the hard copy of the presence protocol are required.

Paragraph 3 In case of limited access to electronic resources by the citizen suggestions might be sent and received in written form during the consultation period to the following address: Agência Nacional de Vigilância Sanitária/Gerência-Geral de Toxicologia - GGTOX, SIA trecho 5, Área Especial 57, Brasília/DF, CEP 71.205-050.

Paragraph 4 International contributions can be sent exceptionally in hard copy to the following address: Agência Nacional de Vigilância Sanitária/Assessoria de Assuntos Internacionais (AINTE), SIA trecho 5, Área Especial 57, Brasília/DF, CEP 71.205-050.

Art. 3. When the period of article 1 is finished the Brazilian Health Surveillance Agency will analyze the contributions and will publish the public consultation result in the Agency portal.

Sole Paragraph. The Agency may meet with the involved bodies and entities and with the parties interested on the matter in order to make future technical discussions and make the final deliberation of the Executive Board as need and convenience reasons, and opportunities.

JARBAS BARBOSA DA SILVA JR.

ANNEX

PUBLIC CONSULTATION PROPOSAL

Process number: 25351.541952/2009-58

Subject: Criteria and requirements for agrochemical, compounds, and related items toxicological evaluation

Regulatory Agenda 2015-2016: Sub-theme number 65.1

Mercosul theme: No

Proceedings: Common

Area in charge: Toxicology General Management

Reporter: Ivo Bucaresky

***RDC* proposal draft**

***RDC* RESOLUTION NUMBER ____, FROM _____, 201__**

Describes the criteria and requirements for toxicological evaluation and classification, establishes the rules for creation, harmonization, and updating of agrochemicals and related items labels and package inserts, and the agrochemicals, components, and related items post-registration changing procedure and wood conservatives within Anvisa scope.

Chapter I

General Provisions

Art. 1. This Resolution establishes the criteria and requirements for toxicological evaluation and classification, risk evaluation, the content of toxicological information in labels and package inserts, and the agrochemicals, their components, and related items post-registration changing procedure and wood preservatives within Anvisa scope.

Art. 2. Without deviating from Law number 7,802 from July 11th 1989 and from Decree number 4,074 from January 4th, 2002 this Resolution's content is applied.

Art. 3. For this Resolution results the following definitions are applied:

I. Risk evaluation - Systematic analysis of the probability of adverse effects onset resulting from the human exposure to agrochemicals or related items, the process of which includes danger identification, dose-response evaluation, exposure evaluation, and the risk characterization;

II. Toxicological evaluation - It comprises the analysis of agrochemical, its components, and related items toxicological data with the aim of classifying them in toxicological categories and at the same time to provide information related to the correct form of use as well as the prevention and treatment measures in case of severe situations resulting from the exposure to agrochemicals;

III. Laboratory Best Practices (BPL) - Quality system that includes the organizational process and the conditions by which the non-clinical health studies of environmental safety are planned, developed, monitored, registered, filed, and reported;

IV. Package insert - Product-related printed information in a separate way with detailed information on the use of the product and other information required by the country;

V. Exposure situation - Theoretical situation assumed for a potential exposure to an agrochemical that is determined by the application type (manual, tractorized , air etc.) and by the subject labor activity (mixer, supplier, applier etc.) which may also be combined (mixer-supplier, mixer-supplier-applier etc.);

VI. Food mean daily consumption *per capita* (C) - Food mean amount ingested daily by one person in a given population;

VII. Correlated plant origin product - Other biological origin products which formulation has biological material extracts or inactive biological material residues as well as animal or mineral origin homeopathic products provided they do not contain genetically modified biological material.

VIII. Raw data - All the original registrations and documents or faithful copies thereof resulting from the original notes and activities of a study, including images, microfilm, or microfiche copies, computer magnetic medium, tapes with recording of dictated notes, automated equipment data registration or any other data stored in a medium that is recognized as being capable of providing a safe storage way of the information during a stated period;

IX. Study plan deviation - Non-planned change of the study plan after the study start date;

X. Plant derivative - Plant drug derived product obtained through improvement technological processes; plant origin fixed oils, water, and/or ethanol may be used as solvents;

XI. Study director - Person in charge of the general execution of the study according to the BPL principles;

XII. Food mean daily availability *per capita* - Food mean daily amount *per capita* acquired by the family without considering food waste and food consumed outside the home;

XIII. Plant drug - Plant or its portions that contain substances or classes of substances responsible for the biological activity after the collecting, stabilization (when applicable), and drying processes; the form may be total, amended, grinded, or pulverized;

XIV. Endpoint - Result or event monitored by a toxicological study;

XV. Qualitative and quantitative composition specification - Statement document from each manufacturer containing the maximum limits for significant and/or relevant impurities and the minimum limit for active component (i.a.) in a technical product;

XVI. Specimen - Any material derived from the test system for exam, analysis, or retention;

XVII. Daily skin exposure (EDC) - Theoretical maximum amount of agrochemical product after the subject exposure through skin route during a working day in a labor exposure specific situation;

XVIII. Daily inhalatory exposure (EDI) - Theoretical maximum amount of agrochemical product after the subject exposure through inhalatory route during a working day in a labor exposure specific situation;

XIX. Phytocomplex - Group of substances of plant primary and/or secondary metabolism origin responsible for the biological effects of a plant drug or its derivatives;

XX. Evidences level - Reliability level on the result of a given well-conducted study based on its statistical and/or biological significance level;

XXI. Test facilities management - Person(s) who is(are) authorized and responsible for the organization and functionality of the operational unit according to the BPL principles;

IXXII. Relevant impurities - Impurities that have additional toxic properties in relation to the active component present in the agrochemical products, its components, and related items at any levels;

IXXIII. Significant impurities - Impurities in amounts greater or equal to 1 g/kg of the technical product originating from the synthesis or degradation process, from cross-contamination within the production cycle process, or from raw materials used in production;

XXIV. Theoretical maximum daily ingestion (IDMT) - Theoretical maximum amount of agrochemical residues in food that is ingested daily by a subject considering the maximum limit values of residues (LMR) and the data of food consumption or availability and body weight in a given population;

XXV. Estimated acute maximum ingestion (IMEA) - Estimative of agrochemical product maximum residues amount considering the greater portion of food consumed in a given population and values related to the largest residue concentrations obtained in field studies;

XXVI. Test facilities - Group of persons, locations, facilities, and equipment required to conduct the non-clinical health study and the environmental safety study;

XXVII. Plant origin raw material - Plant drug or plant derivative used in the final formulation of plant origin products;

XXVIII. Phytochemical marker - Substance or chemical substance class originating from the plant metabolism that preferably has correlation with the plant drug and/or plant derivative action form and that is used as a reference in the plant raw material and final formulation quality control as well as for controlling the production process;

XXIX. Reference monograph for the plant derivative - Agrochemical products and related items monograph created by the toxicological evaluation of the first plant derivative or drug used in the agrochemicals formulation.

XXX. No observed adverse effect level (- NOAEL) - The higher tested dose of a test-substance in relation to which adverse effects are not observed in test animals, expressed in milligrams by kilogram of body weight each day;

XXXI. Lowest observed adverse effect level (- LOAEL) - The lowest tested dose of a test-substance in relation to which adverse effects are observed in test animals, expressed in milligrams by kilogram of body weight each day;

XXXII. Analog patterns - Analytical patterns of a substance that is structurally similar to another substance to be quantified.

XXXIII. Sponsor - Institution or person who prepares or sponsors a study or submits the study to the regulatory authority;

XXXIV. Evidence strength - General term that refers to the toxicological data interpretation in the context of all available information on agrochemicals, their components, and related items;

XXXV. Pictogram - Graphic symbol used to communicate specific information on the health risks of an agrochemical or related item and the adequate measures for intoxication prevention or risk minimization and must be represented with the black symbol over a white background and delimited by a lozenge with red edges;

XXXVI. Study plan - Document defining the study objective and the experimental detailing for the study conduction and that may include any amendments;

XXXVII. Active component - Substance or chemical substances class (ex.: alkaloids, flavonoids, fatty acids etc.) present in the chemically characterized plant raw material which action is known and totally or partially responsible for the biological effects of a plant or its derivatives;

XXXVIII. Biological origin products - Formulated product which active component is a microorganism, control biological agent, semiochemical, or plant origin product and its correlated products provided they do not contain genetically modified biological material;

XXXIX. Plant origin products - Formulated product which active component contains one or more plant drugs or plant derivatives provided they do not contain genetically modified biological material;

XL. "Plant drug:plant derivative" ratio - Expression that defines the ratio between a plant drug amount and the respective amount of the obtained plant derivative, which value is given as a first number (integer number or fraction number) corresponding to the used amount of drug followed by a colon (:) and the number corresponding to the obtained amount of plant derivative.

XLI. Label - Identification applied directly on the primary or secondary packages or general packages that cannot be removed nor changed during the use of the product and during its transportation or storage;

XLII. Reference substance - Any substance used to provide a comparison basis to the test-substance; and

XLIII. Test-substance - Object under investigation in a study.

Chapter II

Studies and Information to Be Presented for Toxicological Evaluation of Agrochemicals, Its Components, and Related Items.

Art. 4. All the documentation required for toxicological evaluation for purposes of agrochemical, its components, and related items registration should also be sent with a copy in electronic medium and indexed with marks that allow for navigation functions and copy of the text.

Art. 5. The information related to the tests results or to the non-published data presented to the relevant authorities as a condition for registration approval according to Article 5 of Law number 10,603 from December 17th, 2002 can only be used by the relevant authority in order to instruct or explain the third party registration granting upon previous authorization of the registration owner. The information must include at least:

a) The information or other data in relation to which the authorization is granted;

b) Whether the authorization purpose is limited only to the use of the information or other data to explain the evaluation for registration purposes or whether the information may be transferred to explain the third party process;

Art. 6. A statement on the use of the active component also as a veterinary medication should be sent as part of the documentation forwarded for registration or post-registration purposes.

Sole Paragraph. The maximum limit of residues (LMR) related to the veterinary medications should be communicated when they are defined by the relevant authority.

Art. 7. For the agrochemicals, their components, and related items toxicological evaluation, the documents of technical products should be presented, described in Annex I; for formulated products, they are described in Annex II.

Art 8. For the toxicological evaluation of a technical product by equivalence the studies and data of Annex III are required for Phases II and III without deviating from paragraph 7, Art. 10 and items 16.7 and 16.8 of Annex II of Decree number 4,074/2002 and according to items 3.2 and 3.3 of Annex X of Decree number 4,074/2002.

Sole Paragraph. In relation to the skin corrosion/irritation and eye corrosion/irritation studies, a technical product toxicological profile will be considered equivalent to the reference product profile when it is not included in a category of higher risk according to the criteria of Annex IV without deviating from item 4.1, Annex X of Decree number 4,074/2002 and according to the equivalence criteria of the Food and Agriculture Organization (FAO) of the United Nations.

Art. 9. The assays on vertebrates should be conducted when there are no validated and internationally recognized alternative methods as substitution to the animal experiment for regulation purposes.

Sole Paragraph. A validated and internationally recognized alternative method as partial substitution to the animal experiment for regulation purposes should follow a phased test

strategy that aims at the evidence strength also considering the operational procedure refining, animal reduced number, and assay method substitution principles.

Art. 10. For evaluation of technical products with new active components the physical-chemical properties studies should be conducted with the product in its higher degree of impurities.

Art. 11. For a technical product with which the qualitative and quantitative analysis study was conducted using batches made in pilot scale a new study with five batches should be conducted immediately after the start of the industrial scale production.

Sole Paragraph. The study report should be provided to Anvisa as an addition within at least 30 days after its conclusion for evaluation and finishing of the dossier.

Art. 12. The toxicological studies should be conducted with batches of the test-substance that provide the likely qualitative and quantitative profile of the product produced in industrial scale.

Sole Paragraph. When it is determined that the qualitative and quantitative profile of the product produced in industrial scale is not equivalent to the profile of the batches used in the toxicological studies new studies should be conducted in order to demonstrate the commercial product toxicological equivalence in relation to the one initially tested according to the same criteria described for registration by equivalence.

Art. 13. The toxicological evaluation of premixtures, agrochemicals, and related items produced from a technical product should be preceded by the toxicological evaluation of its respective technical product.

Art. 14. The premixtures that are commercialized or transported between the factory units should be toxicologically evaluated for registration purposes.

Paragraph 1 For premixtures not included in the *caput* of this article a quality control process should be conducted previously to its use in the formulation containing at least the active component content.

Paragraph 2 For premixtures that are not included in the *caput* of this article and that are stored in containers located outside of the production line a stability study should be conducted demonstrating the integrity of the premixtures within the conditions and within the maximum period of storage containing at least the active component content and the toxicologically relevant impurities content.

Paragraph 3 The quality control and the stability studies registrations mentioned in the previous paragraphs of this article should be available to the fiscal authorities during the expiration period defined for the premixture.

Art. 15. The processes for premixtures evaluation should have the same requirements for formulated product according to Annex II of this Resolution without deviating from Decree number 4,074/2002.

Sole Paragraph. In case of premixtures obtained from chemical or biological processes the description of the production process should be provided by the manufacturer considering its synthesis, subproducts, and impurities steps.

Art. 16. For formulated products the detailed description of the production process should be presented including the use of a flowchart with all the preparation steps of intermediary mixtures and general description of the conditions that are controlled during the process.

Art. 17. All the studies should be conducted according to the effective protocols published by the Organization for Economic Co-operation and Development (OECD) or other internationally accepted organizations.

Paragraph 1 If the protocols mentioned in the *caput* are not available the procedures used for conducting the study should be described and its use should be rationalized.

Paragraph 2 The tests for toxicological evaluation of biological origin products may be replaced by copy of published scientific studies, information, tests, and toxicological studies conducted by public or private educational institutions, technical assistance, and research at the discretion of Anvisa.

Paragraph 3 Tests developed for toxicological evaluation of biological origin products should follow local methodologies and/or internationally recognized methodologies at the discretion of Anvisa.

Art. 18. All the studies should be conducted according to the Laboratory Best Practices (BPL) of OECD adopted by the Brazilian Institute of Metrology (Inmetro).

Art. 19. The study reports on physical-chemical and toxicological properties should be originated from recognized test facilities and monitored according to the BPL principles by Inmetro.

Paragraph 1 For the mutual acceptance of laboratory data the toxicological and physical-chemical properties studies reports from countries that do not completely follow the OECD regulations should contain the Certificate of Knowledge of the Laboratory Best Practices Compliance issued by Inmetro or by authorities that monitor the BPL principles in relation to another country that is member of OCDE.

Paragraph 2 The studies may be rejected by Anvisa if the monitoring authority for compliance with the BPL principles reports any situation of termination, cancelling, warning, or other situations that compromise the integrity of the studies forwarded to the sanitary authorities.

Art. 20. By signing the study final report the study director acknowledges the compliance with the BPL principles and assumes the technical and scientific responsibilities in relation to the study conduction and to the accurate representation of the raw data in the final report.

Art. 21. The study plan should be approved and signed by the test facilities management and by the study sponsor; both of them are responsible for the study.

Paragraph 1 The study plans should be presented to Anvisa when there are changes in relation to the internationally accepted protocols.

Paragraph 2 The study plan deviations should be reported attached to the study final report and followed by discussion on the impacts on the results.

Art. 22. The following documents should be stored and retained in safety and proper conditions during the registration validity and for at least five (5) years after the product registration cancelling in Brazil:

I. Study plans, raw data, and final report of each study;

II. Registration of the inspections conducted by the Quality Control program as well as the master agendas;

III. Registrations of qualification, training, experiences, and descriptions of the staff functions;

IV. Equipment maintenance and calibration registrations and reports;

V. Validation documents for computerized systems;

VI. Standard Operating Procedures (POP) used in the study; and

VII. Environmental monitoring registrations.

Sole Paragraph. Samples of test-substance, reference substance, and specimens used in the study should be stored under proper conditions and in amounts enough for conducting new studies and while their integrity allows for evaluation according to the items validity.

Chapter III

Toxicological Evaluation

Art. 23. According to this Resolution the agrochemicals, their components, and related items are considered mutagenic when it is known they cause mutations in germinative cells of human beings or when there are enough evidences in *in vitro* and *in vivo* studies suggesting that such products cause mutations in germinative cells of human beings.

Sole Paragraph. The agrochemicals, their components, and mutagenic items in somatic cells will be considered mutagenic in germinative cells unless additional studies show they do not induce mutagenicity in germinative cells of mammals.

Art. 24. The agrochemicals, their components, and related-items are classified in relation to the mutagenicity according to the criteria defined in item 5 of Annex IV.

Paragraph 1. The agrochemicals, their components, and related-items classified in Categories 1A or 1B are considered mutagenic to human beings and therefore are not considerable for registration according to Art. 31 of Decree number 4,074/2002.

Paragraph 2. The agrochemicals, their components, and related-items classified in Category 2 are not considered mutagenic to human beings but can be classified again in case of new relevant information.

Paragraph 3. The agrochemicals, their components, and related-items not included in categories 1A, 1B, or 2 are not classified in relation to the mutagenicity.

Art. 25. According to this Resolution the agrochemicals, their components, and related items are considered carcinogenic when it is known they can induce or increase the cancer incidence in human beings or when there are evidences that they induce or increase the cancer incidence in animals in experimental studies suggesting that such products have carcinogenic potential in human beings unless there are strong evidences that the action form or mechanism of tumor formation in animals is not relevant to human beings.

Art. 26. The agrochemicals, their components, and related-items are classified in relation to the carcinogenicity according to the criteria defined in item 6 of Annex IV.

Paragraph 1 The agrochemicals, their components, and related-items classified in Categories 1A or 1B are considered carcinogenic to human beings and therefore are not considerable for registration according to Art. 31 of Decree number 4,074/2002.

Paragraph 2 The agrochemicals, their components, and related-items classified in Category 2 are not considered carcinogenic to human beings but can be classified again in case of new relevant information.

Paragraph 3. The agrochemicals, their components, and related-items not included in categories 1A, 1B, or 2 are not classified in relation to the carcinogenicity.

Art. 27. According to this Resolution the reproductive system damages, described in Art. 28, the teratogenic effects, described in Art. 29, and the effects on lactation or resulting from lactation are consequences of the reproductive toxicity.

Art. 28. A product will be considered as causing damages to the reproductive system when it causes adverse effects on the reproductive physiology of human beings or when there are enough evidences in studies with animals suggesting that such product causes adverse effects on the reproductive physiology of human beings.

Sole Paragraph. Adverse effects on the reproductive physiology are any effects with potential of interfering with the structure and function of the reproductive system and/or with the reproductive ability including, but not limited to, female and male reproductive system changes, adverse effects on puberty onset, gamets production and transportation, reproductive cycle normal function, sexual behavior, fertility, delivery, pregnancy result, premature reproductive senescence, or changes in other functions that depend on the reproductive systems integrity.

Art. 29. According to this Resolution, the agrochemicals, their components, and related items are considered teratogenic when they cause adverse effects on the embryo fetal or neonatal development in human beings or when there are enough evidences in studies with animals suggesting that such products cause adverse effects on the embryo fetal or neonatal development in human beings.

Sole Paragraph. Adverse effects on the embryo fetal or neonatal development are any effects that can interfere with the normal development of the conceptus before or after the birth resulting from the exposure of any one of the ancestors before fertilization or resulting from the embryo or fetus exposure in the uterus; the primary effects include embryo or fetus death, malformations, functional impairment, and neurobehavioral changes.

Art. 30. The agrochemicals, their components, and related items are classified in relation to the reproductive toxicity according to the criteria defined in item 7 of Annex IV.

Paragraph 1 The agrochemicals, their components, and related items classified in Categories 1A or 1B are considered toxic to the reproductive physiology or to the embryo fetal or neonatal development in human beings and therefore are not considerable for registration according to Art. 31 of Decree number 4,074/2002.

Paragraph 2 The agrochemicals, their components, and related items classified in Category 2 are not considered toxic to the reproductive physiology or to the embryo fetal or neonatal development in human beings but can be classified again in case of new relevant information.

Paragraph 3. The agrochemicals, their components, and related-items not included in categories 1A, 1B, or 2 are not classified in relation to the reproductive toxicity.

Art. 31. Studies for clarifying the toxicological action form and/or mechanism for a better interpretation of the adverse effects observed in the toxicological studies can be requested during the process evaluation when necessary and at the discretion of Anvisa.

Art. 32. The components toxicological evaluation except for the technical product will be handled in a specific regulation.

Art. 33. The toxicological evaluation process for purposes of registration and post-registration of a formulated product will be rejected if its toxic action in human beings is greater than formulated products already registered for the same targets, same cultures, based on the same active components, with the same type of formulation, and within the same concentration range.

Paragraph 1. The comparison between the formulated products mentioned in the *caput* will be conducted according to the criteria of classification described in Annex IV, considering the *endpoints* of acute, oral, skin, and inhalatory toxicity; skin corrosion and irritation; eye corrosion and irritation, and skin sensibility.

Paragraph 2. The toxicological evaluation process for purposes of registration and post-registration of a formulated product that is included in the conditions of this article will be granted only for the use in targets and cultures that are not included in the products already registered.

Paragraph 3. The concentration range described in the *caput* refers to the maximum and minimum limits of active component variation according to item 13.1 of Annex II of Decree number 4,074/2002.

Chapter IV

Toxicological Classification Criteria

Art. 34. For this Resolution purposes Anvisa classifies the agrochemicals in toxicological classes from I to IV wherein class 1 shows the greater toxicity.

Art. 35 The toxicological classes are identified with the respective colors in the label strips according to the criteria described in this Resolution:

I. Class I – Extremely Toxic Product – red strip;

II. Class II – Highly Toxic Product – yellow strip;

III. Class III – Relatively Toxic Product – blue strip; and

IV. Class IV – Low Toxic Product – green strip;

Art. 36. The agrochemicals and related items are classified within one of the four toxicological classes based on the most restrictive category assigned to the results of acute oral toxicity experimental studies (oral DL_{50}), acute skin toxicity (skin DL_{50}) and acute inhalatory toxicity (inhalatory CL_{50}), according to the criteria defined in Annex IV.

Paragraph 1. Classes I, II, III, and IV correspond respectively to categories 1, 2, 3, and 4 of agrochemicals classification in relation to acute toxicity.

Paragraph 2. Products for purposes of Temporary Special Registration (RET) issuing are classified in Class I.

Art. 37. In relation to the potential of skin corrosion/irritation, eye corrosion/irritation, and skin sensibility, the agrochemicals and related items are classified for the purposes of hazard communication according to the criteria defined in Annex IV.

Art. 38. After the technical product is evaluated a technical monograph on the active component should be published with at least the following items (when applicable):

I. Active component common name;

II. Synonymity;

III. Registration number at the *Chemical Abstracts Service* (CAS);

IV. Chemical name defined by the International Union of Pure and Applied Chemistry (IUPAC);

V. Molecular or raw formula;

VI. Molecular mass;

VII. Structural formula;

VIII. Chemical group;

IX. Class of use;

X. Reference technical product;

XI. Physical-chemical properties;

XII. Technical product's minimum acceptable purity grade;

XIII. Relevant impurities;

XIV. Toxicologically relevant metabolites;

XV. Results of the following studies comprising the study title, year, and number, toxicological category, and when applicable:

a) oral DL_{50} ;

b) skin DL_{50} ;

c) inhalatory CL_{50};

d) Eye irritation;

e) Skin irritation;

f) Skin sensibility;

g) Genetic mutation;

h) Chromosome damages;

i) Toxicokinetics comprising the toxicologically relevant impurities data;

j) Chronic studies mentioned in the monograph in the following format: study title, year, and number, and summary of the toxicologically relevant information (*endpoints*, NOAEL, LOEL, LOAEL);

XVI. Authorized use comprising: applying modality, culture, LMR, expressed in milligrams by kilogram (mg/kg), safety interval, and restrictions in relation to the applying equipment;

XVII. Acceptable daily intake (ADI), acute reference dose (ARfD), and Acceptable Operator Exposure Level (AOEL);

XVIII. Application as a sanitizing product: authorized as indicated;

XIX. Rules number and publishing dates of the monograph and of all its versions.

Paragraph 1 The monograph data are those provided by the first solicitant of the active component and updated according to the intended use, new evaluation results, or new data.

Paragraph 2 The monographs of the active components registered previously to the publishing of this Resolution may be updated at the discretion of Anvisa.

Paragraph 3 At the discretion of Anvisa, for purposes of evaluation of the active components risks which monographs do not contain the reference doses (ADI, ARfD, and/or AOEL) and until they are established by Anvisa, the values published by the *Codex Alimentarius* or by other internationally recognized entities will be adopted.

Art. 39. In case of plant origin products the company should submit a monograph text proposal according to the model available in Annex V.

Chapter V
Biological Origin Products

Section I
Control Biological Agents, Microorganisms, and Semiochemicals.

Art. 40. The technical products, agrochemicals, and related items that are classified as microorganisms, control biological agents, and semiochemicals are regulated by this Resolution in a complementary way to its respective specific rules.

Art. 41. The control biological and microbiological agents will not receive a toxicological classification.

Paragraph 1 Formulations showing toxicological tests results indicating toxicity of its components may receive toxicological classification.

Paragraph 2 The label and package insert of products mentioned in the *caput* should show the warning text mentioned in items 1.1.1, 1.1.4, and 1.1.5 of Annex VI.

Art. 42. Products containing microorganisms included in biological risk classes 2, 3, or 4 are not approved from a toxicological point of view according to the regulating rule number 32 of the Ministry of Labor or other locally and/or internationally recognized entities.

Sole Paragraph. Microorganisms included in the biological risk class 2 may have their use authorized if a technical rationale is presented to be evaluated individually.

Section II
Plant Origin Products

Art. 43. For the toxicological evaluation of plant origin products the documents mentioned in Annex VII should be presented.

Paragraph 1 If any tests or information cannot be presented or if there is an exemption request the solicitant should submit a technical rationale.

Paragraph 2 The lack of rationale or the non-acceptance of the rationale results in the process rejection.

Art. 44. Residues assays in relation to the plant origin products may be requested at the discretion of Anvisa.

Sole Paragraph. Products not required to be included in residues assays may have their use authorized for any culture.

Art. 45. Co-reports of plant origin products may be evaluated according to the criteria described for plant origin products observing the specifications of each product; the criteria applicable to each type of material used as raw material should be followed.

Art. 46. Products comprising dynamized derivatives registered with toxicological studies exemption do not receive toxicological classification; the warning test mentioned in item 1.1.2 of Annex VI should be indicated in the label and package insert.

Art. 47. Products registered based on the common use do not receive toxicological classification; the warning test mentioned in item 1.1.3 of Annex VI should be indicated in the label and package insert.

Art. 48. Products registered with toxicological studies exemption based on the other exemption cases should receive the same toxicological classification mentioned in the reference monograph in relation to the plant derivative.

Chapter VI

Components With Suspicious Of Having Registration Prohibitive Characteristics

Art. 49. Components mentioned in Annex VIII cannot be present in the agrochemicals and related items because they are suspicious of having registration prohibitive characteristics according to items *c* and *d* of paragraph 6 of Article 3 of Law number 7,802/89.

Paragraph 1. Products already registered and comprising such components should request a formulation change within 6 months of the publishing of this Resolution for their replacement under penalty of toxicological evaluation suspension.

Paragraph 2. For components described in the *caput* the solicitant may send the toxicological dossier according to the requirements for technical product mentioned in Annex I for purposes of corroborating their safety.

Chapter VII

Wood Conservatives

Art. 50. For toxicological evaluation for purposes of wood conservatives registration according to Interministry Directive number 292 from April 28th, 1989, documents described in Annexes I and II are required; both the technical product and the formulated product should be evaluated.

Art. 51. Wood conservatives are classified and categorized according to the criteria defined in Annex IV.

Chapter VIII

Agrochemicals Risk Evaluation

Art. 52. Anvisa is responsible for the risk evaluation in relation to health and it is applied only to agrochemicals not included in Art. 3, paragraph 6, sub-headings "a" to "f" of Law number 7,802/89.

Art. 53. The agrochemicals and related items risk evaluation comprises the following steps:

I. Hazard identification;

II. Dose-response evaluation;

III. Exposure evaluation;

IV. Risk characterization.

Section I

Hazard Identification and Dose-Response Evaluation

Art. 54. It is considered as hazard identification the step where the type and nature of the adverse effects that may be caused by the test-substance to the organism, system, or population as a result of its intrinsic properties are evaluated.

Art. 55. It is considered as dose-response evaluation the step where the relation between the concentrations (doses) of the test-substance administered to an organism, system, or population and the incidence of adverse effects resulting from the substance administration is analyzed.

Art. 56. For the steps described in Art. 54 and 55 the parameters for toxicological reference, Acceptable Daily Intake (ADI), Acute Reference Dose (ARfD), and Acceptable Operator Exposure Level (AOEL) are established when relevant.

Paragraph 1. It is considered that the reference doses are the numeric values obtained by dividing the Point of Departure (POD) value, as for example NOAEL, LOAEL, by the uncertainty factors and indicate the exposure level to the test-substance in a defined period of time (for example, 24 hours, whole life) without the possibility of unacceptable risk to the health.

Paragraph 2. POD is obtained from the evaluation of the toxicological studies and the existing epidemiologic data for identification of the toxicological *endpoint* of higher relevance generally based on the lowest dose in the most sensible species.

Paragraph 3. The Uncertainty Factors (UF) consider the intra-specific and inter-specific differences and may receive additional factors for extrapolation of LOAEL values to NOAEL values, factors that consider the type and severity of the effects, the vulnerabilities of specific groups in the population etc.

Paragraph 4. The established reference doses may be reviewed according to updated technical and scientific data.

Art. 57. ADI is considered as being the estimated amount of test-substance present in food that may be ingested daily during the whole life without causing adverse effects to the health and is expressed in milligrams of test-substance by kilogram of body weight (b.w.).

Sole Paragraph. For purposes of dietary risk evaluation the ADI should be based on adverse effects observed in studies of repeated doses preferably by oral route.

Art. 58. ARfD is considered as being the estimated amount of test-substance present in food that may be ingested during a period of up to 24 hours without causing adverse effects to the health and is expressed in milligrams of test-substance by kilogram of body weight (b.w.).

Paragraph 1. For purposes of acute dietary risk evaluation the ARfD is established when specific *endpoints* relevant to acute effects are observed, such as hematotoxicity, immunotoxicity, neurotoxicity, nephrotoxicity, hepatotoxicity, any effects on the embryo fetal development or descendants etc.

Paragraph 2. All the basis for toxicological data should be evaluated using the evidence strength and the ARfD is derived from acute adverse effects observation, preferably resulting from the single exposure by oral route or from studies with repeated doses that show effects relevant to single exposures or from studies with repeated doses which effects have not been properly evaluated in a single dose study.

Paragraph 3. The DRfA do not need to be established when there are no effects resulting from the acute exposure with doses up to 500 mg/kg b.w. daily and/or when there are no mortalities in single oral exposure studies with doses up to 1000 mg/kg b.w. daily and/or when the mortality is the only result and the exposure route is not relevant to humans.

Art. 59. AOEL is the estimative of the test-substance absorbed amount in relation to which the agricultural worker may be exposed to daily without causing adverse effects to the health and is expressed in milligrams of test-substance by kilogram of body weight.

Paragraph 1. For the AOEL estimative the absorption of the test-substance may occur by any exposure route.

Paragraph 2. For purposes of labor risk evaluation "agricultural worker" is defined as the individual who mixes and/or supplies residues in the application equipment and/or supplies residues for the culture treatment.

Paragraph 3. All the basis for toxicological data and toxicokinetics studies should be evaluated using the evidence strength.

Paragraph 4. AOEL is preferably derived from short-duration studies of repeated dose, generally 90-day studies by oral route or depending on the case studies with more critical/sensible *endpoints* , as reproductive toxicity studies and/or studies on the embryo fetal development, neurotoxicity, or other effects observed in chronic toxicity studies when there are evidences that such effects were triggered by short-duration exposures.

Paragraph 5. AOEL will be derived from observations of systemic effects and not from local skin effects; the later will be used for risk communication.

Paragraph 6. Since the AOEL is expressed as the absorbed dose the POD value (external dose) should be converted to absorbed dose from the appropriate absorption data (data applicable to POD from which the AOEL will be derived).

Paragraph 7. The study should not be used for AOEL derivation if the most critical or sensible *endpoint* is a result from the test-substance exposure exclusively by a specific route not relevant to labor exposure.

Section II
Exposure Evaluation

Art. 60. The evaluation of an organism, system, or population exposure to an agrochemical is subdivided in:

I. Evaluation of chronic and acute dietary exposure; and

II. Evaluation of labor exposure.

Subsection I
Evaluation of Chronic Dietary Exposure

Art. 61. For calculation of the Theoretical Maximum Daily Ingestion (IDMT) the Maximum Limit of Residues (LMR) values and the most recent data of food consumption or availability and mean body weight by Federative Unit will be used, made available by the Brazilian Institute of Geography and Statistics (IBGE), according to the equation of Annex IX.

Subsection II

Evaluation of Acute Dietary Exposure

Art. 62. For the calculation of the Estimated Acute Maximum Ingestion (IMEA) the values referring to the highest residues concentration (HR) obtained from field studies and the most recent data of the larger portion (LP) consumed of a given food by the population of all the Federative Units (97.5 percentile of consumers), the unit weight of each food (U), and the mean body weight will be used, made available by IBGE according to the equation of Annex IX.

Subsection III

Labor Exposure Evaluation

Art. 63. The estimative of the labor exposure is made using an appropriate internationally recognized calculation model that allows for the evaluation of the likely exposure level of the agricultural worker in the proposed conditions of use.

Art. 64. For the estimative of the labor exposure the indications of use, maximum doses, and the formulated product application equipment are considered according to the recommendations in the label and package insert, mean body weight from the most recent data made available by IBGE and the skin absorption rate and areas treated according to the criteria of Annex IX.

Art. 65. The initial estimative of the labor exposure is made assuming the principle that the agricultural worker does not use any personal protective equipment and if necessary additional estimative are made assuming the principle that the agricultural worker does use certain types of personal protective equipment.

Section III

Risk Characterization

Art. 66. The risk characterization is the process of combining the hazard evaluations, dose-response evaluations, and exposure evaluations in order to determine the likely of adverse effects from an agrochemical in an organism, system, or population under specific conditions of exposure and is applicable to the chronic and acute dietary risks and to the labor risks according to the following.

Subsection I

Chronic Dietary Risk Characterization

Art. 67. The chronic dietary risk characterization of the population exposed to the test-substance is made comparing the IDMT with the ADI.

Paragraph 1. In order to consider an acceptable risk the IDMT should be lower than the IDA.

Paragraph 2. In relation to the risk management it is assumed that up to twenty percent (20%) of the IDA is reserved to the relative exposure to water consumption.

Paragraph 3. In relation to the risk evaluation of active components which monographs do not include LMR for animal origin products and until they are established by Anvisa, the values

published by *Codex Alimentarius* or by other internationally recognized entities are adopted at the discretion of Anvisa.

Paragraph 4. At the discretion of Anvisa, in relation to the risk management, an IDA percentile may be reserved to the relative exposure to active components that are also used in veterinary medications.

Subsection II

Acute Dietary Risk Characterization

Art. 68. The acute dietary risk characterization is made by comparing the IMEA with the ARfD.

Paragraph 1 In order to consider an acceptable risk the IMEA should be lower than the ARfD

Paragraph 2 For substances that do not have ARfD established by Anvisa the risk may be characterized using the ARfD recommended by the Codex Alimentarius or by other internationally recognized entities.

Subsection III

Labor Risk Characterization

Art. 69. For the labor risk characterization in each exposure situation the estimated labor exposure is compared to the AOEL.

Paragraph 1. In order to a risk to be considered acceptable in each exposure situation according to the recommendations in the label and package insert the estimated labor exposure should be lower than the AOEL.

Paragraph 2. The recommendations in the label and package insert for personal protective equipment (PPE), doses, areas, and application equipment should be adapted to the exposure conditions that show the acceptable risk.

Chapter IX

Low Toxicity Products

Art. 70. For purposes of toxicological analysis the low toxicity products included in Art. 12 of Decree number 4,074/2002 are the agrochemicals, their components, and related items that do not comprise the following characteristics:

I. Suspicious of carcinogenicity;

II. Suspicious of mutagenicity;

III. Suspicious of toxicity for reproduction;

IV. Suspicious of causing endocrine dysregulation;

V. Skin sensibility;

VI. Skin or eye corrosion/irritation;

VII. Neurotoxic effects;

VIII. Immunotoxic effects;

IX. Oral DL_{50} lower than or equal to 300 mg/kg b.w.;

X. Skin DL_{50} lower than or equal to 1000 mg/kg b.w.;

XI. Inhalatory CL_{50} lower than or equal to 2500 ppm/V for gases or lower than or equal to 1,0 mg/L for solid or liquid products.

Art. 71. Also considered as low toxicity products are all the biological origin products included in the categories of semiochemicals, control biological agents, and control microbiologic agent provided they comply with the following conditions:

I. A product included in the category of control biological agents defined by INC number 2 from January 23rd, 2006; or

II. A semiochemical product which toxicological evaluation is limited to phase I of toxicological evaluation as defined by INC number 1 from January 23rd, 2006 and that comprises characteristics included in class IV of toxicological classification; or

III. A microbiological product which toxicological evaluation is limited to phase I of the toxicological evaluation as defined in INC number 3 from March 10th, 2006.

Chapter X

Agrochemicals and Related Items Labels and Package Inserts

Art. 72. The solicitant company should provide Anvisa with a technical document about the active component and the components with toxicologically relevant characteristics.

Paragraph 1. The document should contain the medical information and the detailed information on the potential harmful effects resulting from the use of the product in the human health, instructions to be adopted in cases of accidents, and precautions to prevent damages to the appliers, manipulators, and third parties.

Paragraph 2. The medical information should contain at least the toxicokinetics data, the toxicity mechanism, the clinical symptoms and signs, diagnosis, treatment procedures, contraindications, synergic effects, and the acute and chronic effects verified in epidemiology and/or toxicological data or studies.

Paragraph 3. The alarm symptoms, first aids procedures, recommendations for physicians, and antidote (when available) should be included in the instructions to be adopted in cases of accidents.

Paragraph 4. The technical document should be signed by a health professional with registration in a Regional Medical Council.

Art. 73. The label and package insert should comply with the criteria of Annex VI.

Art. 74. All the information included in the labels and package inserts of agrochemicals and related items including the PPE recommendations for residues preparation and for the different application situations are responsibility of the solicitant company.

Sole Paragraph. The company requesting the registration of an agrochemical or related item is responsible for assuring that the information provided in the labels and package inserts are updated.

Art. 75. Anvisa reserves the right to require changes in the text of labels and package inserts to the agrochemical or related item registration solicitant whenever it considers necessary due to technical-scientific and/or epidemiology reasons considering the risk evaluation with the purpose of clarifying to the agricultural workers, agronomists, and health professionals about the use of the product and the safety of the exposed population in order to prevent accidents and intoxication.

Art. 76. The biological origin products labels and package inserts should follow the general dispositions of this resolution and the necessary adaptations to the specificities of each category should be made in addition to the items and orientations already included in specific devices and rules.

Art. 77. There is no need to include the skull with the two crossed shinbones in the labels and package inserts since these are products with low toxicity and hazards and low applicator exposure:

I - Semiochemical products included in item II of Art. 71;

II - Products registered in the category of Control Biological Agents defined by INC number 2 from January 23rd, 2006;

III - Products containing microbiological agents included in item III of Art. 71.

Chapter XI

Post-Registration Changes

Art. 78. The technical nature changes defined in clause I of Paragraph 2 of Art. 22 of Decree number 4,074/2002 should be requested to the registering federal body.

Paragraph 1. The requests for technical nature changes defined by the notification procedure established in specific rule are not subjected to this Resolution.

Paragraph 2. The documents for technical evaluation should be registered directly with Anvisa with the copy of the change request protocol submitted to the registering body.

Paragraph 3. The documentation should be instructed in the following order:

I – Copy of the change request protocol submitted to the registering body;

II - Petition form;

III - Documents for the specific process of post-registration change in the order established in the *checklist* items according to the petitioning system of Anvisa; and

IV – Fee payment receipt.

Paragraph 4. All the petition form fields should be completed including the subject code of the change to be made and the process number at Anvisa in relation to which the change is being processed.

Paragraph 5. Each petition should contain only one type of change explaining the respective subject code available in the Anvisa's petitioning system.

Art. 79. For the inclusion of the manufacturer in the technical product registration the following criteria must be met:

I – the maximum limit of each impurity related to the new source must be lower than or equal to the one defined in the registered technical product qualitative and quantitative composition statement;

II – there are no new impurities quantified above 1 g/kg (one gram by kilogram) in the new source in relation to the registered technical product qualitative and quantitative composition statement; and

III – the minimum limit of active component must be equal to or greater than the one defined in the registered technical product qualitative and quantitative composition statement.

Paragraph 1 Where there is the need of amending the registered technical product qualitative and quantitative composition statement, it can only be amended based on the results of the five batches of already registered sources and the quality control data when relevant.

Paragraph 2 The amendments in the respective statement should be made upon corroboration of the post-registration process additament registered in the registering body.

Paragraph 3 Differences between raw materials, solvents, and catalysts may occur provided there is no toxicity increment and the criteria included in clauses I, II, and III of this article are complied with.

Art. 80. The change in the formulation of agrochemicals and related items is regulated by specific rule.

Sole Paragraph. The criteria for absence of toxicological studies defined in this Resolution may be applied to the studies required by specific rule.

Chapter XII

Temporary and Final Dispositions

Art. 81. The company requesting the registration of an agrochemical, its components, and related items is responsible for assuring that the studies and information provided in the toxicological dossier are updated.

Art. 82. The companies demanding toxicological evaluation for registration purposes should update the toxicological dossier of its products according to this resolution.

Sole Paragraph. The toxicological evaluation processes for registration purposes that are still not evaluated should be adapted to the dispositions of this Resolution within 180 days.

Art. 83. The attachments of this Resolution will be updated through publications in the Federal Official Gazette of Brazil whenever it is necessary and at the discretion of Anvisa.

Art. 84. The "DIRECTIVES AND REQUIREMENTS OF THE MINISTRY OF HEALTH IN RELATION TO THE REGISTRATION AUTHORIZATION AND EXTENDED USE OF AGROCHEMICALS AND RELATED ITEMS" approved by the Departments of Human Ecology and Environmental Health and Risks Evaluation as "DIRECTIVES AND REQUIREMENTS OF THE MINISTRY OF HEALTH IN RELATION TO THE REGISTRATION AUTHORIZATION AND EXTENDED USE OF AGROCHEMICALS AND RELATED ITEMS number 01 FROM DECEMBER 9, 1991" published in the Federal Official Gazette of Brazil on December 13th, 1991 and confirmed by Directive number 03, from January 16th, 1992 of the Technical-Normative Department of the Health Surveillance Agency of the Ministry of Health are revoked.

Art. 85. This Resolution takes effect on the date of its publishing.

Annexes

Annex I

Requirements For Technical Products Toxicological Evaluation

For purposes of technical products toxicological evaluation the documents should be presented in the following order separated by title pages identifying each section:

SECTION 1. Registration Solicitation

1.1 Registration solicitation according to Annex II of Decree number 4,074/2002;

1.2 Technical report;

1.3 Corroboration that the solicitant company is duly registered in such a modality in a State, Federal District, or Regional relevant body;

1.4 Corroboration that the manufacturers settled in the country are duly registered in such a modality in a State, Federal District, or Regional relevant body;

1.5 Document corroborating the legal representative condition of the solicitant company;

1.6 Product's physical analyses certificate;

1.7 Information on the situation of the product, registration, authorized uses, restrictions, and reasons relevant to the country of origin;

1.8 Information on restrictions or prohibitions in relation to products based on the same active component and the reasons in other countries;

1.9 Detailed description of the product's deactivation methods followed by technical document indicating the components reduction strength, identifying the remaining residues and the entity settled in Brazil able to conduct the process;

1.10 Payment receipt of the health surveillance fee;

1.11 Other information.

SECTION 2. Technical product identification

2.1 Single statement from the solicitant on the product's qualitative and quantitative composition created based on the laboratory documents that analyze the five batches of each manufacturer, which should follow the statement according to Annex II of Decree number 4,074/2002;

2.2 Description of the effects observed related to the relevant impurities (for example, toxicological effects or effects on the active component stability);

2.3 Description of the analytic methodology for qualitative and quantitative determination of the active component, impurities at concentrations above or equal to 0.1%, and toxicological impurities relevant in concentrations below 0.1%;

2.4 Description of the analytic methodology of the main products for active component degradation for purposes of monitoring and supervision;

2.5 Description of the technical product production process comprising the synthesis steps and its subproducts and impurities provided by the manufacturer according to Annex II of Decree number 4,074/2002;

SECTION 3. Physical and chemical properties study.

3.1 Aspect, color, and physical state;
3.2 Thermal and air stability;
3.3 Solubility/miscibility in water and other solvents;
3.4 Hydrogenionic potential (pH);
3.5 Fusion point/range;
3.6 Ebullition point/range;
3.7 Apparent or specific density;
3.8 Dissociation constant;
3.9 Octanol/water partition coefficient;
3.10 Vapor pressure;
3.11 Hydrolysis;
3.12 Particles size distribution.

SECTION 4. Toxicological and toxicokinetics study

4.1 Acute oral toxicity (oral DL_{50});
4.2 Acute skin toxicity (skin DL_{50});
4.3 Acute inhalatory toxicity (inhalatory CL_{50});
4.4 Acute skin corrosion/irritation;
4.5 Acute ocular corrosion/irritation;
4.6 skin sensibility;
4.7 Studies related to absorption, distribution, metabolism, and excretion (ADME) in mammals and *in vitro* metabolism;
4.8 Mutagenicity studies

a. Study of genetic mutation in bacterial cells;
b. *In vitro* study of genetic mutation in mammals cells;
c. *In vitro* study of chromosome damages in mammals cells; and
d. *In vivo* study of chromosome damages in somatic cells.

4.9 Oral toxicity with repeated doses

a. Oral toxicity with repeated doses for ninety (90) days in rats;
b. Oral toxicity with repeated doses for ninety (90) days in mice;
c. Oral toxicity with repeated doses for ninety (90) days in non-rodents;
d. Skin toxicity with repeated doses for twenty one/twenty eight (21/28) days;
e. Study with repeated doses via other routes;

4.10 Studies of chronic toxicity in rats
4.11 Studies of carcinogenicity conducted on rats.
4.12 Studies of carcinogenicity conducted on mice.

4.13 Study of reproductive toxicity for two generations or study of reproductive toxicity for an extended generation conducted on rats;
4.14 Study of toxicity on the prenatal development in rats;
4.15 Study of toxicity on the prenatal development in rabbits;
4.16 Neurotoxicity studies;
4.17 Studies on the action form and/or mechanism;
4.18 Study of metabolism in plants; and
4.19 Complementary studies.

5 - General considerations

5.1 The tests should be conducted and the data should be analyzed by means of appropriate statistic methods.
5.2 If the solicitant has conducted additional studies not mentioned in this Annex these studies should be included in the technical product toxicological dossier.

6 - Considerations on the registration solicitation

6.1 Documents listed in Section 1 should be presented in the original form, certified copy, or accompanied by the original copy for authentication by the public body that receives such documents.
6.2 Without deviating from item 12.1 of Annex II of Decree number 4,074/02, the qualitative and quantitative composition statement should contain the CAS (*Chemical Abstracts Service*) number when available, the chemical name, and the common name of the active component (i.a.) and all the significant and/or relevant impurities.

6.3 The solicitant should present the synthesis process history of each manufacturer of the technical product in addition to the requirements listed in item 12 of Annex II of Decree number 4,074/2002, specifying whether the product development is at laboratory scale, pilot scale, scale amplification, or commercial production phase.

6.3.1 The description should contain general information on the raw materials such as nomenclature, structural formula, CAS number, and minimum impurity.

6.3.2 The following documents provided by each manufacturer should be presented:

a. Information on which quality control tests are conducted in relation to the raw materials;

b. Identification and form of control of the synthesis process critical points;

c. Discussion on the formation of degradation products according to the thermal and air stability studies presented; and

d. Specification of the product's qualitative and quantitative composition taking the discussion on the impurities formation and items "b" and "c" into account.

6.3.3 Impurities specified by the manufacturer should be investigated in the laboratory study with five batches.

6.4 The laboratory document based on the analysis of five batches of the technical products should contain at least:

a. Identification of each batch in the study or corroboration by the manufacturing unit;

b. Unequivocal identification and quantification of the active component and all the impurities greater than or equal to 1.0 g/kg (0.1% m/m) and of toxicologically relevant impurities at any levels;

c. Active component characterization by means of two analytical techniques such ultraviolet, infrared, nuclear magnetic resonance, mass spectrometry;

d. Analytical sweep showing the analyzed product impurities profile.

The scale used should allow for evaluation in relation to the existence of impurities and show the area proportions corroborating whether they exist. In addition it should show the spectrum with readings at different wave lengths and evaluation of the peak purity (when available by the analytic technique) assuring the use of the appropriate wave length;

e. Analytical conclusion of each batch, which should be greater than or equal to 980 g/kg, i.e., the non-identified fraction should be lower than 20 g/kg;

f. Chemical name, CAS number (when available), molecular mass, molecular formula, and structural formula of each significant and/or relevant impurity;

g. Detailed description of the analytical methods applied for identification and quantification of the active component and the impurities;

h. Certificates of the analytical patterns of the active component and each impurity analyzed containing at least the manufacturing date, the expiration date, and their origin; and

i. Results of the analyses showing mean, standard deviation, characteristic chromatograms and spectrum, chromatography peaks retaining areas and times, followed by calibration curves, calculation memories, and detailed discussion of such results.

6.5 The validation reports of the analytical methods used should follow the analysis document of five batches.

6.5.1 The validation parameters of the analytical methods should follow the local and/or internationally accepted rules for quantification of the active component and impurities.

6.5.2 The use of local and/or internationally recognized methods does not exclude the presentation of the minimum criteria for validation/verification used by the laboratory conducting the study.

6.5.3 If adaptations are made to the internationally recognized method, the need of complete validation of the method should be verified.

6.6 The use of an analog pattern will be exceptionally accepted when a correction factor can be determined.

6.6.1 The impurities should be isolated or synthesized by the manufacturer or laboratory in an amount enough to allow for the unequivocal identification of the substance.

6.6.2 For quantification of impurities by means of such a technique it should be verified whether the correction factor was considered as being the ratio between the response of the impurity pattern and the response of the substance pattern determined as analog. For determination of the correction factor at least three different concentrations of impurities/analog pattern should be used in the concentration range in which the impurities are expected and with duplicate area determinations.

7 – Considerations on the skin corrosion/irritation study.

7.1 The studies investigating skin corrosion and irritation should follow a phased tests strategy approaching the evidence strength according to internationally recognized protocols. This strategy will determine whether the skin corrosion/irritation *in vivo* test should be conducted.

8 – Considerations on the eye corrosion/irritation study.

8.1 The studies investigating eye corrosion and irritation should follow a phased tests strategy approaching the evidence strength according to internationally recognized protocols. This strategy will determine whether the eye corrosion/irritation *in vivo* test should be conducted.

9 - Considerations on toxicokinetics and toxicological studies

9.1 For a study to be conducted the pertinence of collecting toxicological data should be considered from models of animals with different metabolic profiles in relation to humans.
In this case a more appropriate model can be selected.

9.2 History of control data when available should be provided and included in the technical product toxicological dossier.

9.3 The history of control data should:

a. Include the *endpoints* representing the critical adverse effects;

b. Come from studies with the same species and race with similar conditions and at the same laboratory; and

c. Comprise a period of five years in which the analyzed study should be centralized when possible.

9.4 Additional data of control history from different laboratories can be provided separately as additional information.

9.5 Whenever the final residue to which the human being will be exposed has substances different from the active component and that do not correspond to the metabolites generated in

the species tested in the toxicological studies additional toxicity studies should be conducted for such a substance when technically possible. These studies will not be necessary if it is possible to demonstrate that the exposure of the human being to such substance does not result in significant risk to the health. This substance may be a result of the metabolism or other changes or transformations that occur inside or at the surface of plants, farmed animals, soil, hydrosphere, atmosphere, or as result of the transformation of the treated products.
9.6 The studies should be conducted preferably via oral route; however the inhalatory route can be more convenient in some studies when the substance is volatile (vapor pressure > 10^{-2} Pa).

10 - Considerations on the absorption, distribution, metabolism, and excretion (ADME) studies after exposure via oral route

10.1 In order to determine the relevance of the toxicological data generated in animals and to guide the interpretation of the results and the assay strategy comparative metabolic *in vitro* studies should be conducted in the animal species used in the ADME studies and in the human materials (microsomes or intact cell systems).
10.2 Whenever a metabolite is detected *in vitro* in human material and not in the animal species tested new assays, information, or data explaining why such a metabolite is not relevant should be presented.

11 - Considerations on ADME studies after exposure via different routes

11.1 ADME data should be presented after exposure via skin route whenever the toxicity after this type of exposure results in concerns in comparison to the toxicity resulting from the exposure via oral route.
11.2 Before investigating the *in vivo* ADME after skin exposure a skin penetration *in vitro* study should be conducted in order to evaluate the magnitude and the likely rate of skin bioavailability.
11.3 The ADME after exposure via skin route should be considered based on the above mentioned information except if the active substance causes skin irritation that compromises the study result.
11.4 For evaluation of the risk of the volatile active components (vapor pressure > 10^{-2} Pa) to the human being an ADME study after exposure via inhalatory route can be useful.

12 - Considerations on the short-term toxicity studies

12.1 The test-substance bioavailability data should be included in the short-term studies. In order to prevent the increased use of animals the data may be derived from studies for determination of the concentrations interval.
12.2 If the immunologic, nervous, or endocrine system are specific targets of the short-term studies at doses that do not cause an acute toxicity specific studies should be conducted.

12.3 For the volatile active components (vapor pressure > 10^{-2} Pa) a specialized document (for example based on kinetics data specific to the exposure route) is necessary to decide whether the short-term studies should be conducted with inhalatory exposure.

13 - Considerations on the mutagenicity studies

13.1 The evaluation of microcores in the bone marrow can be conducted as part of the toxicity studies with repeated dose at the time of euthanasia. In this case it is not necessary to conduct an *in vivo* study of chromosome damage in somatic cells.
13.2 If genetic mutation and chromosome damage are detected in the studies of genetic mutation in bacterial cells and of chromosome damages *in vitro* in mammals cells, respectively, it will not be necessary to conduct the genetic mutation *in vitro* study in mammal cells.
13.3 If the studies requested in section 4, item 4.8, show negative results additional studies in somatic and germinative cells will not be necessary unless there are evidences showing that the technical product can reach the germinative cells or that the gonads are affected.
13.4 If any of the *in vitro* studies of genetic mutation shows positive or equivocal result a study to investigate the *in vivo* genetic mutation induction should be conducted.
13.5 If any of the *in vivo* studies using somatic cells shows positive result it will not be necessary to conduct additional studies since the technical products are considered as potential mutagens of germinative cells. However mutagenicity studies in germinative cells can be conducted to demonstrate whether a mutagen in somatic cells is a mutagen in germinative cells.
13.6 Other studies of genotoxic effects (not mutagenic effects) can be presented and considered in the evaluation.

14 - Considerations on chronic toxicity and carcinogenicity studies

14.1 When the toxicokinetics data indicate that rats and/or mice are not appropriate models for the evaluation of the carcinogenic effect in human beings the studies can be conducted in other species.
14.2 History of control data when available should always be provided and included in the technical product toxicological dossier.
14.3 The history of control data should:

a. Include the *endpoints* representing the critical adverse effects;

b. Come from studies with the same species and race with similar conditions and at the same laboratory; and

c. Comprise a period of five years in which the analyzed study should be centralized when possible.

14.4 Additional data of control history from different laboratories can be provided separately as additional information.

15 - Considerations on toxicity studies for reproductive physiology

15.1 When indicated by observations from other studies or by the test-substance action form additional data or studies can be required in order to provide information on the manifestation of post-natal effects such as neurotoxicity effects on the development.
15.2 When necessary additional studies can be required for an improved interpretation of the adverse effects on the reproductive physiology in order to provide information on the gender affected and the possible action forms and/or mechanisms.
15.3 History of control data when available should always be provided and included in the technical product toxicological dossier.
15.4 The history of control data should:

a. Include the *endpoints* representing the critical adverse effects;

b. Come from studies with the same species and race with similar conditions and at the same laboratory; and

c. Comprise a period of five years in which the analyzed study should be centralized when possible.

15.5 Additional data of control history from different laboratories can be provided separately as additional information.

16 - Considerations on the neurotoxicity studies

16.1 The following studies are necessary:

16.1.1 Neurotoxicity in rodents when there are indications of neurotoxicity in the acute toxicity studies;

16.1.2 Late neurotoxicity after acute exposure when there are indications of neurotoxicity in the acute toxicity studies;

16.1.3 Late neurotoxicity with repeated doses (28 days) when there are indications of neurotoxicity:

a. In the studies of late neurotoxicity after acute exposure; or

b. In other studies with repeated doses;

16.2 Neurotoxicity in the development when there are indications of neurotoxicity in the toxicity studies on the reproductive physiology.

17 - Considerations on the action form and/or mechanism studies

17.1 If studies for clarifying the toxicological action form and/or mechanism have been conducted they should be included in the toxicological dossier and in the process for purposes of registration of the technical product for an improved interpretation of the adverse effects observed in the toxicological studies.

17.2 If studies for clarifying the toxicological action form and/or mechanism have not been conducted they can be requested during the process evaluation when necessary and at the discretion of Anvisa.

18 - Considerations on the additional studies

18.1 Additional studies can be requested in order to clarify the effects observed taking into account the results of the toxicological and toxicokinetics studies as well as the main exposure routes. These studies may include:

a. Absorption, distribution, metabolism, and excretion (ADME) studies in a different species;

b. Studies on the immunotoxicological potential;

c. Studies on the effects in the endocrine system;

d. Studies on different administration routes;

e. Studies with metabolites.

18.2 Additional studies related to substances different from the active component may be requested when it is verified that such substances are different from the metabolites found in animals used in the toxicological studies or that were detected in a low proportion in these animals. These substances may be a result of the metabolism or other processes of plants transformation in animal origin products, soil, hydrosphere, or atmosphere. The decisions on the need of these studies will be made case by case.

Annex II

Requirements for formulated products toxicological evaluation

For purposes of formulated products toxicological evaluation the documents should be presented in the following order separated by title pages identifying each section:

SECTION 1. Registration Solicitation

1.1 Registration solicitation according to Annex II of Decree number 4,074/2002;

1.2 Technical report;

1.3 Corroboration that the solicitant company is duly registered in such a modality in a State, Federal District, or Regional relevant body;

1.4 Corroboration that the manufacturers settled in the country are duly registered in such a modality in a State, Federal District, or Regional relevant body;

1.5 Document corroborating the legal representative condition of the solicitant company;

1.6 Product's physical analyses certificate;

1.7 Information on the situation of the product, registration, authorized uses, restrictions, and reasons relevant to the country of origin;

1.8 Information on restrictions or prohibitions in relation to products based on the same active component and the reasons in other countries;
1.9 Detailed description of the product's deactivation methods followed by technical document indicating the components reduction strength, identifying the remaining residues and the entity settled in Brazil able to conduct the process;
1.10 Payment receipt of the health surveillance fee;
1.11 Other information.

SECTION 2 – Formulated product data

2.1 Statement by the solicitant on the product's qualitative and quantitative composition indicating the maximum and minimum limits of variation of each component and its specific function followed by laboratory findings of each formulator;
2.2 Printed version of the product's label and package insert when available in the country of origin;
2.3 Indication of use (cultures and biologic targets), detailed information on the product's action form, applying modality (pre-emergency, post-emergency etc.), recommended dose, concentration, type of residue preparation, application form and equipment, period, number, and applications interval;
2.4 Restrictions of use and special recommendations;
2.5 Safety interval;
2.6 New entry interval;
2.7 Specification of the appropriate personal protective equipment for the product application as well as collective protective measures;
2.8 Procedures for packages and application equipment decontamination;
2.9 System of collection and final destination of packages and remaining products;
2.10 Label and package insert template;
2.11 Receipt or protocol of registration in Brazil of all the components including the technical product;

a. The component registration should be linked to the requested intended use

b. The components in relation to which the registration was requested should be described.

2.12 Detailed description of the production process according to Art. 16 of this Resolution.

SECTION 3 – Physical-chemical properties studies, when applicable

3.1 Aspect, color, and physical state;
3.2 Thermal and air stability;
3.3 Fulgency point;
3.4 Solubility/miscibility in water and other solvents;

3.5 Hydrogenionic potential (pH);
3.6 Apparent or specific density;
3.7 Volatility;
3.8 Particles size distribution;
3.9 Viscosity;

SECTION 4 – Toxicological studies

4.1 Acute oral toxicity (oral DL_{50});
4.2 Acute skin toxicity (skin DL_{50});
4.3 Acute inhalatory toxicity (inhalatory CL_{50});
4.4 Acute eye corrosion/irritation;
4.5 Acute skin corrosion/irritation;
4.6 skin sensibility;
4.7 Mutagenicity studies:

a. Study of genetic mutation in bacterial cells; and
b. *In vitro* study of chromosome damages in mammals cells.

4.8 Other studies.

SECTION 5 – Residues Studies

According to specific legislation.

6. General considerations

6.1 The tests should be conducted and the data should be analyzed by means of appropriate statistic methods.
6.2 If the solicitant has conducted additional studies not mentioned in this Annex these studies should be included in the formulated product toxicological dossier.

7. Considerations on the formulated product data

7.1 Statement on the qualitative and quantitative composition proposed to the formulated product should be presented by the solicitant indicating the CAS number and SIC (Components Information System) number, its specific function, nominal concentration, maximum and minimum limits of each component variation expressed in g/kg or g/L, and the mass percentile/mass of each component, duly signed by the solicitant company's legal representative or placed before with specific powers to provide information to Anvisa.

7.2 The components mixtures should be presented with the description of each component and its respective concentrations.

7.3 The mass balance for liquid formulations should be appropriate to the product's density obtained in the report of the physical-chemical properties study; the total amount of solid formulations should be 1000 g/kg.
7.4 The laboratory findings of each formulator included in item 2.1 of section 2 of this annex should contain at least the active component concentration, aspect, color, physical state, and apparent or specific density of batches of the formulated products manufactured in pilot scale and/or industrial scale.

8 Considerations on the toxicological studies for formulated products

8.1 The formulated product batch analysis certificate used in the toxicological studies should contain at least the active component concentration, aspect, color, physical state, and apparent or specific density.
8.2 Before conducting the *in vivo* toxicological studies the company should obtain all the available information on the test-substance following a phased tests strategy that varies according to the test, approaching the evidence strength in order to determine the need of conducting assays *in vivo*. The factors considered in the test strategy may include:

a. Evaluation of the existing data on humans from clinical trials or labor studies and reports of cases and/or test data in animals with single exposure or repeated exposure of the toxicological studies;

b. Other toxicological studies;

c. Results of *in vitro* or *ex vivo* test validated and internationally recognized as potential substitutions to the *in vivo* test;

d. Physical-chemical and reactivity properties data;

e. Analysis *in silico* of the structure-activity ratio;

f. Results of the *in vivo* test, if necessary.

9 - Considerations on the inhalatory toxicity

9.1 The acute inhalatory toxicity studies may be absent:

9.1.1 When the product is in solid formulation with a significant proportion (> 99% in mass) of particles with diameter ≥ 50 µm.

9.1.2 When there are acute inhalatory toxicity data of all the components or reliable prediction from validated methods indicating an inhalatory toxicity lower than or equal to the one of the technical product already analyzed. The potential additive or synergic effects of the components over the mixture total toxicity should be taken into account.
9.2 The inhalatory toxicity studies will be required in case of absence of the data on the components' inhalatory toxicity or when the components show evidences of being more toxic than the technical product via such route.

10 – Considerations on the skin corrosion/irritation study.

10.1 - The studies investigating skin corrosion and irritation should follow a phased tests strategy approaching the evidence strength according to internationally recognized protocols. This strategy will determine whether the skin corrosion/irritation *in vivo* test should be conducted.

11 – Considerations on the eye corrosion/irritation study.

11.1 - The studies investigating eye corrosion and irritation should follow a phased tests strategy approaching the evidence strength according to internationally recognized protocols. This strategy will determine whether the eye corrosion/irritation *in vivo* test should be conducted.

12 - Considerations on the mutagenicity tests.

12.1 If the genetic mutation study in bacterial cells shows positive or equivocal result an additional study to investigate the *in vivo* genetic mutation induction should be conducted.
12.2 If the *in vitro* study of chromosome damages shows positive or equivocal result an additional study to investigate *in vivo* chromosome damages should be conducted.
12.3 If the studies requested in section 4 item 4.7 show negative results *in vivo* studies will not be necessary;
12.4 If any of the *in vivo* studies using somatic cells shows positive result it will not be necessary to conduct additional studies since the formulated products are considered as potential mutagens of germinative cells. However mutagenicity studies in germinative cells can be conducted to demonstrate whether a mutagen in somatic cells is a mutagen in germinative cells.
12.5 Other studies of genotoxic effects (not mutagenic effects) presented may be considered in the evaluation.

Annex III

Evaluation of the technical products equivalence – Phase II

Required Studies and Data

1. In all cases of new impurities or incremented levels of impurities structure-activity ratio studies including all the *endpoints* necessary to the evaluation of a technical product using different specialized systems or data explaining why the impurities are not relevant are necessary;
2. In case of new impurity or incremented level of impurity stated in the maximum limit of ≥0.1 to <1% the following *in vitro* studies with the technical product or the impurity may be required:
a. Study of genetic mutation in bacterial cells;

b. *In vitro* study of genetic mutation in mammals cells;
c. *In vitro* study of chromosome damages in mammals cells;
3. In case of new impurity or incremented level of impurity stated in the maximum limit of ≥1% the following studies with the technical product or the impurity may be required:
a. Study of genetic mutation in bacterial cells;
b. *In vitro* study of genetic mutation in mammals cells;
c. *In vitro* study of chromosome damages in mammals cells;
d. *In vivo* study of chromosome damages in somatic cells;
e. Acute oral toxicity study;
f. Eye corrosion/irritation study;
g. Skin corrosion/irritation study;
h. Skin sensibility study.

4 . Considerations on the mutagenicity studies

4.1 The evaluation of the mutagenic potential from the studies required in items 2 and 3 occurs according to the following approach:
a. If genetic mutation and chromosome damages are detected respectively in the studies of genetic mutation in bacterial cells and of chromosome damages *in vitro* in mammals cells it will not be necessary to conduct the study of genetic mutation *in vitro* in mammals cells;
b. If all the mutagenicity studies required in items 2 and 3 show negative results additional studies in somatic and germinative cells will not be required unless there are evidences that the technical product or the impurity may reach the germinative cells or that the gonads are affected;
c. If any of the *in vitro* studies of genetic mutation shows positive or equivocal result a study to investigate the *in vivo* genetic mutation induction should be conducted;
d. If the *in vitro* study of chromosome damages required in item 2 and 3 shows negative or equivocal result the study to investigate the *in vivo* chromosome damage induction should be conducted;
e. Of any of the *in vivo* studies using somatic cells shows positive result it will not be necessary to conduct additional studies since the technical products or the impurities are considered as potential mutagens of germinative cells. However mutagenicity studies in germinative cells can be conducted to demonstrate whether a mutagen in somatic cells is a mutagen in germinative cells;
f. Other studies of genotoxic effects (not mutagenic effects) may also be presented and considered in the evaluation of the technical products or impurities.
g. When the toxicological studies are conducted with the technical product batches of the product which qualitative and quantitative composition is determined and with impurities level next to the stated value should be used.

5. Specific considerations on the acute oral toxicity study

5.1 The acute oral toxicity study is required when there are evidences that the presence of the impurity may result in a more severe hazard of the technical product from current or predicted data. The hazard increment calculation is performed according to the following equation:

Calculation

(i) Impurity relative hazard calculation (RelHazimp) based on the impurity hazard data (Hazimp) and the active component data (Hazai).

RelHazimp = (Hazai/Hazimp)

The relative hazard of the active component (RelHazai) is 1.

(ii) Calculation of the maximum hazard theoretical increase of the active component/impurity mixture (MTIHaz) as a proportion of the active component hazard (Hazai), the technical product minimum purity (%aimin), and the impurity theoretical maximum content (%impmax).

MTIHaz = [(%aimin x RelHazai) + (%impmax x RelHazimp)]/(%aimin x RelHazai)

(iii) Calculation of the maximum acceptable level of the impurity concentration (%Impmaxaccept) by substitution of limit 1.1 (i.e. +10%) for MTIHaz and %Impmaxacceptt of %impmax in equation (ii):

1.1 = [(%aimin x RelHazai) + (%Impmaxaccept x RelHazimp)]/(%aimin x RelHazai)

And rearranging equation (iii):

%Impmaxaccept = [(1.1 x %aimin x RelHazai) – (%aimin x RelHazai)]/RelHazimp

Wherein
Hazai = active component hazard value;
Hazimp = impurity hazard value;
RelHazimp = ratio between the impurity hazard and the active component hazard
RelHazai = ratio of the active component hazard(=1);
%aimin = active component minimum limit;
%impmax = impurity maximum theoretical limit;
MTIHaz = hazard maximum theoretical increase due to the impurity;
%impmaxaccept = impurity level maximum acceptable limit.

5.2 In the absence of impurity data an oral DL_{50} value of 1 mg/kg b.w. is assumed;

5.3 If the above calculations show MTIHaz results lower than 10% the impurity is non-relevant and the need of requesting an acute toxicity study should be considered.
5.4 When the toxicological study is conducted with the technical product batches of the product which qualitative and quantitative composition is determined and with impurities level next to the stated value should be used.

6. Considerations on the skin sensibility study

6.1 The skin sensibility study should be preferably the local lymph node assay.
6.2 When the toxicological study is conducted with the technical product batches of the product which qualitative and quantitative composition is determined and with impurities level next to the stated value should be used.

7. Considerations on the skin corrosion/irritation or eye corrosion/irritation study

7.1 Skin corrosion/irritation or eye corrosion/irritation tests should be requested whenever there are indications that the impurity may be corrosive to the skin or eyes from structure-activity ratio studies or other sources of information.
7.2 If the impurity is considered as causing only skin or eye irritation the study should be requested if the impurity content is greater than 3%. If more than one impurity is being evaluated and both of them have indications of irritation and/or corrosion from the structure-activity ratio studies or other sources of information the study should be requested if the content sum is greater than or equal to 5%.
7.3 These tests should not be conducted if the reference product is already considered as causing skin or eye corrosion/irritation.

8 - Evaluation of the technical products equivalence – Phase III
Required Studies

8.1 The toxicological studies required for equivalence evaluation in Phase III according to item 16.8, Annex II, of Decree number 4,074/2002 are defined based on the results of the structure-activity ratio studies or other available toxicological data.
8.2. When the toxicological studies are conducted with the technical product batches of the product which qualitative and quantitative composition is determined and with impurities level next to the stated value should be used.

Annex IV

Toxicological Classification

1 . Toxicological Classification of agrochemicals and related items due to the oral (DL_{50}), skin (DL_{50}), and inhalatory (CL_{50}) acute toxicity

1.1 For purposes of toxicological classification the agrochemicals and related items that are assigned to category 1 are classified in class I as extremely toxic; the ones that are assigned to category 2 are classified in class II as highly toxic; the ones that are assigned to category 3 are classified in class III as relatively toxic, and the ones assigned to category 4 are classified in class IV as low toxic.

1.2 The criteria for classification are included in table 1

Table 1 – Classification of the agrochemicals and related items due to the acute toxicity

Exposure route		**Category 1**	**Category 2**	**Category 3**	**Category 4**
Oral (mg/kg b.w.)		≤ 5	>5 - ≤50	>50 - ≤300	>300
Skin (mg/kg b.w.)		≤ 50	>50 - ≤200	>200 - ≤1000	>1000
Inhalatory	**Gases** (ppm/V)	≤ 100	>100 - ≤500	>500 - ≤2500	>2500
	Solid and liquid products (mg/L)	≤ 0.05	>0.05 - ≤0.5	>0.5 - ≤1.0	>1.0

b.w. = body weight;
ppm/V = parts per million by volume

1.3 The concentration limits for toxicity via inhalatory route presented in table 1 are based on 4-hour exposure assays.

1.4 The toxicological classification of an agrochemical or related item will be determined by the category of the most restrictive result obtained in the acute toxicological studies.

1.5 When a breathable atmosphere is not reached within the conditions required by the study protocol with concentrations ≥ 1.0 mg/L and there is no mortality in the inhalatory toxicity study these data will not be used for purposes of product classification; however these information will be used for communicating the hazard.

1.6 When a formulated product has not been tested for determination of its acute toxicity but there are enough data on each component and also on other similar formulated products already tested the acute toxicity determination of this new formulated product may be made according to the following extrapolation rules:

a) If an already-tested formulated product is diluted with a new solvent/diluents that has a toxicity similar to or lower than the already-tested product and it is not expected that this new solvent/diluents affects the toxicity of other components the new formulated product may be classified in the same category of the original formulated product.

b) Products formulated with identical components:

Three products: (1)A
(2)B
(3)C

i) Products A and B have been tested and have the same toxicological category;
ii) Product C has the same toxicologically relevant components of products A and B but in intermediary concentrations between mixtures A and B;
iii) Then product C is considered as being in the same toxicologically relevant category of products A and B.

c) Substantially similar formulated products according to the following model:

Two products: (1) A + B
(2) C + B

i) Component B concentration is essentially the same in both products;
ii) Component A concentration in product (1) is equivalent to the one of component C in product (2);
iii) Toxicological classification data for A and C are available and are substantially equivalent, i.e., they are in the same hazard category and it is not expected that they affect the toxic potential of B.
iv) If any of the products (1 or 2) is already classified based on the toxicological studies then the other product (1 or 2) will be classified in the same hazard category.

2- Skin corrosion/irritation

2.1 For purposes of hazard communication the agrochemicals, their components, and related items may be classified in categories 1 or 2 depending on the injury level observed in the skin corrosion/irritation test or in the results of the phased tests with approach on the evidence strength.

2.2 The classification criteria should follow a phased tests strategy approaching the evidence strength in order to determine the need of conducting *in vivo* tests, considering the existing data in humans and animals as well as the result of the *in vitro*, *in silico* tests, physical-chemical data etc.

2.3 The classification via test strategy based on the evidence strength should follow the following phases:

2.3.1 The first line of evaluation should include information on existing data in humans and animals after single or repeated exposure with direct relevance on the skin effects.

2.3.2 The data on the acute skin toxicity may be used for classification mainly if the test-substance is highly toxic via skin route.

2.3.3 The data of alternative, validated, and internationally recognized methods for regulatory purposes may be used to select a classification.

2.3.4 The data on the physical-chemical properties of a test-substance may indicate effects in the skin. In the absence of any other information a test-substance with pH ≤2 or ≥11.5 is classified in category 1 as being corrosive to the skin.

2.3.5 In some cases the data of the *in silico* methods may be used to select a classification.

2.4 The criteria for classification from *in vivo* studies are included in table 2. Classified in category 1 are the agrochemicals, components, or related items that show evidences of causing skin corrosion with skin tissue destruction, resulting in a visible necrosis at the entire epidermis and reaching the dermis or when there are evidences of this destruction when applying the phased tests strategy.

Classified in category 2 are the agrochemicals or related items that show evidences of causing skin irritation with: (1) Score means ≥ 2.3 and ≤ 4 for erythema/bedsores or edema or when there are evidences of this type of injury when applying the phased tests strategy; or (2) Persistent inflammation during 14 days; or (3) Cases where there is an acute variability of responses among the animals with well-defined positive effects related to the exposure to the test-substance in a single animal but not reaching the above defined criteria.

Table 2 - Classification of agrochemicals, components, and related items according to the tests strategy results for skin corrosion/irritation.

	Criteria
Category 1	Skin tissue destruction resulting in visible necrosis at the entire epidermis and reaching the dermis in at least one animal subjected to the assay after exposure ≤ 4 hours.
Category 2	(1) Score means ≥ 2.3 and ≤ 4 for erythema/bedsores or edema in at least 2 of 3 animals tested in readings of 24, 48, and 72 hours after removal of the patches or in case of late reactions observations obtained during 3 consecutive days after the skin reactions onset and/or (2) Inflammation persistence until the end of the observational period (normally 14 days) in at least 2 animals particularly taking into account alopecia (limited zone), hyperkeratosis, hyperplasia, and scaling, and/or (3) Cases where there is an acute variability of responses among the animals with well-defined positive effects related to the exposure to the test-substance in a single animal but not reaching the above defined criteria.

2.5 Classification of agrochemicals or related items when there are data in relation to the product.

2.5.1 The agrochemicals or related items should be classified according to the criteria adopted for active components considering the phased approach for evaluation of this hazard category.

2.6 Agrochemicals or related items classification according to the extrapolation principles when there are not data related to the product.

2.6.1 When the agrochemical or related item itself has not been tested for determination of its skin corrosion/irritation potential but there are enough data on each component individually and tests conducted with similar formulated products that may properly characterize the hazards of the mentioned product these data are used in accordance with the following extrapolation principles:

a) Dilution: if an already-tested formulated product is diluted with a new solvent/diluents that has a skin corrosion/irritation potential similar to or lower than the one of the original product and it is not expected that this new solvent/diluents affects the toxicity of other components the new formulated product may be classified in the same category of the original formulated product.

b) If a product is classified in category 1 and the concentration of the components classified in this category is higher the new formulated product should be classified in this same hazard category.

c) Interpolation within the same category of skin corrosion/irritation potential:

Products formulated with identical components:

Three products: (1)A

(2)B

(3)C

i) Products A and B have been tested and have the same toxicological category;

ii) Product C has the same toxicologically relevant components of products A and B but in intermediary concentrations between mixtures A and B;

iii) Then product C is considered as being in the same toxicologically relevant category of products A and B.

d) Substantially similar formulated products according to the following model:

Two products: (1) A + B

(2) C + B;

i. Component B concentration is essentially the same in both products;

ii. Component A concentration in product (1) is equivalent to the one of component C in formulated product (2);

iii. Skin corrosion/irritation data for A and C are available and are substantially equivalent, i.e., they are in the same hazard category and it is not expected that they affect the corrosion/irritation potential of B.

iv. If any of the products (1 or 2) is already classified based on the toxicological studies then the other product (1 or 2) will be classified in the same hazard category.

2.7 Classification of the agrochemicals or related items when there are data for all or some of the product components

2.7.1 In relation to the agrochemicals or related items the following assumptions are established and applied when appropriate in a phased approach in order to make use of all the available data for purposes of classification in relation to the skin corrosion/irritation potential:

a) When there are available data for all the components but not for the final formulated product the approach for classification as skin corrosive/irritant product of the formulated products is based on the increment theory wherein each skin irritant/corrosive component adds for the corrosive or irritant properties of the formulated product in the proportion of its strength and concentration. A weight factor of 10 is used for corrosive components when they are present in a concentration below the limit concentration for classification in category 1 but which concentration adds for the classification of the mixture as irritant. The product is classified as corrosive or irritant to the skin when the sum of the concentrations of each component exceeds a cut-off/limit concentration value.

b) Table 1 shows the cut-off limit values/concentrations used for the formulated product classification as corrosive or irritant to the skin.

Table 1. Concentration of components by category used for the formulated product hazard classification in categories 1 or 2 of skin corrosion/irritation.

Sum of the components classified in relation to the corrosion/irritation potential	**The reached concentration results in the product being classified as:**	
	Skin corrosive	**Skin irritant**
	Category 1	**Category 2**
Category 1	≥ 5 %	≥ 1% but < 5%
Category 2		≥ 10%
(10 x category 1) + Category 2		≥ 10%

2.7.2 The approach explained in item "a" for certain types of chemical compounds, as acids and bases, inorganic salts, aldehydes, phenols, and surfactants may not be enough since many of such compounds are corrosive or irritant in concentrations <1%.

2.7.3 For formulated products containing strong acids or bases the pH should be used as classification criterion provided that the pH is a better indicative of corrosion than the limit concentrations described in table 1.

2.7.4 A mixture containing corrosive or irritant components and that cannot be classified based on the increment approach according to table 1 due to chemical characteristics that make such an approach impracticable should be classified as skin corrosive in category 1 if it contains ≥ 1% of corrosive components and classified as skin irritant in category 2 if it contains ≥ 3% of irritant components. The classification of products with components that cannot be approached according to table 1 is summarized in table 2.

Table 2 Concentration of a formulated product components when the increment approach is not applicable for the skin corrosion/irritation potential

Component	Concentrations	Formulated product classification
Acids with pH ≤ 2	≥ 1%	Category 1
Bases with pH ≥ 11.5	≥ 1%	Category 1
Other corrosive components (Category 1)	≥ 1%	Category 1
Other irritant components (Category 2), including acids and bases	≥ 3%	Category 2

3. Eye corrosion/irritation

3.1 For purposes of hazard communication the agrochemicals, their components, and related items may be classified in categories 1 or 2 depending on the injury level observed in the eye corrosion/irritation test or in the results of the phased tests with approach on the evidence strength.

3.2 For purposes of classification a test-substance corrosive to the eyes is classified in category 1; a test-substance severely irritant to the eyes is classified in category 1; and a test-substance irritant to the eyes is classified in category 2.

3.3 The classification criteria should follow a phased tests strategy approaching the evidence strength in order to determine the need of conducting *in vivo* tests, considering the existing data in humans and animals as well as the result of the *in vitro/ex vivo*, *in silico* tests, physical-chemical data etc.

3.4 The classification via test strategy based on the evidence strength should follow the following phases:

3.4.1 The first line of evaluation should include information on existing data in humans and animals with direct relevance on the eye effects. Substances demonstrating corrosive properties to the skin are considered corrosive to the eyes and classified in category 1.

3.4.2 The data on the acute skin toxicity may be used for classification mainly if the test-substance is highly toxic via skin route.

3.4.3 The data of alternative, validated, and internationally recognized methods for regulatory purposes may be used to select a classification.

3.4.4 The data on the physical-chemical properties of a test-substance may indicate effects in the eyes. In the absence of any other information a test-substance with pH ≤2 or ≥11.5 is classified in category 1 as being corrosive to the eyes.

3.4.5 In some cases the data of the *in silico* methods may be used to select a classification.

3.5 The criteria for classification from *in vivo* studies are included in table 3. Classified in category 1 are the agrochemicals, components, and related items capable of causing serious injuries to the eyes, i.e., irreversible effects in the eyes with evidences of causing severe eye corrosion or irritation with: (a) effects on the cornea, iris, or conjunctiva without total reversion for 21 days or when there are evidences of this type of injury when applying the phased tests strategy; or (b) corneal opacity ≥ 3 and/or iritis > 1.5 or when there are evidences of this type of injury when applying the phased tests strategy. Classified in category 2 are the agrochemicals, components, or related items that show evidences of causing irritation to the eyes with: (a) corneal opacity ≥ 1 and/or iritis ≥ 1 and/or conjunctival hyperemia ≥ 2 and/or conjunctival swelling (chemosis) ≥ 2.

Table 3 - Classification of agrochemicals, components, and related items according to the tests strategy results for eye corrosion/irritation.

	Criteria
Category 1	A substance that produces: (a) Effects on the cornea, iris, or conjunctiva that cannot be reversed or in relation to which it is expected that there is no total reversion within the observational period of 21 days in at least one of the animals tested; and/or (b) In at least 2 of 3 animals tested a positive response of: (i) Corneal opacity with mean score ≥ 3; and/or (ii) Iritis with mean score >1.5; The score means should be calculated in evaluations conducted within 24, 48, and 72 hours of test-substance instillation
Category 2	Substances that produce in at least 2 of 3 animals tested a positive response of: i. Corneal opacity with mean score ≥ 1 and/or ii. Iritis with mean score ≥ 1 and/or iii. Conjunctival hyperemia with mean score ≥ 2 and/or iv. Conjunctival swelling (chemosis) with mean score ≥ 2 The score means should be calculated in evaluations conducted within 24, 48, and 72 hours of test-substance instillation. The observed effects should be totally reversed after the observational period of 21 days.

3.6. Classification of agrochemicals or related items when there are data in relation to the product.

3.6.1 The agrochemical or related item should be classified using the same criteria for active components and taking into account the phased approach for evaluation of this hazard category.

3.7. Agrochemicals or related items classification according to the extrapolation principles when there are not data related to the product.

3.7.1 When the agrochemical or related item itself has not been tested for determination of its eye corrosion/irritation potential but there are enough data on each component individually and tests conducted with similar formulated products that may properly characterize the hazards of the mentioned product these data are used in accordance with the following extrapolation principles:

a) If an already-tested formulated product is diluted with a new solvent/diluents that has potential for producing severe injuries to the eyes/eye irritation similar to or lower than the one of the original product and it is not expected that this new solvent/diluents affects the toxicity of other components the new formulated product may be classified in the same category of the original formulated product.

b) If a product is classified in category 1 and the concentration of the components classified in this category is increased the new formulated product should be classified in this same hazard category without the need of additional studies.

c) Interpolation within the same category of potential for producing severe injuries to the eyes/eye irritation:

Products formulated with identical components:
Three products: (1)A
(2)B
(3)C

i) Products A and B have been tested and have the same toxicological category;

ii) Product C has the same toxicologically relevant components of products A and B but in intermediary concentrations between mixtures A and B;

iii) Then product C is considered as being in the same toxicologically relevant category of products A and B.

d) Substantially similar formulated products according to the following model:

Two products: (1) A + B
(2) C + B

i) Component B concentration is essentially the same in both products;

ii) Component A concentration in product (1) is equivalent to the one of component C in formulated product (2);

iii) Eye corrosion/irritation data for A and C are available and substantially equivalent, i.e., they are in the same hazard category and it is not expected that this affects the potential for causing severe damages to the eyes/eye irritation of B.

iv) If any of the products (1 or 2) has already been considered as potentially causing severe damages to the eyes/eye irritation based on the toxicological studies then the other product (1 or 2) will be classified within the same hazard category.

3.8 Classification of the agrochemicals or related items when there are data for all or some of the product components.

3.8.1 In relation to the agrochemicals or related items the following assumptions are established and applied when appropriate in a phased approach in order to make use of all the available data for purposes of classification in relation to the potential for causing severe damages to the eyes/eye irritation:

a) When there are available data on all the components but not on the final formulated product the approach of classifying the agrochemicals or related items as capable of producing severe damages to the eyes/eye irritation will be based on the increment theory wherein each component capable of producing severe damages to the eyes/eye irritation adds for the corrosive or irritant properties of the formulated product in the proportion of its strength and concentration. A weight factor of 10 is used for components that produce irreversible damages to the eyes when they are present in a concentration below the limit concentration for classification in category 1 but which concentration adds for the classification of the mixture as irritant. The product will be classified as corrosive or irritant to the eyes when the sum of the concentrations of each component exceeds a cut-off/limit concentration value.

b) Table 3 shows the cut-off limit values/concentrations to be used for classifying the formulated product as corrosive or irritant to the eyes.

Table 3. Concentration of components by category for the formulated product hazard classification in categories 1 or 2 in relation to the potential for producing severe damages to the eyes or eye irritation.

Sum of the components classified as:	**The reached concentration results in the product being classified as:**	
	Severe damages to the eyes (irreversible effects on the eyes)	Irritant to the eyes (reversible effects on the eyes)
	Category 1	**Category 2**
Skin corrosive in category 1 and/or with potential for causing severe damages to the eyes in category 1[a]	≥ 3 %	≥ 1% but < 3%
Eye irritant in category 2		≥ 10%[b]
10 x (skin corrosive in category 1 + with potential for causing severe damages to the eyes in category 1)[a] + eye irritant in category 2		≥ 10%

[a]*: if a component is classified as skin corrosive (category 1) and is capable of producing severe damages to the eyes (category 1) its concentration should be considered only once in the calculation;*

[b]*: A formulated product may be classified as eye irritant - category 2B - when all the relevant components are classified as eye irritant in category 2B.*

3.8.2 The approach explained in item "a" for certain types of chemical compounds, as acids and bases, inorganic salts, aldehydes, phenols, and surfactants may not be enough since many of such compounds may produce severe damages to the eyes or eye irritation in concentrations <1%.

3.8.3 For formulated products containing strong acids or bases the pH should be used as classification criterion provided that the pH is a better indicative of corrosion than the limit concentrations described in table 3.

3.8.4 A mixture containing corrosive or irritant components and that cannot be classified based on the increment approach according to table 3 due to chemical characteristics that make such an approach impracticable should be classified as being capable of producing severe damages to the eyes in category 1 if it has ≥ 1% of corrosive components and as eye irritant in category 2 if it has ≥ 3% of irritant components.

3.8.5 The classification of products with components that cannot be approached according to table 3 is summarized in table 4.

Table 4. Concentration of a formulated product components when the increment approach is not applicable for the potential of producing severe damages to the eyes or eye irritation:

Component	Concentrations	Formulated product classification
Acids with pH ≤ 2	≥ 1%	Category 1
Bases with pH ≥ 11.5	≥ 1%	Category 1
Other corrosive components (Category 1)	≥ 1%	Category 1
Other irritant components (Category 2)	≥ 3%	Category 2

4. Criteria for classification of skin sensitizer

4.1 The substances are classified as skin sensitizer in category 1 according to the following criteria:

a) If there are evidences obtained in human beings showing that the substance may cause hypersensitivity through contact with the skin; or

b) If an appropriate assay conducted in animals has positive results.

4.2 Studies in animals:

4.2.1 The following results are considered in skin sensibility studies for classifying a substance as sensitizer following the limitations and indications of each protocol:

(a) ≥30% positive results in assays of skin sensibility using an adjuvant.

(b) ≥15% positive results in skin sensibility studies not using adjuvants.

(c) Stimulation index ≥ 3 in the local lymph node study.

4.3 The solicitant company should inform cases where the product or its components are suspected of being potential respiratory sensitizers.

4.4 Criteria for formulated products classification when there are no available data on the product itself

4.4.1 When the formulated product itself has not been tested for evaluation of its sensibility properties but there are enough data both on the individual components and similar mixtures tested that may appropriately characterize the hazards of such formulated product these data will be used according to the following extrapolation principles:

a) If an already-tested formulated product is diluted with a new solvent/diluents that has a skin sensibility potential similar to or lower than the one of the original product and it is not expected that this new solvent/diluents affects the toxicity of other components the new formulated product may be classified in the same category of the original formulated product.

(b) Interpolation within the same category of sensibility potential:

Products formulated with identical components:

Three products: (1)A

(2)B

(3)C

i) Products A and B have been tested and have the same toxicological category;

ii) Product C has the same toxicologically relevant components of products A and B but in intermediary concentrations between mixtures A and B;

iii) Then product C is considered as being in the same toxicologically relevant category of products A and B.

(c) Substantially similar formulated products according to the following model:

Two products: (1) A + B

(2) C + B

i) Component B concentration is essentially the same in both products;

ii) Component A concentration in product (1) is equivalent to the one of component C in formulated product (2);

iii) Sensibility data for A and C are available and are substantially equivalent;

iv) If product (1) or (2) is already considered as a sensitizer based on studies the other product will also be considered as a sensitizer.

4.5 Classification of the agrochemicals or related items when there are data for all or some of the product components

4.5.1 The formulated product is classified as skin sensitizer when at least one of the components has been classified as skin sensitizer in concentrations ≥ 0.1%.

5. Mutagenicity

Table 4 - Hazard categories for classification of agrochemicals, their components, and related items in relation to the mutagenicity.

Categories	Descriptions and Criteria
Category 1A	**Agrochemicals, their components, and related items known as inducing hereditary mutations in germinative cells of human beings.** This classification is based on positive evidences from epidemiologic studies in human beings.
Category 1B	**Agrochemicals, their components, and related items that presumably induce hereditary mutations in germinative cells of human beings.** This classification is based on: - positive results in studies that show mutagenic effects or other genotoxic effects in germinative cells of human beings without demonstrating transmission to progeny, e.g., when an increase in the aneuploidy frequency is observed in sperm cells of exposed individuals; or - positive results of *in vivo* mutagenicity studies in germinative cells of mammals; or - positive results of *in vivo* mutagenicity studies in somatic cells of mammals in combination with evidences that the substance has potential for causing mutations in germinative cells. This evidence can be based on mutagenicity studies or studies of other genotoxic effects in germinative cells *in vivo* or by demonstrating the ability of the substance or its metabolites of interacting with the genetic material of germinative cells; or - positive results of *in vivo* mutagenicity studies in somatic cells of mammals in the absence of an *in vivo* mutagenicity study in germinative cells.
Category 2	**Agrochemicals, their components, and related items that show indication of causing genotoxic effects but without evidences of causing mutagenicity in germinative cells.** This classification is based on: - positive results of *in vivo* mutagenicity studies in somatic cells of mammals in combination with negative results of mutagenicity studies and studies of other genotoxic effects (not mutagenic effects) in germinative cells *in vivo*; or - positive results of *in vivo* genotoxicity studies in somatic cells (not mutagenic cells) that are supported by positive results of *in vitro* mutagenicity studies; or - positive results in *in vitro* mutagenicity studies in mammals cells in combination with evidences of the structure-activity ratio of the test-substance with mutagens known in germinative cells

5.1 The agrochemicals, their components, and related items not included in categories 1A, 1B, or 2 are not classified in relation to the mutagenicity.

5.2 The agrochemicals, their components, and related items are classified in categories 1A, 1B, or 2 when at least one of the components is classified within these categories.

5.3 When the agrochemicals, their components, and related items are classified in category 2 warning text should be inserted in the labels and package insert of the agrochemicals and related items according to Annex VII.

5.4 The classification of agrochemicals, their components, and related items in relation to the mutagenicity is made based on the evidence strength evaluation according to the following considerations:

a) The evidence strength is influenced by factors such as the studies quality, the number of tested doses, the consistency and reproducibility of the results, the statistic significance level for the differences among the groups, and the presence or absence of deviations and confounding factors;

b) Data of substances analog to the active component, the other components, the impurities, and/or the metabolites and analyses of structure-activity ratio may be considered in the evaluation of the evidence strength;

c) Mutagenicity and/or genotoxicity studies not included in Annex I or Annex II may be considered in the evaluation of the evidence strength.

6 - Carcinogenicity

6.1 In relation to carcinogenicity the agrochemicals, their components, and related items are classified in hazard categories 1A, 1B, or 2.

Table 5 Hazard categories for classification of agrochemicals, their components, and related items in relation to carcinogenicity.

Categories	Descriptions and Criteria
Category 1A	**Agrochemicals, their components, and related items known for showing carcinogenic potential for human beings.** This classification is widely based on evidences from epidemiologic studies in human beings. There are enough evidences of carcinogenicity in epidemiologic studies when a causal relationship is established between the exposure to the products and the onset of cancer in human beings in studies in which chances, deviations, and confounding factors may be excluded with reasonable confidence. Agrochemicals, their components, and related items may also be included in this category when the carcinogenicity evidence in human beings is not enough but there are enough evidences of carcinogenicity in tested animals supported by mechanistic studies except if there is strong evidences that the action form or mechanism of tumor formation in animals is not relevant for human beings.
Category 1B	**Agrochemicals, their components, and related items that presumably have carcinogenic potential for human beings.** This classification is widely based on enough evidences of carcinogenicity in tested animals. There are enough evidences of carcinogenicity in tested animals when a causal relationship is established between the exposure to the products and the increase in the incidence of malignant tumors or the increase of a combination of benign and malignant tumors in: (a) More than one animal species; or

	(b) More than one independent study in a species conducted in different times or in different laboratories or under different protocols; or (c) A well-conducted study in which there was an increase in the incidence of tumors in both genders of a single species; or (d) A single study in only one species and one gender of animals when malignant tumors occur in uncommon level of incidence, location, type of tumor, or early onset, or when there are findings of tumors in various tissues/organs. Limited evidence of carcinogenicity in epidemiologic studies with limited evidence of carcinogenicity in tested animals can also justify the product classification in category 1B. Agrochemicals, their components, and related items are classified in this category when there are evidences that the action form or mechanism of tumor formation in animals is relevant to human beings even if the evidence is limited to one test and one gender. Agrochemicals, their components, and related items are not classified in this category when there are strong evidences that the action form or mechanism of tumors formation in animals is not relevant to human beings.
Category 2	**Agrochemicals, their components, and related items suspected of being carcinogenic in human beings.** This classification is based on evidences obtained from epidemiologic data and/or studies in animals but that are not convincing enough for determining the classification in categories 1A or 1B based on the evidence strength. The data can be from limited evidence of carcinogenicity in epidemiologic studies or limited evidence of carcinogenicity in studies with animals. There is limited evidence of carcinogenicity in epidemiologic studies when a positive association is observed between the exposure to the products and the onset of cancer in human beings, but the chances, deviations, and confounding factors may not be excluded with reasonable confidence. There is limited evidence of carcinogenicity in studies with animals when the data suggest a carcinogenic effect but are limited for a definitive evaluation because, for example: (a) There are open questions in relation to the design adequacy, study conduction or interpretation; or (b) The product increases only the incidence of benign tumors or injuries of uncertain neoplastic potential; or (c) The carcinogenicity evidence is restricted to a single test and to a single gender of a single species; or (d) The carcinogenicity evidence is restricted to studies that show only promotion activity in a few tissues or organs. <u>Note</u>: agrochemicals, their components, and related items classified in category 2 are not considered as carcinogenic but can be re-evaluated when additional and relevant information are available.

6.1 The agrochemicals, their components, and related items not included in categories 1A, 1B, or 2 are not classified in relation to carcinogenicity.

6.2 In certain cases a classification for a specific route may be justified if it is corroborated that no other exposure route represents a hazard by the product registration solicitant.

6.3 The agrochemicals, their components, and related items are classified in categories 1A, 1B, or 2 when at least one of the components is classified within these categories. However when reliable evidences from epidemiologic studies in human beings or from studies in animals are available for the agrochemicals and related items these will be classified by the evaluation of the evidence strength of these data.
6.4 When the agrochemicals, their components, and related items are classified in category 2 warning text should be inserted in the labels and package insert of the agrochemicals and related items according to Annex VII.
6.5 The classification of agrochemicals, their components, and related items in relation to carcinogenicity is made based on the evaluation of the evidence strength.
6.6 The evidence strength includes the listing of tumors in the epidemiologic studies and in the studies in animals and the determination of its statistic significance level, the number of tested doses, its relevance for the human health, and the response reproducibility.
6.7 The evaluation of the evidence strength means considering together all the information available for carcinogenicity including epidemiologic studies and reports of cases in humans, subchronic and chronic studies, structure-activity ratio, action form and/or mechanism studies, and other studies. The evidence strength is influenced by factor such protocols used in the studies, study quality, results consistency, the effects nature and severity, the statistic significance level for the differences between the groups, the number of affected *endpoints*, and the presence or absence of deviations or confounding factor.

6.8 Evidences resulting from other studies such as data on physical-chemical characteristics, toxicokinetics and toxicological studies as well as information on the structure-activity ratio, *in vitro* assays and other tests when available are also considered.
6.9 The results of the toxicokinetics studies, location of action, and action form or mechanism may provide relevant information that reduce or increase the concerns about the hazards to the human health. If it is conclusively demonstrated that the action form or mechanism clearly identified is not relevant to human beings or when the toxicokinetics differences are so high that it is concluded that there will be no hazards to human beings then the agrochemicals, their components, and related items that are carcinogenic to laboratory animals are not classified as carcinogenic to human beings (Category 1).
6.10 It is recognized that genetic events are a priority in the global process of cancer development. This evidence of *in vivo* mutagenic activity can indicate that the substance has potential for causing carcinogenic effects and adds for the evidence strength of carcinogenicity in human beings.

7– Reproductive toxicity

7.1 In relation to the reproductive toxicity the agrochemicals, their components, and related items are classified in hazard categories 1A, 1B, or 2. Within each category the adverse effects on the reproductive physiology and the adverse effects on the embryo fetal or neonatal development are considered separately.

Table 6 Hazard categories for classification of agrochemicals, their components, and related items in relation to the reproductive toxicity.

Categories	Descriptions and Criteria
Category 1A	**Agrochemicals, their components, and related items known for causing human reproductive toxicity.** Classification in category 1A is widely based on evidences in human beings. Agrochemicals, their components, and related items are classified in this category when: - they are known for causing adverse effects on the human reproductivity physiology; and/or - they are known for causing adverse effects on the embryo fetal or neonatal development in human beings.
Category 1B	**Agrochemicals, their components, and related items that presumably cause human reproductive toxicity.** Classification in category 1B is widely based on data of studies in animals. Agrochemicals, their components, and related items are classified in this category when: - there are limited evidences on the human reproductive toxicity supported by evidences of reproductive toxicity in studies in animals; - there are evidences in studies in animals possibly supported by other information that provide strong assumption that the product can cause adverse effect on the human reproductive toxicity. The data should provide clear evidences of the adverse effect on the reproductive physiology in the absence of other toxic effects. If the adverse effects occur together with other toxic effects they should not be considered as a non-specific secondary consequence of other effects; and/or - there are evidences in studies in animals possibly supported by other information that provide a strong assumption that they can cause adverse effects on the embryo fetal or neonatal development. The data should provide clear evidences of the adverse effect on the embryo fetal or neonatal development in the absence of other toxic effects. If the adverse effects occur together with other toxic effects they should not be considered as a non-specific secondary consequence of other effects. Note: Agrochemicals, their components, and related items are not classified in this category when there are strong evidences that the reproductive toxicity form or mechanism in animals is not relevant to human beings.
Category 2	**Agrochemicals, their components, and related items suspected of causing human reproductive toxicity.** Agrochemicals, their components, and related items are classified in this category when: - there are evidences of the adverse effect on the reproductive physiology in human beings or in tested animals possibly supported by other information but the evidences are not convincing enough for classification in category 1; and/or - there are evidences of the adverse effect on the embryo fetal or neonatal development in human beings or in tested animals possibly supported by other information but the evidences are not convincing enough for classification in category 1.

	Note: agrochemicals, their components, and related items classified in category 2 are not considered as toxic to the reproductive physiology nor to the embryo fetal or neonatal development in human beings but can be re-evaluated when additional and relevant information are available.

7.1 The agrochemicals, their components, and related-items not included in categories 1A, 1B, or 2 are not classified in relation to the reproductive toxicity.

7.2 The agrochemicals, their components, and related items that interfere with lactation or that may be present (including their metabolites) in the breast milk in amount enough to cause concerns in relation to the health of infants are classified in relation to this property for purposes of labeling separately from the adverse effects on the reproductive physiology and the adverse effects on the embryo fetal or neonatal development. This classification for purposes of labeling is based on:

a) evidences in human beings indicating hazard to the infants during the lactation period; and/or

b) results from studies with one or two generations conduced in animals that provide clear evidences of adverse effects on the descendants due to the substance transferring through the milk or of adverse effects on the milk quality; and/or

c) toxicokinetics studies indicating the possible presence of active component, other components, impurities, and/or metabolites at potentially toxic levels in breast milk.

7.3 When the agrochemicals, their components, and related items are classified in relation to the reproductive toxicity in category 2 a warning text should be inserted in the label and package insert of the agrochemicals and related items.

7.4 In relation to the reproductive toxicity, the agrochemicals, their components, and related items are classified in categories 1A, 1B, or 2, and/or for effects on the lactation or through lactation when at least one of the components is classified in these categories.

7.5 The agrochemicals, their components, and related items classification in relation to the reproductive toxicity is made based on the evaluation of the evidence strength, i.e., considering together all the information available for evaluation of the reproductive toxicity such as epidemiologic studies and reports of cases in humans, and studies conducted in animals such as reproductive toxicity studies together with subchronic, chronic, and other studies according to the following ponderations:

a) The evidence strength is influenced by factors such as study quality, results consistency, the effects nature and severity, presence of maternal or paternal toxicity in the studies in animals, the statistic significance level for the differences between the groups, the number of affected *endpoints*, the relevance of the administration route to human beings, presence or absence of deviations and confounding factors;

b) Data of substances analog to the active component, the other components, the impurities, and/or the metabolites and analyses of structure-activity ratio, *in vitro* assays and tests with non-mammals may be considered in the evaluation of the evidence strength;

c) A single reproductive toxicity study that has provided statistically or biologically significant-positive results and that has been conducted according to the scientific good practices may be enough for classifying the agrochemicals, their components, and related items in relation to the reproductive toxicity. The classification within a category depends on the positive responses types and extension, on the study conditions, and on additional information;

d) If it is conclusively demonstrated that the action form or mechanism clearly identified in the tested animals is not relevant to human beings or when the toxicokinetics differences are so high that it is concluded that there will be no hazards to human beings then the agrochemicals, their components, and related items that cause reproductive toxicity in laboratory animals are not classified in category 1.

e) When the effects on the development occur in the presence of maternal toxicity these effects will be considered as evidences of the test-substance's direct action unless it can be unequivocally demonstrated that the effect on the development is secondary to the maternal toxicity.

Annex V

Monograph template for plant derivatives or plant drug

MONOGRAPH INDEX	NAME
Completed by Anvisa	Plant species binomial

a) Active component or common name: repeat the plant species binomial included in the header

b) Synonymity: complete with one or more popular names of the plant species

c) Taxonomic classification:

Complete according to the taxonomic classification of the plant raw material

c.1. Kingdom:

c.2. Phylum:

c.3. Class:

c.4. Order:

c.5. Family:

c.6. Genus:

c.7. Species:

c.8. Identification: Plant species binomial, species descriptor name

c.11. Other scientific names: : if applicable. Complete in italics.

d) Agriculture use: authorized as indicated in label and package insert

d.1) Applying modality: application (foliaceous, terrestrial, air, directly in soil etc) in the following culture (mention the culture if the product has restrictions in relation to the culture indication) for the control of (mention the biological target inserting the scientific name binomial followed by the common name between parentheses).

Complete the below table according to the above information.

Cultures	Applying modality	LMR	Safety interval

Information specific to each plant drug or derivative

Monograph index 1 – Identification of the plan drug or derivative (classification and part used)

a) Part used: mention the part used for obtaining the plant phytoactive or derivative

b) Type of plant derivative or drug: mention the type of plant derivative or description of the plant drug characterizing them when appropriate

c) Chromatographic profile:

c.1) Chromatographic method: mention the method name

Stationary phase: Description

Moving phase: Description

Revealer: Description

Reference pattern: Description

c.2) Result description:

It should contain the main points that allow for the characterization and identification of the plant derivative or drug differentiating them from other ones obtained from other species.

d) Phytochemical marker: mention one or more active components of the plant that function as a marker

d.1) Active component: Complete

d.2) CAS number: Complete if any

d.3) Chemical name: Complete

d.4) Raw formula: Complete

d.5) Structural formula: it should be included in a table

e) Chemical group: mention the active component group

f) Type of authorized formulation: complete according to the ABNT NBR classification number 12976/2004 for the analyzed formulation

f.1) Plant/extract ratio:

f.2) Maximum concentration of the marker active component in g/kg of formulated product.

g) Toxicological classification: according to the classification criteria adopted after evaluation of the acute toxicity studies presented in the process

i) Agronomic class: according to the agriculture indication of the formulated product

j) Insert information on the results of the toxicological evaluation described in item XV of Article 38 of this resolution when applicable.

k) Complementary notes: insert complementary information deemed necessary

Annex VI

Section 1- Label

1. Without deviating from Law number 7.802/89 and Decree number 4.074/02 the label should comply with the following dispositions according to the template presented in item 2:

1.1. The following should be in the center column:

Product composition: indicating the active component(s) by chemical name and common name in Portuguese or internationally accepted scientific name as well as the total of other components. When the technical document described in item 72 indicates the presence of components with toxicologically relevant characteristics their chemical names, function, and amount in the formulation should be described;

1.1.1. In labels of control biological agents the following text should be present replacing the toxicological classification: "NOT DETERMINED DUE TO THE BIOLOGICAL NATURE OF THE PRODUCT".

1.1.2. In labels of dynamized products that do not require toxicological studies the following text should be present replacing the toxicological classification: "NOT DETERMINED DUE TO THE HOMEOPATHIC (OR DYNAMIZED) NATURE OF THE FORMULATION".

1.1.3. In labels of traditional use products that not require toxicological studies the following text should be included replacing the toxicological classification: "PLANT ORIGIN PRODUCTS REGISTERED BASED ON THE TRADITIONAL USE".

1.1.4. In labels of microbiological agents the following text should be present replacing the toxicological classification: "NOT DETERMINED DUE TO THE MICROBIOLOGICAL CONDITION OF THE PRODUCT".

1.1.5. In labels of microbiological agents the following text should be included "THIS PRODUCT CONTAINS LIVE MICROORGANISMS".

1.2. The following should be included in the right column:

a) "BEFORE USING THE PRODUCT READ CAREFULLY THE PACKAGE INSERT INFORMATION ON GENERAL PRECAUTIONS, RESIDUE PREPARATION PRECAUTIONS, PRODUCT APPLYING PRECAUTIONS, AND PRECAUTIONS AFTER PRODUCT APPLICATION".

b) Communication of hazards by mean of pictograms and warning text according to Annex X.

c) General precautions and recommendations highlighted inside rectangles containing:

i) First aids indicating the exposure routes and the main precautions to be taken in case of accident;

ii) Antidote and treatments;

iii) "EMERGENCY PHONE NUMBERS FOR MEDICAL INFORMATION": making available the phone number of Intoxication Emergencies and the company's emergency phone number;

iv) Mention to the Brazilian Network of Information and Toxicological Care Centers (Renaciat)/Anvisa/MS), to the Brazilian Case Registry Database (Sinan/MS), and to the Health Surveillance Notification System (Notivisa).

1.2.1. In labels of microbiological agents the following text should be included: "IMMUNOSUPPRESSED INDIVIDUALS OR THOSE WITH RECENT HISTORY OF IMMUNOSUPPRESSION SHOULD NOT HANDLE NOR APPLY THIS PRODUCT SINCE EVERY LIVE MICROORGANISM CAN ACT AS AN OPPORTUNISTIC INFECTION AGENT".

1.3. A colored strip notably separated from the remaining of the label should be included in the below portion of the label with a height equivalent to 15% of the package printing. The colors of this strip correspond to the different toxicological classes according to Art. 35.

a) Along this strip the specific pictograms should be included according to item 3 from the center to the margin and should occupy 50% of the strip height.

b) the pictograms should be printed according to the company presentation and confirmation by Anvisa due to the product characteristics. It should be inserted according to the personal protective equipment (PPE) indicated in "RESIDUE PREPARATION PRECAUTIONS" and "PRECAUTIONS DURING THE APPLICATION". The pictograms included at the left side refer to the handling precautions, and the ones included in the right side refer to the precautions during the application. The pictograms should always be disposed at the clothing order.

2. Label model

[IMAGE]

PRECAUTIONS IN RELATION TO THE ENVIRONMENT
According to the recommendations approved by the responsible body [ILLEGIBLE]
TradeMark®
Registered by the Brazilian Ministry of Agriculture, Livestock and Food Supply under number
_____
COMPOSITION
Chemical name (common name) [ILLEGIBLE]
Other components: [ILLEGIBLE]
NET WEIGHT: According to MAPA
TYPE OF FORMULATION: According to MAPA
REGISTRATION SOLICITANT: According to MAPA
TECHNICAL PRODUCT MANUFACTURER: According to MAPA
FORMULATOR/MANIPULAOR: According to MAPA
Batch number [ILLEGIBLE]
Manufacturing date:
Expiration date:
See Package
BEFORE USING THE PRODUCT READ THE LABEL, PACKAGE INSERT, PRESCRIPTION, AND THE INFORMATIVE DOCUMENT FOR ADDITIONAL INFORMATION ON [ILLEGIBLE] AND KEEP THEM REACHABLE.
THE USE OF PERSONAL PROTECTIVE EQUIPMENT IS MANDATORY.
PROTECT YOURSELF
THE RETURN OF THE EMPTY PACKAJE IS MANDATORY.
Indications and Restrictions of use. See package insert and prescription.
State, federal, and local restrictions: see package insert.
Product registered for culture of: According to MAPA
Brazilian Industry
TOXICOLOGICAL CLASSIFICATION: CLASS _____ TOXIC
CLASSIFICATION OF THE ENVIRONMENTAL HAZARD POTENTIAL: According to the Environmental Body
PRECATUTIONS RELATED TO THE HUMAN HEALTH
BEFORE USING THE PRODUCT READ CAREFULLY THE PACKAGE INSERT INSTRUCTIONS ON GENERAL PRECAUTIONS, RESIDUES PREPARATION PRECAUTIONS, PRODUCT APPLICATION PRECAUTIONS, AND PRECAUTIONS AFTER THE PRODUCT'S APPLICATION.

[FRASE DE PERIGO] = HAZARD TEXT
[PALAVRA DE ADVERTÊNCIA] = WARNING TEXT

FIRST AIDS: [ILLEGIBLE]
INGESTION [ILLEGIBLE]
EYES [ILLEGIBLE]
SKIN [ILLEGIBLE]
INHALATION (BREATHING [ILLEGIBLE]

ANTIDOTE AND EMERGENCY MEDICAL CARE

EMERGENCY PHONE NUMBERS FOR MEDICAL INFORMATION
Intoxication Emergencies [ILLEGIBLE]
Brazilian Network of Information and Toxicological Care Centers (Renaciat)/Anvisa/MS)
Company's emergency phone number

Notify to the Brazilian Case Registry Database/SINAN/MS
Health Surveillance Notification System (NOTIVISA/ANVISA).

PICTOGRAMS RELATED TO HAZARD COMMUNICATION
PICTOGRAMS RELATED TO THE PROPER MEASURES OF INTOXICATION PREVENTION OR RISK MINIMIZING

Strip color: ACCORDING TO THE TOXICOLOGICAL CLASSIFICATION

A: Package's printing height
B: 15% of the package's printing height
C: 50% of the strip's height

3. Pictograms

Maintain it locked and out of the reach of children and domestic animals

Use safety goggles with side protection

Take a shower immediately after the product's application

Use mask with chemical filter against smoke and mist and class P2 or P3 mechanical filter.

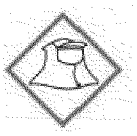
Use water-repellent overalls

Use mask with chemical filter whenever there is no liquid mixture (class P2 or P3 mechanical filter).

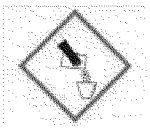
Use impermeable apron

Use nitrile gloves.

Use impermeable boots



Use hood



Indicative of PPE for solid product

Indicative of PPE for liquid product

Indicative of PPE for application

Motorized application

[Caution; poison]

Section 2 - Package Insert

1. Without deviating from Law number 7.802/89 and Decree number 4.074/02 and in addition to all the data included in the label the following information must also be included in the label of agrochemicals and related items:

1.1. GENERAL PRECAUTIONS:

a. "Product exclusively for agriculture use/non-agricultural use".;

b. "Do not eat, drink, nor smoke during the handling and application of the product".;

c. "Do not transport the product together with food, medications, animal's food, animals, and people".;

d. "Do not handle nor apply the product without the recommended personal protective equipment (PPE)".

e. "Do not use equipment with leakage or defects nor remove nozzles, holes, or valves using the mouth.";

f. "Do not use personal protective equipment that are damaged, moist, or expired and follow the manufacturer's recommendations.";

g. "Do not apply next to schools, homes, and other locations with the presence of people and areas of animals farming. Follow the specific technical orientations of a certified professional".;

h. "In case of accidental contact of the person with the product follow the orientations described in the first aids and seek for an emergency clinical service.";

1.2. RESIDUES PREPARATION PRECAUTIONS:

a. "Handle the product in open and ventilated area using the recommended personal protective equipment (PPE).";

b. "In case of accidental contact of the person with the product follow the orientations described in the first aids and seek for an emergency clinical service.";

1.3. PRODUCT APPLICATION PRECAUTIONS:

a. "Safety additional recommendations may be adopted by the technician responsible for the application due to the method used or the safety collective measures used.";

b. "Avoid contact with the treated area to the maximum.";

c. "Apply the product only in the recommended doses and observe the safety interval (time interval between the last application and the harvest).";

d. "Do not allow that animals or not-authorized children or people remain in the area of product application or in areas treated after the application.";

e. "Properly use all the recommended personal protective equipment (PPE) for product application.".

1.4. PRECAUTIONS AFTER THE PRODUCT APPLICATION:

a. "If it is needed to enter in the treated area with the product before the end of the new entry interval use the recommended personal protective equipment (PPE) for use during the application.";

b. "Keep the remaining product closed in its original package in a locked location without the reach of children and animals.";

c. "Take a shower immediately after the product application.";

d. "Change and wash the cloths and the PPE separated from other cloths". When washing the cloths use gloves and impermeable apron.";

e. "Make the maintenance and washing of the equipment after each product application.";

f. "Do not reuse the empty package";

2. Data in relation to the protection of the human health:

2.1 Table of medical information on the active components and other components of toxicological interest containing the following data:

a) chemical group;

Inform the chemical group of each component with toxic potential. These information stipulate the indication of treatment, complications preventions, and the case evolution prevision.

b) toxicological class;

c) exposure route (oral, inhalatory, eye, and skin);

d) Toxicokinetics;

Inform the toxicokinetics of each component with toxic potential discussing the effects interaction (absorption, distribution, metabolism, and elimination).

e) toxicity mechanisms;

Inform the toxicity mechanism of each component with toxic potential.

f) clinical symptoms and signs;

The clinical symptoms and signs should be presented for each component with toxic potential. The symptoms should be included by systems (skin, mucous membranes, nervous system, respiratory system, cardiovascular system etc). The symptomatology evolution should be described.

g) diagnosis;

Describe the signs that should call the attention of the health professional. Describe the clinical situation comparable to the exposure to close the intoxication diagnosis.

Indicate the possible necessary complementary exams.

h) treatment;

Explain with details the procedure of decontamination to be adopted by the health professionals and recommend the use of appropriate personal protective equipment (PPE): apron,

impermeable boots, and nitrile gloves. Explain that in the presence of high concentration of solvents the use of mask with activated charcoal is recommended. It is also necessary to describe the symptomatic treatment and the maintenance treatment of the vital functions according to each case as well the specific treatment of each component with toxic potential or of the interactions of antagonists and antidotes when available.
Also describe the clinical and biological parameters that should be monitored or expected in the case evolution and inform the patient observational period (symptomatic or asymptomatic).

i) contraindications;
Clarify if the vomit inducing is contraindicated or not due to the aspiration risk. Indicate the drug contraindications.

j) synergic effects;
Indicate the additive, synergic, and/or promoting effects of the effects related to the different components.

k) "ATTENTION". The information related to the "EMERGENCY PHONE NUMBERS FOR MEDICAL INFORMATION" should be included in this item making available the phone numbers of Intoxication Emergencies and the company's emergency phone number in addition to mentioning the Brazilian Network of Information and Toxicological Care Centers (Renaciat)/Anvisa/MS. It is necessary to grant a special reservation for notification of aggravations to the Brazilian Case Registry Database/SINAN/MS.

2.2. Action mechanism, absorption, and excretion for laboratory animals;

2.3. Based on the toxicological dossier of the product include the acute toxicology studies results or when available toxicological information on human beings:
a) oral DL50 ;
b) skin DL50 ;
c) inhalatory CL50;
d) skin corrosion/irritation;
e) eye corrosion/irritation;
f) Skin sensibility.

2.4. Chronic effects in laboratory animals or when available in human beings associated to the active component(s) and other components.

2.5. The medical information and the chronic effects in laboratory animals present in the label and package insert of agrochemicals and related items should be duly referenced in the proposals of label and package insert submitted by the company to Anvisa.

Annex VII

Requirements for toxicological evaluation of plant origin products

For purposes of toxicological evaluation plant origin products the documents should be presented in the following order separated by title pages identifying each section:

SECTION 1. Registration Solicitation

1.1 Registration solicitation according to Annex II of Decree number 4.074/2002;
1.2 Technical report;
1.3 Corroboration that the solicitant company is duly registered in such a modality in a State, Federal District, or Regional relevant body;
1.4 Corroboration that the manufacturers settled in the country are duly registered in such a modality in a State, Federal District, or Regional relevant body;
1.5 Document corroborating the legal representative condition of the solicitant company;
1.6 Product's physical analyses certificate;
1.7 Information on the situation of the product, registration, authorized uses, restrictions, and reasons relevant to the country of origin;
1.8 Information on restrictions or prohibitions in relation to products based on the same active component and the reasons in other countries;
1.9 Detailed description of the product's deactivation methods followed by technical document indicating the components reduction strength, identifying the remaining residues and the entity settled in Brazil able to conduct the process;
1.10 Payment receipt of the health surveillance fee;
1.11 Other information.

SECTION 2 – Formulated product data

2.1 Statement by the solicitant on the product's qualitative and quantitative composition indicating the maximum and minimum limits of variation of each component and its specific function followed by laboratory findings of each formulator;
2.2 Printed version of the product's label and package insert when available in the country of origin;
2.3 Indication of use (cultures and biologic targets), detailed information on the product's action form, applying modality (pre-emergency, post-emergency etc.), recommended dose, concentration, type of residue preparation, application form and equipment, period, number, and applications interval;
2.4 Restrictions of use and special recommendations;
2.5 Safety interval;

2.6 New entry interval;
2.7 Specification of the appropriate personal protective equipment for the product application as well as collective protective measures;
2.8 Procedures for packages and application equipment decontamination;
2.9 System of collection and final destination of packages and remaining products;
2.10 Label and package insert template;
2.11 Receipt or protocol of registration in Brazil of all the components including the technical product.

2.11.1 The component registration should be linked to the requested intended use

2.11.2 The components in relation to which the registration was requested should be described.

SECTION 3 – Practicability technical report

3.1. Information on the formulation's indication of use.
3.2. Information available in relation to the product's use restrictions.
3.3. Information on the validity, transportation, and appropriate storing of the product based on the stability studies conducted with the final formulation.
3.4. Other available scientific information.

SECTION 4 - Report on the characterization and qualification of the plant derivative or drug

4.1 Analysis document of the formulated product indicating the method used, specifications, and results obtained for one batch;
4.2 Taxonomic identification and botanic description of the plant species used in the formulation signed by an expert and obtained by the research institution;
4.3 Qualitative and quantitative composition and description of the physical state, aspect, and product's color as well as of the equipment and analytical methods applied to the characterization;
4.4 Detailed action form of the target organism(s);
4.5 Description of the production process including collection of plants and definition of the plant derivatives types according to Annex XI;
4.6 Other available scientific information on the formulated product and its plant drug or derivative.

SECTION 5 – Physical and chemical characterization of the product

5.1. Content of active component in the formulation;
5.2. Chromatographic profile;

5.3. Content of marker;
5.4. Plant drug:plant derivative ratio;
5.5. Solubility/miscibility;
5.6. Density
5.7. pH;
5.8. Thermal and air stability.

SECTION 6. Toxicological studies

6.1 - Acute oral toxicity (oral DL_{50});
6.2 - Acute skin toxicity (skin DL_{50});
6.3 - Acute inhalatory toxicity (inhalatory CL_{50});
6.4 - Acute eye corrosion/irritation;
6.5 - Acute skin corrosion/irritation;
6.6 - Skin sensibility;
6.7 - Mutagenicity studies:
a) Study of genetic mutation in bacterial cells; and
b) *In vitro* study of chromosome damages in mammals cells.
6.8 – Other studies.

SECTION 7 – Residues Studies

7.1 According to specific legislation.

8. General considerations

8.1 The tests should be conducted and the data should be analyzed by means of appropriate statistic methods.
8.2 If the solicitant has conducted additional studies not mentioned in this Annex such studies should be included in the toxicological dossier of the plant origin product.

10 Considerations on the registration solicitation

9.1 Statement on the qualitative and quantitative composition proposed to the plant origin product should be presented by the solicitant indicating when applicable the CAS number and/or SIC (Components Information System) number, its specific function, nominal concentration, maximum and minimum limits of each component variation expressed in g/kg or g/L, and the mass percentile/mass of each component, duly signed by the solicitant company's legal representative.

9.1.1 When the component is a mixture of substances such substances should be described as well as their respective concentrations.
9.2 The mass balance for liquid formulations should be appropriate to the product's density obtained in the report of the physical-chemical properties study; the total amount of solid formulations should be 1000 g/kg.

10 General considerations on the plant derivative or drug characterization and qualification report

10.1 For associations of plant species for which the quantitative determination of a marker by species is not possible the chromatographic profiles that include the presence of at least one marker specific to each species in the association can be presented complemented by the quantitative determination of the greatest number possible of specific markers to each species.

10.2 The technical impossibility of the quantitative determination of a marker for each species of the association should be duly rationalized.

10.3 The production process description should include:

I - Collecting time, phenological stage, and portion of the plant to be used;
II - Substances and methods used for its obtaining and its proportions;
III - Identification of the plant derivative used in the final formulation according to the obtaining process described in Annex V of this rule whether it is obtained in the production process itself of the formulated product or obtained as it is from a third party. In the latest case the production process of the plant derivative should be forwarded with the signature of the company's representative and/or its supplier.
IV - Discussion about likely impurities (microorganisms, foreign material, other portions of the plant) or presence of mycotoxins and presentation of quality control tests showing their maximum and minimum limits.
V - Copy of the Temporary Special Registration (RET) or corroboration of the traditional use of the plant derivative and/or of the product formulation.
VI - Description of the production and the quality control processes conducted at all the steps since the plant raw material obtaining until the final formulation including analysis document of the formulated product, method used, specification and results obtained for a batch of the chromatographic profile assays, or phytochemical prospection and qualitative analysis of the markers specific to each species or quality biological control;

10.4 If the plant derivative or drug is included in a Pharmacopoeia recognized by Anvisa the impurities controlling method described in it should be followed.

11 Considerations on the physical and chemical properties studies

11.1 The chromatographic profile test can be conducted with the plant derivative or drug alone or in the formulation.
11.2 The marker content is the concentration present in the phytochemical marker formulation in the plant derivative or drug.
11.3 The information of the parameters of chromatographic profile and marker content may be presented by means of a complete scientific publishing.

12 Considerations on the toxicological studies for formulated products composed by plant drugs or derivatives

12.1 The toxicological studies may be absent in the following cases:
12.1.1 When the plant derivative or drug is included in active components characterization already published in monographs; it should present the same concentration, phytochemical marker, and obtaining form. The formulation should be only in the form of inert fixed oil, water, and/or ethanol or should contain only the plant derivative as component;
12.1.2 When all the formulation components have feeding use including the plant derivative provided its concentration present in the formulation is equal to or lower than the concentration at feeding use;
12.1.3 When the product is characterized as dynamized formulation with strength greater than 12CH or when the strength of each active supply is above the lower limit mentioned in Anvisa's legislation specific to dynamized pharmaceutical products and all the remaining components in the formulation are not toxicologically relevant.
12.1.4 When the formulated product is composed exclusively by the drug derivative or drug and is identified in Anvisa's monograph as a plant origin product with no need of toxicological evaluation for purposes of registration;
12.1.5 When the plant derivative and/or the formulation has its traditional use corroborated.

13 Considerations on dynamized formulations

13.1 The derivatives prepared from one or more active supplies at any strengths according to preparation or controlling methods described in the Brazilian Homeopathic Pharmacopoeia, current edition, or other homeopathic pharmacopoeias or official compendium recognized by Anvisa will be considered dynamized.
13.1.1 For purposes of registration of dynamized formulations the technical document of the vehicle used in the dynamization should be presented instead of the toxicological studies, and a description supported in reference publication of the homeopathy recognized by Anvisa of the potential effects of skin, oral, or inhalatory exposure to repeated doses or to a great amount of the product.

13.1.2 The information on the potential effects of skin, oral, or inhalatory exposure to repeated doses or to a great amount of a dynamized formulation should be included in the label of the formulated product.

14 Considerations on the traditional use corroboration

14.1 The traditional character of use of a plant origin product will be evaluated individually and should be corroborated by means of ethnopharmacological study or ethno-oriented study of use, technical-scientific documents, such as Agronomy Compendium, or other publications that will be evaluated by Anvisa according to the following criteria:
14.1.1.1 indication of application type;
14.1.1.2 coherence of the indications of use proposed with the ones corroborated by traditional use;
14.1.1.3 absence of the toxic risk to the applicator;
14.1.1.4 absence of the toxic chemical substances or groups or if present within the corroborated safety limits; and
14.1.1.5 corroboration of the safety use for a period of 20 years or more.

14.2 The toxicological studies should be evaluated according to the same criteria and considerations established for formulated products included in Annex of this resolution.
14.2.1 Other studies may be rightly requested taking into account the results of the toxicological studies or other sources of information.

Annex VIII

List of components suspected of having registration prohibitive characteristics

Substance	**CAS number**	**Classification**
1-[(2-methoxyphenyl)azo]-2-naphthol	1229-55-6	Carcinogenic 1B
1-Methoxy-2-propanol with a content ≥ 0.3% of 2-methoxypropanol	107-98-2	Reproductive toxic 1B
1-Methyl-2-pyrrolidone	872-50-4	Reproductive toxic 1B
2-Ethoxyethanol	110-80-5	Reproductive toxic 1B
Acrylamide	79-06-1	Carcinogenic 1B Mutagenic 1B
Asbestos, tremolite	77536-68-6	Carcinogenic 1A
Borax anhydrous	1330-43-4	Reproductive toxic 1B

Borax decahydrate	1303-96-4	
Borax pentahydrate	12179-04-3	Reproductive toxic 1B
Boric acid	10043-35-3	Reproductive toxic 1B
Sodium perborate tetrahydrate	10486-00-7	Reproductive toxic 1B
Diisobutyl phthalate	84-69-5	Reproductive toxic 1B
Dimethylformamide	68-12-2	Reproductive toxic 1B
Petroleum distillates, heavy naphthenics treated with hydrogen with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)	64742-52-5	Carcinogenic 1B
Petroleum distillates, heavy paraffinics treated with hydrogen with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)	64742-54-7	Carcinogenic 1B
Petroleum distillates, light naphthenics treated with hydrogen with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)	64742-53-6	Carcinogenic 1B
Petroleum distillates, light paraffinics treated with hydrogen with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)	64742-55-8	Carcinogenic 1B
Petroleum distillates, heavy paraffinics deparaffinized with solvent with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)	64742-65-0	Carcinogenic 1B
Petroleum distillates, heavy paraffinics refined with solvent with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)	64741-88-4	Carcinogenic 1B
Petroleum distillates, light paraffinics refined with solvent with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)	64741-89-5	Carcinogenic 1B
Ethylene oxide (monomer)	75-21-8	Carcinogenic 1B Mutagenic 1B
Petroleum lubricating oils, C15-30, neutral base oil treated with hydrogen with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)	72623-86-0	Carcinogenic 1B
Petroleum lubricating oils,	101316-70-5	Carcinogenic 1B

C17-32, extracted with solvent, deparaffinized, hydrogenated, with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)		
Petroleum lubricating oils, C20-50, neutral base oil treated with hydrogen with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)	72623-87-1	Carcinogenic 1B
Petroleum lubricating oils, C20-50, neutral base oil treated with hydrogen, high-viscosity, with content ≥ 3.0% of extractable materials in DMSO (measured by IP 346)	72623-85-9	Carcinogenic 1B
Heavy alkylate petroleum naphtha, predominantly branched-chain C9-C12, with a content ≥ 0.1% of benzene	64741-65-7	Carcinogenic 1A Mutagenic 1B
Hydrodesulfurized heavy petroleum naphtha predominantly C7-C12, with a content ≥ 0.1% of benzene	64742-82-1	Carcinogenic 1A Mutagenic 1B
Hydrodesulfurized light, dearomatized petroleum naphtha, predominantly paraffins and cycloparaffins C7, with a content ≥ 0.1% of benzene	92045-53-9	Carcinogenic 1A Mutagenic 1B
Heavy hydrogen-treated petroleum naphtha, predominantly C6-C13, with a content ≥ 0.1% of benzene	64742-48-9	Carcinogenic 1A Mutagenic 1B
Light aromatic petroleum naphtha solvent, predominantly C8-C10, with a content ≥ 0.1% of benzene	64742-95-6	Carcinogenic 1A Mutagenic 1B
n-Butane with a content ≥ 0.1% of 1,3-butadiene	106-97-8	Carcinogenic 1A Mutagenic 1B
Nonylphenol ethoxylate	009016-45-9; 009036-19-5	Endocrine dysregulation
Pyridine, alkyl derivative with a content ≥ 0.1% of benzene	68391-11-7	Carcinogenic 1A Mutagenic 1B
Quinoline	91-22-5	Carcinogenic 1B

Annex IX

Hazard evaluation

1 - Formulas for Calculation of Skin and Inhalatory Daily Exposures

Skin daily exposure (EDC):

EDC (mg i.a./kg b.w./day) = (UEd x DMA x AMT) / Body weight

Inhalatory daily exposure (EDI)

EDI (mg i.a./kg b.w./day) = (UEi x DMA x AMT) / Body weight

Where:

mg i.a./kg b.w./day = milligrams of active component by kilogram of body weight each day;

UEc = skin exposure unit

UEi = inhalatory exposure unit

DMA = application maximum dose

AMT = maximum area treated

2 - Formula for Calculation of the Theoretical Maximum Daily Ingestion (IDMT)

$$IDMT = \frac{\Sigma(LMR \times C)}{\text{Body weight}}$$

Where:

LMR = Residue Maximum Limit of Agrochemical in the food

C = Mean daily consumption or availability *per capita* of the food

3 - Formulas for Calculation of the Estimated acute maximum ingestion (IMEA)

Case 1 – when U < 25g or when it is meat, liver, kidney, pastern parts, eggs, grains, oil, and *commodities.*

$$IMEA = \frac{LP \times HR}{\text{Body weight}}$$

Case 2 – when U < LP

$$IMEA = \frac{(U \times HR \times v) + [(LP - U) \times HR]}{\text{Body weight}}$$

Case 3 – when U ≥ LP

IMEA = LP x HR x v _
Body weight

Where:
LP = larger portion consumed
HR = higher concentration of residue
U = weight of each food unit
v = variability factor

4 - Absorption rates and maximum areas of application

4.1 When AOEL is established from a oral route exposure study the skin absorption rate should be considered for purposes of estimative of the labor exposure specific to each formulation being evaluated obtained by means of *in vivo* skin absorption studies in rats and *in vitro* permeation studies in rats and humans or in the absence of such studies the skin absorption rates of 75% for diluted product (<5% of active component) and of 25% for concentrated product (>5% of active component) will be used.
4.2 The inhalatory absorption rate will be of 100% at all cases.
4.3 The maximum areas of application treated by day will be described below but if there are local data validated and rationalized by the solicitant they can be subjected to Anvisa for purposes of evaluation.

	Small size cultures		Large size cultures		Air equipment
	Manual/coastal air equipment	Tractorized equipment	Manual/coastal equipment	Tractorized equipment	
Area treated by day (ha/day)	1	20	1	8	500

Annex X

Hazard communication

1. The agrochemicals, their components, and related items should include a label according to the classification criteria for oral, skin, and inhalatory acute toxicity, skin corrosion/irritation, eye corrosion/irritation, skin sensibility, suspected mutagenicity, suspected carcinogenicity, and suspected reproductive toxicity.

2. The elements of labels and package inserts will vary according to the results of oral, skin, and inhalatory acute toxicological classification and are described in Table 7.

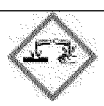
Table 7 - Elements of labels and package inserts for oral, skin, and inhalatory acute toxicity.

	Category 1	Category 2	Category 3	Category 4
Symbol				
Warning text	Hazard	Hazard	Hazard	Attention
Exposure routes	Hazard text			
Oral exposure	Fatal if ingested	Fatal if ingested	Toxic if ingested	Harmful if ingested
Skin exposure	Fatal in contact with the skin	Fatal in contact with the skin	Toxic in contact with the skin	Harmful in contact with the skin
Inhalatory exposure	Fatal if inhalated	Fatal if inhalated	Toxic if inhalated	Harmful if inhalated

Note: If in addition to the inhalatory route toxicity classification there are data indicating that the toxicity mechanism is the corrosivity the substance or mixture should also be labeled as "corrosive to respiratory routes". In addition to the pictogram appropriate for acute toxicity a pictogram of corrosivity can be added (used for skin and eye corrosivity).

3. The elements of labels and package inserts will vary according to the skin corrosion/irritation tests results and are described in Table 8.

Table 8 - Elements of labels and package inserts for skin corrosion/irritation potential.

	Category 1	**Category 2**
Symbol		
Warning text	Hazard	Attention

Hazard texts:	It causes serious damages to the skin and eyes	It causes skin irritation

4. The elements of labels and package inserts will vary according to the eye corrosion/irritation tests results and are described in Table 9.

Table 9 - Elements of labels and package inserts for eye corrosion/irritation potential.

	Category 1	**Category 2**
Symbol		
Warning text	Hazard	Attention
Hazard texts:	Is causes serious damages to the eyes	It causes severe irritation to the eyes

5. The elements of labels and package inserts will vary according to the skin sensibility tests results and are described in Table 10.

Table 10 - Elements of labels and package inserts for skin sensibility potential.

	Skin sensibility category 1
Symbol	
Warning text	Attention
Hazard texts:	It can cause allergic reaction to the skin

6. The elements of labels and package inserts will vary according to the genotoxicity tests results and are described in Table 11.

Table 11 - Elements of labels for genotoxicity potential but without evidences of causing mutagenicity in germinative cells

	Category 2
Symbol	

Warning text	Attention
Hazard texts:	Suspected of causing genotoxic effects (not mutagenic effects)

7. The elements of labels and package inserts will vary according to the carcinogenicity tests results and are described in Table 12.

Table 12 - Elements of labels for products suspected of being carcinogenic in humans

	Category 2
Symbol	
Warning text	Attention
Hazard texts:	**Suspected of being carcinogenic**

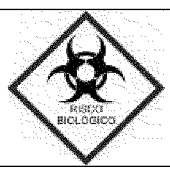
8. The elements of labels and package inserts will vary according to the reproductive toxicity tests results and are described in Table 13.

Table 13 - Elements of labels for products suspected of reproductive toxic in humans

	Category 2
Symbol	
Warning text	Attention
Hazard texts:	**Suspected of causing reproductive toxicity**

9. The elements of labels and package inserts for products that contain microorganism are described in Table 14.

Table 14 - Elements of labels for products that contain microorganisms

Symbol	

Warning text	Attention
Hazard texts:	Biological hazard since it is an agrochemical containing live microorganisms

Annex XI

Definition of the types of plant derivatives used in the formulation of Plant Origin Products

Plant derivatives	Obtaining forms
Raw derivatives	
Pure essential oil	Obtained by vapor entrainment with posterior depauperation of the non-oily fraction.
Active plant oil (pure)	Obtained directly by pressing of the plant raw material.
Seeds raw cake	Trituration followed by pressing of seeds or dry nuts wherein the pressed seed will be used after the oil extraction by pressing or other means.
Plant cake	Trituration of plant raw material that might be: Must - followed by fermentation process.
Aqueous extract	Infusion in water – spillage of boiling water on the plants and permanency for 10 minutes or more. Product of decoction or cooking – Addition of the plant to boiling water with posterior cooking of the plant for 10 minutes or more. Tea – it can be obtained by infusion of decoction, using the teared, smashed, cutted, tritured, or powder plant. Simple maceration with water – tritured plant placed in contact with water, mixtured, and maintained at rest for 10 to 24 hours for juice extraction. Turbolisis (trituration) in water: process in which the teared or cutted plant is placed in hot or cold water and the turbolisis process is initiated (process of agitation and cutting of the plant material similar to the liquefaction process).
Ethanolic extract	Product obtained by cold maceration in ethanol (tinting), hot maceration in ethanol, turbolisis in ethanol, or percolation with ethanol.
Dynamized alcoholic extract	Obtained by cold maceration in ethanol followed by dilution procedure and mechanic or manual succussion.
Homeopathic compound	Product obtained by association of two or more dynamized alcoholic extracts.

Oily extract	Product obtained by cold maceration in inert plant oil. Product obtained by hot maceration in inert plant oil. Product obtained by turbolisis (trituration) in oil.
Dry extract	Extract obtained by infusion, decoction, maceration, percolation, or turbolisis with posterior solvent elimination (water or ethanol) until the complete drying of the initial liquid raw extract.
Fractional derivatives	
Aqueous fraction	Derivatives obtained by secondary steps of extraction from raw extracts fractionated in water.
Alcoholic fraction	Derivatives obtained by secondary steps of extraction from raw extracts fractionated in ethanol.
Dry fraction	Fractionated extracts which solvent (water and ethanol) has been completely evaporated
Others	Derivatives obtained in a different way from the above.
Note: when other solvents are used additional studies will be required as well as the total corroboration of their depauperation in the final plant derivatives.	

To: Parrott, Patricia[parrott.patricia@epa.gov]
From: Dawson, Jeffrey
Sent: Fri 1/29/2016 3:50:02 PM
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
EPA commnets BRA TBT 648 pesticides 12-8-15 d_JD.doc

Ex. 5 - Deliberative Process

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Parrott, Patricia
Sent: Friday, January 29, 2016 10:46 AM
To: Vogel, Dana <Vogel.Dana@epa.gov>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Sent from my iPhone

On Jan 29, 2016, at 9:50 AM, Vogel, Dana <Vogel.Dana@epa.gov> wrote:

Ex. 5 - Deliberative Process

Sub

Dana Vogel

Sent from my iPhone

Begin forwarded message:

From: "Dawson, Jeffrey" <Dawson.Jeff@epa.gov>
Date: January 28, 2016 at 3:38:12 PM EST
To: "Vogel, Dana" <Vogel.Dana@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Thanks

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Vogel, Dana
Sent: Thursday, January 28, 2016 3:27 PM
To: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ok, I'll

Wait to reply to patty.

Thanks

Dana Vogel

Sent from my iPhone

On Jan 28, 2016, at 3:26 PM, Dawson, Jeffrey <Dawson.Jeff@epa.gov> wrote:

Ex. 5 - Deliberative Process

Jeffrey L Dawson

Acting Deputy Director

Health Effects Division

Office of Pesticide Programs, U.S. EPA

Phone: 703-305-7329

Email: dawson.jeff@epa.gov

From: Vogel, Dana
Sent: Thursday, January 28, 2016 3:23 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Middleton, Karlyn <Middleton.Karlyn@epa.gov>; Mendez, Elizabeth <Mendez.Elizabeth@epa.gov>
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Dana Vogel

Sent from my iPhone

On Jan 28, 2016, at 2:19 PM, Lowit, Anna <Lowit.Anna@epa.gov> wrote:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Anna B. Lowit, Ph.D.

Senior Scientist

Health Effects Division

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Vogel, Dana
Sent: Wednesday, January 27, 2016 11:27 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Dawson, Jeffrey <Dawson.Jeff@epa.gov>
Subject: Fwd: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Dana Vogel

Sent from my iPhone

Begin forwarded message:

From: "Parrott, Patricia" <parrott.patricia@epa.gov>
Date: January 27, 2016 at 11:22:38 AM EST
To: "Vogel, Dana" <Vogel.Dana@epa.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

parrott.patricia@epa.gov

From: Sanchez, Becxi - FAS [mailto:Becxi.Sanchez@fas.usda.gov]
Sent: Wednesday, January 27, 2016 10:48 AM
To: Avila, Marielsie - FAS <Marielsie.Avila@fas.usda.gov>; Parrott, Patricia <parrott.patricia@epa.gov>; Taveau, Daniella <Taveau.Daniella@epa.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration
Importance: High

Ex. 5 - Deliberative Process

Cheers,

Becxi

From: Avila, Marielsie - FAS
Sent: Wednesday, January 27, 2016 8:27 AM
To: Parrott, Patricia; Taveau, Daniella; Sanchez, Becxi - FAS
Cc: Keigwin, Richard; Wise, Louise
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Patricia,

Ex. 5 - Deliberative Process

Thanks,

Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

From: Parrott, Patricia [mailto:parrott.patricia@epa.gov]
Sent: Wednesday, January 27, 2016 8:24 AM
To: Avila, Marielsie - FAS; Taveau, Daniella; Sanchez, Becxi - FAS
Cc: Keigwin, Richard; Wise, Louise
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Patricia Parrott

Deputy Director

Field and External Affairs Division

US EPA (Mail Code 7506P)

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 703 305-0744

parrott.patricia@epa.gov

From: Avila, Marielsie - FAS [mailto:Marielsie.Avila@fas.usda.gov]
Sent: Wednesday, January 27, 2016 7:41 AM
To: Taveau, Daniella <Taveau.Daniella@epa.gov>; Parrott, Patricia <parrott.patricia@epa.gov>; Sanchez, Becxi - FAS <Becxi.Sanchez@fas.usda.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Subject: RE: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

+Becxi Sanchez

Marielsie Avila

International Trade Specialist

International Regulations and Standards Division |Foreign Agricultural Service |United States Department of Agriculture|1400 Independence Ave. SW, Room 5932-S |Washington, DC 20250 USA|Phone: 202-720-2151|Email: Marielsie.avila@fas.usda.gov

From: Taveau, Daniella [mailto:Taveau.Daniella@epa.gov]
Sent: Tuesday, January 26, 2016 5:11 PM
To: Parrott, Patricia
Cc: Keigwin, Richard; Avila, Marielsie - FAS; Wise, Louise
Subject: Re: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Daniella

On Jan 26, 2016, at 3:14 PM, Parrott, Patricia
<parrott.patricia@epa.gov> wrote:

Ex. 5 - Deliberative Process

Sent from my iPhone

On Jan 26, 2016, at 3:05 PM, Taveau, Daniella
<Taveau.Daniella@epa.gov> wrote:

Patty,

Ex. 5 - Deliberative Process

Daniella

On Jan 26, 2016, at 1:40 PM, Parrott, Patricia
<parrott.patricia@epa.gov> wrote:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Sent from my iPhone

Begin forwarded message:

From: "Jordan, William" <Jordan.William@epa.gov>
Date: November 9, 2015 at 3:36:35 PM EST
To: "Parrott, Patricia" <parrott.patricia@epa.gov>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Ex. 5 - Deliberative Process

Bill

William Jordan

Deputy Director, Programs

Office of Pesticide Programs

U. S. Environmental Protection Agency

Phone: 703-305-1049

Fax: 703-308-4776

Mailing Address: Courier Address:

USEPA Headquarters Potomac Yards South

Clinton Building 2777 Crystal Drive

1200 Pennsylvania Ave., NW Room 12-235

Mail Code (7501P) Arlington, VA

Washington, DC 20460

From: Taveau, Daniella
Sent: Monday, November 09, 2015 2:53 PM
To: Jordan, William <Jordan.William@epa.gov>
Cc: Wise, Louise <Wise.Louise@epa.gov>; Lewis, Susan <Lewis.Susan@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Herndon, George <Herndon.George@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Helfgott, Daniel <Helfgott.Daniel@epa.gov>
Subject: Fwd: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Bill,

Ex. 5 - Deliberative Process

Daniella

Begin forwarded message:

From: "Ray McAllister" <RMcAllister@croplifeamerica.org>
To: "Taveau, Daniella" <Taveau.Daniella@epa.gov>
Cc: "Janet Collins" <jcollins@croplifeamerica.org>
Subject: FW: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

I've also attached the translation of the Brazilian proposed regulation that we have been working from. I still haven't figured out who did the translation (industry or Brazilian government). I need to do a bit more ch3ecking before sharing the CropLife draft comments to Brazil with you.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Friday, October 30, 2015 11:35 AM
To: 'Lance, Jennifer - FAS' <Jennifer.Lance@fas.usda.gov>; Rasmussen, Mark - FAS <Mark.Rasmussen@fas.usda.gov>; Allen, Maurice - FAS <Maurice.Allen@fas.usda.gov>
Subject: FW: New WTO Notification

G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Jennifer:

This is the notification that was received by our European colleagues.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Benjamin.MUSALL@ec.europa.eu [mailto:Benjamin.MUSALL@ec.europa.eu]
Sent: 20 October 2015 15:45
To: Euros Jones; Joan Scott
Cc: Martin.PILSER@ec.europa.eu
Subject: New WTO Notification G/TBT/N/BRA/648 - pesticides toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration

Dear Euros and Joan,

We have just received a new WTO TBT notification from Brazil (see enclosed). According to the short content description, this concerns the following:

Draft Technical Resolution nº 87, 2 October 2015, regarding the pesticides' toxicological evaluation and classification, labels and leaflets, and the procedure to post-register alteration.

This Resolution establishes the requirements and criteria to toxicological evaluation and classification, risk evaluation, the toxicological information in labels and leaflets, besides the procedures of pesticides' post-register alteration, its components and wood preservers in ANVISA's regulation.

Have you been alerted by some of your members about this? In any case, don't hesitate to share your concerns with us, if any.

Kind regards,

Benjamin

Benjamin MUSALL
Policy Co-ordinator

European Commission

DG TRADE
Unit G.3 - Market Access, Industry, Energy and Raw Materials

CHAR 05/23
B-1049 Brussels/Belgium
+32 2 295 60 12
benjamin.musall@ec.europa.eu

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More on the TTIP

Follow the EU's TTIP Negotiating Team on Twitter

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<BRA648_EN.doc>

<CP_87_-_2015_English_Version - Oct 13.doc>

<Comments on Brazil Anvisa tox requirements_draft_compiled.docx>

<EPA commnets BRA TBT 648 pesticides 12-8-15 d_JD.doc>

Crop Life America Proposal for setting MRLs in honey

CLA Residue Expert Working Group

January 27, 2016

CropLife AMERICA

The **objective** of this proposal is to provide a tiered regulatory approach for setting tolerances (MRLs) in honey. This tolerance will be used to assess consumer safety based on US consumption information and would be available as a trading standard to support international trade.

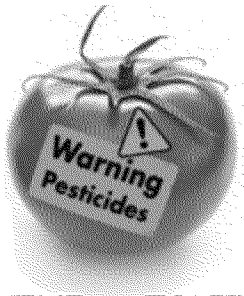
The **scope** of this proposal is limited to Honey.

Although bees also produce other consumables such as wax, pollen loads, propolis, bee bread and royal jelly, their consumption is very low. Honey is the main beehive product used as human food.

The **scope** of this proposal is limited to the inadvertent transfer of pesticide residues from nectar or pollen to honey.

The direct application of pest products to the bee hive or surrounding structure could lead to residues in honey. There is a process already in place for establishing MRLs in honey for these uses.

ROMEO GACAD/AFP/GETTY IMAGES



What's on my food?

Inadvertent Residues in Honey *Trade Issue or Health Concern?*

a project of Pesticide Action Network

SHARE

HONEY

12 Pesticide Residues Found by the USDA Pesticide Data Program[1,2,3]

Human Health Effects:

2 — Known or Probable Carcinogens[4]
6 — Suspected Hormone Disruptors
2 — Neurotoxins
2 — Developmental or Reproductive Toxins

Environmental Effects:

4 — Honeybee Toxins[5]

TOXICITY LEGEND

Carcinogens	Hormone Disruptors	Neurotoxins	Developmental or Reproductive Toxins	Bee Toxins
KNOWN	SUSPECTED	PRESENT	PRESENT	HIGH
PROBABLE				MODERATE
POSSIBLE				SLIGHT

Pesticide Residues Found in Honey:

What Pesticide?	How Often is it Found?[6]	Conventional vs. Organic	Toxicity[7]	Other Foods with this Pesticide

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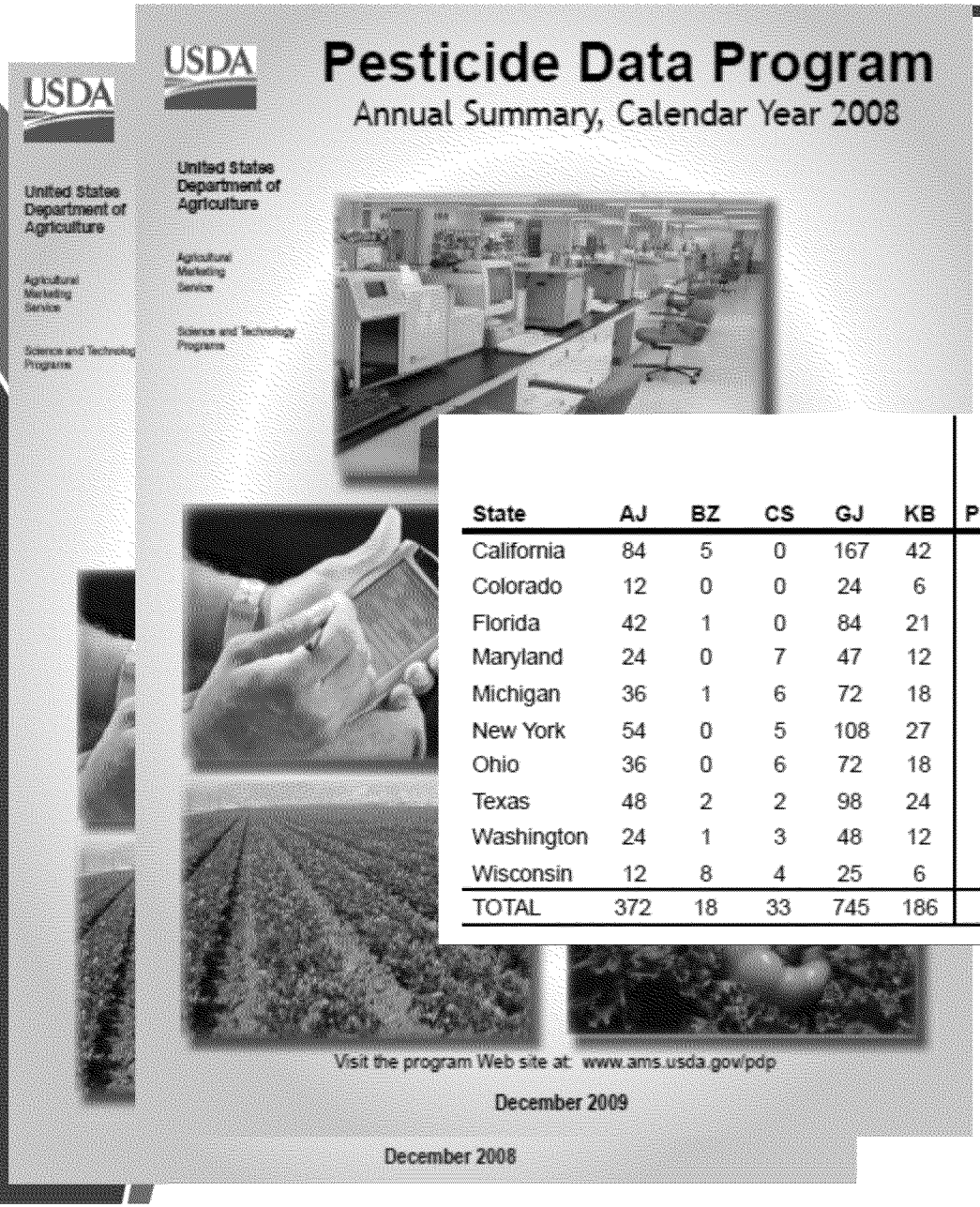
TAKE ACTION »
Join the movement for food system reform

FIND OUT :: WHAT'S ON YOUR FOOD?

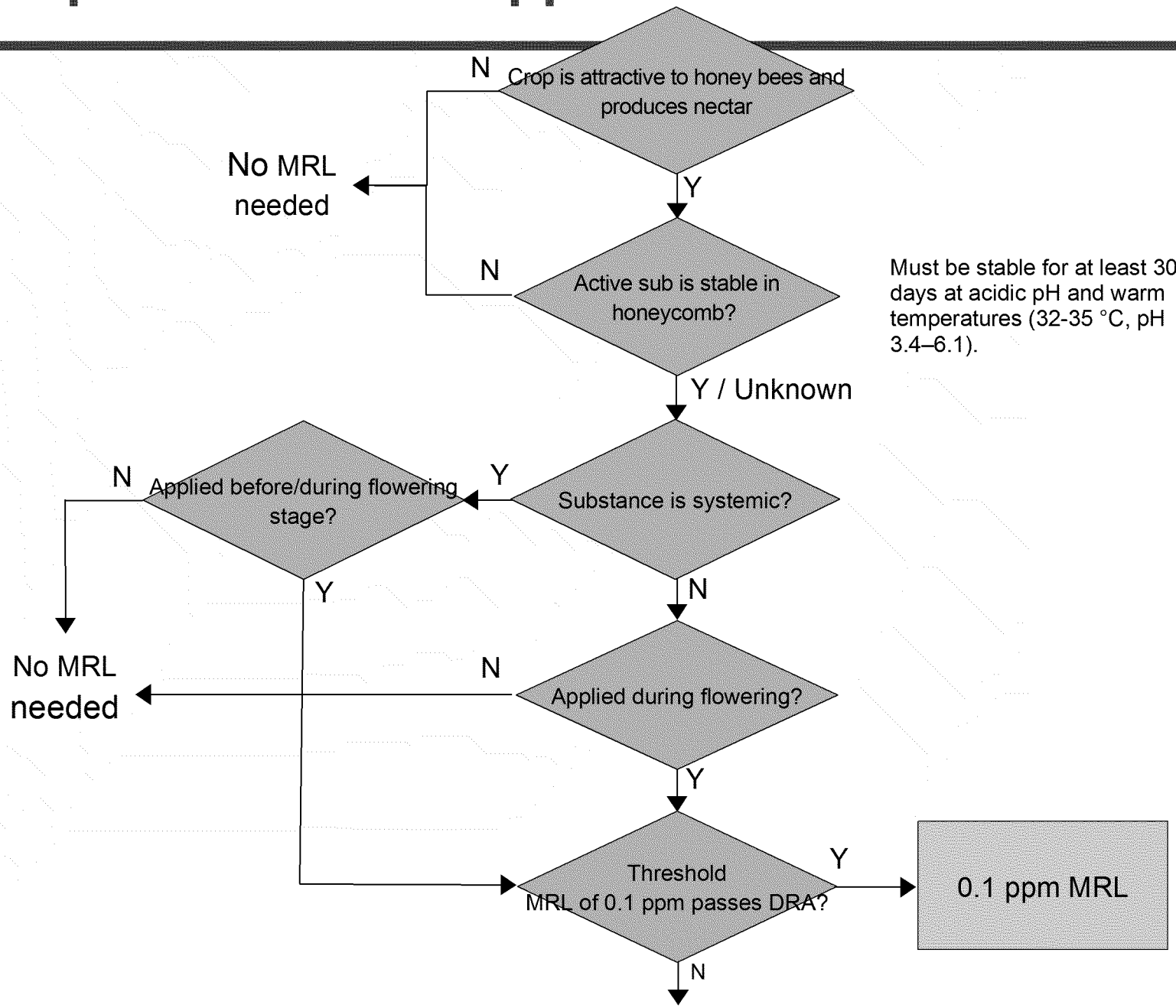
Almonds
Apple Juice
Apple Sauce
Apples
Apples-Single Servings
Asparagus
Asparagus, Canned
Avocado
Baby Food - Applesauce
Baby Food - Carrots
Baby Food - Green Beans
Baby Food - Peaches
Baby Food - Pears
Baby Food - Peas
Baby Food - Sweet Potato

US Monitoring Data



State	AJ	BZ	CS	GJ	KB	Total Processed	Total Fresh & Proccessed F&V	Nuts AL	Honey HY	Fish FC	Grain RI
California	84	5	0	167	42	298	2,351	42	126	125	42
Colorado	12	0	0	24	6	42	329	6	18	18	6
Florida	42	1	0	84	21	148	1,174	21	63	63	21
Maryland	24	0	7	47	12	90	669	12	36	35	12
Michigan	36	1	6	72	18	133	1,021	18	54	54	18
New York	54	0	5	108	27	194	1,537	27	81	81	27
Ohio	36	0	6	72	18	132	968	18	54	54	18
Texas	48	2	2	98	24	174	1,361	24	72	72	72
Washington	24	1	3	48	12	88	653	12	36	35	12
Wisconsin	12	8	4	25	6	55	319	6	18	15	6
TOTAL	372	18	33	745	186	1,354	10,382	186	558	552	184

Proposal – Tiered Approach



Must be stable for at least 30 days at acidic pH and warm temperatures (32-35 °C, pH 3.4–6.1).

Threshold MRL – based on PDP data

Pesticide Data Program

2007 Su
in .

Pesticide	# of Samples Analyzed	S w
1-Naphthol	186	
2,4-dimethyl aniline (2,4 DMA)	186	
2,4-dimethylphenyl formamide (2,4-DMPF)	186	
3-Hydroxycarbofuran	186	
4,4-dibromobenzophenone	186	
Acephate	186	
Acetamiprid	186	
Acetochlor	186	
Alachlor	186	
Aldicarb	186	
Aldicarb sulfone	186	
Aldicarb sulfoxide	186	
Aldrin	186	
Allethrin	186	
Amicarbazone	186	
Amitraz	186	
Atrazine	186	
Azinphos methyl	186	
Azoxystrobin	186	
Bendiocarb	186	
Benoxacor	186	
BHC alpha	186	
Bifenazate	186	
Bifenthrin	186	

Pesticide Data Program

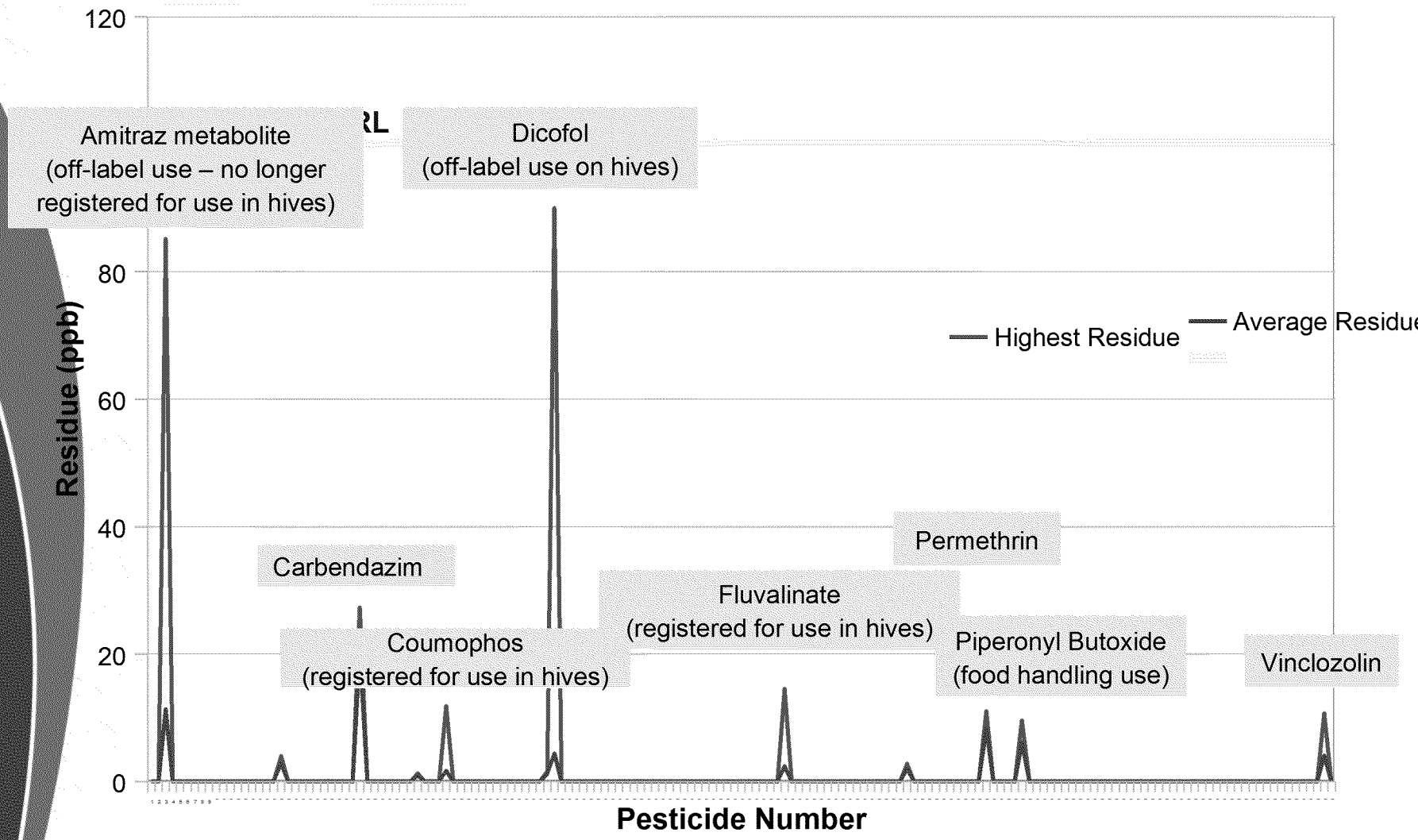
2008 Summary of Residue Findings in Honey for All Pesticides

Pesticide	# of Samples Analyzed	# of Samples w/Detects	% of Samples w/Detects	Min Value Detected	Max Value Detected	Avg Value Detected	Range of LODs	Unit pp_
1-Naphthol	558						10 - 10	B
2,4-dimethyl aniline (2,4 DMA)	558						50 - 50	B
2,4-dimethylphenyl formamide (2,4-DMPF)	558	73	13.1	4.1	85.1	12.189	4 - 4	B
3-Hydroxycarbofuran	558						4 - 4	B
4,4-dibromobenzophenone	558						4 - 4	B
Acephate	558						50 - 50	B
Acetamiprid	558						40 - 40	B
Acetochlor	558						10 - 10	B
Alachlor	558						10 - 10	B
Aldicarb	558						4 - 4	B
Aldicarb sulfone	558						15 - 15	B
Aldicarb sulfoxide	558						20 - 20	B
Aldrin	558						10 - 10	B
Allethrin	558						10 - 10	B
Amicarbazone	558						30 - 30	B
Amitraz	558						4 - 4	B
Atrazine	558						6 - 6	B
Azinphos methyl	558						6 - 6	B
Azoxystrobin	558	3	0.5	3.3	4	3.667	2 - 2	B
Bendiocarb	558						2 - 2	B
Benoxacor	558						4 - 4	B
BHC alpha	558						4 - 4	B
Bifenazate	558						20 - 20	B
Bifenthrin	558						2 - 2	B

Threshold MRL – based on PDP data

Program	Pesticide	Number of Samples	Samples with Detections	% of Samples	Range of Values Detected ppb	Range of LODs ppb	US Tolerance ppb
2007 PDP	Coumaphos	186	*Registered for use on hives*		1.0 – 11.8	1.0	150
	Dicloran	186	1	0.5	1.0	1.0	--
	Dicofol p,p'	186	3	1.6	1.3 – 3.6	1.0	--
	2,4-DMPF	186	8	4.3	4.2 - 27.5	4.0	200
	Fluvalinate	186	*Registered for use on hives*		1.0 - 6.7	1.0	20
	Vinclozolin	186	2	1.1	10.6 – 10.7	1.0	--
2008 PDP	Azoxystrobin	558	3	0.5	3.3 - 4.0	2.0	--
	Carbendazim	558	1	0.2	27.3	5.0	--
	Chlorpyrifos	558	*Food handling use*		1.3	1.0	100
	Coumaphos	558	*Registered for use on hives*		1.0 - 8.2	1.0	150
	Dicloran (V-2)	558	2	0.4	1.1 - 1.6	1.0	--
	Dicofol p,p'	558	32	5.7	1.0 - 90	1.0	--
	2,4-DMPF	558	73	13.1	4.1 - 85.1	4.0	200
	Fluvalinate	558	*Registered for use on hives*		1.0 - 14.5	1.0	20
	Methoxyfenozide	558	1	0.2	2.8	2.0	--
	Permethrin Total	558	1	0.2	11	10	--
	Piperonyl butoxide	558	*Food handling use*		6.3 - 9.6	6.0	10000
	Vinclozolin	558	3	0.5	1.3 - 2.1	1.0	--

Threshold MRL – based on PDP data



Dietary Impact

Risk Cup Utilization for 363 compounds in the HHBM database from Residues in Honey at Threshold MRL of 0.1 mg/kg	Acute at 95%tile (mg/kg bw/day)	Chronic (mg/kg bw/day)
No. of compounds where honey exposure exceeds the reference dose for children age 1-2	0	1 (0.3%)
No. of compounds where honey exposure is more than 5% of reference dose for children age 1-2*	4 (1%)	10 (3%)
No. of compounds where honey exposure is less than 5% of reference dose for children age 1-2*	235 (65%)	345 (95%)
No. of compounds in HHBM with no reference dose	124 (34%)	8 (2%)

*Honey exposure at the threshold MRL of 0.1 mg/kg would exceed 5% of the RfD for pesticides with acute RfDs lower than 0.000283 mg/kg bw/day and/or chronic RfDs lower than 0.000073 mg/kg bw/day.

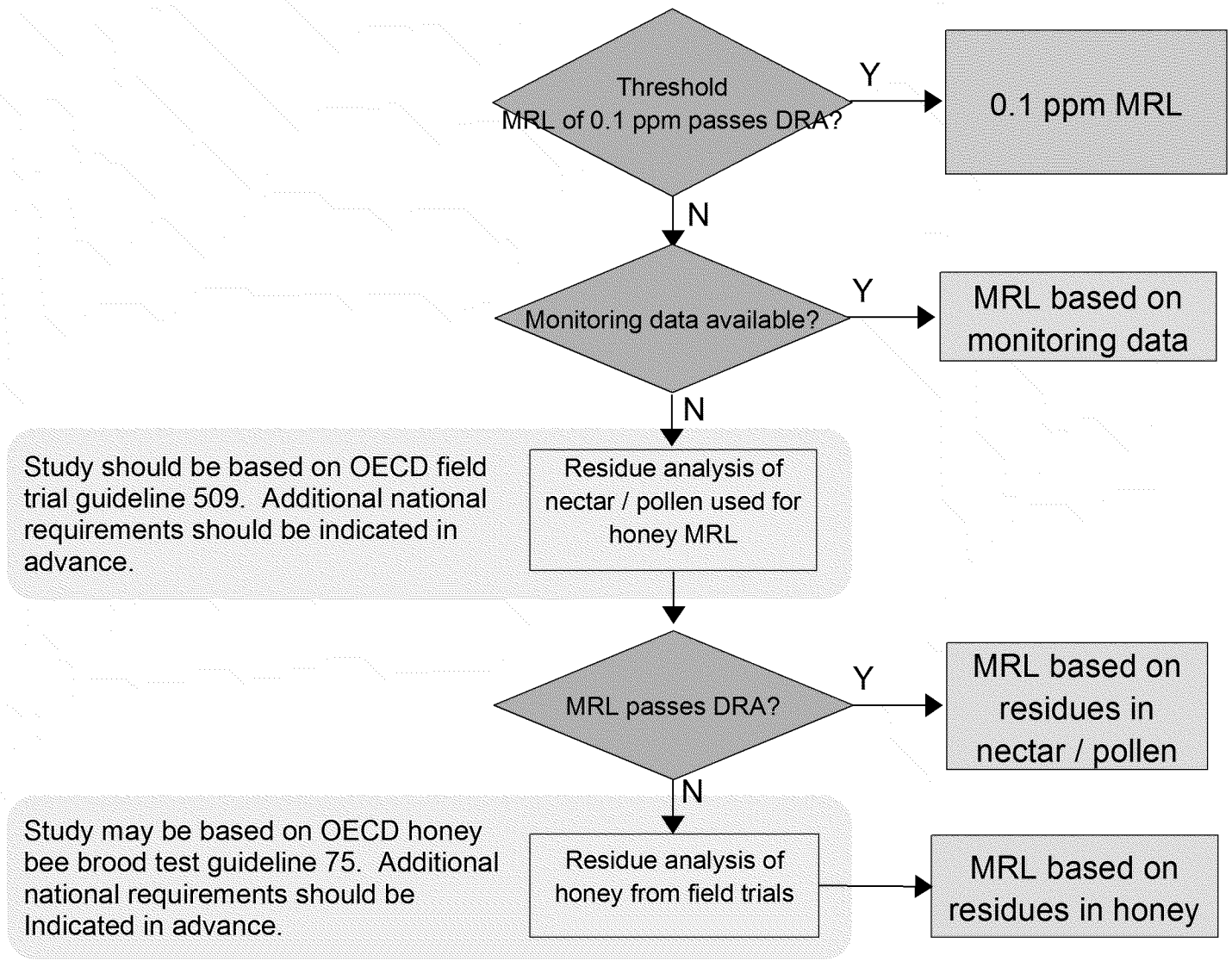
Dietary Impact

Impact of 0.1 mg/kg Threshold Honey MRL on Acute and Chronic Dietary Risk for Selected Compounds

Compound	aPAD	cPAD	% children aPAD 95%, 99.9	% children cPAD
Fipronil	0.025	0.0002	0.06, 1.10	1.8
Imidacloprid**	0.14	0.057	0.1, 1.96	<0.1
Boscalid	NA	0.218	-	~0
Pyrethins	0.07	0.044	0.02, 0.39	<0.1
Cadusafos***	0.00002	0.000001	70.50, 1372.35	358.1
Coumaphos*	0.0025	0.0003	0.56, 10.98	1.2
Fluvalinate*	0.005	0.005	0.28,5.49	0.1

*registered on hives
** neonicotinoid
*** No US registration. Only one import tolerance on bananas.

Proposal – Tiered Approach



Advantages of the CLA Proposal

- Pragmatic, yet conservative
- Threshold MRL based on real residue data
- threshold MRL will be acceptable for most pesticides
- Tiered approach allows for refinement for highly toxic or tightly managed pesticides
- Harmonized with EU/OECD

Thank you for your time!

CropLife AMERICA

To: Ray McAllister[RMcAllister@croplifeamerica.org]; Hrdy, David[Hrdy.David@epa.gov]
Cc: Nako, Steve[Nako.Steve@epa.gov]; Jane M Stewart[jane.stewart@basf.com]; Tiu, Carmen (C)[tcarmen@dow.com]; Philip A Brindle[philip.brindle@basf.com]; Cheryl Cleveland[cheryl.cleveland@basf.com]; Nguyen, James[Nguyen.James@epa.gov]; Reshma Arrington[rarrington@croplifeamerica.org]
From: Miller, David
Sent: Wed 1/27/2016 2:36:24 PM
Subject: RE: Meeting on Wednesday?
EFSA Zoning email from December 2016.docx
GlobalMRL.com MRLs for Honey.xlsx

We will have a projector, too.

You talk in one of the honey slides about these being OECD/EU harmonized. Here is the output from GlobalMRL.com - it seems to me that these vary. I've attached output

Also, I've attached an MS Word version of the EFSA email on zoning. We can project this and discuss, too.

Cheryl – probably easier for you to provide number for us to call if you will be the only one on the phone – can you send this to us.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, January 27, 2016 9:18 AM
To: Hrdy, David <Hrdy.David@epa.gov>
Cc: Nako, Steve <Nako.Steve@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: Re: Meeting on Wednesday?

I have paper copies of the two documents.

On Jan 27, 2016, at 9:13 AM, Hrdy, David <Hrdy.David@epa.gov> wrote:

Ray,

Look forward to seeing then!

David

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David E. Hrdy
Senior Scientist
CEB/HED/OPP/OCSPP
US EPA www.epa.gov/pesticides
Mailcode 7509P
Telephone: **703.305.6990**
Fax: 703.305.5147
OFFICE 10248 Potomac Yard 1 (South)
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From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Wednesday, January 27, 2016 9:02 AM
To: Nako, Steve <Nako.Steve@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: RE: Meeting on Wednesday?

I will arrive shortly before 10 a.m.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Nako, Steve [mailto:Nako.Steve@epa.gov]
Sent: Wednesday, January 27, 2016 8:34 AM
To: Miller, David <Miller.DavidJ@epa.gov>; Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: RE: Meeting on Wednesday?

I am here.

Call if you are coming and need to get upstairs.

-Steve

Office: 703.308.8092

Cell: 703.609.9357

From: Miller, David
Sent: Wednesday, January 27, 2016 7:56 AM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>; Nako, Steve <Nako.Steve@epa.gov>
Subject: Re: Meeting on Wednesday?

James and I will be there. I don't know about David Hrdy.

david.

From: Ray McAllister <RMcAllister@croplifeamerica.org>
Sent: Wednesday, January 27, 2016 6:07 AM
To: Miller, David
Cc: Hrdy, David; Jane M Stewart; Tiu, Carmen (C); Philip A Brindle; Cheryl Cleveland; Nguyen, James; Reshma Arrington; Nako, Steve
Subject: Re: Meeting on Wednesday?

David & David:

With the federal government opening 3 hours late today, will we still be able to meet at 10 a.m. at your offices?

On Jan 26, 2016, at 3:45 PM, Ray McAllister <RMcAllister@croplifeamerica.org> wrote:

Attached is the draft paper on honey MRLs and a slide presentation explaining the approach, for

discussion tomorrow. These are not ready for sharing widely.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Tuesday, January 26, 2016 3:04 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>; Nako, Steve <Nako.Steve@epa.gov>
Subject: Re: Meeting on Wednesday?

David & David:

I'm working on a background paper and slide presentation to share with you for tomorrow's meeting. If my computer will cooperate from home, I'll get it to you in the next half hour.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

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+1-202-577-6657 (cell)

ray@croplife.us

On Jan 25, 2016, at 5:28 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

It looks like Steve N. booked a room last week in advance. Thanks, Steve !

So, we will meeting in Room 10771, 10-11 am.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 4:16 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: Re: Meeting on Wednesday?

I will reserve a room at CLA as a backup, in case there is not a room available at Potomac Yards.

On Jan 25, 2016, at 3:43 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

I've booked a 10 am to 11 am slot for this. Not able to book a room, so we may have to play it by ear (as of a few weeks back, EPA has moved folks from OSWER, OGC, and other EPA offices onto our building to save rent, so we are all compressed and competing for the same conference rooms so they are less available.)

David H. has his calender marked off for this time (10 to noon), but I don't know what it is – I will leave it to him to get back to you about whether he can make it or not and if alternate arrangements need to be made.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
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From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 3:30 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Re: Meeting on Wednesday?

Thanks. We'll plan on it.

On Jan 25, 2016, at 1:15 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Meeting on Wednesday morning should be fine. I think you said 10:00 or 10:30. I will check caLANder and see what available times are.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
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703-305-5147 (fax)

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From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 12:19 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Hrdy, David <Hrdy.David@epa.gov>
Cc: Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Meeting on Wednesday?

David & David:

How soon might you be able to confirm whether our meeting on Wednesday can take place?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

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ray@croplife.is

<CLA Paper on Pesticide Residues in Honey_EPA rsm.pdf>

<CLA Proposal for setting MRLs in honey_EPA.PPTX>

Dear David,

Sorry for my late reply, but we are struggling with a number of urgent issues in EFSA. But I assume this is the same everywhere.

Last week in the Standing Committee on Plants, Animals, Food and Feed (SCPAFF) meeting we had an exchange of views with Member States and the European Commission on the Global Zoning project.
I presented your assessments and your conclusions regarding the question whether there are systematic differences in pesticide residue concentrations between zones and I shared our preliminary findings with the participants of the SCPAFF. The EFSA views are summarised in the following bullet points:

- In our opinion, the pooling of residue trials with different types of pesticides (i.e. systemic and non-systemic pesticides, insecticides/fungicides/etc.), different types of applications and on different types of crops may not be the most appropriate approach to demonstrate that trials from different zones do not contribute statistical significantly to the overall variability of trials. Combining these trials leads necessarily to a very wide variability that would mask effects that may mask effects that would be relevant only for one type of crops or pesticides or application methods. Thus, pooling data from different geographical zones may for certain crops/pesticides lead to inappropriate MRLs for certain situations.
- EFSA is also of the opinion that the residue trials with very short PHIs cannot be used to proof that in general the residue situation is comparable in different zones. The initial residue concentration (PHI 0) or within the first days of application should be very similar. The same would be true for indoor trials. (I do not know if in your analysis indoor trials were used. If not, the comment is not relevant).
- We are think that the basic question of your hypothesis testing should be revised: the generic question you asked (i.e. "Are there systematic differences in pesticide residue concentrations between zones?") is not very relevant, since there are probably only few cases where comparable GAPs exist in different zones of the world. Instead, in our view, it would be more appropriate to define under which conditions data from different zones can be pooled, provided that the GAP and the agricultural practices are comparable, e.g. indoor uses on certain crops, uses on crops with very short PHIs, post-harvest uses or uses on crops that grow only under very specific climatic conditions.
- EFSA is also of the opinion that clear criteria for the selection of trials, the minimum number of trials per zone and statistical assessment tools would be needed to decide whether the trials can be pooled (e.g. in the framework of MRL setting at international level).
- At the moment in the EU we do not have a legal framework to set MRLs based on a global dataset.
- In the current EU data requirements it is defined that for setting EU MRLs it is necessary to provide residue trials representative for the EU zones; a limited number of trials can be replaced by trials performed outside the EU provided that they correspond to the critical GAP and that the production conditions (such as cultural practices, climatic conditions) are comparable.
- To decide if data from non-EU zones can be used to replace trials, EFSA would use statistical tests to demonstrate comparability. For this purpose a minimum number of trials would be required, otherwise the statistical tests would not have sufficient power.

Please note that the above mentioned views reflect EFSA's preliminary considerations and are

not necessarily shared by all Member States or the European Commission.
During the discussions in the SCPAFF meeting in general the European Commission and Member States considered these findings as interesting and worthwhile to be further explored in the long term and at international level. It is however clear that there are still many practical and legal questions associated with the findings. Given the many priority issues that are currently on the Commission's agenda and the fact that the other project pursued at international level – the change of the IESTI equation- will require input and resources, the Commission considers the Global Zoning Project a project rather for the future, but not for the short or medium term. A Member State shared its doubts that a global GAP would be achievable given the agricultural and climatic diversity in the world. Further work is considered necessary.

I hope this feedback is useful for you.

Best regards,

Hermine

- In our opinion, the pooling of residue trials with different types of pesticides (i.e. systemic and non-systemic pesticides, insecticides/fungicides/etc.), different types of applications and on different types of crops may not be the most appropriate approach to demonstrate that trials from different zones do not contribute statistical significantly to the overall variability of trials. Combining these trials leads necessarily to a very wide variability that would mask effects that would be relevant only for one type of crops or pesticides or application methods. Thus, pooling data from different geographical zones may for certain crops/pesticides lead to inappropriate MRLs for certain situations.

- EFSA is also of the opinion that the residue trials with very short PHIs cannot be used to prove that in general the residue situation is comparable in different zones. The initial residue concentration (PHI 0) or within the first days of application should be very similar. The same would be true for indoor trials. (I do not know if in your analysis indoor trials were used. If not, the comment is not relevant).

- Instead, in our view, it would be more appropriate to define under which conditions data from different zones can be pooled, provided that the GAP and the agricultural practices are comparable, e.g. indoor uses on certain crops, uses on crops with very short PHIs, post-harvest uses, or uses on crops that grow only under very specific climatic conditions.

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- At the moment in the EU we do not have a legal framework to set MRLs based on a global dataset.

- In the current EU data requirements, it is defined that for setting EU MRLs it is necessary to provide residue trials representative for the EU zones; a

limited number of trials can be replaced by trials performed outside the EU provided that they correspond to the critical GAP and that the production conditions (such as cultural practices, climatic conditions) are comparable.

- To decide if data from non-EU zones can be used to replace trials, EFSA would use statistical tests to demonstrate comparability. For this purpose a minimum number of trials would be required, otherwise the statistical tests would not have sufficient power.
- We are think that the basic question of your hypothesis testing should be revised: the generic question you asked (i.e. "Are there systematic differences in pesticide residue concentrations between zones?") is not very relevant, since there are probably only few cases where comparable GAPs exist in different zones of the world.

Please note that the above mentioned views reflect EFSA's preliminary considerations and are not necessarily shared by all Member States or the European Commission. During the discussions in the SCPAFF meeting in general the European Commission and Member States considered these findings as interesting and worthwhile to be further explored in the long term and at international level. It is however clear that there are still many practical and legal questions associated with the findings. Given the many priority issues that are currently on the Commission's agenda and the fact that the other project pursued at international level – the change of the IESTI equation- will require input and resources, the Commission considers the Global Zoning Project a project rather for the future, but not for the short or medium term. A Member State shared its doubts that a global GAP would be achievable given the agricultural and climatic diversity in the world. Further work is considered necessary.

LEGEND

RAC MRLs: Raw Agricultural Commodity Maximum Residue Levels (or Limits)

Processed MRLs: Other MRLs relevant to the search query such as those set on processed food products.

The "Market" column indicates the country for which the MRL information is applicable.

The "Origin Market" column indicates the source of the MRL for countries which defer to other markets' MRL regulations.

The "Active Ingredient" column lists the pesticide chemical substance. These terms should not be considered residue definitions

The "Published Commodity" column indicates the commodity term as published in the regulation on which the MRL is set. Whe
commodity term is not listed this indicates that the MRL is a default tolerance.

The "Index Commodity" column indicates the BCI Global Crop Dictionary term that was included in the search query and for wh
regulation is applicable.

The "MRL (ppm)" column lists the numeric value of the MRL in parts per million (ppm). The word "Exempt" will be listed to indic
MRL is not required for the active ingredient use on the relevant published commodity.

The "MRL Type" column includes:
General - a general MRL.
"Default" indicates that the MRL value displayed is a default tolerance. Some markets defer to a default MRL value when a spec
not been established for a commodity and active ingredient. Policies regarding the use of default MRLs vary by country. The f

The "Expiry Date" column lists the expiration date for an MRL if a revocation has been officially indicated in the MRL regulations
field lists "Proposed Revocation" the MRL has been proposed to be revoked in a draft proposal, amendment, or petition that is i
regulatory process. These proposed actions are subject to change or withdrawal.

The "Effective Date" column indicates the in force date of the relevant MRL regulation. For Pending MRLs this is the future date
the MRLs will enter into force.

The “US Import Tolerance” column indicates that in the US Code of Federal Regulations (CFRs), the tolerance was noted speci
import tolerance established for imported product into the US, or was noted as having no current US registrations.

The “US CFR Prescribed Use” indicates a US tolerances for which registered use and application information are prescribed in
in addition to the residue level. These tolerances are typically established for uses such as food or feed handling and processin
treatments; mosquito adulticide applications; preharvest treatment of pest burrows; area fly and mosquito control; and other spe
situations. Please read carefully the information provided in the User Guide, and FAQs about US EPA enforcement of these US

The "Undefined Published Commodity" column indicates if the Published Commodity term is not clearly defined by the country i
regulations. In these cases the Global Crop Dictionary term (index commodity) is assumed to be relevant based on the Codex
Classification of Foods and Animal Feeds" but should be confirmed with official sources.

The "Commodity Notes" column includes any additional regulatory information relevant to the MRL.

The "LOD" column indicates that the MRL is set at the Limit of Determination.
The "LOQ" column indicates that the MRL is set at the Limit of Quantification.
The "Seed Treatment" column indicates if the MRL is set for seed treatment use.
The "Post Harvest" column indicates if the MRL is set for post harvest.
The "Residue Definition" column lists the exact active ingredient term cited in a market's regulation along with any residue defin information provided.
The "Regulation Name" column indicates the name of the MRL regulation for MRLs currently in effect (in force) or that are pend
The “Source Document Name” column indicates the name of the document announcing the draft MRL proposal, amendment, o
The “Publication Date” column lists the date when the source document announcing the draft MRL proposal, amendment, or pe published.
The “Comments Due Date” column indicates when comments on MRL proposals are due to the regulatory authority considering MRL revisions. If comments are solicited, this date is obtained from the Source Document.

REPORT CONTENTS

This report was generated on January 26, 2016.
Commodities: Honey
Markets: Argentina; Australia; Austria; Belgium; Bulgaria; Canada; Croatia; Cyprus; Czech Republic; Denmark; Dominican Repu Estonia; European Economic Area; European Union; Finland; France; French West Indies; Germany; Greece; Honduras; Hung Ireland; Italy; Japan; Latvia; Lithuania; Luxembourg; Malaysia; Malta; Mexico; Morocco; Netherlands; New Zealand; Norway; Po Portugal; Romania; Slovakia; Slovenia; South Africa; Spain; Sweden; Switzerland; Turkey; United Arab Emirates; United Kingd
Pesticides: Boscalid; Cadusafos; Coumaphos; Fipronil; Imidacloprid; Pyrethrins; Tau-fluvalinate
Report Options: Order results by Commodity.

Market	Origin Market	Active Ingredient	Published Commodity
Australia		Boscalid	All Other Foods
Austria	European Union	Boscalid	Honey and other apiculture products
Belgium	European Union	Boscalid	Honey and other apiculture products
Bulgaria	European Union	Boscalid	Honey and other apiculture products
Canada		Boscalid	
Croatia	European Union	Boscalid	Honey and other apiculture products
Cyprus	European Union	Boscalid	Honey and other apiculture products
Czech Republic	European Union	Boscalid	Honey and other apiculture products
Denmark	European Union	Boscalid	Honey and other apiculture products
Dominican Repul	European Union	Boscalid	Honey and other apiculture products
Egypt	European Union	Boscalid	Honey and other apiculture products
Estonia	European Union	Boscalid	Honey and other apiculture products
European Econo	mic Area	Boscalid	Honey and other apiculture products
European Union		Boscalid	Honey and other apiculture products
Finland	European Union	Boscalid	Honey and other apiculture products
France	European Union	Boscalid	Honey and other apiculture products
French West Indi	European Union	Boscalid	Honey and other apiculture products
Germany	European Union	Boscalid	Honey and other apiculture products
Greece	European Union	Boscalid	Honey and other apiculture products
Hungary	European Union	Boscalid	Honey and other apiculture products

Iceland	European Econoı	Boscalid	Honey and other apiculture products
Ireland	European Union	Boscalid	Honey and other apiculture products
Italy	European Union	Boscalid	Honey and other apiculture products
Japan		Boscalid	
Latvia	European Union	Boscalid	Honey and other apiculture products
Lithuania	European Union	Boscalid	Honey and other apiculture products
Luxembourg	European Union	Boscalid	Honey and other apiculture products
Malaysia		Boscalid	
Malta	European Union	Boscalid	Honey and other apiculture products
Morocco	European Union	Boscalid	Honey and other apiculture products
Netherlands	European Union	Boscalid	Honey and other apiculture products
New Zealand		Boscalid	
Norway	European Econoı	Boscalid	Honey and other apiculture products
Poland	European Union	Boscalid	Honey and other apiculture products
Portugal	European Union	Boscalid	Honey and other apiculture products
Romania	European Union	Boscalid	Honey and other apiculture products
Slovakia	European Union	Boscalid	Honey and other apiculture products
Slovenia	European Union	Boscalid	Honey and other apiculture products
South Africa	European Union	Boscalid	Honey and other apiculture products
Spain	European Union	Boscalid	Honey and other apiculture products
Sweden	European Union	Boscalid	Honey and other apiculture products

Switzerland		Boscalid	Honey (Royal jelly, pollen)
Turkey		Boscalid	Honey and other apiculture products
United Arab Emir	European Union	Boscalid	Honey and other apiculture products
United Kingdom	European Union	Boscalid	Honey and other apiculture products
Austria	European Union	Cadusafos	Honey and other apiculture products
Belgium	European Union	Cadusafos	Honey and other apiculture products
Bulgaria	European Union	Cadusafos	Honey and other apiculture products
Canada		Cadusafos	
Croatia	European Union	Cadusafos	Honey and other apiculture products
Cyprus	European Union	Cadusafos	Honey and other apiculture products
Czech Republic	European Union	Cadusafos	Honey and other apiculture products
Denmark	European Union	Cadusafos	Honey and other apiculture products
Dominican Repul	European Union	Cadusafos	Honey and other apiculture products
Egypt	European Union	Cadusafos	Honey and other apiculture products
Estonia	European Union	Cadusafos	Honey and other apiculture products
European Econo	mic Area	Cadusafos	Honey and other apiculture products
European Union		Cadusafos	Honey and other apiculture products
Finland	European Union	Cadusafos	Honey and other apiculture products
France	European Union	Cadusafos	Honey and other apiculture products
French West Indi	European Union	Cadusafos	Honey and other apiculture products
Germany	European Union	Cadusafos	Honey and other apiculture products

Greece	European Union	Cadusafos	Honey and other apiculture products
Hungary	European Union	Cadusafos	Honey and other apiculture products
Iceland	European Econoı	Cadusafos	Honey and other apiculture products
Ireland	European Union	Cadusafos	Honey and other apiculture products
Italy	European Union	Cadusafos	Honey and other apiculture products
Japan		Cadusafos	
Latvia	European Union	Cadusafos	Honey and other apiculture products
Lithuania	European Union	Cadusafos	Honey and other apiculture products
Luxembourg	European Union	Cadusafos	Honey and other apiculture products
Malaysia		Cadusafos	
Malta	European Union	Cadusafos	Honey and other apiculture products
Morocco	European Union	Cadusafos	Honey and other apiculture products
Netherlands	European Union	Cadusafos	Honey and other apiculture products
New Zealand		Cadusafos	
Norway	European Econoı	Cadusafos	Honey and other apiculture products
Poland	European Union	Cadusafos	Honey and other apiculture products
Portugal	European Union	Cadusafos	Honey and other apiculture products
Romania	European Union	Cadusafos	Honey and other apiculture products
Slovakia	European Union	Cadusafos	Honey and other apiculture products
Slovenia	European Union	Cadusafos	Honey and other apiculture products
South Africa	European Union	Cadusafos	Honey and other apiculture products

Spain	European Union	Cadusafos	Honey and other apiculture products
Sweden	European Union	Cadusafos	Honey and other apiculture products
Turkey		Cadusafos	Honey and other apiculture products
United Arab Emir	European Union	Cadusafos	Honey and other apiculture products
United Kingdom	European Union	Cadusafos	Honey and other apiculture products
Argentina		Coumaphos	Honey
Austria	European Union	Coumaphos	
Belgium	European Union	Coumaphos	
Bulgaria	European Union	Coumaphos	
Canada		Coumaphos	Honey
Croatia	European Union	Coumaphos	
Cyprus	European Union	Coumaphos	
Czech Republic	European Union	Coumaphos	
Denmark	European Union	Coumaphos	
Dominican Repul	United States	Coumaphos	Honey
Egypt		Coumaphos	
Estonia	European Union	Coumaphos	
European Econo	mic Area	Coumaphos	
European Union		Coumaphos	
Finland	European Union	Coumaphos	
France	European Union	Coumaphos	

French West Indi	European Union	Coumaphos	
Germany	European Union	Coumaphos	
Greece	European Union	Coumaphos	
Honduras	United States	Coumaphos	Honey
Hungary	European Union	Coumaphos	
Iceland	European Econoı	Coumaphos	
Ireland	European Union	Coumaphos	
Italy	European Union	Coumaphos	
Japan		Coumaphos	
Latvia	European Union	Coumaphos	
Lithuania	European Union	Coumaphos	
Luxembourg	European Union	Coumaphos	
Malaysia		Coumaphos	
Malta	European Union	Coumaphos	
Mexico	United States	Coumaphos	Honey
Morocco		Coumaphos	
Netherlands	European Union	Coumaphos	
New Zealand		Coumaphos	
Norway	European Econoı	Coumaphos	
Poland	European Union	Coumaphos	
Portugal	European Union	Coumaphos	

Romania	European Union	Coumaphos	
Slovakia	European Union	Coumaphos	
Slovenia	European Union	Coumaphos	
South Africa		Coumaphos	
Spain	European Union	Coumaphos	
Sweden	European Union	Coumaphos	
Turkey		Coumaphos	
United Kingdom	European Union	Coumaphos	
United States		Coumaphos	Honey
Australia		Fipronil	Honey
Austria	European Union	Fipronil	Honey and other apiculture products
Belgium	European Union	Fipronil	Honey and other apiculture products
Bulgaria	European Union	Fipronil	Honey and other apiculture products
Canada		Fipronil	
Croatia	European Union	Fipronil	Honey and other apiculture products
Cyprus	European Union	Fipronil	Honey and other apiculture products
Czech Republic	European Union	Fipronil	Honey and other apiculture products
Denmark	European Union	Fipronil	Honey and other apiculture products
Dominican Repul	European Union	Fipronil	Honey and other apiculture products
Egypt	European Union	Fipronil	Honey and other apiculture products
Estonia	European Union	Fipronil	Honey and other apiculture products

European Economic Area		Fipronil	Honey and other apiculture products
European Union		Fipronil	Honey and other apiculture products
Finland	European Union	Fipronil	Honey and other apiculture products
France	European Union	Fipronil	Honey and other apiculture products
French West Indi	European Union	Fipronil	Honey and other apiculture products
Germany	European Union	Fipronil	Honey and other apiculture products
Greece	European Union	Fipronil	Honey and other apiculture products
Hungary	European Union	Fipronil	Honey and other apiculture products
Iceland	European Econoı	Fipronil	Honey and other apiculture products
Ireland	European Union	Fipronil	Honey and other apiculture products
Italy	European Union	Fipronil	Honey and other apiculture products
Japan		Fipronil	Honey (including royal-jelly)
Latvia	European Union	Fipronil	Honey and other apiculture products
Lithuania	European Union	Fipronil	Honey and other apiculture products
Luxembourg	European Union	Fipronil	Honey and other apiculture products
Malaysia		Fipronil	
Malta	European Union	Fipronil	Honey and other apiculture products
Morocco	European Union	Fipronil	Honey and other apiculture products
Netherlands	European Union	Fipronil	Honey and other apiculture products
New Zealand		Fipronil	
Norway	European Econoı	Fipronil	Honey and other apiculture products

Poland	European Union	Fipronil	Honey and other apiculture products
Portugal	European Union	Fipronil	Honey and other apiculture products
Romania	European Union	Fipronil	Honey and other apiculture products
Slovakia	European Union	Fipronil	Honey and other apiculture products
Slovenia	European Union	Fipronil	Honey and other apiculture products
South Africa	European Union	Fipronil	Honey and other apiculture products
Spain	European Union	Fipronil	Honey and other apiculture products
Sweden	European Union	Fipronil	Honey and other apiculture products
Switzerland		Fipronil	Honey (Royal jelly, pollen)
Turkey		Fipronil	Honey and other apiculture products
United Arab Emir	European Union	Fipronil	Honey and other apiculture products
United Kingdom	European Union	Fipronil	Honey and other apiculture products
Austria	European Union	Imidacloprid	Honey and other apiculture products
Belgium	European Union	Imidacloprid	Honey and other apiculture products
Bulgaria	European Union	Imidacloprid	Honey and other apiculture products
Canada		Imidacloprid	
Croatia	European Union	Imidacloprid	Honey and other apiculture products
Cyprus	European Union	Imidacloprid	Honey and other apiculture products
Czech Republic	European Union	Imidacloprid	Honey and other apiculture products
Denmark	European Union	Imidacloprid	Honey and other apiculture products
Dominican Repul	European Union	Imidacloprid	Honey and other apiculture products

Egypt	European Union	Imidacloprid	Honey and other apiculture products
Estonia	European Union	Imidacloprid	Honey and other apiculture products
European Economic Area		Imidacloprid	Honey and other apiculture products
European Union		Imidacloprid	Honey and other apiculture products
Finland	European Union	Imidacloprid	Honey and other apiculture products
France	European Union	Imidacloprid	Honey and other apiculture products
French West Indi	European Union	Imidacloprid	Honey and other apiculture products
Germany	European Union	Imidacloprid	Honey and other apiculture products
Greece	European Union	Imidacloprid	Honey and other apiculture products
Hungary	European Union	Imidacloprid	Honey and other apiculture products
Iceland	European Econo	Imidacloprid	Honey and other apiculture products
Ireland	European Union	Imidacloprid	Honey and other apiculture products
Italy	European Union	Imidacloprid	Honey and other apiculture products
Japan		Imidacloprid	
Latvia	European Union	Imidacloprid	Honey and other apiculture products
Lithuania	European Union	Imidacloprid	Honey and other apiculture products
Luxembourg	European Union	Imidacloprid	Honey and other apiculture products
Malaysia		Imidacloprid	
Malta	European Union	Imidacloprid	Honey and other apiculture products
Morocco	European Union	Imidacloprid	Honey and other apiculture products
Netherlands	European Union	Imidacloprid	Honey and other apiculture products

New Zealand		Imidacloprid	
Norway	European Econo	Imidacloprid	Honey and other apiculture products
Poland	European Union	Imidacloprid	Honey and other apiculture products
Portugal	European Union	Imidacloprid	Honey and other apiculture products
Romania	European Union	Imidacloprid	Honey and other apiculture products
Slovakia	European Union	Imidacloprid	Honey and other apiculture products
Slovenia	European Union	Imidacloprid	Honey and other apiculture products
South Africa	European Union	Imidacloprid	Honey and other apiculture products
Spain	European Union	Imidacloprid	Honey and other apiculture products
Sweden	European Union	Imidacloprid	Honey and other apiculture products
Turkey		Imidacloprid	Honey and other apiculture products
United Arab Emir	European Union	Imidacloprid	Honey and other apiculture products
United Kingdom	European Union	Imidacloprid	Honey and other apiculture products
Canada		Pyrethrins	
Egypt		Pyrethrins	
European Econo	mic Area	Pyrethrins	PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS
Iceland	European Econo	Pyrethrins	PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS
Japan		Pyrethrins	
Malaysia		Pyrethrins	
Morocco		Pyrethrins	
New Zealand		Pyrethrins	

Norway	European Econo	Pyrethrins	PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS
South Africa		Pyrethrins	
Switzerland		Pyrethrins	PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS
Turkey		Pyrethrins	Honey and other apiculture products
United States		Pyrethrins	All food items in food handling establishments where food and food products are held, processed, prepared
Australia		Tau-fluvalinate	Honey
Austria	European Union	Tau-fluvalinate	Honey and other apiculture products
Belgium	European Union	Tau-fluvalinate	Honey and other apiculture products
Bulgaria	European Union	Tau-fluvalinate	Honey and other apiculture products
Canada		Tau-fluvalinate	Honey
Croatia	European Union	Tau-fluvalinate	Honey and other apiculture products
Cyprus	European Union	Tau-fluvalinate	Honey and other apiculture products
Czech Republic	European Union	Tau-fluvalinate	Honey and other apiculture products
Denmark	European Union	Tau-fluvalinate	Honey and other apiculture products
Dominican Repul	United States	Tau-fluvalinate	Honey
Egypt	European Union	Tau-fluvalinate	Honey and other apiculture products
Estonia	European Union	Tau-fluvalinate	Honey and other apiculture products
European Econom	ic Area	Tau-fluvalinate	Honey and other apiculture products
European Union		Tau-fluvalinate	Honey and other apiculture products
Finland	European Union	Tau-fluvalinate	Honey and other apiculture products
France	European Union	Tau-fluvalinate	Honey and other apiculture products

French West Indi	European Union	Tau-fluvalinate	Honey and other apiculture products
Germany	European Union	Tau-fluvalinate	Honey and other apiculture products
Greece	European Union	Tau-fluvalinate	Honey and other apiculture products
Honduras	United States	Tau-fluvalinate	Honey
Hungary	European Union	Tau-fluvalinate	Honey and other apiculture products
Iceland	European Econoı	Tau-fluvalinate	Honey and other apiculture products
Ireland	European Union	Tau-fluvalinate	Honey and other apiculture products
Italy	European Union	Tau-fluvalinate	Honey and other apiculture products
Japan		Tau-fluvalinate	Honey (including royal-jelly)
Latvia	European Union	Tau-fluvalinate	Honey and other apiculture products
Lithuania	European Union	Tau-fluvalinate	Honey and other apiculture products
Luxembourg	European Union	Tau-fluvalinate	Honey and other apiculture products
Malaysia		Tau-fluvalinate	
Malta	European Union	Tau-fluvalinate	Honey and other apiculture products
Mexico	United States	Tau-fluvalinate	Honey
Morocco	European Union	Tau-fluvalinate	Honey and other apiculture products
Netherlands	European Union	Tau-fluvalinate	Honey and other apiculture products
New Zealand		Tau-fluvalinate	
Norway	European Econoı	Tau-fluvalinate	Honey and other apiculture products
Poland	European Union	Tau-fluvalinate	Honey and other apiculture products
Portugal	European Union	Tau-fluvalinate	Honey and other apiculture products

Romania	European Union	Tau-fluvalinate	Honey and other apiculture products
Slovakia	European Union	Tau-fluvalinate	Honey and other apiculture products
Slovenia	European Union	Tau-fluvalinate	Honey and other apiculture products
South Africa	European Union	Tau-fluvalinate	Honey and other apiculture products
Spain	European Union	Tau-fluvalinate	Honey and other apiculture products
Sweden	European Union	Tau-fluvalinate	Honey and other apiculture products
Switzerland		Tau-fluvalinate	Honey (Royal jelly, pollen)
Turkey		Tau-fluvalinate	Honey and other apiculture products
United Arab Emir	European Union	Tau-fluvalinate	Honey and other apiculture products
United Kingdom	European Union	Tau-fluvalinate	Honey and other apiculture products
United States		Tau-fluvalinate	Honey

Index Commodity	MRL (ppm)	MRL Type	Expiry Date	Effective Date
Honey	0.5	General		May 05, 2011
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.1	Default		
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Feb 02, 2013
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012

Honey	0.5	General		Feb 02, 2013
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.01	Default		
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.01	Default		
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.1	Default		
Honey	0.5	General		Feb 02, 2013
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012

Honey	0.5	General		May 29, 2010
Honey	0.5	General		Jul 21, 2015
Honey	0.5	General		Jun 14, 2012
Honey	0.5	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.1	Default		
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Feb 02, 2013
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012

Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Feb 02, 2013
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	Default		
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	Default		
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.1	Default		
Honey	0.01	General		Feb 02, 2013
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012

Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jul 21, 2015
Honey	0.01	General		Jun 14, 2012
Honey	0.01	General		Jun 14, 2012
Honey	0.1	General		Aug 26, 2011
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.02	General		Aug 29, 2008
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.15	General		May 23, 2007
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		

Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.15	General		May 23, 2007
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.15	General		May 23, 2007
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.1	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		

Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.01	Default		
Honey	0.15	General		May 23, 2007
Honey	0.01	General		Jan 28, 2014
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.1	Default		
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015

Honey	0.005	General		May 01, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 01, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.05	General		Apr 15, 2011
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.01	Default		
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.1	Default		
Honey	0.005	General		May 01, 2015

Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.01	General		May 07, 2012
Honey	0.01	General		Jul 21, 2015
Honey	0.005	General		May 13, 2015
Honey	0.005	General		May 13, 2015
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.1	Default		
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010

Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Dec 13, 2014
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Dec 13, 2014
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.01	Default		
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.01	Default		
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010

Honey	0.1	Default		
Honey	0.05	General		Dec 13, 2014
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Jul 21, 2015
Honey	0.05	General		Oct 10, 2010
Honey	0.05	General		Oct 10, 2010
Honey	0.1	Default		
Honey	0.01	Default		
Honey	0.05	General		May 30, 2009
Honey	0.05	General		May 30, 2009
Honey	0.01	Default		
Honey	EXEMPT			Jan 01, 1985
Honey	0.01	Default		
Honey	0.1	Default		

Honey	0.05	General		May 30, 2009
Honey	0.01	Default		
Honey	0.05	General		May 07, 2012
Honey	0.05	General		Jul 21, 2015
Honey	1	General		Jan 29, 2008
Honey	0.01	General		Nov 08, 2011
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.02	General		Mar 18, 2011
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.02	General		Sep 10, 2008
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Dec 12, 2015
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014

Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.02	General		Sep 10, 2008
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Dec 12, 2015
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Jun 05, 2015
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.01	Default		
Honey	0.05	General		Nov 01, 2014
Honey	0.02	General		Sep 10, 2008
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.1	Default		
Honey	0.05	General		Dec 12, 2015
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014

Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.01	General		Sep 01, 2008
Honey	0.01	General		Jul 21, 2015
Honey	0.05	General		Nov 01, 2014
Honey	0.05	General		Nov 01, 2014
Honey	0.02	General		Sep 10, 2008

US Import Tolerance?	CFR Prescribed Use?	Undefined Published Commodity?
NO	NO	YES
NO	NO	NO
NO	NO	NO
NO	NO	NO
NO	NO	NO
NO	NO	NO
NO	NO	NO
NO	NO	NO
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Commodity Notes	LOD?	LOQ?	Seed Treatment?
	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO

	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO

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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	NO	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO

Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO

Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO

	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO

Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO

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	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
	NO	NO	NO
	NO	NO	NO
	YES	NO	NO
	YES	NO	NO
	NO	NO	NO
Pyretrum is listed as “Not prescribed”, meaning that Maximum Residue Limits are not required	NO	NO	NO
	NO	NO	NO
	NO	NO	NO

	YES	NO	NO
	NO	NO	NO
	YES	NO	NO
	YES	NO	NO
Food must be removed or covered prior to use.	NO	NO	NO
	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO

Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO

Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
	YES	NO	NO
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Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
Other products to which the EU Honey and other apiculture products MRL applies are Pollen (residues of vegetal pollen) and	YES	NO	NO
	NO	NO	NO

Post Harvest?	Residue Definition
NO	Commodities of plant origin: Boscalid.
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Sum of boscalid and M 510F01 including its congugates expressed as boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)

NO	Sum of boscalid and M 510F01 including its congugates expressed as boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	
NO	Sum of boscalid and M 510F01 including its congugates expressed as boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)

NO	Sum of boscalid and M 510F01 including its congugates expressed as boscalid.
NO	Boscalid
NO	Boscalid (Fat Soluble)
NO	Boscalid (Fat Soluble)
NO	Cadusafos
NO	Cadusafos
NO	Cadusafos
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NO	Cadusafos
NO	Cadusafos
NO	Cadusafos
NO	Cadusafos
NO	Cadusafos
NO	Coumafós
NO	
NO	
NO	
NO	Coumaphos: O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) O,O-diethyl phosphorothioate, including the oxygen
NO	
NO	
NO	
NO	
NO	Coumaphos: Tolerances for residues of the insecticide coumaphos (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran
NO	
NO	
NO	
NO	
NO	
NO	

NO	
NO	
NO	
NO	Coumaphos: Tolerances for residues of the insecticide coumaphos (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran
NO	
NO	
NO	
NO	
NO	
NO	
NO	
NO	
NO	
NO	
NO	Coumaphos: Tolerances for residues of the insecticide coumaphos (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran
NO	
NO	
NO	
NO	
NO	
NO	

NO	
NO	
NO	
NO	
NO	
NO	
NO	
NO	
NO	Coumaphos: Tolerances for residues of the insecticide coumaphos (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran
NO	Sum of fipronil, the sulphenyl metabolite (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)

NO	Fipronil: Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil: Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
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NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	
NO	Fipronil: Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil (Fat Soluble)

NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Sum fipronil and sulfone metabolite (MB46136) expressed as fipronil.
NO	Fipronil (fipronil ve sulfone metaboliti (MB46136) toplami; fipronil cinsinden) (fat soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Fipronil (Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (Fat Soluble)
NO	Imidacloprid
NO	Imidacloprid
NO	Imidacloprid
NO	
NO	Imidacloprid
NO	Imidacloprid
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NO	Imidacloprid
NO	Imidacloprid
NO	Imidacloprid
NO	Imidacloprid
NO	
NO	
NO	Pyrethrins
NO	Pyrethrins
NO	
NO	
NO	
NO	

NO	Pyrethrins
NO	
NO	Pyrethrins
NO	Pyrethrins
NO	Pyrethrins: Tolerances for residues of the insecticide pyrethrins ((1S)-2-methyl-4-oxo-3-(2Z)-2,4-pentadienylcyclopenten-1-yl
NO	Tau-fluvalinate: Fluvalinate, sum of isomers.
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-fluvalinate: cyano(3-phenoxyphenyl)methyl N-[2-chloro-4-(trifluoromethyl)phenyl]-D-valinate
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-fluvalinate: Tolerances are established for residues of the insecticide tau-fluvalinate, cyano(3
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)

NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-fluvalinate: Tolerances are established for residues of the insecticide tau-fluvalinate, cyano (3
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	MRLs for fluvalinate are established for the sum of residues of the isomers of fluvalinate
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-fluvalinate: Tolerances are established for residues of the insecticide tau-fluvalinate, cyano (3
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)

NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-fluvalinate
NO	Tau-Fluvalinate (Fat soluble).
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-Fluvalinate (Fat Soluble)
NO	Tau-fluvalinate: Tolerances are established for residues of the insecticide tau-fluvalinate, cyano (3

Regulation Name	Source Document
Australia New Zealand Food Standards Code-Amendment No. 122-2011 to FSANZ Standard 1.4.2 (Australia Only) (5/5/2011)	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation (EU) No 441/2012 added by Decision No 6/2013	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	

Commission Regulation (EU) No 441/2012 added by Decision No 6/2013	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation (EU) No 441/2012 added by Decision No 6/2013	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	

Reg. (EC) No 459/2010	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation (EU) No 441/2012 added by Decision No 6/2013	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	

Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation (EU) No 441/2012 added by Decision No 6/2013	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation (EU) No 441/2012 added by Decision No 6/2013	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	

Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Commission Regulation 441/2012	
Resolución 559/2011	
EMRL2008-18 (08/29/08)	
CFR 180.189; 64 FR 39077, July 21, 1999 thru 72 FR 28876, May 23, 2007	

CFR 180.189; 64 FR 39077, July 21, 1999 thru 72 FR 28876, May 23, 2007	
CFR 180.189; 64 FR 39077, July 21, 1999 thru 72 FR 28876, May 23, 2007	

CFR 180.189; 64 FR 39077, July 21, 1999 thru 72 FR 28876, May 23, 2007	
Australia New Zealand Food Standards Code - Amendment Instrument No. APVMA 1, 2014 (Gazette No. 2)	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	

Commission Regulation (EU) No 1127/2014 added by Decision No 83/2015	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014 added by Decision No 83/2015	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Japan Food Chemical Research Foundation Online MRL Database	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014 added by Decision No 83/2015	

Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Ordonnance du DFI sur les substances étrangères et les composants dans les denrées alimentaires (Ordonnance sur les	
Commission Regulation (EU) No 1127/2014	
Commission Regulation (EU) No 1127/2014	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	

Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Commission Regulation (EU) No 491/2014 added by Decision No 257/2014	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Commission Regulation (EU) No 491/2014 added by Decision No 257/2014	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	

Commission Regulation (EU) No 491/2014 added by Decision No 257/2014	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Reg. (EU) N° 893/2010	
Commission Regulation (EC) No 149/2008 added by Decision No 58/2009	
Commission Regulation (EC) No 149/2008 added by Decision No 58/2009	
Food Regulations 1985, Sixteenth Schedule (1/1/1985)	

Commission Regulation (EC) No 149/2008 added by Decision No 58/2009	
Ordonnance du DFI sur les substances étrangères et les composants dans les denrées alimentaires (Ordonnance sur les	
CFR 180.128; 71 FR 74814, Dec. 13, 2006 thru 73 FR 5108, Jan. 29, 2008	
Australia New Zealand Food Standards Code - Amendment Instrument No. APVMA 4, 2011 (Gazette No. 22)	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
EMRL2011-13 (03/18/11)	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
CFR 180.427; 65 FR 33701, May 24, 2000, as amended at 67 FR 49617, July 31, 2002; 73 FR 52616, Sept. 10, 2008	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) 2015/846	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	

Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
CFR 180.427; 65 FR 33701, May 24, 2000, as amended at 67 FR 49617, July 31, 2002; 73 FR 52616, Sept. 10, 2008	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) 2015/846	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Japan Food Chemical Research Foundation Online MRL Database	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
CFR 180.427; 65 FR 33701, May 24, 2000, as amended at 67 FR 49617, July 31, 2002; 73 FR 52616, Sept. 10, 2008	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) 2015/846	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	

Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
Reg. (EC) No 149/2008	
Commission Regulation (EU) No 2015/401	
Commission Regulation (EU) No 2015/401	
CFR 180.427; 65 FR 33701, May 24, 2000, as amended at 67 FR 49617, July 31, 2002; 73 FR 52616, Sept. 10, 2008	

Publication Date	Comments Due Date

Market	Origin Market	Active Ingredient	Published Commodity
Canada		Coumaphos	Honeycombs
Dominican Repul	United States	Coumaphos	Honeycomb
Honduras	United States	Coumaphos	Honeycomb
Mexico	United States	Coumaphos	Honeycomb
United States		Coumaphos	Honeycomb

Index Commodity	MRL (ppm)	MRL Type	Expiry Date	Effective Date
Honey	0.1	General		Aug 29, 2008
Honey	45	General		May 23, 2007
Honey	45	General		May 23, 2007
Honey	45	General		May 23, 2007
Honey	45	General		May 23, 2007

US Import Tolerance?	CFR Prescribed Use?	Commodity Notes
NO	NO	
NO	NO	
NO	NO	
NO	NO	
NO	NO	

LOD?	LOQ?	Seed Treatment?	Post Harvest?
NO	NO	NO	NO
NO	NO	NO	NO
NO	NO	NO	NO
NO	NO	NO	NO
NO	NO	NO	NO

Residue Definition	Regulation Name
Coumaphos: O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) O,O-diethyl phosphorothioate, including the oxygen	EMRL2008-18 (08/29/08)
Coumaphos	CFR 180.189; 64 FR 39077, July 21, 1999 thru 72 FR 28876, May 23, 2007
Coumaphos	CFR 180.189; 64 FR 39077, July 21, 1999 thru 72 FR 28876, May 23, 2007
Coumaphos	CFR 180.189; 64 FR 39077, July 21, 1999 thru 72 FR 28876, May 23, 2007
Coumaphos: Tolerances for residues of the insecticide coumaphos (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran	CFR 180.189; 64 FR 39077, July 21, 1999 thru 72 FR 28876, May 23, 2007

Source Document	Publication Date	Comments Due Date

To: Miller, David[Miller.DavidJ@epa.gov]
Cc: Hrdy, David[Hrdy.David@epa.gov]; Jane M Stewart[jane.stewart@basf.com]; Tiu, Carmen (C)[tcarmen@dow.com]; Philip A Brindle[philip.brindle@basf.com]; Cheryl Cleveland[cheryl.cleveland@basf.com]; Nguyen, James[Nguyen.James@epa.gov]; Reshma Arrington[rarrington@croplifeamerica.org]; Nako, Steve[Nako.Steve@epa.gov]
From: Ray McAllister
Sent: Tue 1/26/2016 8:46:17 PM
Subject: RE: Meeting on Wednesday?
CLA Paper on Pesticide Residues in Honey_EPA rsm.pdf
CLA Proposal for setting MRLs in honey_EPA.PPTX

Attached is the draft paper on honey MRLs and a slide presentation explaining the approach, for discussion tomorrow. These are not ready for sharing widely.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

From: Ray McAllister
Sent: Tuesday, January 26, 2016 3:04 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>; Nako, Steve <Nako.Steve@epa.gov>
Subject: Re: Meeting on Wednesday?

David & David:

I'm working on a background paper and slide presentation to share with you for tomorrow's meeting. If my computer will cooperate from home, I'll get it to you in the next half hour.

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

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ray@croplife.us

On Jan 25, 2016, at 5:28 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

It looks like Steve N. booked a room last week in advance. Thanks, Steve !

So, we will meeting in Room 10771, 10-11 am.

David.

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 4:16 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>; Nguyen, James <Nguyen.James@epa.gov>; Reshma Arrington <rarrington@croplifeamerica.org>
Subject: Re: Meeting on Wednesday?

I will reserve a room at CLA as a backup, in case there is not a room available at Potomac Yards.

On Jan 25, 2016, at 3:43 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

I've booked a 10 am to 11 am slot for this. Not able to book a room, so we may have to play it by ear (as of a few weeks back, EPA has moved folks from OSWER, OGC, and other EPA offices onto our building to save rent, so we are all compressed and competing for the same conference rooms so they are less available.)

David H. has his calender marked off for this time (10 to noon), but I don't know what it is – I will leave it to him to get back to you about whether he can make it or not and if alternate arrangements need to be made.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 3:30 PM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Hrdy, David <Hrdy.David@epa.gov>; Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>

Subject: Re: Meeting on Wednesday?

Thanks. We'll plan on it.

On Jan 25, 2016, at 1:15 PM, Miller, David <Miller.DavidJ@epa.gov> wrote:

Meeting on Wednesday morning should be fine. I think you said 10:00 or 10:30. I will check caLANder and see what available times are.

David.

David J. Miller CAPT | USPHS

Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Monday, January 25, 2016 12:19 PM
To: Miller, David <Miller.DavidJ@epa.gov>; Hrdy, David <Hrdy.David@epa.gov>
Cc: Jane M Stewart <jane.stewart@basf.com>; Tiu, Carmen (C) <tcarmen@dow.com>; Philip A Brindle <philip.brindle@basf.com>; Cheryl Cleveland <cheryl.cleveland@basf.com>
Subject: Meeting on Wednesday?

David & David:

How soon might you be able to confirm whether our meeting on Wednesday can take place?

Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

+1-202-872-3874 (office)

+1-202-577-6657 (cell)

ray@croplife.is

Crop Life America Proposal for setting MRLs in honey

CLA Residue Expert Working Group

January 27, 2016

CropLife AMERICA

The **objective** of this proposal is to provide a tiered regulatory approach for setting tolerances (MRLs) in honey. This tolerance will be used to assess consumer safety based on US consumption information and would be available as a trading standard to support international trade.

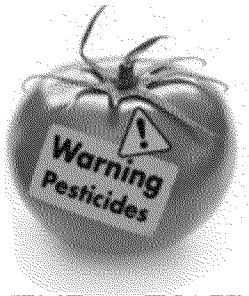
The **scope** of this proposal is limited to Honey.

Although bees also produce other consumables such as wax, pollen loads, propolis, bee bread and royal jelly, their consumption is very low. Honey is the main beehive product used as human food.

The **scope** of this proposal is limited to the inadvertent transfer of pesticide residues from nectar or pollen to honey.

The direct application of pest products to the bee hive or surrounding structure could lead to residues in honey. There is a process already in place for establishing MRLs in honey for these uses.

ROMEO GACAD/AFP/GETTY IMAGES



What's on my food?

Inadvertent Residues in Honey *Trade Issue or Health Concern?*

a project of Pesticide Action Network

SHARE

HONEY

12 Pesticide Residues Found by the USDA Pesticide Data Program[1,2,3]

Human Health Effects:

2 — Known or Probable Carcinogens[4]
6 — Suspected Hormone Disruptors
2 — Neurotoxins
2 — Developmental or Reproductive Toxins

Environmental Effects:

4 — Honeybee Toxins[5]

TOXICITY LEGEND

Carcinogens	Hormone Disruptors	Neurotoxins	Developmental or Reproductive Toxins	Bee Toxins
KNOWN	SUSPECTED	PRESENT	PRESENT	HIGH
PROBABLE				MODERATE
POSSIBLE				SLIGHT

Pesticide Residues Found in Honey:

What Pesticide?	How Often is it Found?[6]	Conventional vs. Organic	Toxicity[7]	Other Foods with this Pesticide

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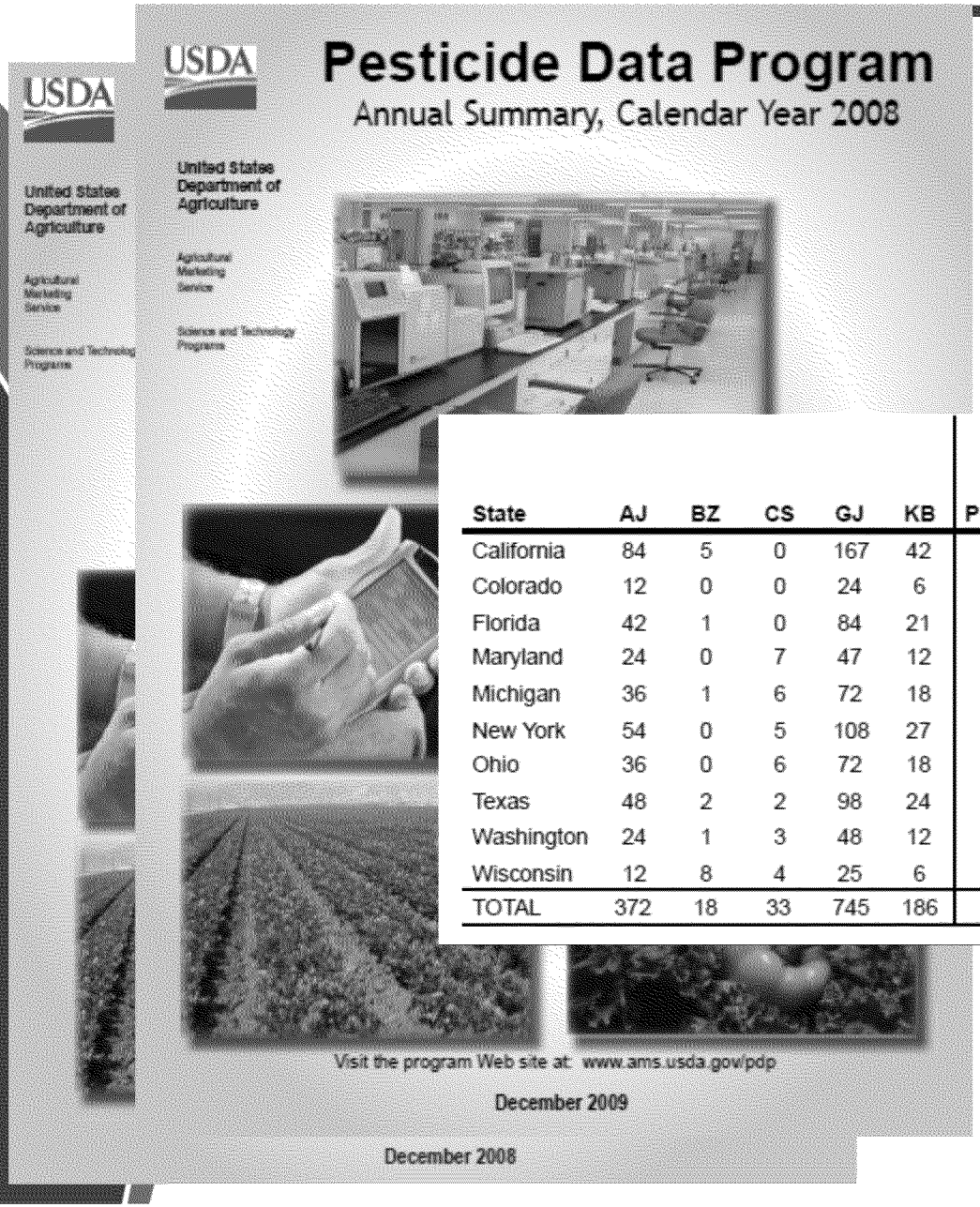
TAKE ACTION »
Join the movement for food system reform

FIND OUT :: WHAT'S ON YOUR FOOD?

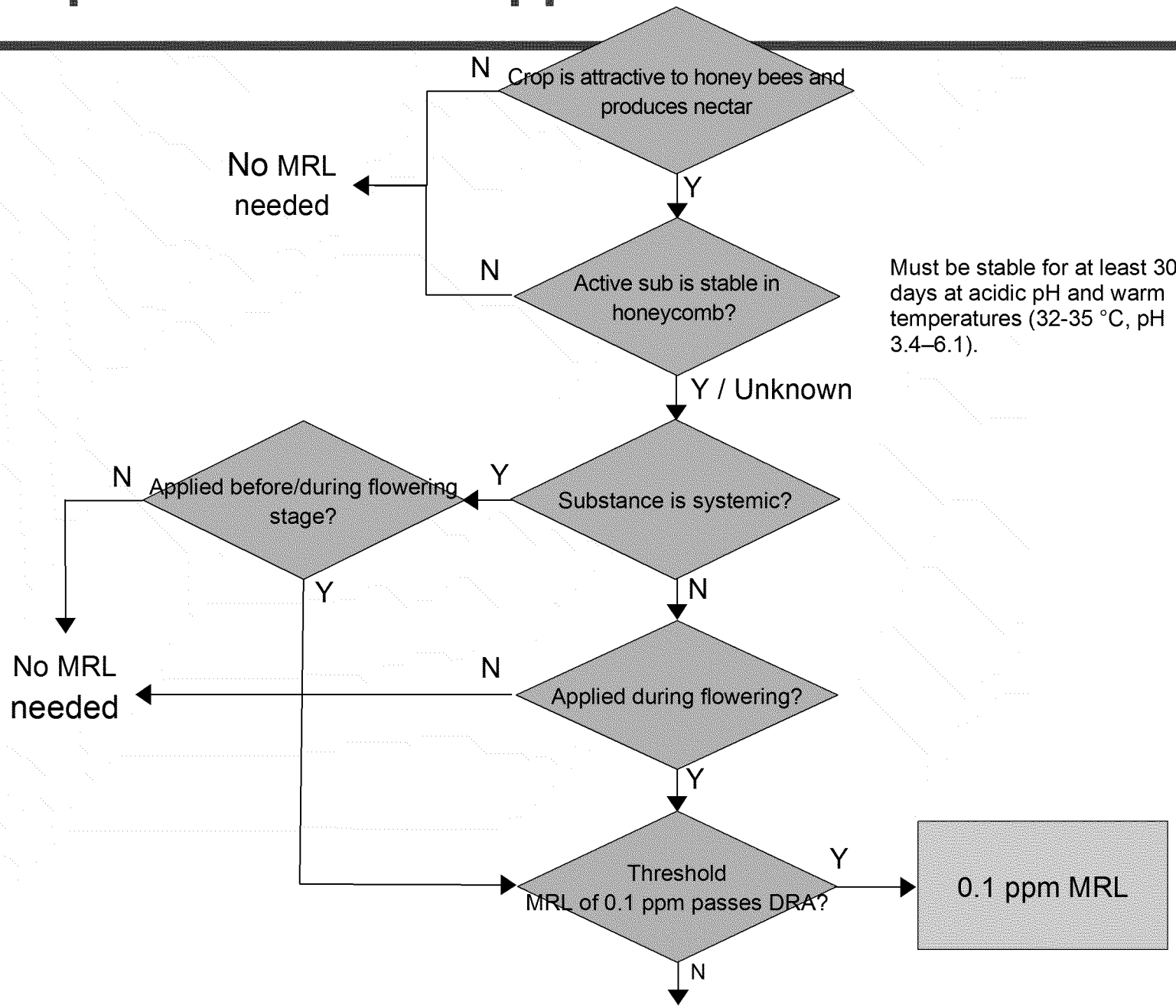
Almonds
Apple Juice
Apple Sauce
Apples
Apples-Single Servings
Asparagus
Asparagus, Canned
Avocado
Baby Food - Applesauce
Baby Food - Carrots
Baby Food - Green Beans
Baby Food - Peaches
Baby Food - Pears
Baby Food - Peas
Baby Food - Sweet Potato

US Monitoring Data



State	AJ	BZ	CS	GJ	KB	Total Processed	Total Fresh & Proccessed F&V	Nuts AL	Honey HY	Fish FC	Grain RI
California	84	5	0	167	42	298	2,351	42	126	125	42
Colorado	12	0	0	24	6	42	329	6	18	18	6
Florida	42	1	0	84	21	148	1,174	21	63	63	21
Maryland	24	0	7	47	12	90	669	12	36	35	12
Michigan	36	1	6	72	18	133	1,021	18	54	54	18
New York	54	0	5	108	27	194	1,537	27	81	81	27
Ohio	36	0	6	72	18	132	968	18	54	54	18
Texas	48	2	2	98	24	174	1,361	24	72	72	72
Washington	24	1	3	48	12	88	653	12	36	35	12
Wisconsin	12	8	4	25	6	55	319	6	18	15	6
TOTAL	372	18	33	745	186	1,354	10,382	186	558	552	184

Proposal – Tiered Approach



Must be stable for at least 30 days at acidic pH and warm temperatures (32-35 °C, pH 3.4–6.1).

Threshold MRL – based on PDP data

Pesticide Data Program

2007 Su
in .

Pesticide	# of Samples Analyzed	S w
1-Naphthol	186	
2,4-dimethyl aniline (2,4 DMA)	186	
2,4-dimethylphenyl formamide (2,4-DMPF)	186	
3-Hydroxycarbofuran	186	
4,4-dibromobenzophenone	186	
Acephate	186	
Acetamiprid	186	
Acetochlor	186	
Alachlor	186	
Aldicarb	186	
Aldicarb sulfone	186	
Aldicarb sulfoxide	186	
Aldrin	186	
Allethrin	186	
Amicarbazone	186	
Amitraz	186	
Atrazine	186	
Azinphos methyl	186	
Azoxystrobin	186	
Bendiocarb	186	
Benoxacor	186	
BHC alpha	186	
Bifenazate	186	
Bifenthrin	186	

Pesticide Data Program

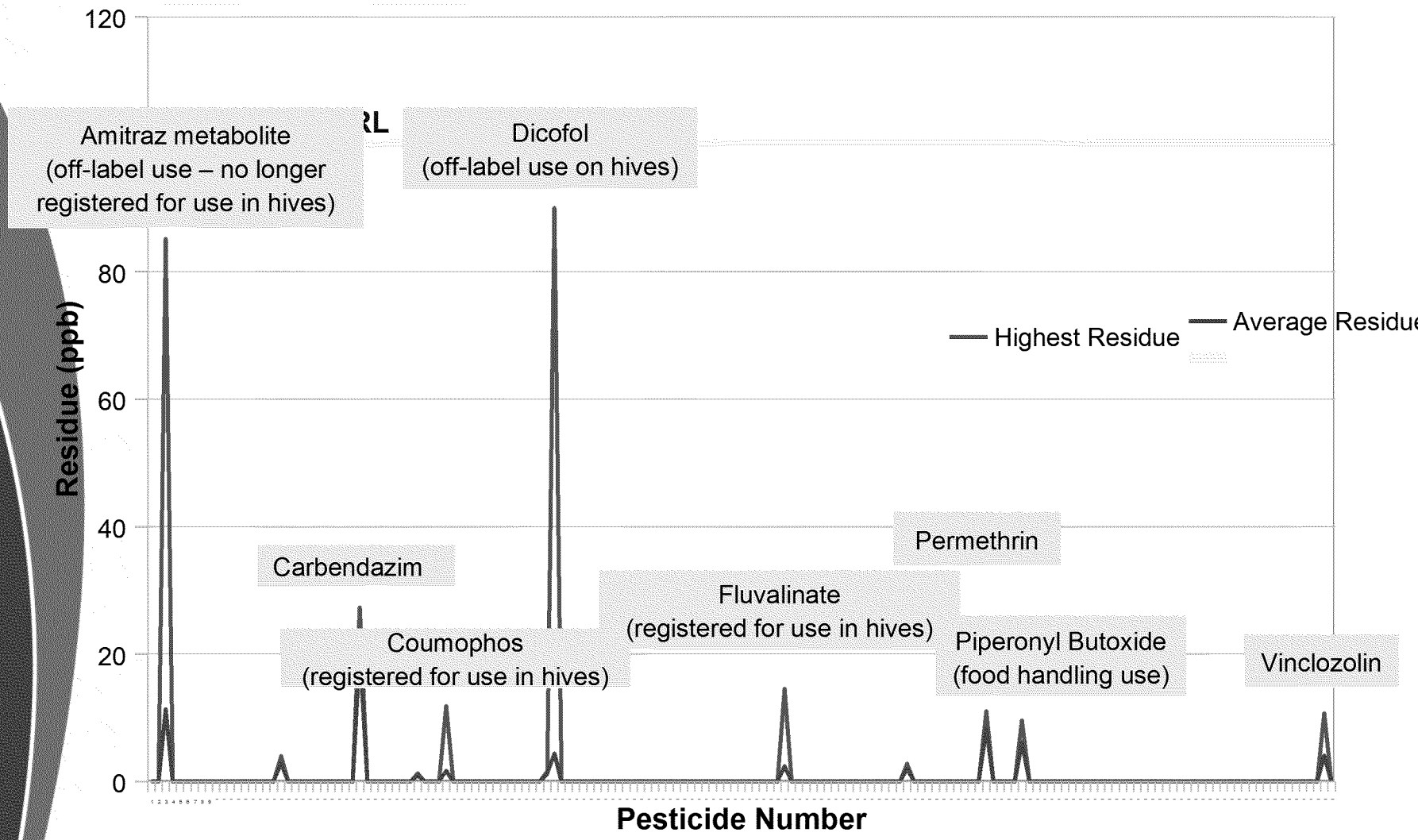
2008 Summary of Residue Findings in Honey for All Pesticides

Pesticide	# of Samples Analyzed	# of Samples w/Detects	% of Samples w/Detects	Min Value Detected	Max Value Detected	Avg Value Detected	Range of LODs	Unit pp_
1-Naphthol	558						10 - 10	B
2,4-dimethyl aniline (2,4 DMA)	558						50 - 50	B
2,4-dimethylphenyl formamide (2,4-DMPF)	558	73	13.1	4.1	85.1	12.189	4 - 4	B
3-Hydroxycarbofuran	558						4 - 4	B
4,4-dibromobenzophenone	558						4 - 4	B
Acephate	558						50 - 50	B
Acetamiprid	558						40 - 40	B
Acetochlor	558						10 - 10	B
Alachlor	558						10 - 10	B
Aldicarb	558						4 - 4	B
Aldicarb sulfone	558						15 - 15	B
Aldicarb sulfoxide	558						20 - 20	B
Aldrin	558						10 - 10	B
Allethrin	558						10 - 10	B
Amicarbazone	558						30 - 30	B
Amitraz	558						4 - 4	B
Atrazine	558						6 - 6	B
Azinphos methyl	558						6 - 6	B
Azoxystrobin	558	3	0.5	3.3	4	3.667	2 - 2	B
Bendiocarb	558						2 - 2	B
Benoxacor	558						4 - 4	B
BHC alpha	558						4 - 4	B
Bifenazate	558						20 - 20	B
Bifenthrin	558						2 - 2	B

Threshold MRL – based on PDP data

Program	Pesticide	Number of Samples	Samples with Detections	% of Samples	Range of Values Detected ppb	Range of LODs ppb	US Tolerance ppb
2007 PDP	Coumaphos	186	*Registered for use on hives*		1.0 – 11.8	1.0	150
	Dicloran	186	1	0.5	1.0	1.0	--
	Dicofol p,p'	186	3	1.6	1.3 – 3.6	1.0	--
	2,4-DMPF	186	8	4.3	4.2 - 27.5	4.0	200
	Fluvalinate	186	*Registered for use on hives*		1.0 - 6.7	1.0	20
	Vinclozolin	186	2	1.1	10.6 – 10.7	1.0	--
2008 PDP	Azoxystrobin	558	3	0.5	3.3 - 4.0	2.0	--
	Carbendazim	558	1	0.2	27.3	5.0	--
	Chlorpyrifos	558	*Food handling use*		1.3	1.0	100
	Coumaphos	558	*Registered for use on hives*		1.0 - 8.2	1.0	150
	Dicloran (V-2)	558	2	0.4	1.1 - 1.6	1.0	--
	Dicofol p,p'	558	32	5.7	1.0 - 90	1.0	--
	2,4-DMPF	558	73	13.1	4.1 - 85.1	4.0	200
	Fluvalinate	558	*Registered for use on hives*		1.0 - 14.5	1.0	20
	Methoxyfenozide	558	1	0.2	2.8	2.0	--
	Permethrin Total	558	1	0.2	11	10	--
	Piperonyl butoxide	558	*Food handling use*		6.3 - 9.6	6.0	10000
	Vinclozolin	558	3	0.5	1.3 - 2.1	1.0	--

Threshold MRL – based on PDP data



Dietary Impact

Risk Cup Utilization for 363 compounds in the HHBM database from Residues in Honey at Threshold MRL of 0.1 mg/kg	Acute at 95%tile (mg/kg bw/day)	Chronic (mg/kg bw/day)
No. of compounds where honey exposure exceeds the reference dose for children age 1-2	0	1 (0.3%)
No. of compounds where honey exposure is more than 5% of reference dose for children age 1-2*	4 (1%)	10 (3%)
No. of compounds where honey exposure is less than 5% of reference dose for children age 1-2*	235 (65%)	345 (95%)
No. of compounds in HHBM with no reference dose	124 (34%)	8 (2%)

*Honey exposure at the threshold MRL of 0.1 mg/kg would exceed 5% of the RfD for pesticides with acute RfDs lower than 0.000283 mg/kg bw/day and/or chronic RfDs lower than 0.000073 mg/kg bw/day.

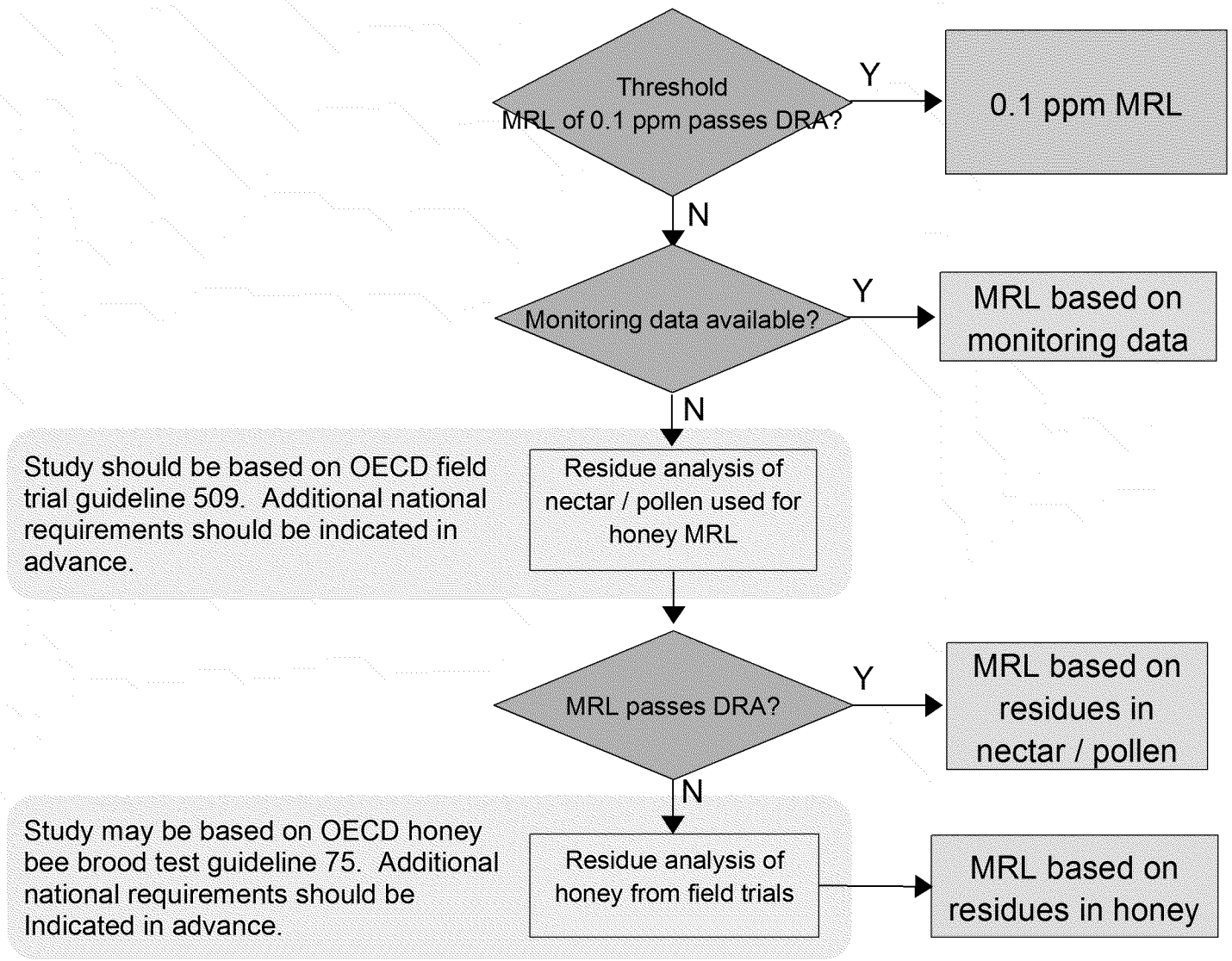
Dietary Impact

Impact of 0.1 mg/kg Threshold Honey MRL on Acute and Chronic Dietary Risk for Selected Compounds

Compound	aPAD	cPAD	% children aPAD 95%, 99.9	% children cPAD
Fipronil	0.025	0.0002	0.06, 1.10	1.8
Imidacloprid**	0.14	0.057	0.1, 1.96	<0.1
Boscalid	NA	0.218	-	~0
Pyrethins	0.07	0.044	0.02, 0.39	<0.1
Cadusafos***	0.00002	0.000001	70.50, 1372.35	358.1
Coumaphos*	0.0025	0.0003	0.56, 10.98	1.2
Fluvalinate*	0.005	0.005	0.28,5.49	0.1

*registered on hives
** neonicotinoid
*** No US registration. Only one import tolerance on bananas.

Proposal – Tiered Approach



Advantages of the CLA Proposal

- Pragmatic, yet conservative
- Threshold MRL based on real residue data
- threshold MRL will be acceptable for most pesticides
- Tiered approach allows for refinement for highly toxic or tightly managed pesticides
- Harmonized with EU/OECD

Thank you for your time!

CropLife AMERICA

To: Miller, David[Miller.DavidJ@epa.gov]; jcranney@calcitrusquality.org[jcranney@calcitrusquality.org]; Johnston, John - FSIS[John.Johnston@fsis.usda.gov]; Angela.S.Klemens@dupont.com[Angela.S.Klemens@dupont.com]; vincent.a.leopold@monsanto.com[vincent.a.leopold@monsanto.com]; RMcAllister@croplifeamerica.org[RMcAllister@croplifeamerica.org]; kent.rupprecht@bayer.com[kent.rupprecht@bayer.com]; Jane M Stewart[jane.stewart@basf.com]; bruce.young@bayer.com[bruce.young@bayer.com]; 'Maratos, Marie - FSIS'[Marie.Maratos@fsis.usda.gov]; 'Basu, Pat - FSIS'[Pat.Basu@fsis.usda.gov]; Bacon, Laura[Bacon.Laura@epa.gov]; Doherty, Michael[Doherty.Michael@epa.gov]
Cc: Janet Collins[jcollins@croplifeamerica.org]
From: Cheryl Cleveland
Sent: Sat 1/21/2017 4:12:35 PM
Subject: CLI draft IESTI comments
Jan 2017 comments table CCPR paper version 2.docx
Discussion paper IESTI 2017_draft to eWG_17-01-2017.pdf

Dear David et al.

I am sharing with you the commenting table that CLI/CLA have drafted regarding the 2nd version of the IESTI eWG paper. (I have attached the .pdf version of eWG paper for ease of reference.) Our comments are not final, but close, we will continue work on them thru Monday afternoon and will submit on Tuesday by the January 24th deadline. I and the CLA membership would be happy to discuss any of these with you or the US delegation team as you are preparing the US response.

Regards,

Cheryl Cleveland, Ph. D.
Global Consumer Safety

Phone: +1 919 547-2407, Mobile: +1-919-593-0194, Email: cheryl.cleveland@basf.com

Postal Address: BASF Corporation, 26 Davis Drive, 27709-3528 Research Triangle Park, United States

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Agenda item xx

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES
Forty-ninth Session
xxx, P.R. China, 24-29 April 2017

DISCUSSION PAPER
REVISITING THE INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKE (IESTI)

Prepared by the eWG chaired by the Netherlands and co-chaired by Australia[1]

Introduction

1. According to the Codex Procedural Manual, the Codex Maximum Limit for Pesticide Residues (MRL) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds.[2]
The Manual further specifies that MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable. The Manual continues by explaining that Codex MRLs, which are primarily intended to apply in international trade, are derived from estimations made by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and that JMPRs assessment should indicate that foods complying with Codex MRLs are safe for human consumption.

2. The toxicological acceptability ('safety') of the MRL is determined by estimating a life-time dietary exposure to the residue and comparing this with the Acceptable Daily Intake (ADI), and, in case the compound has acutely toxic properties, by estimating a short-term dietary exposure and comparing this with the Acute Reference Dose (ARfD)[3]. It is a matter of principle that the exposure should not exceed the ARfD or ADI when a food commodity contains residues at the level of the MRL.

3. To address the estimation of the short-term intake of pesticide residues at the international level, the International Estimate of Short Term Intake (IESTI) was developed in two subsequent FAO/WHO consultations. In analogy, the National Estimate of Short Term Intake (NESTI) was defined. Since its 1999 meeting, JMPR has performed IESTI assessments and has further refined the methodology, see Appendix 1 for the current equations.
4. In Australia and the EU, the IESTI equations are used to estimate the short term dietary intake from pesticides for both authorisation of use and MRL setting. Codex Member

[1] See Appendix 3 for the list of participants of the eWG
[2] Codex Alimentarius Commission, 2016, Procedural Manual twenty-fifth edition. Section I: Basic texts and definitions.
[3] The Acute Reference Dose (ARfD) of a chemical is an estimate of the amount of a substance in food and/or drinking-water, normally expressed on a body-weight basis, which can be ingested in a period of 24 hours or less without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation. (JMPR 2002)

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States which use Codex MRLs, implicitly use the IESTI equations too. Although the same IESTI equations are used, the input parameters (residues, variability factors, unit weights, large portions) may differ among international bodies (JMPR, EFSA) and individual countries. Because of differences in these input parameters, the outcome of short-term dietary risk assessments may differ for a particular commodity-pesticide combination in different parts of the world.
Also, there is a concern that conducting the assessment using the HR value instead of the MRL might not assure the safety of consumers, mainly when the MRL is much higher than the HR and the short-term exposure is close to 100 % of the ARfD [JMPR, 2006]. In addition, a number of MRLs were identified that allow for residue levels resulting in short term dietary exposures - as calculated with IESTI - exceeding the acute reference dose (ARfD).

The use of different input parameters may create trade barriers and concerns among the general public as to whether the MRL can be considered safe. Therefore, an evaluation of the IESTI methodology was proposed by JMPR (2006, 2007, 2010). In order to achieve this, JMPR recommended organising a consultation, including all relevant stakeholders. JMPR 2010 stressed the fact that to ensure international harmonisation of the methodology, changes in the IESTI equations and their input parameters cannot be implemented by JMPR alone, but should be discussed at the international level.

2015 International scientific workshop on IESTI

5. In response to the above and recognizing the need to harmonize the IESTI methodology on a world-wide level, the European Food Safety Authority (EFSA) and the Dutch WHO Collaborating Centre on Chemical Food Safety (RIVM[4]) organised a 2-day Scientific Workshop in September 2015 to seek the views of experts on the IESTI methodology. FAO and WHO co-sponsored this event. A stakeholder meeting was held on the day before the Scientific Workshop, which took place in Geneva.

The overall goal of the Geneva Workshop was to evaluate and where possible harmonise the parameters within the IESTI equations, as well as the equations themselves in order to propose ways to adapt the methodology. To facilitate the discussions, a background document describing the issues to be discussed and proposals for possible ways forward was provided[5].

6. During the workshop these issues and proposals were discussed. The participants to the workshop recommended replacing the current IESTI equations (see Appendix I) by the following:
New IESTI equation replacing case 1 and case 3 of the current IESTI equation:

$$IESTI = LP_{bw} \cdot MRL \cdot CF \cdot PF$$

New IESTI equation replacing case 2a and case 2b of the current IESTI equation:

$$IESTI = LP_{bw} \cdot MRL \cdot \cdot CF \cdot PF$$

[4] RIVM is a Dutch acronym for the Dutch National Institute for Public Health and the Environment
[5] Annex A – **Background document** in the Event Report of the EFSA/RIVM Scientific Workshop, co-sponsored by FAO and WHO, 'Revisiting the International Estimate of Short-Term Intake (IESTI equations) used to estimate the acute exposure to pesticide residues via food', 8/9 September 2015, Geneva, Switzerland. http://www.efsa.europa.eu/en/supporting/pub/907e

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In the proposed equations, several changes in the derivation of the input parameters were foreseen. Further background to these changes was described in the **workshop report**[5]**,** in particular in the **Annex A – background document**.

A general concern that is expressed during the workshop is that the proposed equation for case 3 does not sufficiently take account of the effects of bulking and blending. This issue needs to be further addressed.

7. Furthermore, a list of future work was identified as required to revise the dietary risk assessment. The report of the EFSA/RIVM workshop, co-sponsored by FAO and WHO, (for short: 2015 Geneva workshop) was published as an EFSA event report in December 2015[Error! Bookmark not defined.5]. An advanced draft of the report was provided to the JMPR 2015 meeting for its consideration.
The JMPR 2015 discussed the draft EFSA event report and acknowledged that the short-term dietary exposure estimates derived from the two proposed IESTI equations as a whole need to be assessed. JMPR recommended that a WHO/FAO working group be established to compare the use of current and proposed equations and to present the outcome to the CCPR in due course.

If the MRL is to be incorporated into equations to estimate human pesticide intake, then it would be critical that the accuracy of the resulting pesticide intake estimates be evaluated. This could be done by comparing the estimates of proposed IESTI equations with estimates generated with JMPR- or FAO/WHO- documented probabilistic based approaches. Prior to conducting such evaluations, CCPR needs to reach consensus on the target upper percentile of intake to be estimated by the equations.

2016 CCPR

8. Two side-events[6] concerning the revision of the IESTI were organised at the 48th Session of CCPR (2016), one by an *ad hoc* working group consisting of members from Australia, European Food Safety Authority, France, Germany, The Netherlands and the United Kingdom, and one by CropLife. During both side-events it was acknowledged that based on preliminary assessments the implementation of all recommendations made by the 2015 Geneva workshop could lead to a loss of up to 5%[7] of Codex MRLs. However, the 2015 Geneva workshop acknowledged that several aspects needed further work, like how to address the effect of bulking and blending. Therefore the extent of potential loss of MRLs may be an overestimation. When the new equations are formulated and their input parameters defined, a more accurate impact assessment can be performed.

9. At its 48th Session, the Committee first discussed revisiting the IESTI under Agenda Item 5a, Report on items of general consideration by the 2015 JMPR. The Committee noted the information contained in Section 2 of the 2015 JMPR Report and the support of Codex members for such activities as follows: (Rep16/PR par 20):

[6] http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCPR&session=48
[7] Based on the JMPR residue data set 2011-2014, including only compounds where the residue definition for enforcement equals the residue definition for risk assessment (=46,5% of all compounds) .The dataset contained 466 MRLs. http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-48%252FCCPR48%2Bside-event1%2Bsupport%2Bdocument.pdf

EPA-HQ 2017-003964_0001327

A scientific workshop co-sponsored by FAO and WHO was organised by EFSA and RIVM to discuss the methodology used to estimate the short-term dietary exposure for compounds having an ARfD. The workshop identified several elements, which could improve the scientific basis for the IESTI equations for further consideration by JMPR. The workshop also made other recommendations related to risk management and risk communication for consideration by CCPR.

10. Furthermore, under Agenda Item 11, the Committee discussed CRD3[8] on a proposal for new work on a possible revision of the IESTI equations, prepared by EU and Australia, as follows. The Delegation of the EU highlighted the challenges the EU was facing in risk communication in relation to residue levels in enforcement samples that were compliant with the MRL but could lead to an exposure estimate exceeding the ARfD. The Delegation of the EU expressed concerns that in the long term, this might undermine public trust in the regulatory system for pesticide residues and contribute to the proliferation of private standards. The Delegation underlined the importance the EU was placing on a methodology for short-term dietary exposure assessment of pesticide residues that was harmonised at the international level, and notably within CCPR. It further recalled the considerations of JMPR in recent years on the need to revisit the IESTI equations. The Delegation clarified that the intention of their proposal was to facilitate further work to better understand the potential impact of possible changes to the IESTI equations, and encouraged other delegations to actively participate in such work[9].

11. The Delegation of Australia, co-author of CRD3, explained that the IESTI, as developed by JMPR, had been in use in their country for 15 years for the purposes of conducting dietary exposure assessments for registration and for re-evaluation of existing compounds in plant protection products. It was important for Australia and other members to make reference to best international practice for dietary exposure assessments as endorsed by FAO and WHO for harmonisation and risk communication. Science changes over time and there is an expectation that assessment methodologies should reflect best science and best practice[10].

12. The Committee's discussion indicated general support for the proposal to explore the potential impact of possible changes to the IESTI equations and highlighted the need to clearly define the issues to be addressed, how they had developed and what should be done. Delegations also acknowledged that, after being in place for more than a decade, it was time for JMPR to review the IESTI procedure and for CCPR to address the need to harmonise approaches for risk assessment, risk management and risk communication.

More specifically, delegations highlighted the need: to examine the impact of the parameters on the short-term dietary intake assessments derived by the current and proposed IESTI equations; to clearly define the protection goals of the proposed IESTI equations; to identify any positive or negative impact of the proposed changes in terms of number of Codex MRLs; to have a broad participation in the eWG (if established) reflecting a wide spectrum of economic development; for FAO and WHO advice on the new equation and its parameters to

[8] http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCPR&session=48
[9] Summarised from Rep16/PR par 184-188
[10] Adopted from Rep16/PR 189

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173 assist CCPR to reach a conclusion on this matter; and to evaluate the wider acceptability of
174 the changed equation[11].
175
176 13. In view of the general support to the proposal to re-evaluate the IESTI, the Committee
177 agreed to establish an eWG, chaired by Netherlands and co-chaired by Australia, and working
178 in English only with the following Terms of Reference[12]:
179
180 **To identify advantages and challenges that might arise from the possible**
181 **revision of the current IESTI equations and the impact on risk management,**
182 **risk communication, consumer protection goals, and trade. The**
183 **recommendations of the international EFSA/RIVM workshop cosponsored by**
184 **FAO and WHO and the discussions in CCPR48 should be taken into account.**
185
186 14 The eWG identified the following list of advantages and challenges that might arise
187 from the possible revision of the current IESTI equations. In addition, the eWG identified a
188 list of technical challenges that were gathered to be forwarded to FAO andWHO for technical
189 / scientific consideration, see Appendix 2
190
191 Please note that in the tables below, advantages and challenges are listed in random order.
192 E.g, advantage 1 has no direct relation to challenge 1.
193
194 **Table 1: Advantages that might arise from the possible revision of the current IESTI**
195 **equations**

1	It is an opportunity to define clear protection goals and to design an equation set that is "tuned" to ensure the goals are met but without being overly conservative and without adverse trade impacts.
2	It is an opportunity to explore alternatives and revise the approach to acute dietary risk assessment by establishing a transparent, credible, and unambiguous calculation approach. There is opportunity to calibrate the revised equations using the best tools and data available for estimating likely actual short-term dietary exposure, to benchmark the level of conservatism and ensure its link to the defined protection goals.
3	Using the MRL instead of the HR in the dietary risk assessment may simplify communication of risk assessment assumptions. This will help to address concerns among the general public in some regions about the safety of MRLs.
4	Using up-to-date scientific knowledge will decrease uncertainties and improve the credibility of the methodology, e.g. on how to express the Large Portion. Additional consideration of consumption for the various types of commodities within the IESTI set of equations warrants periodic review and any new data to support such revisions should be thoughtfully considered
5	Harmonisation of the methodology may increase the acceptance of CCPR and CXLs.
6	Uniformity of understanding the IESTI methodology world wide
7	World-wide harmonisation of the IESTI methodology including the clarification of its parameters, will allow and facilitate its use by a larger number of countries thereby helping to prevent trade barriers.
8	Moving from GAP specific HRs to the MRLs in consumer risk assessment reflects in a more transparent way international trade standards irrespective of the kind of treatment.

[11] Rep16/PR par 190/191
[12] Rep16/PR par 193

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9	Removing the unit weight of a commodity, a poorly defined parameter, from the equation improves strongly the practicability and understanding of the methodology.

Table 2: Challenges that might arise from the possible revision of the current IESTI equations

1	To manage executing the technical work needed in an acceptable time frame, like developing further guidance on the derivation of conversion factors, developing databases with conversion factors and processing factors, and P97.5 large portion value derived from the distribution of consumption values of dietary surveys expressed as g/kg body weight. It is noted that part of this work would also be required to underpin the current methodology.
2	To undertake a comprehensive analysis on the impacts of any proposed changes to the IESTI methodology on existing CXLs, noting that depending on the changes agreed on, some CXLs may be lost. It is noted that the loss of CXLs may have an impact on the availability of specific pesticides and hence food production.
3	To effectively communicate/explain to the consumer, the growers, importers and exporters how some CXLs currently considered to be safe are considered unacceptable once revised IESTI equations are adopted.
4	Given the possible loss of MRLs, instructions regarding how countries can use Codex MRLs as reference for their national regulations, must be considered. Generating orientation and guidelines for developing and less developed countries, will be necessary for them.
5	To produce an easy-to-understand document, especially by the developing countries, related to this equation. Note that this would be useful in the current situation as well
6	To provide training regarding this equation and its potential use by the countries. Note that this would be useful in the current situation as well
7	Growers need to have multiple Modes of Action available to prevent the development of pesticide resistance to any single pesticide. A reduction in the number of CXLs may lead to the loss of products alternative for the grower.
8	Consideration needs to be given on how to address residues in products of animal origin e.g. the different policies in the EU compared to Codex of setting MRLs for muscle and not meat.
9	The loss of some of the current CXLs may impact global trade. This potential impact may be disproportionally affecting developing countries trading in food crops and having limited access to alternative compounds
10	Reaching consensus regarding the upper percentile of intake that should be estimated by the IESTI equations.

Conclusions and recommendations.

15. Improving the scientific basis for the IESTI is the remit of JMPR. It is proposed that the Committee supports the recommendation by JMPR to establish a FAO/WHO technical working group that can work in between JMPR Meetings to consider the proposals that are related to risk assessment as made by the EFSA/RIVM workshop (expression of LP on an

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individual bodyweight basis, use of CFs and PFs, loss of unit-weight for IESTI Case 2a) and to compare the use of current and proposed equations and to present the outcome to CCPR. In addition, the OECD's Residue Chemistry Expert Group might be consulted for specific questions.

16. Risk management and risk communication are within the remit of CCPR. Using the MRL instead of the HR (i.e. Highest Residue found in the relevant supervised residue trials) in the equations is a risk communication and risk management issue.

17. In addition, the Committee should agree on the consumer protection goal that should be achieved by using the IESTI. Although the level of conservativeness of the current IESTI is not clearly defined, it is well accepted world-wide. Therefore, it is proposed that changes to the IESTI should not lead to a lower level of conservativeness. The above-mentioned FAO/WHO technical working group should be requested to develop a suitable approach to quantify the differences between the current and proposed IESTI, e.g to benchmark the outcome of the current and the newly proposed IESTI to a suitable distribution of actual exposures. To ensure that an assessment of the impact of changes to the IESTI is accepted, this approach, as developed by the FAO/WHO technical working group, should be agreed by the Committee beforehand.

18. Based on the list in par 14 and the findings of the FAO/WHO working group (see par 15), a list of anticipated problems for trade could be established at a future session of the Committee. E.g. some MRLs or commodities could be disproportionally affected by the changes. The Committee then should weigh the advantages for risk management and risk communication against the expected impact on trade.

19. It is clear both from the complexity of the issue and from the comments of delegations at CCPR 2016 that the discussion on a possible revision of the IESTI equations will require continuous work over several years. It is proposed to re-establish the eWG to interact with the proposed FAO/WHO technical working group and to prepare the discussions at the Committee by further elaborating the document on advantages and challenges and anticipated impact on risk management, risk communication, consumer protection goals, and trade, informed by the findings of the FAO/WHO working group.

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Appendix 1[13]: Acute dietary exposure estimates currently used by JMPR

LP_{person} Highest large portion reported (97.5th percentile of consumers only), kg of food per person per day.

HR Highest residue in composite sample[14] of raw edible portion found in the supervised trials performed according to GAP used for estimating the maximum residue level (in mg/kg).

HR-P Highest residue in a processed[15] commodity, mg/kg, calculated by multiplying the highest residue in the raw commodity by the processing factor.

bw Mean body weight, kg, provided by the country from which the LP was reported. The bodyweight represents the mean body weight of the population group of the dietary survey from which the LP was derived (e.g. general population, adults, children).

U_e Unit weight of the raw edible portion, kg, provided by the country where the trials that gave the highest residue were carried out.

U_{RAC} Unit weight of the raw agricultural commodity (RAC), kg, provided by the country where the trials that gave the highest residue were carried out.

v Variability factor, the factor applied to the composite residue to estimate the residue level in a high-residue unit.

STMR Supervised trials median residue in the raw edible portion of a food commodity (expressed as mg/kg), derived from the same set of supervised field trials as the HR.

STMR-P Supervised trials median residue in processed commodity (in mg/kg).

Case 1

The residue in a composite sample (raw or processed) reflects the residue level in a portion of the commodity that would be consumed at one meal (whole fruit or vegetable unit weight (expressed as RAC) is below 0.025 kg). Case 1 also applies to meat, liver, kidney, edible offal and eggs, and for grains, oilseed and pulses commodities when the estimates were based on post-harvest use of the pesticide.

$$\text{IESTI} = \frac{LP_{person} \times (HR \text{ or } HR\text{-}P)}{bw}$$

[13] From Annex A – **Background document** in the Event Report of the EFSA/RIVM Scientific Workshop, co-sponsored by FAO and WHO, 'Revisiting the International Estimate of Short-Term Intake (IESTI equations) used to estimate the acute exposure to pesticide residues via food', 8/9 September 2015, Geneva, Switzerland. http://www.efsa.europa.eu/en/supporting/pub/907e

[14] Composite sample = samples composed of multiple units of the same commodity

[15] 'Processing' can either relate to removing inedible parts of a commodity, e.g. peeling a banana, or to further (industrial or household) preparation, e.g. milling of grain, cooking of spinach.

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Case 2

The one meal portion, such as a single fruit or vegetable unit, might have a higher residue than the composite (whole fruit or vegetable unit weight (expressed as RAC) is equal or above 0.025 kg).

Case 2a

The unit weight (raw edible portion) of the commodity is lower than the large portion weight.

$$\text{IESTI} = \frac{U_e \times (\text{HR or HR - P}) + (LP_{person} - U_e) \times (\text{HR or HR - P})}{\text{bw}}$$

The Case 2a formula is based on the assumption that the first unit contains residues at the [HR × *v*] level and the next ones contain residues at the HR level, which represents the residue in the composite from the same lot as the first one.

Case 2b

The unit weight (raw edible portion) of the commodity exceeds the large portion weight.

$$\text{IESTI} = \frac{LP_{person} \times (\text{HR or HR - P})}{\text{bw}}$$

The Case 2b formula is based on the assumption that there is only one consumed unit and it contains residues at the [HR × *v*] level.

Case 3

Case 3 is for those processed commodities where, because of bulking or blending, the STMR-P represents the likely highest residue. Case 3 also applies to milk and to grains, oilseeds and pulses for which the estimates were based on pre-harvest use of the pesticide.

$$\text{IESTI} = \frac{LP_{person} \times (\text{STMR or STMR - P})}{\text{bw}}$$

The concept of variability factor was introduced to take into account the different concentrations of residues in individual portions of a composite sample and average residue concentration in the sample lot represented by the composite sample. The variability factor (*v*) was defined as the 97.5th percentile of the residue concentrations present in commodity units (RAC) divided by the mean residue concentration of the sample population: P97.5 residue in units / mean residue in units.

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322 In the IESTI methodology, the estimates are performed for each crop individually, as it is
323 unlikely that an individual will consume, within a meal or 24 h, a large portion of more than
324 one food containing the highest residue level (the one that incorporates the variability factor).
325 The IESTI calculations can be performed separately to estimate dietary exposure from
326 consumption of the unprocessed or processed form of a food commodity, when relevant.
327
328 **Appendix 2, Table 3: Technical / risk assessment challenges that either arise from the**
329 **possible revision of the current IESTI equations, or are current challenges as well. To be**
330 **forwarded to the FAO/WHO working group**

1	Developing further guidance on the derivation of conversion factors, and developing a database with conversion factors
2	Developing a database with processing factors,
3	Developing a database with P97.5 large portion value derived from the distribution of consumption values of dietary surveys expressed as g/kg body weight. In order to develop this database, internationally agreed criteria must be developed for dietary surveys, used for the assessment of consumer exposure.
4	Information on bulking and blending practices needs to be gathered in order to decide on cases where a median residue instead of the MRL could be used in the dietary risk assessment.
5	Reconsider the number of supervised field trials used for the OECD MRL Calculator, which results in high MRL estimates based on small data sets. This will especially affect minor crops with low data requirements.
6	The suitability of common moiety residue definitions needs to be reconsidered when multiple active substances are included (e.g. CS_2 for all dithiocarbamates) and one of those is potentially exceeding the ARfD.
7	The acute exposure assessment using the proposed IESTI will merely depend on the LP_{bw} values. Especially LP of children are crucial in risk assessment. The food consumption data are very heterogeneous and based on dietary survey studies of different design, quality and origin. An important reason for heterogeneity is also the preference of certain foods by the population. The more popular a particular food, the more data are available and the more reliable and robust are the P97.5 values. A pragmatic approach has to be established which addresses this issues; e.g. setting the same consumption value for a group of commodities (extrapolation rules).
8	Further guidance/decision making needed on the use of the variability factors relative to the MRL. The current use of the varibility factor is not mathematically appropriate for use with an MRL. Using the MRL with current variability factors is overly conservative and will lead to loss of MRLs and disruption of global trade. Since MRLs are now determined consistently by algorithms in the OECD MRL calculator simulation modeling to determine how single item residues might relate to the MRL could be useful.
9	More information might be needed on environment factors like weather or wind speed that might influence the short term intake estimation, and on pesticide characteristics studies. Uniformity is necessary. Uniformity of time estimation (range time term definition)
10	To estimate the impact of removing the unit weight from the equation and especially for case 1 and case 2 which distinction currently relies on the unit weight.
11	Reaching consensus regarding the approach to be used to evaluate the level of conservatism of proposed updated IESTI equations and how it compares to both the

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	present set of IESTI equations and state-of-the-science probabilistic methods.
12	Current consumption data on processed commodities in almost all territories of the world are not available to make meaningful estimates of acute consumer exposure. Many crops which are consumed in large amounts in the processed form (e.g. apples or citrus consumed as juice) will be disproportionately if these data are not collected.
13	For blended foods (e.g. fruit juice, seed/nut oil, flour, corn meal), it is suggested to add a homogenization factor (<1) to the equation to reflect the decreased variability in pesticide residues resulting from processing.

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333 **Appendix 3: Composition of the eWG**
334
335 **Countries:** Argentina, Australia (co-chair), Belgium, Brazil, Canada, Chile, Costa Rica,
336 Denmark, EU, Finland, France, Germany, India, Indonesia, Iran, Italy, Japan, Kenya, Korea,
337 Malaysia, Malta, Marocco, The Netherlands (chair), New-Zealand, Nigeria, Norway, Peru,
338 Poland, Spain, Switzerland, Thailand, Uganda, United Kingdom, United States.
339
340 **International governmental organisations:** EFSA (European Food Safety Authority), IICA
341 (Inter-American Institute for Cooperation on Agriculture)
342
343 **International non-governmental organisations:** AgroCare Latinoamerica (formerly called
344 ALINA), CropLife International, GAFTA (The Grain and Feed Trade Association), GPC
345 (Global Pulse Confederation), ICA (International Confectioners Association), ICBA
346 (International Council of Beverages Associations,) ICGMA (International Council of Grocery
347 Manufacturers Associations), IFFA (International Frozen Food Association), IFU
348 (International Fruit and Vegetable Juice Association), INC (International Nut and Dried Fruit
349 Council), IOSTA (International Organization of Spice Trade Associations), ISC (International
350 Society of Citriculture), IUPAC (International Union Of Pure And Applied Chemistry)

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Discussion paper IESTI 2017 draft version 2_comments

	Country / Observer	Indicate text (page/line)	Comment
	CropLife International	Full text	We appreciate the opportunity to input on refinement of this document for the upcoming CCPR meeting. We recognize the amount of work that has already occured and that current draft is a significant and altered version of the initial draft. **For transparency, we strongly request additional changes so that the finalized paper wil better reflect the differences of opinion raised in the commenting periods by the eWG.** If differences are clearly flagged, all CCPR delegates can clearly recognize the scope of further work needed to achieve completion. The paper should **clarify that in order to address the full remit of the eWG additional work and analysis is still needed.** CropLife International welcomes oppotunities to remain active in the on-going work.
	CropLife International	Overall Document Organization and Order	The paper is currently organized along a historical timeline and thus the ewG remit is buried within the body of the paper. **Please consider moving the remit of the eWG to the beginning of the document**, before the history and the workshop equations, to better clarify the purpose of this work by the eWG. Currently the 2015 workshop equations are presented as final, rather than a starting pount for the eWG. **Please clarify that listed equations were recommended during the 2015 workshop, but they are not the final product of this eWG.** Finally, the work of this eWG so far has captured comments on the 2015 IESTI equations; an improved outcome would be conclusions on **a more specific workplan clarified in the document – inclusing a List of future work for the eWG or the mentioned FAO/WHO workgroup. Table 3 is better placed in the body of the report and more fully discussed rather than as an Appendix.**
1	CropLife International	Line 33-34/Page 1	It is agreed that that *dietary exposure* should not exceed a reference dose, but there is not agreement across the eWG that the proposed equations are the appropriate way to calculate that *exposure*. It it also not agreed that use of the MRL in the current equation is the only way to assess residues supporting the MRL. Please r**emove exisiting paragraph and replace** with the following to elminate ambiguity and better reflect the work of the eWG. **Consumer safety as related to pesticide residues is assessed by estimating a life-time dietary exposure to the residue and comparing this with the Acceptable Daily Intake (ADI), and, in case the compound has acutely toxic properties, by estimating a short-term dietary exposure and comparing this with the Acute Reference Dose (ARfD). The foundation for**

			acceptable consumer safety from an acute intake perspective is that dietary exposure should not exceed the ARfD. The overall objective of all the work is to review in detail the existing IESTI equations and proposed updates to those equations, if necessary. The work of this eWG indicated there is not full agreement that the 2015 proposed equations using the MRL are the best estimates of dietary exposure.
3	CropLife International	Page 2 Line 49-53, Paragraph 4	The current statement ignores the compounded conservatism built into the full IESTI approach. **Please add**: **However, the stated concern regarding risk assessment with the HR rather than MRL level needs further discussion in the eWG**. **Additional conservatism exists in both the toxicity endpoint (with multiplied uncertainty factors for possible interspecies and intraspecies differences), and the IESTI methodology (use of large portion consumption, variability factors)**. The scenario leading to a possible consumer risk is not just a residue value above the HR (rare), but a combination of a number of rare events. For example, an individual must encounter a rare food item with residues above 3xHR (variability factor x HR), they must encounter it on a day when they are eating a particularly large portion of that food item, the pesticide in question is one in which humans are more sensitive than the most sensitive test species, and the consumer must be a member of a sensitive subpopulation. The compounded low probabilities of each of these occurrences makes the probability of them co-occurring extremely low. **Please add: The IESTI equation as it stands is quite conservative and protective of consumer safety, even when using HR/STMR. However, if the intention is to improve communicating to a lay audience, replacement of HR by MRL in the equation should be accompanied by adjustment of the other variables to provide a reasonable realistic exposure scenario.**
	CropLife International	Page 2 Line 51	**Please add** the following to the text or as a footnote for transparency to the reader who is not familiar with the OECD MRL calculator. **When the MRL is derived with the OECD calculator, the MRL can only be much higher than the HR if it is from a small or highly variable dataset. In either case a variability estimate is included in the calculator algorithms for established MRL (mean + 4 * SD). The MRL thus incorporates the uncertainty**

			of small or highly variable datasets. Thus use of the MRL with an extra variability factor would be an unnecessary form of double counting.
	CropLife International	Page 2 Line 53	**Please provide examples of the stated ARfD exceedances, and which IESTI equations were used for these assessments. If type of this exceedance is a driving reason for change, the issue should be better illustrated with clear examples** and documented frequency of exceedence. Under what circumstances – based upon a flaw in info used, formula problem, etc.? Is this using the current JMPR equations, or the proposed equations which are not adopted yet or the EU IESTI with higher variability factors of > 3? We agree with the US delegation that "using the CXL and "v" will likely overestimate variability and overestimate pesticide intake. We expect that determining what "v" would be most appropriate to pair with the CXL will require a substantial effort, but we believe that this is an important effort"**.**
	CropLife International	Page 2 Line 56	**Please remove** "and concerns among the general public as to whether the MRL can be considered safe". The general public is not typically not aware of the differences in the input parameters from various regions and regulatory agencies.
2	CropLife International	Paragraph 6, page 2 Lines 78	Please **add** an important clarification **These listed equations were recommended during the 2015 workshop, but they are not the final product of this eWG. Instead the work of this eWG is to use them as a starting point for additional discussion. The eWG has collected challenges to these as listed in Table 2 and 3.**
3	CropLife International	Paragraph 6, page 2 Lines 78	Please **add** a clarification that reflects the concerns raised during commenting: **Many are concerned that the proposed equations are unnecessarily conservative, especially for the cases which mathmatically use the following to estimate the exposure at the consumer dinner plate: a) 3X the MRL, b) the MRL for a blended or c) the MRL for animal commodity.**
4	CropLife International	Paragraph 6, page 3, line 87	Instead of a general reference to the workshop report, for clarity to all readers, **this CCPR document needs to better specify the"several changes in the input parameters" expected.**
5	CropLife International	Paragraph 6, page 3, 92	Please **clarify** how the effects of bulking and blending will be addressed.
6	CropLife International	Paragraph 7, page 3, line 109	CropLife International agrees with the principle of benchmarking; **please clarify the path** to achieve a "FAO/WHO –documented probabilistic based approach". Would it be the work of the eWG to explore models? To ensure transparency, utilized probabilistic models need to be publically available and validated. International agreement on

			a FAO/WHO model will require aditional agreement beyond that for input to the IESTI. **Use of existing national models rather than development of a new FAO/WHO could be used in initial benchmarking**.
7	CropLife International	Paragraph 8, page 3, line 119	The *5% number quoted is extremely preliminary* and is *likely to be an underestimate* given that the CF factor (conversion factor for differences in residue defintion) of the equation was not explored in the analysis and adjusted LP data was not available to all. **Please remove the statement that the 5% may be an overestimate. Please add : Many are concerned that incremental changes to the equation should not be considered, but rather the changed equation as a whole needs to be considered. The full impact on number of MRLs lost can not be assessed while the inputs and equations are not finalized.**
8	CropLife International	Paragraph 8, page 3, line 119	For balance, **please add that the loss of any MRLs without a clearer and stronger justification is a concern to many serving in the EWG.**
9	CropLife International	Paragraph 8, page 3, line 119	Part of the *remit of the eWG is to assess impact on trade*. A preliminary estimate of the overall average of MRLs lost does not adequately address impact on trade. **A further analysis by crop and sector is needed to understand impact. What is planned process for impact assessment?**
10	CropLife International	Paragraph 13, page 5	**Please move the remit of the eWG to the beginning of the document**, to clarify the purpose of the paper.
	CropLife International	Table 1 item 3	**Recommend rewording** to better reflect diversity of thought expressed on eWG. Many doubt it will improve risk communication to the public. And it is not agreed that use of MRL is the only option. **Please change to:** **When communicating about pesticide residues and dietary risk assessment, the use of the MRL instead of the HR in IESTI equations *may* be more accepting to the public in some regions**
	CropLife International	Table 1 item 5	**Recommend rewording** to be more transparent that impact on trade has not been explored in depth by the eWG**:** **Updating the IESTI methodology, including clarification of the input parameters, *may* encourage its use by a larger number of countries thereby helping to prevent trade barriers.**
	CropLife International	Table 1 item 7	**Recommend rewording** because full world-wide harmonization is not realistic. **Please change to:** **Updating the IESTI methodology, including clarification of the input parameters, *may* encourage its use by a larger number of countries thereby helping to prevent trade barriers.**

	CropLife International	Table 1 item 8	This is a very general statement and was not agreed at least in previous discussions at the CCPR 2016. It is confusing because MRL's can be considered as GAP specific too. The "transparency" of MRLs as international trade standards irrespective of the kind of treatment (eg application type) is not improved by a change in the IESTI equation **Please remove.**
	CropLife International	Table 1 item 9	Please **consider deleting** or inserting the words ***may improve***, to reflect discussion at the CCPR 2016 as controversial. The topic should be highlighted as subject of future work along with improving other parameters in the equation.
		Table 2, point 1	**Please add: a substantial effort will be also required to derive scientifically based variability factors, and homogenization factors for bulk and blended commodities**.
11	CropLife International	Table 2	Please add: **the loss of any MRLs without a clearer justification is a concern to many serving in the EWG.**
	CropLife International	Page 7 Paragraph 17	It is agreed quantifying the differences between the current and proposed IESTI is important, please **consider state-of-the-science probabilistic methods and monitoring data** for consumer dietary exposrue as part of the comparison..
	CropLife International	Page 7 Paragraph 18	Proposed changes need to **clearly define the level of conservativeness** based on scientifically valid and defensible data.
	CropLife International	Page 7 Paragraph 19	**Please Insert after '... Establish a FAO/WHO technical working group 'open to members and observers...'** Also please consider OECD residue chemistry expert groups should be consulted for specific questions. It is suggested that this consultation include other residue chemistry expert groups at CLI, CLA etc
		Table 3, Point 5	Any increased trial # requirements for minor crops, need to consider work already agreed upon by eWG on MU.
		Table 3, Point 8	***Strongly agree*, this is a critical point.**
		Table 3, Point 9.	**Please delete this point. Environmental factors** only affect the measured pesticide residue at the field level. They are one of the many variabilites that are embodied in the MRL setting process & the resulting MRL reflects those additional variabilities. **Weather or wind speed should not have a further role in estimating exposure at the diet level**.
		Table 3/ point 13	CropLife International agrees that if the MRL must be used in assessment of bulk and blended commodities, **appropriate homogenization and bulk commodity factors must be developed for specific crops and commodities to accurately reflect consumer exposure.**