[redacted]

From: Marianne Tegel <Marianne.Tegel@foodauthority.nsw.gov.au>
Sent: Tuesday, 23 October 2012 10:35 AM
To: incident
Cc: [redacted]; Craig Shadbolt; Ian Beer
Subject: FW: Supplements Information on analysis [CRAZE]

Please find below additional information and advice from TGA via Ian Beer.

Regards

Marianne Tegel
Team Leader, Foodborne Illness Investigation Unit
NSW Food Authority
safer food, clearer choices
6 Avenue of the Americas Newington NSW 2127 | PO Box 6682 Silverwater NSW 1811
Switch +61 2 9741 4777 | Helpline 1300 552 406 | www.foodauthority.nsw.gov.au
Direct line 9741 4858 | Fax +61 2 9741 4895 | Mob 0438 943851
marianne.tegel@foodauthority.nsw.gov.au
please consider the environment before printing this email

From: Ian Beer
Sent: Monday, 22 October 2012 4:41 PM
To: Marianne Tegel
Cc: Alan Edwards; Janine Curll; Greg Vakaci; Edward Jansson
Subject: FW: Supplements Information on analysis [CRAZE]

Marianne

See our advice from TGA on the issue. I'm reluctant to go further till we get some test results confirming the substance in the product but FSANZ should get the heads up prior to that to do some risk assessment. Once we get the test results we would be looking at a recall at this stage and knowledge of the substance. Our Analyst is confident of finding it in the Craze product.

We are unsure if only one major importer or a number of individual ones.

Regards

Ian Beer
Team Leader Enforcement
NSW Food Authority
safer food, clearer choices
Direct line 9741 4859 | Fax +61 2 9741 4898 | Mob 0413 018 521

please consider the environment before printing this email

From: [redacted]
Sent: Monday, 22 October 2012 4:23 PM
To: Ian Beer
Subject: RE: Supplements Information on analysis [SEC=UNCLASSIFIED]

Hi Ian,

I should have that quote to you tomorrow.

Given that this product seems to be sitting on the food side of the interface, you may need to seek the tox/safety

advice from FSANZ.

The following advice on phenylisobutylamine (more correctly referred to below as 1-phenylbutan-2-amine) was provided to the TGA by

[redacted] at Drug Import/Export Licensing and Compliance, Office of Chemical Safety, Department of Health and Ageing

[Website: www.health.gov.au/treaties Fax: 02 6289 2500 Email: tmu@health.gov.au]

"1-Phenylbutan-2-amine

Is chemical closely related to amphetamine, and research indicates it offers similar physiological stimulus and effects to amphetamines, however it is not considered a prohibited import or prohibited export.

I would recommend contacting the Australian Federal Police about the status of both these substances in regards to the *Criminal Code Act 1995.*"

I assume that the Office of Chemical Safety should also be responsible for advice on whether it would be captured under the derivatives definition with respect to Schedule 9 of the SUSMP although this often seems to be left up to the
individual State and Territory enforcement agencies via their own legislation.

Regards,

[redacted]

[redacted] |Director of Chemistry | Office of Laboratories and Scientific Services l Therapeutic Goods Administration
[redacted] | Fax: 02 6232 8442 | [redacted]

From: Ian Beer <Ian.Beer@foodauthority.nsw.gov.au>
To: [redacted]
Date: 22/10/2012 01:46 PM
Subject: RE: Supplements Information on analysis [SEC=UNCLASSIFIED]

Hi [redacted]

Any news on a quotation for the analysis of the supplements?

NMI will be doing the analysis for Phenylisobutylamine so we would like to have the other products tested soon.

Would the TGA have an expert who would have knowledge of the health effects of Phenylisobutylamine and what its legal status would be?

Regards
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From: [redacted]
Sent: Thursday, 11 October 2012 2:22 PM
To: Ian Beer

Subject: RE: Supplements Information on analysis [SEC=UNCLASSIFIED]

Ian,

I suspect that the short answer is 'no'. A reference standard for the compound does not appear to be readily available so we would be restricted to trying to match literature data for mass spectra, UV etc, which would be supportive evidence of its presence but not conclusive.

The problem is that there are a number of different possible compounds with the same molecular formula (C10H15N) so proving that a compound had that particular structure as against one of the other structural isomers would be problematic in the absence of compelling literature data that differentiated between isomers in this respect. So we might be able to tell you that a compound consistent with that molecular formula is present but not be able to tell you its precise structure.

The NMI lab is the best one placed to do this work since they also have the ability to synthesise their own reference standards.

Regards,

[redacted]

[redacted] |Director of Chemistry | Office of Laboratories and Scientific Services l Therapeutic Goods Administration
[redacted] | Fax: 02 6232 8442 | [redacted]

From: Ian Beer <Ian.Beer@foodauthority.nsw.gov.au>
To: [redacted]
Cc: Alan Edwards <Alan.Edwards@foodauthority.nsw.gov.au>, Greg Vakaci <Greg.Vakaci@foodauthority.nsw.gov.au>
Date: 11/10/2012 01:09 PM
Subject: RE: Supplements Information on analysis

[redacted]

We received advice from the Australian Sports Drug Testing Laboratory that they are attempting to identify the substance "Phenylisobutylamine" in the Craze supplement following advice presumably from Australian Sports Anti-Doping Authority. Have you a means of identifying or testing for this?

Regards

Ian Beer
Team Leader Enforcement
NSW Food Authority
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From: Ian Beer
Sent: Thursday, 11 October 2012 9:52 AM
To: [redacted]
Cc: Alan Edwards; Greg Vakaci
Subject: Re: Supplements Information on analysis [SEC=UNCLASSIFIED]

Thanks [redacted] no problem with next week
Ian

From: [redacted]
Sent: Thursday, October 11, 2012 09:45 AM

To: Ian Beer
Cc: [redacted]
Subject: RE: Supplements Information on analysis [SEC=UNCLASSIFIED]

Hi Ian,

Please excuse the slow response. I've been out of the office for the last couple of days.

I will work on getting a quote together on testing for the ingredients you mention below. Probably get back to you early next week if that's not too late.

Regards,

[redacted]

[redacted] |Director of Chemistry | Office of Laboratories and Scientific Services l Therapeutic Goods Administration
[redacted] | Fax: 02 6232 8442 | [redacted]

From: Ian Beer <Ian.Beer@foodauthority.nsw.gov.au>
To: [redacted]>
Cc: Greg Vakaci <Greg.Vakaci@foodauthority.nsw.gov.au>, [redacted]>, Alan Edwards <Alan.Edwards@foodauthority.nsw.gov.au>, Edward Jansson <Edward.Jansson@foodauthority.nsw.gov.au>, Marianne Tegel <Marianne.Tegel@foodauthority.nsw.gov.au>
Date: 09/10/2012 02:39 PM
Subject: RE: Supplements Information on analysis [SEC=UNCLASSIFIED]

Hi [redacted]

Thanks for the advice of you previous email. We were hoping you could do some testing of the new extract (Dendrobium) on the block that claims to be the next DMAA. It looks from the literature attached that it has been around a long time but recently been able to be synthesised as Dendrobine. Not something that should used in a food. Is there any one in Australia who is expert about this substance?

We would like to get a quote for testing 6-10 samples of supplement products for the following

1. XANTHINOL NICOTINATE, if possible getting a reference standard we if not with a tentative identification of xanthinol by characterisation with quantitation against caffeine.
2. Caffeine; with quantification
3. BITTER ORANGE EXTRACTS (containing Synephrine (aka oxedrine) with quantitation
4. PHENETHYLAMINE (PEA) – with quantitation as best you can,
5. Geranium extract - with quantitation .
6. L-Dopa - - with quantitation

regards

Ian Beer
Team Leader Enforcement
NSW Food Authority
safer food, clearer choices
Direct line 9741 4859 | Fax +61 2 9741 4898 | Mob 0413 018 521

From: [redacted]
Sent: Wednesday, 3 October 2012 2:41 PM
To: Ian Beer

Cc: Greg Vakaci; [redacted]
Subject: Re: Supplements Information on analysis [SEC=UNCLASSIFIED]

Hi Ian,

we have seen a number of the compounds referred to below in previous samples however we do not currently have valid reference standards for all of these compounds.

Please see annotations below for our current capacity to test for individual compounds. Other than where we have methods and reference standards for particular compounds (e.g. synephrine, DMAA and L-dopa) then the testing is only indicative and would be for information only and not suitable for use in legal proceedings. Most of the amine compounds that we don't have methods for should not be terribly difficult to analyse for but it would require some method development and obtaining reference standards.

In regard to the presence of amphetamine, I suspect this product contains related compound/s which are close enough in structure to amphetamine to be classed as amphetamine derivatives or analogues. We have recently seen some of these derivatives in a couple of other products. Methamphetamine is (+)-N,alpha-dimethylbenzeneethanamine so the compound referred to in Paul's email below, ALPHA-DIETHYL-BENZENEETHAMINE, is not methamphetamine itself but is presumably a close structural analogue (the naming is not exact hence the actual structure is a bit ambiguous). We may be able to provide some guidance on what amphetamine analogues are present however results would not be definitive and would need follow-up confirmation.

If you would like a quote for testing then please specify the products to be tested and which analytes you want them tested for. It would also be helpful if you could indicate where quantitation of the analyte is desired.

Regards,

[redacted]

[redacted] |Director of Chemistry | Office of Laboratories and Scientific Services l Therapeutic Goods Administration
[redacted] | Fax: 02 6232 8442 | [redacted]

With the Craze product TGA ([redacted]) has advised of possible methamphetamine although the products claims ingredients:-

1. Dendrobex™ : (Dendrobium extract) concentrated for alkaloid including Dendroxine, Dendramine and a number of versions of b-phenylethlamine) and
2. Citramine™ : (Citrus reticulata extract) concentrated for N-methyltyramine content.

With other products declared therapeutic substances

- XANTHINOL NICOTINATE, - in the absence of a reference standard we normally do tentative identification of xanthinol by characterisation with quantitation against caffeine.
- BITTER ORANGE EXTRACTS (containing N-Methyltyramine (NMT), Octopamine & Synephrine) - we can ID and quantitate Synephrine (aka oxedrine); we don't currently have a method or ref stds for NMT or octopamine.
- PHENETHYLAMINE (PEA) - we can ID and semi-quantitate.
- DMAA Geranium extract - - we can ID and quantitate.
- L-Dopa - - we can ID and quantitate.

From: Ian Beer <Ian.Beer@foodauthority.nsw.gov.au>
To: [redacted]
Cc: Greg Vakaci <Greg.Vakaci@foodauthority.nsw.gov.au>
Date: 02/10/2012 06:55 PM
Subject: Supplements Information on analysis

Hi [redacted]

Just a question in relation to analysis of Sports Supplements we are currently investigating some of the pre-workout supplements that claim to contain some weird and wonderful extracts. From our past experience with the slimming coffee products many of the claimed extracts are replaced with therapeutic drugs.

With the Craze product TGA ([redacted]) has advised of possible methamphetamine although the products claims ingredients:-

1. Dendrobex™ : (Dendrobium extract) concentrated for alkaloid including Dendroxine, Dendramine and a number of versions of b-phenylethlamine) and
2. Citramine™ : (Citrus reticulata extract) concentrated for N-methyltyramine content.

With other products declared therapeutic substances

- XANTHINOL NICOTINATE,
- BITTER ORANGE EXTRACTS (containing N-Methyltyramine (NMT), Octopamine & Synephrine)
- PHENETHYLAMINE (PEA)
- DMAA Geranium extract
- L-Dopa

Are you able to undertake screening tests for these substances?

We are looking at testing Craze with the NSW illicit drug lab this week for presence of Methamphetamines but if that is unfruitful may wish to test for the other declared substances.

Regards

Ian Beer
Team Leader Enforcement
NSW Food Authority
safer food, clearer choices
Direct line 9741 4859 | Fax +61 2 9741 4898 | Mob 0413 018 521
please consider the environment before printing this email

From: [redacted]
Sent: Thursday, 27 September 2012 1:49 PM
To: Ian Beer
Cc: Janine Curll
Subject: Fw: Supplements Information [SEC=UNCLASSIFIED]

Ian

Re the product 'craze'.

We have received advice from the Treaties and Monitoring Section (part of Dept of Health) that the product Craze does contain an ingredient which is considered to be a prohibited import. See following email.

I am unsure if you have had the product tested at all or if a recall should be considered.

We have notified Customs of this so hopefully the market will dry up.

Happy to have a chat about the other issues. I will be away next week, returning on the 9th of October.

[redacted]
Chief Investigator
Regulatory Compliance Unit
Therapeutic Goods Administration
[redacted]

----- Forwarded by [redacted] on 27/09/2012 01:42 PM -----

From: [redacted]
To: [redacted]
Date: 27/09/2012 12:15 PM
Subject: Re: Supplements Information [SEC=UNCLASSIFIED]

[redacted],

As the CRAZE pre-workout supplement powder is considered to be a food, it is not a product that is regulated by the TGA.

However, the product CRAZE is now considered to be a prohibited import.

Testing has revealed that the product CRAZE contains the undeclared ingredient ALPHA-DIETHYL-BENZENEETHAMINE
which is considered to be a synonym for the substance METHAMPHETAMINE.

METHAMPHETAMINE contains the stereoisomer Levomethamphetamine which would therefore be captured under Schedule 4 Item 116 of the CPI Regs.

[redacted]
Regulatory Liaison Officer
TGA Regulatory Compliance Unit
[redacted]

From: [redacted]
To: [redacted]
Date: 27/09/2012 11:50 AM
Subject: Re: Supplements Information [SEC=UNCLASSIFIED]

Thanks

Can I get that information re Craze

[redacted]
Chief Investigator
Regulatory Compliance Unit
Therapeutic Goods Administration
[redacted]

From: [redacted]
To: [redacted]
Date: 27/09/2012 10:26 AM
Subject: Supplements Information [SEC=UNCLASSIFIED]

[redacted]

In relation to the email you received from IAN BEER I can provide the following information on the ingredients of concern:

DENDROBINE - extracted from the plant Dendrobium noble is a traditional Chinese medicine with analgesic properties (pain relief). It is currently not a prohibited import ingredient or a scheduled substance.

CINNAMOMUM BURMANNII BARK EXTRACT - Also known as Indonesian cinnanmon it is not a prohibited import ingredient or a scheduled substance. This herb contains Eugenol which has antiseptic and anti-inflammatory properties.

PHENETHYLAMINE - is not a prohibited import ingredient. It is also not a scheduled ingredient. It has very minor weight loss properties and is a minor mood enhancer.

BITTER ORANGE EXTRACTS (containing N-Methyltyramine (NMT), Octopamine & Synephrine) - Bitter orange extracts have weight loss properties and therefore are commonly found in complementary medicines and also in body building / sports supplements. NMT, Octopamine & Synephrine are not prohibited import ingredients. Synephrine (also known as Oxedrine) however, is considered to be a prescription medicine when the daily dose of Oxedrine exceeds 30mg per day.

XANTHINOL NICOTINATE - is not a prohibited import ingredient but it is a prescription only medicine which is used as a vasodilator (widens blood vessels). It appears in body building / sports supplements such as Animal Pak.

[redacted]
Regulatory Liaison Officer
TGA Regulatory Compliance Unit
[redacted]

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or not) resulting from the use of any attached files. The Authority regularly monitors emails and attachments to ensure compliance with its electronic Messaging Policy.

[redacted]

From: [redacted]
Sent: Thursday, 25 October 2012 9:30 AM
To: Fisher, Melanie
Cc: Healy, Marion; [redacted]
Subject: RE: Supplements Information on analysis [CRAZE] [SEC=UNCLASSIFIED]

The key question in my mind is whether any of these compounds are captured under the derivatives definition of the amphetamine-like compounds in schedule 9. One of the ingredients in the product differs by only one methyl group from a schedule 9 listed amphetamine –like compound, so it may qualify. I believe that we would need to get some information from TGA on this question because they run the scheduling committee for medicines. I assume that NSW are currently doing this but probably might beneficial for us to know as well.

Melanie perhaps you could ask that helpful DMAA-scheduling person in the TGA for help on this one as well?

[redacted]

From: Fisher, Melanie
Sent: Thursday, 25 October 2012 9:14 AM
To: Healy, Marion
Cc: [redacted]
Subject: RE: Supplements Information on analysis [CRAZE] [SEC=UNCLASSIFIED]

What is the best course of action for getting some clarification on the status of this substance? I don't know how the criminal legislation works and whether it relies on info re whether it can be considered a scheduled substance. Should we wait for NSW and TGA to work it out, ring TGA ourselves or ring OCS ourselves?

Melanie

Melanie Fisher
Deputy Chief Executive Officer
and
Executive Manager Food Standards (Canberra)

Ph +61 2 62712246
Mob +61 419255005

www.foodstandards.gov.au

From: Healy, Marion
Sent: Wednesday, 24 October 2012 10:25 PM
To: Fisher, Melanie
Subject: RE: Supplements Information on analysis [CRAZE] [SEC=UNCLASSIFIED]

There seems to be slightly different information in the various emails so needs to be checked, probably with OCS who will probably will need to check the original decision.

Marion

From: Fisher, Melanie
Sent: Tuesday, October 23, 2012 1:12 PM
To: Healy, Marion
Subject: RE: Supplements Information on analysis [CRAZE] [SEC=UNCLASSIFIED]

weren't they asking whether it was a derivative of a scheduled substance and if so whether it was captured under the scheduling or was that a different amphetamine like substance?

Melanie Fisher
Deputy Chief Executive Officer
and
Executive Manager Food Standards (Canberra)

Ph +61 2 62712246
Mob +61 419255005

www.foodstandards.gov.au

From: Healy, Marion
Sent: Tuesday, 23 October 2012 1:11 PM
To: Fisher, Melanie; [redacted]
Subject: RE: Supplements Information on analysis [CRAZE] [SEC=UNCLASSIFIED]

The info supplied by NSWFA indicates that the substance of most interest and like amphetamine is not scheduled –info from food incident notification. However, this can be checked

Marion

UNCLASSIFIED

From: Fisher, Melanie
Sent: Tuesday, 23 October 2012 1:03 PM
To: [redacted]; Healy, Marion
Subject: RE: Supplements Information on analysis [CRAZE] [SEC=UNCLASSIFIED]

don't we need the advice re whether it is schedule 9 first? if it is sched 9 then am I correct in thinking we don't need a risk assessment as it will be a prohibited substance and enforcement action can proceed on that basis?

Melanie Fisher
Deputy Chief Executive Officer
and
Executive Manager Food Standards (Canberra)

Ph +61 2 62712246
Mob +61 419255005

www.foodstandards.gov.au

From: [redacted]
Sent: Tuesday, 23 October 2012 11:44 AM
To: [redacted]; Fisher, Melanie; [redacted]; Healy, Marion; Brent, Paul
Subject: FW: Supplements Information on analysis [CRAZE] [SEC=UNCLASSIFIED]

As discussed…further email from NSWFA.

Cheers

[redacted]

UNCLASSIFIED

From: Marianne Tegel [mailto:Marianne.Tegel@foodauthority.nsw.gov.au]
Sent: Tuesday, 23 October 2012 10:35 AM
To: incident
Cc: [redacted]; Craig Shadbolt; Ian Beer
Subject: FW: Supplements Information on analysis [CRAZE]

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Regards

Marianne Tegel
Team Leader, Foodborne Illness Investigation Unit
NSW Food Authority
safer food, clearer choices
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marianne.tegel@foodauthority.nsw.gov.au
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Cc: Alan Edwards; Janine Curll; Greg Vakaci; Edward Jansson
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We are unsure if only one major importer or a number of individual ones.

Regards

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Hi Ian,

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Given that this product seems to be sitting on the food side of the interface, you may need to seek the tox/safety advice from FSANZ.

The following advice on phenylisobutylamine (more correctly referred to below as 1-phenylbutan-2-amine) was provided to the TGA by

[redacted] at Drug Import/Export Licensing and Compliance, Office of Chemical Safety, Department of Health and Ageing

[Website: www.health.gov.au/treaties Fax: 02 6289 2500 Email: tmu@health.gov.au]

"1-Phenylbutan-2-amine

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Regards,

[redacted]

[redacted] |Director of Chemistry | Office of Laboratories and Scientific Services l Therapeutic Goods Administration
[redacted] | Fax: 02 6232 8442 | [redacted]

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To: [redacted]
Date: 22/10/2012 01:46 PM
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Hi [redacted]

Any news on a quotation for the analysis of the supplements?

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Sent: Thursday, 11 October 2012 2:22 PM
To: Ian Beer
Subject: RE: Supplements Information on analysis [SEC=UNCLASSIFIED]

Ian,

I suspect that the short answer is 'no'. A reference standard for the compound does not appear to be readily available so we would be restricted to trying to match literature data for mass spectra, UV etc, which would be supportive evidence of its presence but not conclusive.

The problem is that there are a number of different possible compounds with the same molecular formula (C10H15N) so proving that a compound had that particular structure as against one of the other structural isomers would be problematic in the absence of compelling literature data that differentiated between isomers in this respect. So we might be able to tell you that a compound consistent with that molecular formula is present but not be able to tell you its precise structure.

The NMI lab is the best one placed to do this work since they also have the ability to synthesise their own reference standards.

Regards,

[redacted]

[redacted] |Director of Chemistry | Office of Laboratories and Scientific Services l Therapeutic Goods Administration
[redacted] | Fax: 02 6232 8442 | [redacted]

From: Ian Beer <Ian.Beer@foodauthority.nsw.gov.au>
To: [redacted]
Cc: Alan Edwards <Alan.Edwards@foodauthority.nsw.gov.au>, Greg Vakaci <Greg.Vakaci@foodauthority.nsw.gov.au>
Date: 11/10/2012 01:09 PM
Subject: RE: Supplements Information on analysis

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Regards
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Team Leader Enforcement
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From: Ian Beer
Sent: Thursday, 11 October 2012 9:52 AM
To: [redacted]
Cc: Alan Edwards; Greg Vakaci
Subject: Re: Supplements Information on analysis [SEC=UNCLASSIFIED]

Thanks [redacted] no problem with next week
Ian

From: [redacted]
Sent: Thursday, October 11, 2012 09:45 AM
To: Ian Beer
Cc: [redacted]
Subject: RE: Supplements Information on analysis [SEC=UNCLASSIFIED]

Hi Ian,

Please excuse the slow response. I've been out of the office for the last couple of days.

I will work on getting a quote together on testing for the ingredients you mention below. Probably get back to you early next week if that's not too late.

Regards,

[redacted]

[redacted] |Director of Chemistry | Office of Laboratories and Scientific Services l Therapeutic Goods Administration
[redacted] | Fax: 02 6232 8442 | [redacted]

From: Ian Beer <Ian.Beer@foodauthority.nsw.gov.au>
To: [redacted]
Cc: Greg Vakaci <Greg.Vakaci@foodauthority.nsw.gov.au>, [redacted], Alan Edwards <Alan.Edwards@foodauthority.nsw.gov.au>, Edward Jansson <Edward.Jansson@foodauthority.nsw.gov.au>, Marianne Tegel <Marianne.Tegel@foodauthority.nsw.gov.au>
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Subject: RE: Supplements Information on analysis [SEC=UNCLASSIFIED]

Hi [redacted]

Thanks for the advice of you previous email. We were hoping you could do some testing of the new extract (Dendrobium) on the block that claims to be the next DMAA. It looks from the literature attached that it has been around a long time but recently been able to be synthesised as Dendrobine. Not something that should used in a food. Is there any one in Australia who is expert about this substance?

We would like to get a quote for testing 6-10 samples of supplement products for the following

1. XANTHINOL NICOTINATE, if possible getting a reference standard we if not with a tentative identification of xanthinol by characterisation with quantitation against caffeine.
2. Caffeine; with quantification
3. BITTER ORANGE EXTRACTS (containing Synephrine (aka oxedrine) with quantitation
4. PHENETHYLAMINE (PEA) – with quantitation as best you can,
5. Geranium extract - with quantitation .
6. L-Dopa - - with quantitation

regards
Ian Beer
Team Leader Enforcement
NSW Food Authority
safer food, clearer choices

Direct line 9741 4859 | Fax +61 2 9741 4898 | Mob 0413 018 521

From: [redacted]
Sent: Wednesday, 3 October 2012 2:41 PM
To: Ian Beer
Cc: Greg Vakaci; [redacted]
Subject: Re: Supplements Information on analysis [SEC=UNCLASSIFIED]

Hi Ian,

we have seen a number of the compounds referred to below in previous samples however we do not currently have valid reference standards for all of these compounds.

Please see annotations below for our current capacity to test for individual compounds. Other than where we have methods and reference standards for particular compounds (e.g. synephrine, DMAA and L-dopa) then the testing is only indicative and would be for information only and not suitable for use in legal proceedings. Most of the amine compounds that we don't have methods for should not be terribly difficult to analyse for but it would require some method development and obtaining reference standards.

In regard to the presence of amphetamine, I suspect this product contains related compound/s which are close enough in structure to amphetamine to be classed as amphetamine derivatives or analogues. We have recently seen some of these derivatives in a couple of other products. Methamphetamine is (+)-N,alpha-dimethylbenzeneethanamine so the compound referred to in Paul's email below, ALPHA-DIETHYL-BENZENEETHAMINE, is not methamphetamine itself but is presumably a close structural analogue (the naming is not exact hence the actual structure is a bit ambiguous). We may be able to provide some guidance on what amphetamine analogues are present however results would not be definitive and would need follow-up confirmation.

If you would like a quote for testing then please specify the products to be tested and which analytes you want them tested for. It would also be helpful if you could indicate where quantitation of the analyte is desired.

Regards,

[redacted]

[redacted] |Director of Chemistry | Office of Laboratories and Scientific Services l Therapeutic Goods Administration
[redacted] | Fax: 02 6232 8442 | [redacted]

With the Craze product TGA ([redacted]) has advised of possible methamphetamine although the products claims ingredients:-

1. Dendrobex™ : (Dendrobium extract) concentrated for alkaloid including Dendroxine, Dendramine and a number of versions of b-phenylethlamine) and
2. Citramine™ : (Citrus reticulata extract) concentrated for N-methyltyramine content.

With other products declared therapeutic substances

- XANTHINOL NICOTINATE, - in the absence of a reference standard we normally do tentative identification of xanthinol by characterisation with quantitation against caffeine.
- BITTER ORANGE EXTRACTS (containing N-Methyltyramine (NMT), Octopamine & Synephrine) - we can ID and quantitate Synephrine (aka oxedrine); we don't currently have a method or ref stds for NMT or octopamine.
- PHENETHYLAMINE (PEA) - we can ID and semi-quantitate.
- DMAA Geranium extract - - we can ID and quantitate.
- L-Dopa - - we can ID and quantitate.

From: Ian Beer <Ian.Beer@foodauthority.nsw.gov.au>
To: [redacted]
Cc: Greg Vakaci <Greg.Vakaci@foodauthority.nsw.gov.au>
Date: 02/10/2012 06:55 PM
Subject: Supplements Information on analysis

Hi [redacted]

Just a question in relation to analysis of Sports Supplements we are currently investigating some of the pre-workout supplements that claim to contain some weird and wonderful extracts. From our past experience with the slimming coffee products many of the claimed extracts are replaced with therapeutic drugs.

With the Craze product TGA ([redacted]) has advised of possible methamphetamine although the products claims ingredients:-

1. Dendrobex™ : (Dendrobium extract) concentrated for alkaloid including Dendroxine, Dendramine and a number of versions of b-phenylethlamine) and
2. Citramine™ : (Citrus reticulata extract) concentrated for N-methyltyramine content.

With other products declared therapeutic substances

- XANTHINOL NICOTINATE,
- BITTER ORANGE EXTRACTS (containing N-Methyltyramine (NMT), Octopamine & Synephrine)
- PHENETHYLAMINE (PEA)
- DMAA Geranium extract
- L-Dopa

Are you able to undertake screening tests for these substances?

We are looking at testing Craze with the NSW illicit drug lab this week for presence of Methamphetamines but if that is unfruitful may wish to test for the other declared substances.

Regards

Ian Beer
Team Leader Enforcement
NSW Food Authority
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From: [redacted]
Sent: Thursday, 27 September 2012 1:49 PM
To: Ian Beer
Cc: Janine Curll
Subject: Fw: Supplements Information [SEC=UNCLASSIFIED]

Ian

Re the product 'craze'.

We have received advice from the Treaties and Monitoring Section (part of Dept of Health) that the product Craze does contain an ingredient which is considered to be a prohibited import. See following email.

I am unsure if you have had the product tested at all or if a recall should be considered.

We have notified Customs of this so hopefully the market will dry up.

Happy to have a chat about the other issues. I will be away next week, returning on the 9th of October.

[redacted]
Chief Investigator
Regulatory Compliance Unit
Therapeutic Goods Administration

[redacted]
----- Forwarded by [redacted] on 27/09/2012 01:42 PM -----

From: [redacted]
To: [redacted]
Date: 27/09/2012 12:15 PM
Subject: Re: Supplements Information [SEC=UNCLASSIFIED]

[redacted],

As the CRAZE pre-workout supplement powder is considered to be a food, it is not a product that is regulated by the TGA.

However, the product CRAZE is now considered to be a prohibited import.

Testing has revealed that the product CRAZE contains the undeclared ingredient ALPHA-DIETHYL-BENZENEETHAMINE
which is considered to be a synonym for the substance METHAMPHETAMINE.

METHAMPHETAMINE contains the stereoisomer Levomethamphetamine which would therefore be captured under Schedule 4 Item 116 of the CPI Regs.

[redacted]
Regulatory Liaison Officer
TGA Regulatory Compliance Unit
[redacted]

From: [redacted]
To: [redacted]
Date: 27/09/2012 11:50 AM
Subject: Re: Supplements Information [SEC=UNCLASSIFIED]

Thanks

Can I get that information re Craze

[redacted]
Chief Investigator
Regulatory Compliance Unit
Therapeutic Goods Administration
[redacted]

From: [redacted]
To: [redacted]
Date: 27/09/2012 10:26 AM
Subject: Supplements Information [SEC=UNCLASSIFIED]

[redacted]

In relation to the email you received from IAN BEER I can provide the following information on the ingredients of concern:

DENDROBINE - extracted from the plant Dendrobium noble is a traditional Chinese medicine with analgesic properties (pain relief). It is currently not a prohibited import ingredient or a scheduled substance.

CINNAMOMUM BURMANNII BARK EXTRACT - Also known as Indonesian cinnanmon it is not a prohibited import ingredient or a scheduled substance. This herb contains Eugenol which has antiseptic and anti-inflammatory properties.

PHENETHYLAMINE - is not a prohibited import ingredient. It is also not a scheduled ingredient. It has very minor weight loss properties and is a minor mood enhancer.

BITTER ORANGE EXTRACTS (containing N-Methyltyramine (NMT), Octopamine & Synephrine) - Bitter orange extracts have weight loss properties and therefore are commonly found in complementary medicines and also in body building / sports supplements. NMT, Octopamine & Synephrine are not prohibited import ingredients. Synephrine (also known as Oxedrine) however, is considered to be a prescription medicine when the daily dose of Oxedrine exceeds 30mg per day.

XANTHINOL NICOTINATE - is not a prohibited import ingredient but it is a prescription only medicine which is used as a vasodilator (widens blood vessels). It appears in body building / sports supplements such as Animal Pak.

[redacted]
Regulatory Liaison Officer
TGA Regulatory Compliance Unit
[redacted]

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http://www.mailguard.com.au

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[redacted]

From: [redacted]
Sent: Monday, 12 November 2012 12:02 PM
To: [redacted]
Subject: FW: request for assistance [DLM=Sensitive]

Categories: Red Category

FYI

From: Fisher, Melanie
Sent: Friday, 9 November 2012 6:23 PM
To: [redacted]
Cc: [redacted]
Subject: Re: request for assistance [DLM=Sensitive]

Thanks tony that is very helpful. I know you have been crazy busy so we appreciate you taking the time to provide this advice

Regards

Melanie

Sent from my iPhone

On 09/11/2012, at 5:06 PM, [redacted] wrote:

> Melanie
> Sorry about the delay in getting back. The advice I have been given by our pharmaceutical chemists is that phenylisobutylamine is not a derivative or a precursor of amphetamine, it cannot be used to make amphetamine and vice versa; phenylisobutylamine has some pharmacological effect however it's very reduced compare to amphetamine.
> Regards
> Tony
> **Dr Tony Gill** | MBBS MPH FAFPHM AFACHSM | Acting Principal Medical Adviser | TGA Executive | Therapeutic Goods Administration | PO Box 100, WODEN ACT 2606 | [redacted]
>
> From: "Fisher, Melanie" <Melanie.Fisher@foodstandards.gov.au>
> To: [redacted]
> Cc: [redacted]
> Steve" [redacted]
> Date: 25/10/2012 02:17 PM
> Subject: request for assistance [DLM=Sensitive]
>
> ---
>
> Hi Tony
>
> FSANZ has been alerted by the NSW Food Authority to an issue that could require either a recall or possibily the activation of the National Food Incident Protocol. NSW has asked us for some preliminary safety advice before they decide whether the Protocol needs to be activated. Before we undertake this work we would appreciate some advice from the TGA about whether these substances are considered to be captured (as derivatives) under Schedule 9 (or any other relevant

schedule). The details of the issue are below. Please feel free to ring either [redacted] on [redacted] or me on the number below if you want to discuss our request.

On 23 October 2012, the NSW Food Authority forwarded information to FSANZ regarding Sports Supplements containing substances that are not listed in Standard 2.9.4. Brand names of these products were stated to be 'C4 Extreme', 'Craze', 'F=MA', 'Nitrolyze Freak Formula', 'Swollen'.

NSWFA indicated that preliminary analysis of 'Craze' revealed the presence of phenylisobutylamine, also known as α-ethylphenethylamine, a compound differing from amphetamine (Schedule 8 of the Poisons Schedule) only by an additional methyl group. NSWFA has contracted NMI to conduct confirmatory analysis. NSWFA is also investigating the presence of a related compound in 'Craze', namely phenethylamine (PEA).

Note that methamphetamine ('speed', 'ice') also differs from amphetamine only by an additional methyl group, albeit at a different position in the molecule. Methamphetamine is also listed under Schedule 8. Several derivatives of amphetamine are listed under Schedule 9 (e.g. MDMA = ecstasy).

FSANZ has conducted a preliminary search of the published scientific literature but has not yet located relevant pharmacological or toxicological data on phenylisobutylamine or synonyms of this compound. In the absence of such data, the question arises whether the close structural similarity with amphetamine would be sufficient to classify phenylisobutylamine in Schedule 9 of the poisons schedule.

regards

Melanie

Melanie Fisher
Deputy Chief Executive Officer
and
Executive Manager Food Standards (Canberra)

Ph +61 2 62712246
Mob +61 419255005

www.foodstandards.gov.au
<mime-attachment.png><mime-attachment.png>

[redacted]

From: Marianne Tegel <Marianne.Tegel@foodauthority.nsw.gov.au>
Sent: Tuesday, 27 November 2012 3:34 PM
To: incident
Cc: [redacted]; Ian Beer
Subject: CRAZE Police Expert Certificate
Attachments: Expert Cert P Ballard.pdf; nihms-105401.pdf

Hi [redacted]

I gather [redacted] is out of the incident loop for a while so I am hoping you are the right person to send this to.

We have been working on the Sports Supplements issue for some time here and finally we have a opinion from a forensic chemist from NSW Police who has concluded that the substance detected in Craze (N,α-diethylbenzeneethanamine) is a structural analogue of methyl amphetamine. To meet the definition of a prohibited drug under the NSW Misuse and trafficking Act the substance need to have psychotropic properties.

This would put it into a category of unsuitable with health implications if not the unsafe category if product is misused. I have attached a paper relating to meth amphetamine and advice from a police expert. We are primarily concerned about what constitutes a safe dose in relation to this product and at the very least its suitability.

As we now have some test results and expert opinion on some of the products we are now in a position to approach the importer requesting a recall of Craze.

I would appreciate it if you would pass on this information to the other jurisdictions for their information and action as required. We can also consider a teleconference on this matter if there is sufficient interest from other jurisdictions.

Regards

Marianne Tegel
Team Leader, Foodborne Illness Investigation Unit
NSW Food Authority
safer food, clearer choices
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Direct line 9741 4858 | Fax +61 2 9741 4895 | Mob 0438 943851
marianne.tegel@foodauthority.nsw.gov.au

From: Ian Beer
Sent: Tuesday, 27 November 2012 10:01 AM
To: Marianne Tegel
Cc: Greg Vakaci; Alan Edwards
Subject: CRAZE Police Expert Certificate

Hi Marianne

Finally we have a opinion from a forensic chemist from NSW Police who has concluded that the substance detected in Craze (N,α-diethylbenzeneethanamine) is a structural analogue of methyl amphetamine. To meet the definition of a prohibited drug under the NSW Misuse and trafficking Act the substance need to have psychotropic properties.

This would put in to a unsuitable with health implications if not the unsafe category if product is misused. I think it is time to discuss in the national forum to alert jurisdictions and achieve removal of products.

Please forward to Barbara and ask for a teleconference to discuss

Ian Beer | Team Leader Enforcement
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W: www.foodauthority.nsw.gov.au

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NSW Police Force

EXPERT CERTIFICATE

Section 177, Evidence Act 1995 No. 25

In the matter of :	N,α-diethylbenzeneethanamine (FC1150704)
Place Statement Taken:	Pemulwuy, NSW
Date:	26 November 2012

Name:	Peter Richard BALLARD
Work Address:	Crime Scene Services Branch, Pemulwuy Laboratories
	6 – 20 Clunies Ross Street
	Pemulwuy NSW 2145
Work Telephone	02 9688 9241
Occupation:	Forensic Chemist

STATES:

1. This statement made by me accurately sets out the evidence that I would be prepared, if necessary, to give in court as a witness. The statement is true to the best of my knowledge and belief and I make it knowing that, if it is tendered in evidence, I will be liable to prosecution if I have wilfully stated in it anything that I know to be false, or do not believe to be true.

   I acknowledge that I:

   (i) have read the Expert Witness Code of Conduct in Schedule 7 of the NSW Uniform Civil Procedure Rules 2005, and,

   (ii) agree to be bound by the Code.

2. I am 43 years of age.

3. I hereby certify I am a forensic chemist employed by the Forensic Services Group of the NSW Police Force. I have a specialised knowledge based on the following training, study and experience as a chemist for the past 20 years. I hold the following qualifications:

Qualification :

Bachelor of Applied Science (Applied Chemistry) from University of Western Sydney.

Other Study/Experience:

I have over twenty (20) years experience as an analytical chemist, including fourteen (14) years in the analysis of illicit drugs and related substances.

Witness: 200946 Daniel COGHLAN 26/11/12

Signature: Peter BALLARD 26/11/12

This experience has been gained whilst working at the NSW Division of Analytical Laboratories (DAL), the Australian Government Analytical Laboratories (AGAL) / National Measurement Institute (NMI) and the NSW Police Force Forensic Services Group (NSWP FSG). I have analysed many samples and I have seen the results of analysis of many samples examined by other analysts.

For more than ten years my duties have included attendance at premises where manufacture of illicit drugs is suspected. Such sites are commonly called "clandestine laboratories" or "clan labs". I have attended numerous sites within New South Wales where there was evidence of processes used in the manufacture of restricted substances. During my employment at the AGAL / NMI I carried out analysis of many items seized in relation to "clan labs".

I have attended state and national training courses related to attendance and processing of clandestine drug laboratories and chemical, biological and radiological (CBR) crime scenes. I have completed the NSW Police Force Bomb Scene Examination Workshop and received training within NSW and interstate on the analysis of explosives and explosive residues. I have also developed protocols for the field sampling and laboratory analysis of unknown and hazardous chemicals.

I have discussed aspects of illicit drugs, explosives and CBR agents with scientific colleagues and law enforcement personnel, both in Australia and overseas. I am the NSW representative for the national Chemical Warfare Agent Laboratory Network (CWALN). I have attended conferences and workshops relating to drug analysis and manufacture both in Australia and overseas.

In the course of my duties I have carried out extensive reading regarding drugs, explosives and CBR agents in relation to analysis, production methods and use. My reading includes scientific publications, periodicals circulated between forensic laboratories, police intelligence information and 'underground' publications.

I have given evidence at legal proceedings on numerous occasions. This has been at the levels of local and District Court, for evidence of both fact and expert opinion. As well as NSW courts, I have given such evidence for courts of law in Queensland, Northern Territory, Western Australia and Victoria.

4. Opinions given in this statement are based wholly or substantially on the above knowledge.

5. On 6th November 2012 I received a request via email from Detective Inspector M COOK of the NSW Police Force Drug Squad to provide advice regarding N,α-diethylbenzeneethanamine being an analogue of methylamphetamine.

6. Methylamphetamine is also known as N,α-dimethylbenzeneethanamine. Methylamphetamine is specified as a prohibited drug in Schedule 1 of the NSW *Drug Misuse and Trafficking Act 1985*.

Witness: 200446
Daniel COGHLAN
26/11/12

Signature:
Peter BALLARD
26/11/12

7. N,α-diethylbenzeneethanamine can be considered an analogue of methylamphetamine (N,α-dimethylbenzeneethanamine) under Schedule 1 of the NSW *Drug Misuse and Trafficking Act 1985* by structural modification obtained by:
   (b) (vii) the replacement of 1 or more of the groups specified in subparagraphs (iii)–(vi), namely subparagraph (v) replacing alkyl (being two methyl groups), with 1 or more other groups so specified, namely subparagraph (v) with alkyl (being two ethyl groups).

8. I am of the opinion that N,α-diethylbenzeneethanamine is a structural analogue of methylamphetamine.

9. To meet the definition of a prohibited drug under the NSW *Drug Misuse and Trafficking Act 1985* N,α-diethylbenzeneethanamine needs to have psychotropic properties.

Witness: 200 2946
Daniel COGHLAN
26/11/12

Signature:
Peter BALLARD
26/11/12

Published in final edited form as:
Mol Psychiatry. 2009 February ; 14(2): 123–142. doi:10.1038/mp.2008.90.

Potential Adverse Effects of Amphetamine Treatment on Brain and Behavior: A Review

Steven M. Berman, **Ronald Kuczenski**, **James T. McCracken**, and **Edythe D. London**
Departments of Psychiatry and Biobehavioral Sciences (Drs. Berman, McCracken, and London), Molecular and Medical Pharmacology (Dr. London), and the Brain Research Institute (Drs. Berman, McCracken and London), David Geffen School of Medicine, University of California Los Angeles, Los Angeles, CA; and Department of Psychiatry, University of California San Diego, La Jolla, California (Dr. Kuczenski)

Abstract

Rationale—Amphetamine stimulants have been used medically since early in the twentieth century, but they have a high abuse potential and can be neurotoxic. Although they have long been used effectively to treat attention deficit hyperactivity disorder (ADHD) in children and adolescents, amphetamines are now being prescribed increasingly as maintenance therapy for ADHD and narcolepsy in adults, considerably extending the period of potential exposure. Effects of prolonged stimulant treatment have not been fully explored, and understanding such effects is a research priority [1]. Because the pharmacokinetics of amphetamines differ between children and adults, reevaluation of the potential for adverse effects of chronic treatment of adults is essential.

Findings—Despite information on the effects of stimulants in laboratory animals, profound species differences in susceptibility to stimulant-induced neurotoxicity underscore the need for systematic studies of prolonged human exposure. Early amphetamine treatment has been linked to slowing in height and weight growth in some children. Because the number of prescriptions for amphetamines has increased several-fold over the past decade, an amphetamine-containing formulation is the most commonly prescribed stimulant in North America, and it is noteworthy that amphetamines are also the most abused prescription medications. Although early treatment does not increase risk for substance abuse, few studies have tracked the compliance and usage profiles of individuals who began amphetamine treatment as adults. Overall, there is concern about risk for slowed growth in young patients who are dosed continuously, and for substance abuse in patients first medicated in late adolescence or adulthood.

Although most adult patients also use amphetamines effectively and safely, occasional case reports indicate that prescription use can produce marked psychological adverse events, including stimulant-induced psychosis. Assessments of central toxicity and adverse psychological effects during late adulthood and senescence of adults who receive prolonged courses of amphetamine treatment are warranted. Finally, identification of the biological factors that confer risk and those that offer protection are also needed to better specify the parameters of safe, long-term, therapeutic administration of amphetamines to adults.

Keywords

amphetamine; methamphetamine; stimulant; ADHD; narcolepsy; drug abuse

Send correspondence to: Edythe D. London, PhD, Professor of Psychiatry and Biobehavioral Sciences, Semel Institute for Neuroscience and Human Behavior, University of California Los Angeles, 760 Westwood Plaza, Box 175919, Los Angeles, California 90024−1759 (310)8250606 fax (310)8250812 (E-mail: E-mail: elondon@mednet.ucla.edu)..

Therapeutic use of amphetamine

Description and history

Amphetamine was initially synthesized in Berlin in 1887 as 1-methyl-2-phenethylamine. It was the first of several chemicals, including methamphetamine and methylenedioxymethamphetamine, which have similar structures and biological properties, and are referred to collectively as "amphetamines" [2]. For 110 years, amphetamine was thought to be a human invention, but the compound was found in 1997, along with methamphetamine, nicotine and mescaline, within two species of Texas acacia bushes [3, 4].

Amphetamine is one of the most potent sympathomimetic drugs, producing its effects by increasing synaptic levels of the biogenic amines, dopamine, norepinephrine and serotonin, through multiple mechanisms [5, 6]. Although amphetamine binds to all monoamine transporters, its behavioral stimulant effects are mediated primarily through dopamine and depend on the dopamine transporter (DAT) [7]. Amphetamine blocks the ability of DAT to clear the neurotransmitter from the synapse and facilitates reverse movement of dopamine across the cell membrane (i.e., cytoplasmic dopamine is transported into the synapse and extracellular space). Amphetamine also disrupts vesicular storage of dopamine, allowing it to accumulate in the cytoplasm, and inhibits the degradative enzymes monoamine oxidase A and B (MAO-A, MAO-B). These actions further promote cytoplasmic accumulation of monoamines, which can then be transported into the synapse.

Other molecular mechanisms by which amphetamine mediates monoamine release have also been implicated. These include amphetamine-induced exchange diffusion, channel-like transport, disruption of vesicular storage by the weak base properties of amphetamine, phosphorylation, and transporter trafficking [2]. Amphetamine is presumed to amplify both tonic and phasic dopamine release through such mechanisms. Noradrenergic effects of amphetamine are less well studied, but are also believed to exist at clinically relevant plasma levels of the drug [8].

Amphetamine exists as two stereoisomers that differ in effects [5]. The *l*- enantiomer (levoamphetamine) produces more cardiovascular and peripheral effects than the *d*-enantiomer (dextroamphetamine). At low doses, levoamphetamine produces greater arousal than dextroamphetamine, acting primarily on norepinephrine. At higher doses, dextroamphetamine has stimulant properties that are three- to four times as strong as those of levoamphetamine, and acts primarily on dopamine. Few clinical studies of ADHD, however, have documented differences among *d*-, *l*- and racemic amphetamine. Just as dextroamphetamine has more central and less peripheral action than levoamphetamine, methamphetamine, which is equipotent to dextroamphetamine in producing behavioral stimulant effects [9], has even fewer peripheral effects than dextroamphetamine [5].

Although primarily valued for their use in the treatment of ADHD, amphetamines are also effective in combating the excessive daytime sleepiness associated with narcolepsy. It was first noted in the 1930s that amphetamines can produce a "paradoxical" relaxing effect in severely disruptive, institutionalized, hyperactive boys [10], paving the way for their more common medical use in ADHD. It was also noted in the 1930s that amphetamines had reinforcing properties, leading to widespread prescription drug abuse (see below). Therefore, by 1980 most countries that regulate drug use had severely restricted legal use of amphetamines, but the number of prescriptions, and prescription abuse, continued to grows, particularly in North America. During 1973 there were eight billion amphetamine-containing tablets manufactured in the United States; and both licit and illicit use of amphetamines increased greatly in subsequent years. In the United States and internationally, under the Convention on Psychotropic Substances [11], amphetamine is classified as a Schedule II drug. Schedule II drugs

have an accepted medical use, but are tightly monitored due to a potential for abuse that can lead to severe psychological and physiological dependence.

Despite recommendations that amphetamines be restricted to use for narcolepsy and ADHD, with very limited use for obesity, some physicians have continued to write off-label prescriptions for other medical uses, such as adjuvant medications in treatment of depression and post-stroke cognitive impairment. In 1991, there were still fewer than 500,000 annual prescriptions written for amphetamine in the US. Over the ensuing decade and a half, however, the amount of amphetamine produced and the number of prescriptions written in the United States increased dramatically.

Events in the early 1990's likely influenced the utilization of amphetamine as a prescribed treatment. In 1991, the United States Federal Education Department began classifying ADHD as an educational disability in terms of the Individuals with Disabilities Education Act. This act mandates a comprehensive behavioral, educational and medical evaluation of children suspected of having an educational disability. A physician visit is not required, but the school district is obligated to provide any diagnostic services that are needed at no cost to parents [12]. Over the next 2 years, ADHD diagnoses tripled, from one to three million.

Other concurrent factors included heightened awareness of the biological basis of ADHD [13], reports supporting the view that the disorder was a neuropsychiatric syndrome [14], books about ADHD in the lay press, and a variety of reports on its persistence and associated impairment. Newer formulations of amphetamine also reached the market. Among these was the mixture of amphetamine salts (Adderall™), with a longer duration of action than other available stimulant preparations.

In 2000, the number of prescriptions for amphetamine exceeded eight million, a 1600% increase over nine years. That same year, US annual manufacture of amphetamine reached 30,000 kg (40 % *d*-amphetamine, 60% mixed *d*/*l* salts). In addition, 1,306 kg of methamphetamine was used primarily for treatment of obesity, although it was also approved for treatment of ADHD [11]. Since over 95% of pharmaceutical amphetamines are either *d*-amphetamine or a mixture of *d*- and *l*-amphetamine salts, this review concentrates on these compounds. Methamphetamine is less frequently used in clinical preparations, and is primarily discussed as a comparative drug.

Preparations & Indications

Pharmaceutical drugs classed as amphetamines include formulations from salts of *d*-amphetamine (DextroStat, Dexedrine), mixed *d*- and *l*-amphetamine (Adderall™), *d*-methamphetamine (Desoxyn), and an amphetamine pro-drug compound, lisdexamfetamine dimesylate (Vyvanse™). Methylenedioxymethamphetamine, commonly known as “ecstasy”, belongs to the amphetamine family; it is illicitly manufactured and widely abused but not contained in any medicinally used pharmaceutical. Methylphenidate, an amphetamine-like phenethylamine stimulant and catecholamine reuptake inhibitor, is the most common alternative to treatment with amphetamine, both for ADHD and for narcolepsy.

In the 1990s, longer acting forms of amphetamine were developed using capsules of mixed *d*- and *l*- salts in both immediate release pellets and enteric-coated, delayed-release beads. The different salts and beads are metabolized at different rates, resulting in a less dramatic onset and termination of therapeutic action. Amphetamine is most often administered twice daily in immediate-release formulations (Dexedrine, DextroStat, or Adderall IR tablets), or once a day in sustained-release formulations (Dexedrine or Adderal XR capsules, Vyvanse tablets). The therapeutic effects begin within 45−60 min after ingestion of an immediate-release tablet, with peak effect in 2 to 3 hours, and a total duration of 4−6 h. Effects peak about 4−7 h after ingestion

of extended-release doses, and last about 12 h, depending on the endpoint and dose. Plasma profiles of *d*- and *l*- amphetamine are similar after a single dose of 20 mg Adderall XR or two 10-mg doses of Adderal IR, given 4 h apart. Maximum plasma concentration for Adderall XR is achieved about 6 h after ingestion [15].

Amphetamine is currently FDA-approved for treatment of ADHD and narcolepsy, and methamphetamine is approved for treatment of ADHD and obesity. Amphetamine is approved for ADHD in doses of 2.5 mg/day for children ages 3 to 6, and between 5 and 40 mg/day for amphetamine in an immediate-release (IR) formulation, for school-age children. Amphetamine in an extended-release (XR) formulation has a maximum approved dosage of 30 mg per day for children. Vyvanse contains a conditionally bioreversible derivative of dextroamphetamine, which has lower pharmacokinetic variability and slightly longer duration than other delayed-release amphetamine medications, but requires higher doses. It is manufactured in tablets ranging in dose from 20 mg to 70 mg, and is approved for up to 70 mg per day for school-age children [16]

For adults, Adderall XR is approved at doses up to 20 mg per day, due to lack of evidence for clearly superior benefits from higher doses. After a report that daily Vyvanse dosages of 30 mg, 50 mg and 70 mg all improved ADHD symptoms in a sample of 414 adults [17], the FDA approved the drug for adult treatment in April 2008. There is evidence suggesting that some adults require higher doses of stimulant medications than the approved maximum levels to achieve maximal benefit [18-20]. Effects of prolonged stimulant treatment in adults, however, have not been fully explored, and this is a current research priority [1].

For narcolepsy, amphetamine is recommended at a dose of 5 mg/day for children aged 6 to 12, and between 10 and 60 mg/day over the age of 11. Although it is rarely used, methamphetamine is approved for ADHD at doses between 5 and 25 mg/day for patients over age 6. Methamphetamine is approved for obesity at a dose of 5 mg taken before meals for patients at age 12 and over. Some physicians continue to write off-label prescriptions for other uses of these drugs.

Most pharmaceutical amphetamine is used in treatment of ADHD. Although the therapeutic mode of action is not fully known, amphetamine is highly efficacious for the reduction of core ADHD symptoms in children, adolescents, and adults. In controlled clinical trials, between 55 −70% of ADHD subjects manifest “clinically significant” improvement lasting up to 4−6 weeks. In the very few studies that have compared the efficacy and safety of amphetamine directly to those of methylphenidate, amphetamine was equivalent or superior to methylphenidate on standard efficacy endpoints. Some research also suggests that a few individuals who do not respond to methylphenidate treatment for ADHD experience significant benefit from amphetamine (and vice versa) [8].

Amphetamines produce objective improvement in 65%-85% of patients with narcolepsy [21]. Many physicians prefer more recently developed medicines with less abuse potential, most notably methylphenidate and modafinil, a stimulant-like drug which increases monoamine release but also has other effects, and is primarily used as a “wakefulness promoting agent” in treatment of sleep disorders. However, while clinical comparison trials have not been conducted, meta-analysis suggests that daytime wakefulness is improved in more narcoleptic patients by amphetamines (80%) than by either modafinil (55%) or methylphenidate (70%) [22].

Amphetamines remain among the most effective appetite suppressants. However, by the 1990s, the United States Pharmacopoeia's resource, “Drug Info for the Health Care Professional”, no longer recommended amphetamine for treatment of obesity due to the high abuse potential and availability of equally effective appetite-suppressants with lower abuse potential.

CNS Side effects

Amphetamines readily cross the blood-brain barrier to reach their primary sites of action in the brain. The acute administration of amphetamine produces a wide range of dose-dependent behavioral changes, including increased arousal or wakefulness, anorexia, hyperactivity, perseverative movements, and, in particular, a state of pleasurable affect, elation, and euphoria, which can lead to the abuse of the drug.

Adverse effects listed in drug labels of prescription amphetamines include disturbances of mood and behavior in addition to cardiac and gastrointestinal effects. Most of these adverse events are considered "time-limited", resolving rapidly after discontinuation of stimulant exposure. The most common drug-related effects are loss of appetite, insomnia, emotional lability, nervousness and fever [23]. The American Academy of Pediatrics [24] also lists jitteriness and social withdrawal as common side-effects of amphetamines in children. Clonidine is increasingly administered in conjunction with stimulants to reduce ADHD-associated impulsive/oppositional behaviors or tics, and to combat insomnia. Although limited in scope, a few studies have compared the types and rates of adverse events associated with administration of amphetamine and methylphenidate to children with ADHD. In general, these studies found similar side effect profiles for the two drugs. One of the larger and best controlled studies noted that the severity of adverse events may be greater for amphetamine, especially with respect to insomnia, negative affect, irritability, proneness to crying, anxiety, sadness/unhappiness, and nightmares [25]. However, tolerability as assessed by drop-out rates due to adverse events, was low (≤2%) and did not differ between medications.

Unfortunately, the extant studies on side effect risk of the stimulants used for ADHD treatment have many limitations. All have been restricted to relatively short durations of exposure; and most are based on an assumption that a dose of methylphenidate is equivalent to half of an equal dose of amphetamine. Therefore, amphetamine is administered at 50% of the methylphenidate dose using fixed-dose designs, rather than titrating to a pre-determined efficacy endpoint before comparing adverse events. Most studies have not incorporated measurement of plasma drug level achieved although few relationships between these common adverse events and plasma levels have been noted [15]. Nevertheless, it is potentially important that treatment within approved dose ranges with amphetamines, especially newer extended-release formulations, have produced residual low, but detectable, steady-state blood levels up to 24 h after administration. Thus many individuals experience some degree of continuous drug exposure. Although not tested, this finding suggests that cardiovascular complications, which have been associated with both normal aging and amphetamine abuse in young addicts, may appear earlier in older adults receiving maintenance amphetamine treatment [26]. Regarding the detection of risk for uncommon or rare severe psychological or behavioral reactions to stimulants, controlled studies have not been large enough to pinpoint risk factors or determine differential risk by treatment assignment. Finally, a common observation across studies of the pharmacokinetics, pharmacodynamics, and safety profiles of amphetamine is the high degree of interindividual variability across most measures and endpoints. This variability calls for additional caution in application of the increasingly common practice of prescribing stimulants concurrent with use of other psychotropic medications [27, 28].

Prevalence

ADHD is the most common reason for mental health, special education or behavioral referral in pediatric medicine, and community studies yield prevalence rates from 1.7% to16% of school age children [14, 29], and 1%-5% of adults. Adoption and twin studies estimate that 60 −80% of the risk for ADHD is heritable, likely reflecting a polygenic or oligogenic risk mechanism [30]. The prescription of chronic stimulant medication for maintenance therapy has long been the most effective treatment for ADHD [31], and stimulant use has continued to

increase over the last decade. Despite this increase, estimates suggest that roughly half of children and adolescents with ADHD do not receive medical treatment for the disorder [29], and even fewer adults with ADHD receive any intervention directed at its amelioration.

ADHD treatment forms the bulk of the total prescriptions for pharmaceutical amphetamines. A study of children receiving licit stimulants in the Netherlands found that 90% of them were diagnosed with ADHD [32]. Medical use of stimulants is highest in North America (1 to 2 % of the population), and Australia, particularly the state of Western Australia (2.4%), with somewhat lower values in Europe (0.8 to 1.7%). This frequency of amphetamine use parallels regional differences in the prevalence estimates of ADHD [33]. In 2004, 70% of the stimulant prescriptions for children in Western Australia were for *d*- amphetamine. However, as methylphenidate was approved for government subsidies in late 2005, its use has probably since increased [33].

Boys are diagnosed with ADHD 2−4 times as frequently as girls. The frequency of diagnoses increases steeply from age 3 to about age 8, and increases at a slower rate or plateaus through the teen years. In a study of almost 10,000 Australian children taking medicinal stimulants, the highest prevalence of ADHD was 5.5%, and was found in 14 year-old boys [33].

The proportion of total stimulant prescriptions written for adults has not been documented, but adult diagnosis of ADHD has increased over recent years, attaining a census-adjusted visit rate of 0.4% in the US by 2003 [34]. In 4,569 adults diagnosed with ADD/ADHD from 1999−2004 in the US, and who received mixed amphetamine salts, methlyphenidate, or atomoxetine (a selective norepinephrine transporter inhibitor), 34% were given amphetamine [35]. Amphetamine treatment lasted for a median of 128 days, longer than treatment periods associated with methylphenidate (99 days), or atomoxetine (86 days). Adults can receive higher amphetamine doses than children, with evidence that doses of up to 0.9 mg/kg/day are required to attain maximal benefits [18-20]. In addition, the elimination half-life of amphetamine in adults is two to three times as long as that observed in children [36]. Because the treatment of adult ADHD could theoretically be quite prolonged if symptoms persist, the careful evaluation of the potential for adverse effects of cumulative amphetamines in adults is needed.

Narcolepsy is a less common disorder than attention deficit disorder, with prevalence estimates ranging from 0.005 % in the US, to 0.05% in five European countries, to 0.15% in Japan [37]. It is characterized by excessive daytime sleepiness, cataplexy, and hypnagogic hallucinations. Narcolepsy is most typically diagnosed in the second or third decade of life. As it is a chronic disorder, treatment needs are essentially life-long.

It is remarkable that the prevalence of problematic use of amphetamine has been rising in the elderly, and that prescription substance abuse in this population may augment associated risks and require unique considerations for diagnosis and treatment [38]. The number of emergency department mentions of amphetamine for illicit substances among patients 55 years and older increased 700% from 1995 to 2002 [39], and it is estimated that the number of adults of this age in need of substance abuse treatment will increase from 1.7 million in 2000 and 2001 to 4.4 million in 2020 [40]. The increased use of amphetamines as maintenance medications in adults, the longer elimination half-life in adults compared with children or adolescents, the larger dosages and treatment durations applied to adults, and the increased prevalence of problematic use in adults all underscore the need for careful evaluation of the potential for adverse effects of cumulative amphetamine administration in adulthood.

Animal studies - Neurotoxicity and implications for therapeutic treatment

Many of the behavioral effects of amphetamines that have been observed in humans can be demonstrated in experimental animals. These include arousal, hyperactivity, stereotypic

perseverative movements, psychomotor depression, cognitive impairment, hallucinatory-like behaviors, and chronic self-administration. Evidence indicates that the effects of amphetamine on the neurotransmitters dopamine and norepinephrine play critical roles in eliciting these effects. After chronic exposure to amphetamines, animals exhibit either tolerance (an attenuated response) or sensitization (an augmented response) during subsequent drug administration, indicating that adaptations in the neurobiological substrates of these behaviors.

Concerns have been voiced that, in addition to neurobiological adaptations, prolonged exposure to amphetamine could damage components of the central nervous system. These concerns arise, in part, from evidence that exposure of experimental animals to acute, high doses of amphetamine or methamphetamine produces damage, generally referred to as "neurotoxicity", to dopaminergic neurons innervating the dorsal striatum (caudate-putamen). The evidence for neurotoxicity in rodents derives almost exclusively from studies utilizing very high parenterally administered doses of the drugs, typically administered in a "binge" pattern; i.e., four successive injections at 2-hr intervals [41, 42]. The damage is evident as deficits in phenotypic markers for dopaminergic nerve terminals, including dopamine, its biosynthetic enzymes tyrosine hydroxylase and aromatic amino acid decarboxylase, and both the plasma membrane dopamine transporter (DAT) as well as the vesicular monoamine transporter. High doses of amphetamines have produced enlarged chromatolytic medulla neurons in cats [43], and parenteral dosing in rodents can also produce swollen or reduced dopaminergic axons, and serotonin deficits. The deficits in dopaminergic nerve terminals are not accompanied by apparent damage to the dopamine-containing cell bodies within the substantia nigra. Nevertheless, they can persist for years following cessation of drug exposure [44]. Although the relevance of these data to the consequences of low dose, prescription use of amphetamines in humans is not entirely clear, the potential for similar damage following prolonged low dose exposure merits some consideration.

The mechanisms responsible for amphetamine-induced neurotoxicity have not been fully identified. However, accumulated evidence suggest that the high levels of cytoplasmic dopamine associated with amphetamine-mediated disruption of vesicular storage lead to accumulation of reactive oxygen species and severe oxidative stress [45], which contribute to the damage to dopamine nerve terminals. Efforts to detect similar stimulant-induced neurotoxicity with high-dose exposure to methylphenidate have produced negative findings [46, 47]. It has been speculated that the absence of such damage reflects the mechanism of action of methylphenidate, which is strictly to block dopamine reuptake at the dopamine transporter in the absence of disruption to the vesicular storage pool. In contrast, amphetamine and methamphetamine appear to have similar potency across a range of acute and chronic neurochemical and behavioral actions [9, 48-50], including their ability to induce neurotoxicity [50, 51], and to disrupt vesicular storage of dopamine. Although unrelated to neurotoxicity, it is remarkable that methylphenidate given to juvenile rats did produce striatal dopamine transporter downregulation that persisted into adulthood [52].

Although evidence for neurotoxicity in rodents derives from studies utilizing very high amphetamine doses, and repeated exposure to lower doses equivalent to the human therapeutic range do not produce toxicity in rodents (e.g., 50), a similar study of non-human primates produced very different results. Adult baboons and squirrel monkeys were treated with a 3:1 mixture of *d/l* –amphetamine similar to the pharmaceutical Adderal for 4 weeks [53]. Plasma concentrations of amphetamine (136 +/− 21 ng/ml) matched the levels reported in human ADHD patients after amphetamine treatment lasting 3 weeks (120 to 140 ng/ml) [54] or 6 weeks in the highest dose (30 mg/day) condition (120 ng/ml) [15]. When the animals were sacrificed 2-weeks after the 4 week amphetamine treatment period, both nonhuman primate species showed a 30−50% reduction in striatal dopamine, its major metabolite 3,4-Dihydroxy-Phenylacetic Acid (DOPAC), its rate-limiting enzyme (tyrosine hydroxylase), its membrane

transporter, and its vesicular transporter. These consequences are similar, if not identical to the effects of neurotoxic doses in rodents.

Though the paradigm used by Ricaurte et al. [53] arguably still incorporates amphetamine exposure at a level above much clinical use [15, 55], it raises important unanswered questions. Is there a threshold of amphetamine exposure above which persistent changes in the dopamine system are induced? One study in rodents reported that 15 daily "binges" with 4 mg/kg amphetamine significantly compromised striatal dopamine integrity, whereas an identical treatment with 2.5 mg/kg did not [50]. What factors influence individual differences in vulnerability to persistent neurochemical changes following exposure to amphetamine? For example, stress augments the neurotoxic effects of the amphetamines (see, for example, [45]), and hormone levels differentially affect methamphetamine neurotoxicity in female and male mice [56]. Does the cumulative exposure consistent with lifelong maintenance medication produce persistent dopaminergic changes associated with behavioral deficits that increase at advanced ages? Older rats, mice and gerbils developed greater methamphetamine neurotoxicity than younger animals, as indicated by striatal dopamine reduction, structural deficits and increased levels of glial fibrillary acid protein [57-59]. In addition, brain amphetamine levels at both 20 and 65 min after intraperitoneal administration of 2.5 mg/kg of amphetamine were twice as high in the brains of old rats as in young rats [60]. On the other hand, prior exposure of rats to progressively increasing nontoxic doses of amphetamine or methamphetamine markedly protects against the neurotoxic effects of subsequent high-dose stimulant exposure [61, 62].

In humans, markers of striatal dopamine function decline with age. Nuclear medicine procedures have indicated that availability of the dopamine transporter in the striatum decline at a rate of 6 − 7% per decade [61-63], and measures of nigrostriatal neurons have indicated a loss of 70% in the putamen after the age of 55 years [64]. In addition, the age-related loss of dopamine appears to accelerate after age 60 [63, 64]. One important question is, "Does exposure to amphetamine during development and/or early adulthood accelerate and enhance the age-related decline in dopaminergic function?" In addition, are humans at increased risk from neurotoxicity when amphetamine is administered in late adulthood or senescence?

Such questions underscore the need to determine which animal paradigms best simulate relevant therapeutic exposure at different periods of the human lifespan. The mechanisms underlying neurotoxicity remain speculative, however; and some evidence suggests marked species differences in vulnerability to stimulant-induced neurotoxicity (see 65 for a review). For example, as noted above, 15 daily "binges" of 2.5 mg/kg amphetamine in rats had no deleterious effects on caudate dopaminergic integrity [50], whereas just two injections of 2 mg/kg amphetamine in vervet monkeys produced a relatively long-lasting near 90% decrease in dopamine levels within the caudate nucleus [51]. Given the potential for profound species differences in susceptibility to stimulant-induced neurotoxicity, preclinical approaches may have limited utility in addressing questions relevant to clinical practice. Rather, systematic longitudinal and cross-sectional studies of the effects of prolonged human stimulant exposure are required.

Human studies- Negative consequences of chronic amphetamine use

Effects on Growth

Amphetamines have long been shown to slow weight gain, but some studies have suggested that these effects fade over several years of exposure (see below). The effects of psychostimulants on height have also generated controversy and concern, but until recently, consensus from studies examining growth changes during stimulant treatment was lacking. Recent reports have added some clarity to the issue, and the NIH National Toxicology Program

concluded that there was concern for neurobehavioral developmental toxicity from amphetamines [23].

Poulton [66] reviewed 29 reports on growth effects. Eleven of them concluded that stimulant treatment reduced height. Negative studies were often hampered by methodological weaknesses, and few conclusions were available. Despite some observations of slowing of height velocity in school-age children, discrepancies regarding attenuation of height in studies of adolescents and adults with earlier stimulant treatment histories have led to suggestions that the long-term significance of stimulant effects on growth are minor and probably transitory. While a variety of mechanisms have been suggested to account for attenuating effects of stimulants on growth, reduced caloric intake may be the major reason, in view of the decrease in appetite associated with these drugs.

Since the 2005 review, additional research reports on growth effects have emerged. Again, some found small or no deficits [67, 68], but these studies lacked an untreated ADHD group. In one of the longest prospective studies, which included a no drug comparison, 370 ADHD children from 7.0 to 9.9 years of age, enrolled in the Multimodal Treatment Study of ADHD (MTA), were contrasted according to the use and continuity of stimulant treatment [69]. Growth deficits in predicted height and weight were noted in continuously, but not inconsistently medicated patients. The deficits were maximal in the first year of stimulant use, decelerated over the second year, and were maintained after the third and final evaluated year of treatment for both height (2.0 cm less than predicted) and weight (2.7 kg less than predicted). Notably, findings from the MTA study did not support the idea that growth deficits rebound during continuous use of stimulant medication.

The only study contrasting effects of amphetamine with those of methylphenidate on growth rate used a retrospective, case-review design, and found slightly larger effects of amphetamine on reducing weight but no differences between the drugs in affecting height [67]. After 5 years of treatment in a prospective longitudinal study, reductions in expected height were noted only after several years of exposure [70]. Estimating from the sample participating, the average reduction in height for a 9-year-old treated for 4 years would amount to 1.9 cm. The study did, however, assess the relationship between drug dosage and growth. Significant effects on weight appeared to require average daily doses of methylphenidate that exceeded 1.5 mg/kg/day, and higher doses were associated with greater reductions in height velocity. Similarly, the MTA analyses [69] demonstrated a significant relationship between cumulative drug exposure and height slowing, and another report found the greatest height reductions occurring in the highest daily dosage quartile of 1.53 − 2.54 mg/kg/day of methylphenidate [68]. The consistency of these findings relating dose and exposure to growth effects provides greater evidence for the association of stimulants with reliable, albeit modest, effects on growth, and suggests the possibility that a threshold may exist for such adverse events. Lastly, the report from the NIMH Preschool ADHD Treatment Study, using normative data as a comparison over a 12-month period of exposure to methylphenidate, found that children between 3−5 years of age may be more vulnerable than older children to the growth-slowing effects of stimulants [71].

Studies of growth effects of stimulants have been hampered by several challenges: the need for monitoring periods of several years; the inability to include an untreated group due to ethical concerns; the high rate of non-compliance with treatment; lack of comparisons between different stimulants; and effects of attrition on statistical power. Furthermore, most samples studied have been limited in the age range and have demonstrated substantial variability in the effects. Some children were unaffected, while others showed strong growth suppression. Study of this interindividual variability may help identify factors that confer risk and/or protection. Overall, it appears that some young patients are at risk for neurobehavioral developmental growth suppression from medical stimulants [23], and concern is heightened for patients from

3 to 5 years of age, patients who receive high doses of stimulant medications for over a year, and patients who are medicated continuously, without drug holidays.

Amphetamine abuse: brief history

The mesolimbic dopamine system, especially the portion terminating within the nucleus accumbens in the ventral portion of the basal ganglia, is the anatomical system most highly implicated in mediating both the stimulant properties and reinforcing properties of amphetamines. Since amphetamines were first used medically, there have been reports of prescription abuse by individuals seeking weight loss, enhanced energy, sleep postponement (student "cramming", long-distance driving), improved athletic performance, or simply enhancement of recreational social activities. Regardless of the original reason for using amphetamines, regular use of these drugs has motivated some to continue their ingestion in order to self-medicate the discomforts associated with withdrawal of an addictive substance [72, 73]. Abuse of amphetamine is associated with tolerance and psychological dependence and is difficult to treat [72, 73]. Withdrawal generally produces fatigue, depression and social disability [72, 73].

Widespread abuse caused Sweden to categorize amphetamine as a "narcotic" in 1944. By 1954, there were over half a million amphetamine abusers in Japan. During the 1960s and early 70s, Japan, the United Kingdom, United States, Canada, and most other countries that regulate pharmaceuticals banned or severely restricted legal use of amphetamines. Despite this legislation, and medical recommendations to limit amphetamine use, some physicians continued to write off-label prescriptions, often with insufficient follow-up monitoring, and abuse continued to grow. In a 1971 survey, 30% of college students reported using amphetamines without a prescription [74]. Aggressive law enforcement and media campaigns succeeded in reducing illicit amphetamine use in the 1980s, but use increased again in the next decade and has continued to rise in young adults. Although there are indications that illicit amphetamine use may have peaked in a 2006 survey from the United States [75], a disturbingly large number of 8th grade students (7.3%) report taking prescription amphetamines without medical instruction.

The steep increase in the diagnosis of ADHD during the 1990's in the United States led to a parallel increase in production and societal exposure to legally distributed amphetamine. This change contributed to the surge in illicit use of pharmaceutical amphetamine, and the illegal manufacture and use of methamphetamine and methylenedioxymethamphetamine that continued to accelerate through the 1990s. Detailed discussion of these epidemics goes beyond the scope of this review, but they continue to be a substantial international public health problem, as detailed in a recent supplement of the journal "Addiction" [76].

Amphetamine abuse: sources and extent

Resale of prescribed amphetamines constitutes one source of illicit stimulants available for abuse. In addition, licit dextroamphetamine is a substrate for manufacture of illicit methamphetamine, which can then be smoked or injected. One of the easiest ways to make methamphetamine is by addition of a single methyl group to the amino group on the middle carbon atom of amphetamine. Conversely, smoked methamphetamine thermally degrades to yield amphetamine by N-demethylation [23, 77].

The proportion of students taking prescription stimulants who are approached to sell, give or barter their drugs has been reported to be 16% in rural Midwestern schools [78], 23% in a racially diverse sample of secondary school students [79], and 54% in Midwestern college undergraduates [80, 81]. Another study found that a disturbing 22% of the Canadian secondary school students who took licit amphetamines either sold or gave away their drugs [82]. Legal

amphetamines can also be diverted to illicit use without the consent of the patients. Secondary school officials responsible for dispensing medication in Iowa reported drug theft from 15% of the school medication storage areas [83]. The Los Angeles Times [84] recently reported that abuse of prescription drugs has actually supplanted illegal substances as the preferred drugs of substance abusers, citing a March 2008 statement to congress by Dr. Nora Volkow, Director of the National Institute on Drug Abuse, that "Unlike illicit drug use, which shows a continuing downward trend, prescription drug abuse . . . has seen a continual rise through the 1990s and has remained stubbornly steady . . . during recent years."

Insufficient physician follow-up care for stimulant-treated children contributes to the problem. A recent study in the Netherlands suggested that such care was deficient, with 1 of 5 patients receiving no follow-up care, and those who did receive care averaging only two physician visits per year [32]. In addition to the risk of stimulant abuse associated with ADHD treatment, clinical reports estimate the risk of addiction from amphetamines prescribed for sleep disorders at 1 −3% [37]. Additional risk accrues in patients prescribed higher amphetamine dosages for longer periods, and those with comorbid psychiatric disease [85].

Some alternative drugs have been marketed as having lower abuse potential than amphetamine. For example, in a direct comparison, methylphenidate scored below amphetamine in ratings of "Willing to Take Again", perhaps the closest subject-rated approximation of the reinforcing effects of a drug [86]. It has been suggested that methylphenidate has pharmacological properties that render it of lower abuse potential than other stimulants, especially for ADHD patients [87]. However, some authors have concluded that the abuse potential of methylphenidate is equivalent to that of amphetamine, on the basis of findings in animal models and human research [88]. The lower frequency of the abuse of methylphenidate, as compared with amphetamines, might reflect lack of availability of intravenous or inhaled forms which provide fast delivery of the drug to the brain, in order to produce the intense pleasurable sensations often described as a "rush".

On a positive note, just as oral administration produces slower dopamine release and is less reinforcing than parenteral routes, the new delayed delivery formulations release drug more slowly than immediate release formulations, and also appear to have less abuse potential. An oral once-a-day osmotic delayed-release formulation of methylphenidate produced lower subject ratings of both detectability and likeability than an immediate-release formulation that was associated with equivalent plasma concentration and dopamine transporter occupancy [89]. Lisdexamfetamine dimesylate (Vyvanse), the delayed release prodrug which is converted into d-amphetamine in the body, produced lower subjective ratings of drug-liking in adult substance abusers than dose-equivalent immediate-release d-amphetamine administered both orally and intravenously [90, 91]. These studies suggest that the abuse potential of stimulants decreases with the rate of delivery to sites of brain action. It remains possible, however, that some individuals may increase their ingestion of delayed-release formulations to titrate their enjoyment of the drug to the levels associated with immediate release formulations.

Amphetamine abuse: developmental stage influences risk

An association between childhood ADHD and increased risk for substance abuse has been described, although some argue that the relationship may reflect the common comorbid problems of oppositional defiant disorder, conduct disorder, or antisocial personality disorder, rather than ADHD *per se*. A recent review concluded that 20% of adults with substance abuse disorders have ADHD, and that ADHD both alone and in combination with co-occurring psychopathology increases risk for the development of substance abuse disorders in adulthood [92]. A case-control family study found that adolescents and young adults (ages 15 − 25) with ADHD reported more cigarette, alcohol, and illicit stimulant use than age-matched without ADHD [93]. It is notable that the motivation for ingesting these substances was reported as

"getting high" in only 22% of ADHD patients, but more often reported as self-medication for tiredness resulting from disturbed sleep (38% of ADHD patients) or self-medication of impaired mood (most ADHD patients).

Concern has been raised over the question of whether stimulant treatment of ADHD might increase the risk of later substance abuse beyond the risk from the diagnosis of ADHD alone. Some reports have supported this idea [94-97]. Most of the studies examining this issue, however, including a meta-analysis, found that stimulant treatment had no effect on the risk for subsequent substance abuse or lowered the risk by as much as 50%, although this protection did not extend to nicotine dependence [92, 98].

A survey of over 9,000 Midwestern college students found that those who initiated prescribed use of stimulant medication for ADHD in secondary school were three times as likely as students never prescribed stimulant medication to report illicit use of prescription stimulants, and that those who initiated such medication in college were seven times as likely to report illicit use [80]. Both groups also reported more use of alcohol, marijuana, cocaine, and all illicit drugs than students never prescribed stimulant medication. Although these results can be explained by an increased risk for substance abuse associated with ADHD, college students who initiated prescribed use of stimulants for ADHD in elementary school did not report more illicit use of prescription stimulants, or more use of any other abused substances, as compared to students never prescribed stimulant medication [80]. This finding supports the idea that stimulant treatment for ADHD can protect against the illicit drug use otherwise associated with an ADHD diagnosis, but suggests that such protection is maximal when stimulant treatment is initiated prior to secondary school. The notion that early stimulant treatment might lower the risk for subsequent stimulant abuse is supported by some [99-101] though not all [102] preclinical studies of administration of low doses of methylphenidate during the equivalent of human adolescence. In supportive studies, methylphenidate decreased subsequent measures that have been linked to drug abuse liability.

Unfortunately, preclinical and clinical data suggesting that early stimulant treatment for ADHD reduces risk for later substance abuse does not eliminate the possibility that prescription stimulants initiated during later developmental periods of high risk, might act as "gateway" drugs and thus increase risk of substance abuse. Given the frequency of substance abuse in high school and college-age samples, the number of students who seek and receive stimulant treatment for ADHD primarily for purposes unrelated to their ADHD symptoms (i.e., weight loss, "cramming", improved athletic or social performance, etc.) is likely to increase during late adolescence and early adulthood. Higher rates of substance use in students initiating licit medical stimulant treatment during these years, and a recent finding of positive correlation between age at initiation of stimulant medication and later substance abuse [103] underscore the need for especially careful monitoring of late initiated stimulant medication.

The idea that risks as well as benefits of stimulant exposure depend on developmental timing is also supported by preclinical studies. The adolescent brain has been described as being in flux [104], undergoing numerous regressive (e.g., pruning of neocortical synapses [105], decreases in receptors of different neurotransmitter systems [106, 107]) and progressive changes [108, 109]. Preclinical investigations suggest there are notable ontogenic alterations during the adolescent transition from childhood to adulthood, including substantial reorganization of mesocorticolimbic dopaminergic neural circuits [110-115]. It has been proposed [104] that these dopaminergic alterations may represent a shift in the relative balance between subcortical and cortical dopamine systems, especially during early adolescence, towards a predominance of cortical dopamine and enhanced dopaminergic tone in the prefrontal cortex. Studies on the ontogeny of drug sensitivity have shown that adolescent rodents are less sensitive than younger animals and adults to the locomotor and stereotypy-inducing effects of amphetamine

116-124. Furthermore, most evidence indicates that methamphetamine treatment of pre-weanling rats produces fewer and/or less marked neurotoxic effects than the results from adult preclinical and clinical studies 125-129.

On the basis of these observations, it has been widely concluded that monoamine systems may be less vulnerable to the neurotoxic effects of methamphetamine in very young as compared to older rats. A few animal studies have specifically examined the effects of methamphetamine exposure during the equivalent of human adolescence. Rats at postnatal day (PND) 35−55 are alleged to be developmentally comparable to humans of about 12−18 years 130. Some of the evidence derived from these studies in rats suggests a transition in susceptibility to methamphetamine-induced neurotoxicity occurring around PND-40 128. Rats treated with methamphetamine at PND-90, but not PND-40, exhibited deficits in striatal dopamine parameters seven days after treatment 131. One hour after treatment, plasma and striatal levels of methamphetamine in the PND-90 group were approximately double the levels in the PND-40 group, suggesting that pharmacokinetic factors represent a potential confound in interpretation of the effects of age.

In another study, methamphetamine pretreatment through much of adolescence and early adulthood; i.e., six biweekly injections of 15 mg/kg, beginning at PND-40, blocked the neurotoxic effects produced by a methamphetamine binge (10 mg/kg × 4, at 2-hr intervals) at PND-90 132. This neuroprotective effect could not be attributed to pharmacokinetic factors, but as commonly observed for stimulant-induced behavioral and neurochemical alterations, the pattern of drug exposure was critical. Neither PND-40 pretreatment with a single methamphetamine binge (10 mg/kg × 4, at 2-hr intervals), nor single weekly injections, produced the neuroprotective effects of the biweekly injections. Clearly, valid extrapolations to human drug users from rodent models rest on the translational utility of the stimulant treatment paradigm that is employed.

Two recent prospective studies have evaluated the relationship of stimulant treatment for ADHD to later substance abuse in humans. In 112 6−17 year old male Caucasians with ADHD, stimulant treatment neither increased nor decreased the frequency of substance use disorders ten years later (mean age = 22) as compared to the ADHD patients not treated with stimulants 133. Among those with alcohol abuse, however, stimulant treatment was associated with a longer duration of abuse by 1.6 years ($p = 0.04$).

The 2nd study assessed 176 methylphenidate-treated 6−12 year old male Caucasians with ADHD (but without conduct disorder), and 178 non-ADHD control subjects, with reassessment during late adolescence (mean age = 18.4) and early adulthood (mean age = 25.3) 103. There was a direct relationship between age at initiation of stimulant treatment and the frequency of both substance use disorder and antisocial personality disorder. Lifetime rates of substance abuse disorder were greater among ADHD patients who initiated treatment after age 7 (44%), as compared to patients who initiated treatment before age 8 (27%), or non-ADHD patients (29%). The authors conclude that early initiation of methylphenidate treatment does not increase risk for negative outcomes and may have protective long-term effects. Because 98% of the sample initiated stimulant treatment by age 11, however, this study can not address the possibility that the increasingly common practice of initiating stimulant medication during the high-risk years of secondary school or college may increase risk for substance abuse. We are unaware of any studies that specifically address this important question.

In summation, abuse of both licit and illicit amphetamines constitutes a serious public health concern. Illicit amphetamines are second only to marijuana as a form of illicit drug abuse in young adults, with a prevalence of 8.1% among 12th grade students 75. Illicit use of prescription medications is currently at its highest level in decades, and amphetamines are the prescription

drugs most commonly abused by adolescents and young adults. Licit amphetamines contribute to amphetamine abuse through multiple mechanisms, including their distribution to individuals who were not given medical prescriptions through sale or theft, and their use as substrates for synthesis of more dangerous drugs. Although stimulant medication for ADHD reduces the frequency of later substance abuse when it begins during early childhood, the effect of initiating stimulant medication in late adolescence or adulthood is currently unknown, and there are indications that there may be neurobehavioral risks associated with this practice.

Brain damage from abuse

Most of the evidence for amphetamine-induced human brain damage comes from examination of current and former amphetamine abusers. Because of the paucity of studies of brain integrity after use of prescription amphetamines, speculation regarding the potential for damage due to prescription amphetamines draws primarily from the consequences of the abuse of these drugs. Almost all reports of brain abnormalities in stimulant abusers have employed retrospective self-reports of abuse history. Highly variable patterns of abuse have been reported across studies of methamphetamine abusers, with minimal durations of abuse ranging from 1 to 7 years, average lifetime use ranging from 276 g to 4930 g, and the duration of abstinence from methamphetamine at time of testing ranging from 0 to 730 days [134]. Estimates of typical human methamphetamine doses in moderate-high abusers range from 15 − 100 mg, corresponding to about 0.25 − 1.5 mg/kg per administration, and 3 − 8 hits/day [135-140]. Drug use reported in some brain imaging studies has been at the higher end of these ranges (e.g., mean daily use of 1.6 g/day [141]. Perhaps of more direct relevance, blood samples obtained from individuals detained by police for possible criminal activity and testing positive for methamphetamine revealed concentrations in the low micromolar range, with a mean value of 2 μM (300 ng/l) [142]. This is several-fold higher than typical therapeutic levels of 25 − 50 ng/ml.

Chronic users of methamphetamine have multiple abnormalities in brain chemistry, function, and structure, particularly in the striatum of the basal ganglia, the brain region with the highest dopamine concentrations. Evidence consistent with the notion that the neurotoxicity demonstrated in animals (discussed earlier) also occurs in humans taking methamphetamine has accrued from neuroimaging findings of reduced availability of transporters for dopamine, serotonin, and vesicular monoamines [143]. Autopsy data, which have demonstrated deficits in dopamine, the dopamine transporter, and tyrosine hydroxylase, can be interpreted as consistent with dopaminergic damage, but little if any deficit in the vesicular monoamine transporter ($VMAT_2$) [43, 144, 145] . In contrast, administration of high stimulant doses to rodents or nonhuman primates promotes a profound decrement in $VMAT_2$ as well as in the other markers for dopaminergic nerve terminals [146-149]. Notably, a decrease in $VMAT_2$ has been considered by some to indicate a decline in intact monoamine nerve terminals [146, 150-152]. In view of these findings, some investigators have suggested that decrements in the dopamine transporter without parallel decrements in $VMAT_2$ may represent neuroadaptational downregulation in dopamine transmission rather than degeneration of dopamine terminals [145].

Proton MR spectroscopy measures of metabolites in the cerebral cortex and basal ganglia have consistently identified reduced markers of neuronal integrity, and increased markers of glial content, suggesting that glial proliferation may follow neural damage [143]. Using cerebral glucose metabolism as an index of functional neural activity, study of methamphetamine abusers during early abstinence from the drug revealed abnormally high activity in amygdala, ventral striatum and lateral orbitofrontal cortex but abnormally low activity in medial prefrontal, and particularly cingulate cortex [153]. With continued abstinence from the drug, there is abnormally high global and cortical glucose metabolism, particularly in the parietal lobe [154, 155], and relatively lower activity, after scaling to global mean activity, in striatal and thalamic regions [155, 156]. Finally, structural magnetic resonance imaging (MRI) studies have

noted abnormalities including apparent reduction of gray matter volume in cingulate cortex and the hippocampus during early abstinence from methamphetamine [157], and later enlargement of the parietal lobe and of portions of the basal ganglia [158, 159]. Size deficits have generally been interpreted as representing cell loss and enlarged areas thought to result from inflammation and possible reactive gliosis, although it has been suggested that volume increases in striatal volume may be compensatory [134, 158].

The dopamine transporter and spectroscopic abnormalities have been positively related to total methamphetamine use, residual psychiatric symptoms [160-166], and motor or memory deficits [167]. Increased parietal glucose metabolism was associated with cognitive deficits [154, 155], and abnormalities in relative glucose metabolism were associated with impaired mood [153] and impaired vigilance [168]. While the enlargement in parietal volume and the deficit in hippocampal volume were also associated with cognitive deficits in the above-cited studies, one report of basal ganglia volume being greater than in a comparison group found the volumetric measure to be positively correlated with verbal fluency and fine motor performance, but negatively associated with duration of methamphetamine use [158]. Striatal enlargement may thus constitute an initially adaptive response to methamphetamine toxicity that fails to maintain either function or structural integrity after prolonged abuse.

More research is needed to characterize the “dose-response” relationship between exposure and brain abnormalities, and the extent and time-course of recovery and normalization of these abnormalities during abstinence from chronic methamphetamine. Postmortem studies of animals and humans suggest that the primary dopaminergic damage involves terminals and processes rather than cell bodies. Some degree of recovery after protracted abstinence has been noted in perfusion of the cingulate cortex [169] and in striatal dopamine transporters [170]. These studies compared subjects tested once during broad periods of early abstinence (< 6 months) with other subjects tested during even broader ranges of prolonged abstinence.

Two additional studies repeated assessments of cerebral glucose metabolism in the same individuals during abstinence from chronic methamphetamine. Wang and associates [156] compared five subjects tested at < 6 months abstinence and again between 12 and 17 months. They noted recovery in thalamic but not striatal deficits in relative glucose metabolism. We recently compared 12 healthy control subjects to 10 methamphetamine abusers who were abstinent only 5−9 days, and then reassessed both groups a month later [154]. Glucose metabolism did not change over the month in subcortical regions of either group or in the cortex of healthy subjects, but increased in the neocortex of the abstinent methamphetamine users, with a maximal increase exceeding 20% in the parietal lobes. Changes in both absolute parietal and relative striatal glucose metabolism were correlated with changes in vigilance performance and depressive symptoms in methamphetamine users but not control subjects. Increased cortical activity was interpreted as reflecting either compensatory processes during early abstinence, unmasking of damage from chronic methamphetamine abuse that is obscured by suppression of cortical glucose metabolism for at least 5 days after cessation of drug use, or new damage after the initial week of abstinence.

The provocative possibility of additional damage during early abstinence from amphetamine is consistent with observations of a methamphetamine abstinence syndrome where symptoms are maximal only after several days of abstinence [171, 172], and a study where a treatment of three daily exposures of rats to methamphetamine was sufficient to induce reactive gliosis that continued for over two weeks after the final exposure [173]. In addition, the P300 event-related potential recorded from the human scalp is modulated by catecholaminergic neurotransmission [174, 175], and it exhibits reduced amplitude during early abstinence from chronic methamphetamine abuse. A rat model reported 15 days of methamphetamine reduced P300

after 7−10 days of abstinence, indicating that the deficit was not an acute effect of methamphetamine [176].

Brain damage from licit amphetamines

It is not known if there are similar alterations in the dopaminergic system of humans receiving long courses of prescription amphetamines [23]. However, in the most relevant animal model, 4 weeks of treatment with an amphetamine similar to the pharmaceutical Adderal produced plasma concentrations in adult baboons and squirrel monkeys that matched human ADHD patients after clinical treatment, and both species showed a 30−50% reduction in striatal dopamine, its major metabolite, its rate-limiting enzyme, its membrane transporter, and its vesicular transporter [53]. Although Parkinsonian symptoms generally require about twice as much dopamine reduction (80−90%), aging itself produces cumulative decrements in dopaminergic cells, dopamine metabolites and dopamine receptor binding [38]. These changes have been associated with modest cognitive and motor losses [177], and age-linked reductions in frontal cortex metabolism [178] similar to those characteristic of cocaine abusers [179]. Therefore, it would be of interest to explore whether there are any indications of delayed adverse motor or cognitive outcomes associated with very prolonged and high-dose stimulant exposure in older adults taking maintenance amphetamines, similar to what has been shown for aging boxers who accrued dopamine loss as a consequence of repeated closed head concussive trauma in their youth [180]. The finding that dopamine levels in autopsied chronic methamphetamine users were reduced more in the caudate (mean = −61%, but maximum reduction = −97%) than in the putamen (mean = −50%), whereas Parkinson's disease shows the opposite pattern, led to the suggestion that chronic amphetamine use may increase risk for cognitive deficits more than for motor deficits [144]. One way to explore the hypothesis of accelerated aging would be to compare functional and structural neuroimaging indices of cerebral integrity during normal aging, which have undergone extensive development in recent years [181], to patients receiving maintenance treatment with amphetamines.

In contrast to concerns about potential adverse effects of amphetamine on the brain during aging, it is remarkable that the reduction of the heightened risk for substance abuse that is otherwise associated with ADHD by the initiation of stimulant treatment during childhood appears to be accompanied by a congruent reduction in structural brain pathology. Unmedicated children with ADHD had smaller brain white matter volume than medicated children with ADHD (−8.9%, P<.001) or children without ADHD (−10.7%, P<.001), suggesting that early stimulant treatment may normalize brain white matter volume in ADHD [182].

Stimulant medication for childhood ADHD, however, has been associated with adverse as well as with beneficial effects. The longest controlled clinical trial of stimulant medication effects followed 579 children age 7− 9.9 years during 14 months of randomized ADHD treatment [183]. Stimulant treatment was superior to behavioral treatment or routine community care. However, undesirable side-effects were reported by 64% of participants, and moderate to severe side-effects by 14%. Only 10% of participants were treated with amphetamine (most children used methylphenidate), and side-effects were not cross-tabulated by the medication received, so it is unclear if amphetamine produced a disproportionate fraction of the unwanted effects, as previously reported when comparing 2-weeks of amphetamine with methylphenidate treatment in 125 ADHD children [25]. In addition, only standard clinical measures were employed, so the association of adverse effects with neurotoxicity could not be assessed. In animals, doses of amphetamine with behavioral effects equivalent to those of methylphenidate produce the same synaptic accumulation of dopamine as methylphenidate but 4 to 10 times the extracellular accumulation of dopamine [184, 185], suggesting the potential for long-term toxicity involving the dopaminergic system if high extracellular concentrations

of dopamine contribute to neurotoxicity. To our knowledge, no controlled studies have explored adverse behavioral, cognitive or neurobiological consequences of years, much less decades, of chronic amphetamine treatment.

Evidence has been reported for sensitization of behavioral effects in healthy adults after three identical administrations of .25 mg/kg of d-amphetamine 48 hours apart [186]. Although this dose is in the clinical range, and less than 1/3 the daily dose prescribed for some adults, vigor and euphoria ratings were maximal after the final dose, especially in women, consistent with evidence from animal studies, suggesting stronger sensitization in females [187]. More efforts are needed to determine under what circumstances sensitization occurs in humans, and to quantify the mediating effects of age and gender. Further questions relevant to clinical treatment and longer-term exposure include the following: Is sensitization maintained or associated with differences in clinical dosages or regimens, extended durations, compliance with treatment, or patterns of abuse? It is important to note, however, that there is no clear evidence for sensitization in stimulant treatment of ADHD. Furthermore, although moderate and high doses of stimulants robustly produce long lasting sensitization in experimental animals [188], preclinical studies that have utilized stimulant doses in the therapeutic range failed to produce evidence for sensitization (see 189 for review). In sum, assessment of long-term effects of prescription amphetamine administration is important for many reasons, including the recent increase in the dosages and durations of pharmaceutical amphetamine treatment for adult ADHD [34], and occasional reports of what might be amphetamine-mediated psychosis in users of prescription amphetamines.

Amphetamine psychosis

High doses of amphetamines can produce psychotic behavior indistinguishable from schizophrenia in asymptomatic schizophrenics and in some healthy human subjects [190, 191]. The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) recognizes diagnoses of amphetamine-induced psychotic disorder with delusions and amphetamine-induced psychotic disorder with hallucinations. In one study of healthy volunteers, repeated administration of 5−10 mg of oral dextroamphetamine produced paranoid delusions in all subjects at cumulative dosages between 55 and 75 mg [192]. The current illicit amphetamine epidemic is increasing the incidence of this problem. Australian methamphetamine users had 11 times the prevalence of psychosis found in the general population, and methamphetamine dependence further tripled the risk for psychosis, even after adjusting for prior history of psychotic disorders [193]. A European study documented recent increases in hospital admissions for amphetamine-induced paranoid psychosis [194].

After the first occurrence, paranoid symptoms can be invoked by psychosocial stress, but also readily reappear after amphetamine injection. This behavioral sensitization is thought to be mediated by catecholaminergic supersensitivity. It has been argued that the behavioral sensitization produced by repeated administration of lower doses of amphetamine to non-human animals is a better model of amphetamine psychosis than the neurotoxicity produced by higher doses, and that this sensitization is at least partially mediated by enhanced mesotelencephalic dopamine release upon re-exposure to the drug [188]. In humans, spontaneous occurrence of amphetamine-induced hallucinatory psychosis (i.e., flashbacks) are accompanied by concurrent increases in plasma norepinephrine and 3-methoxytyramine, a major metabolite of released dopamine in frontal cortex [195, 196] Several genetic studies also implicate dopamine in amphetamine-mediated psychosis, including an association of nine or fewer repeat alleles of the dopamine transporter gene hDAT1 with increased severity of amphetamine-mediated psychosis [197] and a report that the Taq1A A1/A1 polymorphism, which codes for reduced density of dopamine D2 receptors, also reduces the risk for development of flashbacks [198].

Amphetamine prescription labels state that psychotic episodes are rare at recommended doses, but that behavioral disturbance and thought disorder may be exacerbated in presence of pre-existing psychoses. A recent review of 54 scientific studies concluded that a single stimulant dose can produce a psychotic response in 50−70% of patients with schizophrenia and pre-existing acute psychotic symptoms and 30% of schizophrenics without acute symptoms [191]. The authors present evidence, however, that low-dose antipsychotic treatment may reduce or prevent sensitization in chronic stimulant users. As a side note, amphetamine abuse has occasionally been clinically linked to choreoathetoid-type involuntary movement disorders, and neuroleptics are thought to effectively treat these disorders by normalizing an excessive ratio of dopamine to acetylcholine in the corpus striatum [199] (but for another possible mechanism see [134]).

About 30−40 % of amphetamines are excreted unchanged. The rest of the parent drug is converted to metabolites. The proportions of amphetamines that are metabolized are strongly affected by urinary pH [23]. Ingestion of acidic substances causes an accelerated excretion of *d*-amphetamine while alkaline agents (e,g., antacids) markedly increase both retention and absorption of amphetamines, sometimes resulting in dangerously high amphetamine levels. It has been suggested that the accumulation of metabolites may contribute to generation of psychotic symptoms [200] and to general amphetamine neurotoxicity [201].

Clinical case reports of the induction of psychotic states by prescription stimulants have appeared occasionally [202-206]. For example, one paper concluded that 10 mg of daily Adderal taken over five weeks for ADHD induced classic psychotic symptoms in a formerly drug-naive adolescent with no personal or family history of psychiatric disorders other than ADHD. Symptoms abated after 7 days (5 half lives) without drug. Recently, the FDA attempted to better appreciate the frequency of any psychotic or manic-like reactions to stimulants in individuals with ADHD receiving psychostimulants. Pooling data from both placebo-controlled trials (5,717 subjects) and open-label studies (15,999 subjects), an average rate of 0.25% or 1 out of 400 subjects was observed [207]. Although the rate was uncommon to rare, the appearance of such adverse events certainly highlights the need to explore predictors of such worrisome effects, such as the dopaminergic genetic risk and protective factors discussed above [197, 198].

In treatment of narcolepsy, use of amphetamine doses greater than 120% the maximum level recommended by the American Academy of Sleep Medicine have been associated with psychosis, psychiatric hospitalizations, substance abuse, and suicide [208]. Although one paper reported that two of eleven adults taking high doses of methylphenidate for narcolepsy developed acute psychotic symptoms [209], we are not aware of any comparable study quantifying such symptoms as a consequence of amphetamine treatment for narcolepsy.

Heritability

Although the mechanisms whereby amphetamines produce adverse effects in humans are largely unknown, it is clear that in contrast to low heritability estimates for abuse of depressant drugs, stimulant abuse is much more heritable. It seems likely that adverse developmental effects and neurotoxicity are also genetically mediated. Amphetamines had the highest heritability of any category of DSM-III drug abuse in twin samples serving in Vietnam [210], and in Minnesota drug abuse treatment programs [211]. In the latter, genetic influences accounted for 78% of variance in amphetamine abuse/dependence in men and 73% in women. Studies of specific genes have focused on regulators of synaptic dopamine activity, the primary mechanism of biological action of the amphetamines. As noted above, a polymorphism associated with reduced density of dopamine D2 receptors also reduced the frequency of flashbacks [198], and presence of a 9- or fewer repeat allele of the dopamine transporter gene was associated with prolonged amphetamine psychosis [197]. The latter paper postulated that

reduced inactivation of dopamine due to lower density of dopamine transporters increased susceptibility to amphetamine neurotoxicity. A study of the gene for catechol-O-methyl transferase reported that the allele which carries lower activity for inactivating dopamine (*met*), was associated with both methamphetamine-triggered psychosis and with spontaneous symptom relapse not triggered by drug use [212]. A third Japanese study identified similar associations for the PICK1 gene, which codes for a protein associated both with schizophrenia and with the dopamine transporter [213]. Although studies of drug abusers involve higher than clinical exposures to amphetamines, the psychotic episodes occasionally reported after licit use of amphetamines may also have been promoted by genetic factors, particularly those that increase synaptic dopamine.

Recommendations

More than 100 studies involving tens of thousands of subjects have demonstrated that stimulants are efficacious and well-tolerated by most patients when taken for up to several years. We know much less than we should, however, about the biological and cognitive effects of more protracted courses of therapeutic stimulants on adult human brains and adult behavior [214]. In cell lines transfected with human catecholamine transporters, amphetamine tripled the expression of the early intermediate gene c-*fos*, which is thought to play an important role in neural plasticity [215]. A growing body of literature suggests that the consequences of modifying neural plasticity with amphetamine vary greatly with both individual and developmental factors. The increased use of amphetamine stimulants as life-long maintenance medications combines with the longer elimination half-life in adulthood to underscore the importance of quantifying the safety and adverse effects associated with such practices. Dose-relevant preclinical investigations of the effects of protracted exposure, particularly in nonhuman primates, and longitudinal studies of markers for brain aging in the adults who have the longest exposure to medical amphetamines, are important initial steps.

Beyond the characterization of generally safe treatment protocols, it is important to identify protective factors. As noted above, a genotype that codes for lower density of dopamine D2 receptors (compared to a parallel functional polymorphism), protects against amphetamine-induced psychosis [198]. Treatment with either lithium or valproate reportedly protect against dextroamphetamine-induced alterations of brain choline concentration in patients with bipolar disorder [216]. Recent studies in animals have produced evidence for neuroprotection against amphetamine-mediated toxicity by several substances, including nomifensine [217], methyllycaconitine [218], coenzyme Q10 [219], baicalein [220] and melatonin [221]. In addition, impairment of learned place preference consolidation by amphetamine-induced neurotoxicity was ameliorated by administration of a glutathione precursor [222].

For clinical safety, it is perhaps even more essential to identify individual risk factors for adverse effects of amphetamines. Cognitive, genetic, and other biological markers associated with risk for adverse events from stimulant exposure should be explored. For example, individuals who are homozygous for the 9- repeat allele of the dopamine transporter protein gene, SLC6A, experience virtually no subjective euphoria or anxiety in response to amphetamines [223]. It is unclear, however, from a clinical perspective, whether possession of this genotype should contraindicate medical use of amphetamines, suggest augmenting dosing regimens, suggest combining amphetamine with other treatments or some other modification of treatment. How can we better understand the implications of such relationships for brain function and clinical practice?

As human genetics and *in vivo* neuroimaging techniques are becoming more accessible than before, combining the accumulating knowledge in these two domains may be extremely useful. Positron emission tomography (PET) ligands, which are well-developed for the dopamine

transporter [214], and magnetic resonance spectroscopy mapping of metabolites, will be useful in assessing human catecholamine adaptation during amphetamine treatment. Potential changes in dynamic connectivity can be explored with functional magnetic resonance imaging (fMRI), which has better temporal and spatial resolution than PET for the study of brain response. Functional brain response results will be informed by studies of anatomical connectivity employing diffusion tensor imaging (DTI), a form of MRI sensitive to water flow in axons [224]. Additional structural effects of amphetamine use can be investigated with other new MRI techniques which sensitively quantify changes in brain morphometry over time, including voxel-based, tensor-based, and cortical thickness mapping [225, 226]. Collecting multimodal imaging datasets and analyzing them using multiple complimentary techniques is becoming increasingly feasible. A single MRI session can incorporate sequences that assess several tissue parameters (volumes of gray and white matter, T1, T2, DTI, iron measures, etc) and also collect functional brain responses with fMRI. One ongoing study assesses drug-naïve young adults who report they will soon start using the amphetamine drug methylenedioxymethamphetamine (“ecstasy”) with proton magnetic resonance spectroscopy, perfusion-weighted imaging, DTI, and psychological questionnaires, and will continue periodic reassessments to determine the relationship of drug use to longitudinal change in these measures [227]. Longitudinal exploration of such multimodal datasets will increase understanding of both the techniques employed, and the underlying safety limits and pathophysiology associated with adverse consequences of amphetamine use.

In sum, clinicians should carefully monitor patients receiving long-term therapeutic administration of stimulant medications for signs of adverse effects on development, substance abuse, central toxicity or psychological problems. Research agencies should study effects of protracted exposure in nonhuman primates, and sponsor longitudinal studies of indices of healthy aging in adults exposed to protracted courses of medical amphetamines. As results of these studies are revealed, the relationships of *a priori* genetic factors and *a posteriori* multimodal brain responses to behavioral and neurobiological consequences of protracted amphetamine treatment must be rapidly transmitted to clinicians in order to facilitate safer use of amphetamines.

Acknowledgements

We gratefully acknowledge support from National Institute on Drug Abuse Grants DA022539, DA020726, and DA024853 (EDL), the Addictive Disorders Research Foundation, and the Bette G. Lee Family Trust.

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[redacted]

From: [redacted]
Sent: Monday, 25 February 2013 9:37 PM
To: [redacted]; Fisher, Melanie; [redacted]
Cc: [redacted];
Subject: RE: Phone call from CUSTOMS re Craze - sports supplements containing non-compliant ingredients [SEC=UNCLASSIFIED]

I think that this is a positive development. The idea of attacking this issue with a more proactive communications strategy appeals to me, but it would need to be a collaborative exercise I believe. Interested in others thoughts. And your report of the conversation was very clear - thanks.
[redacted]

Sent from my Windows Phone

From: [redacted]
Sent: 25/02/2013 18:12
To: Fisher, Melanie; [redacted]
Cc: [redacted],
[redacted]
Subject: Phone call from CUSTOMS re Craze - sports supplements containing non-compliant ingredients [SEC=UNCLASSIFIED]

Phone call from Customs re Craze - sports supplements containing non-compliant ingredients
Good evening,

[redacted] and I spoke to Stacy Ward (Manager Communication and Media, Australian Customs and Border Protection Service) about her concerns relating to the on-going issue of drugs in sports supplements.

Dot point summary of my conversation -

- Customs have 30 consignments of Craze on hold which tested positive for amphetamines.
- The product is in powder form
- It is coming in via air cargo and international mail
- The AFP have been advised
- She phoned the AFP media area and found them disinterested in the issue and not willing to cooperate in any joint communication activities
- She was wondering if FSANZ was going to do a recall of these products
- She does not understand the interactions, enforcement responsibilities, and cooperative arrangements between FSANZ, the TGA, DAFF and the states and territories (food v's drugs and poisons enforcement and triggering a recall)
- I explained how the food recalls and food incident response is managed
- I also made her aware of the work being done by the TGA and FSANZ to clarify issues at the food:medicine interface noting that the policy has not been finalised, we understand that there is some confusion in operational/enforcement areas, and communication messages are reactive at this stage
- She is proposing to work with agencies to develop communication messages and educational material on the risk associated with some sports supplements. Her approach to the AFP did not work and she was very frustrated when she phoned (she was a bit happier when she was aware of our work in the area and that I would raise her concerns with Exec)
- She is very keen to start a conversation with us

Actions –

- I said I would contact the relevant FSANZ executives and make them aware of her concerns

- I suggested that building an evidence base would support the need to drive a communication plan. In addition to the information on the 30 consignments on hold Stacy is going to see if she can get some data on the growth in the imports of sports supplements and she may be able to get figures on the imports of Craze.

I suppose the question is – *Are we willing (do we have the capacity) to work with Customs on this issue and perhaps coordinate with the TGA, DoHA and DAFF?*

Considering the variation in enforcement responses from the states and territories there may be more value in developing messages at a national level and disseminating them to the S/T's to allow the most approximate section of their government to channel the messages within their jurisdiction.

I hope this email makes sense to you.

Regards,
[redacted]

[redacted]
Senior Food Scientist

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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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UNCLASSIFIED

[redacted]

From: [redacted]
Sent: Wednesday, 27 February 2013 12:52 PM
To: 'FOSTER Lyn'
Cc: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Importance: High

Hi Lyn

Thanks for your email – apologies for not replying sooner, I was on leave and away for work too. I actually am not working directly in incident management at the moment as I've moved temporarily into another Section at FSANZ. However, I've cc'd in the incident team in the Food Safety Section and they'll be able to follow up with the states and territory health authorities and let you know if there's any additional consumer advice; the current advice we have on our website is here and the info on the TGA scheduling decision is here . There has also been a debrief on the DMAA incident and it may be useful for you to be aware of the outcomes of the debrief. If you require a direct contact in the incident team please contact [redacted] (incident secretariat) at [redacted]

Hope this helps,

[redacted]

[redacted]
Senior Scientist
Strategic Science International and Surveillance Section
Chief Scientists Branch

Food Standards Australia New Zealand
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From: FOSTER Lyn [mailto:lyn.foster@customs.gov.au]
Sent: Friday, 22 February 2013 2:53 PM
To: [redacted]
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

Hi [redacted]

[redacted] forwarded me some of the information on the CRAZE product as it involves my team. I have also been forwarded a copy of the testing results and reports.

CRAZE, as you know, contains *N,α-diethylbenzeneethanamine* and the AFP advised us that they consider this to be an analogue of the border controlled substance methamphetamine under the Criminal Code (C'wth). Accordingly, Customs and Border Protection have been seizing this product and transferring it to the AFP.

Of course, prior to us becoming aware that the product contained this ingredient (it's certainly a novel chemical to put in a sports supplement) it has been available in Australia and we have been told that there is an official Australian distributor of the product.

We are in the process of writing to a few overseas suppliers of the product to outline our legislation and ask them to desist.

I was wondering whether there was any update with regard to the possibility of a food recall or consumer advice relating to the health risks of consuming the product.

This would fortify any statement that Customs and Border Protection makes as to why we are seizing the goods which have been sold previously and in some cases are still available for seemingly legitimate sale (if approached by the media) although I understand that the domestic legislation and border controls are different, and the product may not meet the requirements for a food recall to be issued.

Could you please let me know if FSANZ and the state health authorities are still considering further action in relation to this product?

Thanks.

Regards,

Lyn Foster

Manager | Drugs and Therapeutic Substances
Community Protection | Trade Policy and Implementation

Australian Customs and Border Protection Service
5 Constitution Ave Canberra ACT 2601

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From: MARSHALL Laura
Sent: Wednesday, 24 October 2012 10:24 AM
To: FOSTER Lyn
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

FYI

Warm Regards,
Laura Marshall
Supervisor, IP Rights & Consumer Goods
Trade Policy & Implementation - Australian Customs and Border Protection Service

Ph: (02) 6275 6157 Fax: (02) 6229 3840
Email: laura.marshall@customs.gov.au or iprights@customs.gov.au

---

From: [redacted]
Sent: Tuesday, 23 October 2012 12:45 PM

To: [redacted]; bill.calder@health.wa.gov.au; [redacted]; Brett Herbert; brian.jones@act.gov.au; [redacted]; bwitherspoon@safefood.qld.gov.au; craig.shadbolt@foodauthority.nsw.gov.au; [IP Rights]; DAFF Food Incidents; Darryl Bourbour; DoHa generic email; Health Ops (Health); eric.johnson@dhhs.tas.gov.au; fay.jenkins@health.sa.gov.au; fiona.jones@health.vic.gov.au; Food Incident QLD; [redacted]; Gerard.Fitzsimmons@Health.gov.au; Glen Neal (glen.neal@mpi.govt.nz); glen.martin@health.sa.gov.au; Goodchild, Stan; [redacted]; MARSHALL Laura; Leigh Nind; Lyall, Chris; Miller, Craig; NSW Food Incident; olivia.mcquestin@dhhs.tas.gov.au; Oz Food Net; paul.dowsett@sa.gov.au; Peter Merell; Rob.Solomon@daff.gov.au; Spry, Zoe; Tegel, Marianne; tenille_fort@health.qld.gov.au; [redacted]; tracy.ward@nt.gov.au; [redacted], [redacted]; Wilson, Andrew; xavier.schobben@nt.gov.au; Yvette.Dethridge@aqis.gov.au
Cc: Food Incident Group; incident
Subject: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

GOVERNMENT-IN-CONFIDENCE

Dear NFIR team,

FYI – NSWFA have notified us of work they are carrying out on sports food supplements (post DMAA) and have sent through the attached information to share with you – please note this is NOT an incident notification, but has been kindly sent by NSWFA as a heads-up. Some testing is still being undertaken, however once the preliminary work is complete NSWFA have indicated they may wish to discuss with the NFIR team about the need to trigger the NFIRP.

Background
The main issue appears to be the continued innovation by the dietary sports industry in the USA reformulating products to include proprietary names of blended ingredients to confuse regulators and continue to supply poorly described ingredients in products that are not permitted and difficult to analyse for. Because of the health consequences the products have extensive health warnings on the labels due to the USA legal system. These labels are not in the form that would comply with the FSC and do not clearly disclose the levels of nutrients and other active substances per serve or per daily amount in many cases.

Once we hear anything further we will notify the NFIR team.

Kind regards

[redacted]
Assistant Manager Food Safety Section
Food Standards Australia New Zealand

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UNCLASSIFIED

[redacted]

From: FOSTER Lyn <lyn.foster@customs.gov.au>
Sent: Wednesday, 27 February 2013 1:30 PM
To: [redacted]
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Importance: High

Hi [redacted]

I had emailed [redacted] for assistance but she advised that she is working on something slightly different at the moment and provided me with your details.

I am just trying to find out if FSANZ is intending to take any further action with specific regard to the product 'CRAZE' which contains a methamphetamine analogue.

As the product contains a border controlled substance, it is considered to be border controlled and we are seizing it (unlike products containing DMAA which we are not able to detain)

We also intend to write to overseas suppliers of the product to outline the reasons why we are taking action at the border.

Some of the importers, who had imported the product to sell commercially, have complained that the product seems to be legitimately for sale within Australia so I am trying to find out if FSANZ has issued any products recalls or warnings for this particular product. Can you let me know if FSANZ or the state health authorities are currently considering any action in relation to this product?

Thanks.

Regards,

Lyn Foster

Manager | Drugs and Therapeutic Substances
Community Protection | Trade Policy and Implementation

Australian Customs and Border Protection Service
5 Constitution Ave Canberra ACT 2601

phone: 02 6275 5963 | fax: 02 6229 3840

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www.customs.gov.au

From: FOSTER Lyn [mailto:lyn.foster@customs.gov.au]
Sent: Friday, 22 February 2013 2:53 PM
To: [redacted]
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

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Regards,

Lyn Foster

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From: MARSHALL Laura
Sent: Wednesday, 24 October 2012 10:24 AM

To: FOSTER Lyn
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

FYI

Warm Regards,
Laura Marshall
Supervisor, IP Rights & Consumer Goods
Trade Policy & Implementation - Australian Customs and Border Protection Service

Ph: (02) 6275 6157 Fax: (02) 6229 3840
Email: laura.marshall@customs.gov.au or iprights@customs.gov.au

---

From: [redacted]
Sent: Tuesday, 23 October 2012 12:45 PM
To: [redacted]; bill.calder@health.wa.gov.au; [redacted]; Brett Herbert; brian.jones@act.gov.au; [redacted]; bwitherspoon@safefood.qld.gov.au; craig.shadbolt@foodauthority.nsw.gov.au; [IP Rights]; DAFF Food Incidents; Darryl Bourbour; DoHa generic email; Health Ops (Health); eric.johnson@dhhs.tas.gov.au; fay.jenkins@health.sa.gov.au; fiona.jones@health.vic.gov.au; Food Incident QLD; [redacted]; Gerard.Fitzsimmons@Health.gov.au; Glen Neal (glen.neal@mpi.govt.nz); glen.martin@health.sa.gov.au; Goodchild, Stan; [redacted]; MARSHALL Laura; Leigh Nind; Lyall, Chris; Miller, Craig; NSW Food Incident; olivia.mcquestin@dhhs.tas.gov.au; Oz Food Net; paul.dowsett@sa.gov.au; Peter Merell; Rob.Solomon@daff.gov.au; Spry, Zoe; Tegel, Marianne; tenille_fort@health.qld.gov.au; [redacted]; tracy.ward@nt.gov.au; [redacted], [redacted]; Wilson, Andrew; xavier.schobben@nt.gov.au; Yvette.Dethridge@aqis.gov.au
Cc: Food Incident Group; incident
Subject: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

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Once we hear anything further we will notify the NFIR team.

Kind regards

[redacted]

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Assistant Manager Food Safety Section
Food Standards Australia New Zealand

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Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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Unsolicited commercial emails MUST NOT be sent to the originator of this email.

[redacted]

From: [redacted]
Sent: Thursday, 28 February 2013 2:39 PM
To: incident
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Attachments: FOR INFORMATION- Sports Supplements/Craze- actions undertaken by NSW Food Authority [DLM=For-Official-Use-Only]

UNCLASSIFIED

From: incident
Sent: Thursday, 28 February 2013 2:25 PM
To: [redacted]
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi [redacted]

Please could you clear this email before I send it. Want to be sure that I'm not suggesting we will do anything and I am correctly articulating the current situation. In addition, I will let Marianne know that she may receive a call/email from Customs.

Hi Lyn,

Thanks for your email. [redacted] has already provided in her email to you below the current consumer advice which is available on our website and currently I am not aware of any plans to update this information at this stage. I have attached the most recent national communication on the product Craze to Food Incident Contact Officers (Laura Marshall is Customs contact member) which was circulated in November 2012 through the incident contact network for information.

As advised in the notification circulated, Marianne Tegel from the NSW Food Authority is happy to be contacted on their proposed actions and it may be appropriate to touch base with her on the overseas suppliers/ importers they have targeted.

In regard to recalls, FSANZ coordinates and monitors food recalls in Australia but does not trigger recalls (…only s/t….), conduct any testing or investigations. This is the role of the state and territory food enforcement agencies. FSANZ have not been advised by any state or territory authority regarding coordination of any recall associated with the product Craze.

The debrief referred to by [redacted] below covers internal operations matters and would not assist with addressing your enquiry. The policy development food/drug interface work between the TGA and FSANZ is an ongoing discussion at this stage.

I hope this information provides some assistance to you.

Kind regards
[redacted]

From: [redacted]
Sent: Wednesday, 27 February 2013 12:52 PM
To: 'FOSTER Lyn'
Cc: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

Hi Lyn

Thanks for your email – apologies for not replying sooner, I was on leave and away for work too. I actually am not working directly in incident management at the moment as I've moved temporarily into another Section at FSANZ. However, I've cc'd in the incident team in the Food Safety Section and they'll be able to follow up with the states and territory health authorities and let you know if there's any additional consumer advice; the current advice we have on our website is here and the info on the TGA scheduling decision is here . There has also been a debrief on the DMAA incident and it may be useful for you to be aware of the outcomes of the debrief. If you require a direct contact in the incident team please contact [redacted] (incident secretariat) at [redacted]

Hope this helps,

[redacted]

[redacted]
Senior Scientist
Strategic Science International and Surveillance Section
Chief Scientists Branch

Food Standards Australia New Zealand
55 Blackall Street, Barton, ACT 2600
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From: FOSTER Lyn [mailto:lyn.foster@customs.gov.au]
Sent: Friday, 22 February 2013 2:53 PM
To: [redacted]
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

Hi [redacted]

[redacted] forwarded me some of the information on the CRAZE product as it involves my team. I have also been forwarded a copy of the testing results and reports.

CRAZE, as you know, contains *N,α-diethylbenzeneethanamine* and the AFP advised us that they consider this to be an analogue of the border controlled substance methamphetamine under the Criminal Code (C'wth). Accordingly, Customs and Border Protection have been seizing this product and transferring it to the AFP.

Of course, prior to us becoming aware that the product contained this ingredient (it's certainly a novel chemical to put in a sports supplement) it has been available in Australia and we have been told that there is an official Australian distributor of the product.

We are in the process of writing to a few overseas suppliers of the product to outline our legislation and ask them to desist.

I was wondering whether there was any update with regard to the possibility of a food recall or consumer advice relating to the health risks of consuming the product.

This would fortify any statement that Customs and Border Protection makes as to why we are seizing the goods which have been sold previously and in some cases are still available for seemingly legitimate sale (if approached by the media) although I understand that the domestic legislation and border controls are different, and the product may not meet the requirements for a food recall to be issued.

Could you please let me know if FSANZ and the state health authorities are still considering further action in relation to this product?

Thanks.

Regards,

Lyn Foster

Manager | Drugs and Therapeutic Substances
Community Protection | Trade Policy and Implementation

Australian Customs and Border Protection Service
5 Constitution Ave Canberra ACT 2601

phone: 02 6275 5963 | fax: 02 6229 3840

dts@customs.gov.au

community.protection@customs.gov.au

www.customs.gov.au

From: MARSHALL Laura
Sent: Wednesday, 24 October 2012 10:24 AM
To: FOSTER Lyn
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

FYI

Warm Regards,
Laura Marshall
Supervisor, IP Rights & Consumer Goods
Trade Policy & Implementation - Australian Customs and Border Protection Service

Ph: (02) 6275 6157 Fax: (02) 6229 3840
Email: laura.marshall@customs.gov.au or iprights@customs.gov.au

---

From: [redacted]
Sent: Tuesday, 23 October 2012 12:45 PM
To: [redacted]; bill.calder@health.wa.gov.au; [redacted]; Brett Herbert; brian.jones@act.gov.au; [redacted]; bwitherspoon@safefood.qld.gov.au; craig.shadbolt@foodauthority.nsw.gov.au; [IP Rights]; DAFF Food Incidents; Darryl Bourbour; DoHa generic email; Health Ops (Health); eric.johnson@dhhs.tas.gov.au; fay.jenkins@health.sa.gov.au; fiona.jones@health.vic.gov.au; Food Incident QLD; [redacted];

Gerard.Fitzsimmons@Health.gov.au; Glen Neal (glen.neal@mpi.govt.nz); glen.martin@health.sa.gov.au; Goodchild, Stan; [redacted]; MARSHALL Laura; Leigh Nind; Lyall, Chris; Miller, Craig; NSW Food Incident; olivia.mcquestin@dhhs.tas.gov.au; Oz Food Net; paul.dowsett@sa.gov.au; Peter Merell; Rob.Solomon@daff.gov.au; Spry, Zoe; Tegel, Marianne; tenille_fort@health.qld.gov.au; [redacted]; tracy.ward@nt.gov.au; [redacted], [redacted]; Wilson, Andrew; xavier.schobben@nt.gov.au; Yvette.Dethridge@aqis.gov.au
Cc: Food Incident Group; incident
Subject: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

GOVERNMENT-IN-CONFIDENCE

Dear NFIR team,

FYI – NSWFA have notified us of work they are carrying out on sports food supplements (post DMAA) and have sent through the attached information to share with you – please note this is NOT an incident notification, but has been kindly sent by NSWFA as a heads-up. Some testing is still being undertaken, however once the preliminary work is complete NSWFA have indicated they may wish to discuss with the NFIR team about the need to trigger the NFIRP.

Background
The main issue appears to be the continued innovation by the dietary sports industry in the USA reformulating products to include proprietary names of blended ingredients to confuse regulators and continue to supply poorly described ingredients in products that are not permitted and difficult to analyse for. Because of the health consequences the products have extensive health warnings on the labels due to the USA legal system. These labels are not in the form that would comply with the FSC and do not clearly disclose the levels of nutrients and other active substances per serve or per daily amount in many cases.

Once we hear anything further we will notify the NFIR team.

Kind regards

[redacted]

[redacted]
Assistant Manager Food Safety Section
Food Standards Australia New Zealand

55 Blackall Street, Barton, ACT 2600
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[redacted]

From: incident
Sent: Wednesday, 28 November 2012 11:24 AM
To: [redacted]; bill.calder@health.wa.gov.au; [redacted]; Brett Herbert; brian.jones@act.gov.au; [redacted]; bwitherspoon@safefood.qld.gov.au; craig.shadbolt@foodauthority.nsw.gov.au; Customs Generic email; DAFF Food Incidents; Darryl Bourbour; DoHa generic email; DoHA generic Incident mail; eric.johnson@dhhs.tas.gov.au; fay.jenkins@health.sa.gov.au; fiona.jones@health.vic.gov.au; Food Incident QLD; [redacted]; Gerard.Fitzsimmons@Health.gov.au; Glen Neal (glen.neal@mpi.govt.nz); glen.martin@health.sa.gov.au; Goodchild, Stan; [redacted]; Laura Marshall; Leigh Nind; Lyall, Chris; Miller, Craig; NSW Food Incident; olivia.mcquestin@dhhs.tas.gov.au; Oz Food Net; paul.dowsett@sa.gov.au; Peter Merrell (peter.merrell@daff.gov.au); Rob.Solomon@daff.gov.au; Spry, Zoe; Tegel, Marianne; tenille_fort@health.qld.gov.au; [redacted]; tracy.ward@nt.gov.au; [redacted]; Wilson, Andrew; xavier.schobben@nt.gov.au; Yvette.Dethridge@aqis.gov.au
Cc: incident
Subject: FOR INFORMATION- Sports Supplements/Craze- actions undertaken by NSW Food Authority [DLM=For-Official-Use-Only]
Attachments: nihms-105401.pdf.pdf

Dear Food Incident Contact Officers,

NSW Food Authority have been working on an issue with sports supplements, specifically a product called 'Craze' and wish to communicate through the National Food Incident Response network the information they have gathered and their proposed action.

Testing conducted by the NSW Food Authority detected N,α-diethylbenzeneethanamine as present in the product Craze. An opinion from a forensic chemist at NSW Police has concluded that N,α-diethylbenzeneethanamine is a structural analogue of methyl amphetamine. To meet the definition of a prohibited drug under the NSW *Misuse and Trafficking Act 1985* the substance would need to have psychotropic properties.

NSW Food Authority are now regarding Craze as unsuitable with health implications if the product is misused. Their primary concern is what constitutes a safe dose in relation to this product and at the very least its suitability. Following the test results and expert opinion, NSW Food Authority feel they are in a position to approach the importer requesting a recall of Craze.

This information and a paper relating to meth amphetamine (attached) is provided for your information. Should you have any specific questions relating to this product or the proposed actions by NSW Food Authority please contact Marianne Tegel at the NSW Food Authority on 02 9741 4858 or marianne.tegel@foodauthority.nsw.gov.au.

Kind regards
[redacted]

[redacted] | **Project Officer**

Incident Secretariat

55 Blackall Street, Barton, ACT 2600
PO Box 7186, Canberra BC, ACT 2610

t [redacted] |

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[redacted]

From: [redacted]
Sent: Thursday, 28 February 2013 2:42 PM
To: incident
Subject: FW: Phone call from CUSTOMS re Craze - sports supplements containing non-compliant ingredients [SEC=UNCLASSIFIED]

Importance: High

UNCLASSIFIED

From: [redacted]
Sent: Monday, 25 February 2013 6:13 PM
To: Fisher, Melanie; [redacted]
Cc: [redacted],
[redacted]
Subject: Phone call from CUSTOMS re Craze - sports supplements containing non-compliant ingredients [SEC=UNCLASSIFIED]
Importance: High

Phone call from Customs re Craze - sports supplements containing non-compliant ingredients

Good evening,

[redacted] and I spoke to Stacy Ward (Manager Communication and Media, Australian Customs and Border Protection Service) about her concerns relating to the on-going issue of drugs in sports supplements.

Dot point summary of my conversation -

- Customs have 30 consignments of Craze on hold which tested positive for amphetamines.
- The product is in powder form
- It is coming in via air cargo and international mail
- The AFP have been advised
- She phoned the AFP media area and found them disinterested in the issue and not willing to cooperate in any joint communication activities
- She was wondering if FSANZ was going to do a recall of these products
- She does not understand the interactions, enforcement responsibilities, and cooperative arrangements between FSANZ, the TGA, DAFF and the states and territories (food v's drugs and poisons enforcement and triggering a recall)
- I explained how the food recalls and food incident response is managed
- I also made her aware of the work being done by the TGA and FSANZ to clarify issues at the food:medicine interface noting that the policy has not been finalised, we understand that there is some confusion in operational/enforcement areas, and communication messages are reactive at this stage
- She is proposing to work with agencies to develop communication messages and educational material on the risk associated with some sports supplements. Her approach to the AFP did not work and she was very frustrated when she phoned (she was a bit happier when she was aware of our work in the area and that I would raise her concerns with Exec)
- She is very keen to start a conversation with us

Actions –

- I said I would contact the relevant FSANZ executives and make them aware of her concerns

- I suggested that building an evidence base would support the need to drive a communication plan. In addition to the information on the 30 consignments on hold Stacy is going to see if she can get some data on the growth in the imports of sports supplements and she may be able to get figures on the imports of Craze.

I suppose the question is – *Are we willing (do we have the capacity) to work with Customs on this issue and perhaps coordinate with the TGA, DoHA and DAFF?*

Considering the variation in enforcement responses from the states and territories there may be more value in developing messages at a national level and disseminating them to the S/T's to allow the most approximate section of their government to channel the messages within their jurisdiction.

I hope this email makes sense to you.

Regards,
[redacted]

[redacted]
Senior Food Scientist

55 Blackall Street, Barton, ACT 2600
PO Box 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
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[redacted]

From: incident
Sent: Thursday, 28 February 2013 2:49 PM
To: 'FOSTER Lyn'
Cc: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi Lyn,

Thanks for your email. [redacted] has already provided in her email to you below the current consumer advice which is available on our website and currently I am not aware of any plans to update this information at this stage. I have attached the most recent national communication on the product Craze to Food Incident Contact Officers (Laura Marshall is Customs contact member) which was circulated in November 2012 through the incident contact network for information.

As advised in the notification circulated, Marianne Tegel from the NSW Food Authority is happy to be contacted on their proposed actions and it may be appropriate to touch base with her on the overseas suppliers/ importers they have targeted.

In regard to recalls, FSANZ coordinates and monitors food recalls in Australia but does not enforce any recall action, conduct any testing or investigations. This is the role of the state and territory food enforcement agencies. FSANZ have not been advised by any state or territory authority regarding coordination of any recall associated with the product Craze.

The debrief referred to by [redacted] below covers internal operations matters and would not assist with addressing your enquiry. The policy development food/drug interface work between the TGA and FSANZ is an ongoing discussion at this stage.

I hope this information provides some assistance to you.

Kind regards
[redacted]

[redacted] | **Project Officer**

Food Safety Section

55 Blackall Street, Barton, ACT 2600
PO Box 7186, Canberra BC, ACT 2610

[redacted] |

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---

From: [redacted]
Sent: Wednesday, 27 February 2013 12:52 PM
To: 'FOSTER Lyn'
Cc: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

Hi Lyn

Thanks for your email – apologies for not replying sooner, I was on leave and away for work too. I actually am not working directly in incident management at the moment as I've moved temporarily into another Section at FSANZ. However, I've cc'd in the incident team in the Food Safety Section and they'll be able to follow up with the states and territory health authorities and let you know if there's any additional consumer advice; the current advice we have on our website is here and the info on the TGA scheduling decision is here . There has also been a debrief on the DMAA incident and it may be useful for you to be aware of the outcomes of the debrief. If you require a direct contact in the incident team please contact [redacted] (incident secretariat) at [redacted].

Hope this helps,

[redacted]

[redacted]
Senior Scientist
Strategic Science International and Surveillance Section
Chief Scientists Branch

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From: FOSTER Lyn [mailto:lyn.foster@customs.gov.au]
Sent: Friday, 22 February 2013 2:53 PM
To: [redacted]
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

Hi [redacted],

[redacted] forwarded me some of the information on the CRAZE product as it involves my team. I have also been forwarded a copy of the testing results and reports.

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Could you please let me know if FSANZ and the state health authorities are still considering further action in relation to this product?

Thanks.

Regards,

Lyn Foster

Manager | Drugs and Therapeutic Substances
Community Protection | Trade Policy and Implementation

Australian Customs and Border Protection Service
5 Constitution Ave Canberra ACT 2601

phone: 02 6275 5963 | fax: 02 6229 3840

dts@customs.gov.au

community.protection@customs.gov.au

www.customs.gov.au

From: MARSHALL Laura
Sent: Wednesday, 24 October 2012 10:24 AM
To: FOSTER Lyn
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

FYI

Warm Regards,
Laura Marshall
Supervisor, IP Rights & Consumer Goods
Trade Policy & Implementation - Australian Customs and Border Protection Service

Ph: (02) 6275 6157 Fax: (02) 6229 3840
Email: laura.marshall@customs.gov.au or iprights@customs.gov.au

---

From: [redacted]
Sent: Tuesday, 23 October 2012 12:45 PM
To: [redacted]; bill.calder@health.wa.gov.au; [redacted]; Brett Herbert; brian.jones@act.gov.au; [redacted]; bwitherspoon@safefood.qld.gov.au; craig.shadbolt@foodauthority.nsw.gov.au; [IP Rights]; DAFF Food Incidents; Darryl Bourbour; DoHa generic email; Health Ops (Health); eric.johnson@dhhs.tas.gov.au; fay.jenkins@health.sa.gov.au; fiona.jones@health.vic.gov.au; Food Incident QLD; [redacted]; Gerard.Fitzsimmons@Health.gov.au; Glen Neal (glen.neal@mpi.govt.nz); glen.martin@health.sa.gov.au; Goodchild, Stan; [redacted]; MARSHALL Laura; Leigh Nind; Lyall, Chris; Miller, Craig; NSW Food Incident; olivia.mcquestin@dhhs.tas.gov.au; Oz Food Net; paul.dowsett@sa.gov.au; Peter Merell; Rob.Solomon@daff.gov.au; Spry, Zoe; Tegel, Marianne; tenille_fort@health.qld.gov.au; [redacted]; tracy.ward@nt.gov.au; [redacted], [redacted]; Wilson, Andrew; xavier.schobben@nt.gov.au; Yvette.Dethridge@aqis.gov.au
Cc: Food Incident Group; incident
Subject: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

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Once we hear anything further we will notify the NFIR team.

Kind regards

[redacted]

[redacted]
Assistant Manager Food Safety Section
Food Standards Australia New Zealand

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[redacted]

From: FOSTER Lyn <lyn.foster@customs.gov.au>
Sent: Friday, 1 March 2013 2:15 PM
To: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi [redacted]

Thanks. I read the consumer advice form the links that [redacted] sent, however, I was wondering whether there would be a different advice for CRAZE in particular as it contains a methamphetamine analog rather than DMAA.

We are not able to control DMAA at the border when presented in a food type supplement as the DMAA itself is not subject to either Customs Regulations or the Criminal Code. CRAZE is different – due to the analog, we are able to seize it under our regulations and pass it to the AFP for action under the Criminal Code.

I'll follow up with Marianne Tegel as suggested as well.

Regards,

Lyn Foster

Manager | Drugs and Therapeutic Substances
Community Protection | Trade Policy and Implementation

Australian Customs and Border Protection Service
5 Constitution Ave Canberra ACT 2601

phone: 02 6275 5963 | fax: 02 6229 3840

dts@customs.gov.au

community.protection@customs.gov.au

www.customs.gov.au

From: incident [mailto:incident@foodstandards.gov.au]
Sent: Thursday, 28 February 2013 2:49 PM
To: FOSTER Lyn
Cc: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi Lyn,

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I hope this information provides some assistance to you.

Kind regards
[redacted]

[redacted] | **Project Officer**

Food Safety Section

55 Blackall Street, Barton, ACT 2600
PO Box 7186, Canberra BC, ACT 2610

[redacted] |

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---

From: [redacted]
Sent: Wednesday, 27 February 2013 12:52 PM
To: 'FOSTER Lyn'
Cc: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

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Hope this helps,

[redacted]

[redacted]
Senior Scientist
Strategic Science International and Surveillance Section
Chief Scientists Branch

Food Standards Australia New Zealand
55 Blackall Street, Barton, ACT 2600

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---

From: FOSTER Lyn [mailto:lyn.foster@customs.gov.au]
Sent: Friday, 22 February 2013 2:53 PM
To: [redacted]
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

Hi [redacted],

[redacted] forwarded me some of the information on the CRAZE product as it involves my team. I have also been forwarded a copy of the testing results and reports.

CRAZE, as you know, contains *N,α-diethylbenzeneethanamine* and the AFP advised us that they consider this to be an analogue of the border controlled substance methamphetamine under the Criminal Code (C'wth). Accordingly, Customs and Border Protection have been seizing this product and transferring it to the AFP.

Of course, prior to us becoming aware that the product contained this ingredient (it's certainly a novel chemical to put in a sports supplement) it has been available in Australia and we have been told that there is an official Australian distributor of the product.

We are in the process of writing to a few overseas suppliers of the product to outline our legislation and ask them to desist.

I was wondering whether there was any update with regard to the possibility of a food recall or consumer advice relating to the health risks of consuming the product.

This would fortify any statement that Customs and Border Protection makes as to why we are seizing the goods which have been sold previously and in some cases are still available for seemingly legitimate sale (if approached by the media) although I understand that the domestic legislation and border controls are different, and the product may not meet the requirements for a food recall to be issued.

Could you please let me know if FSANZ and the state health authorities are still considering further action in relation to this product?

Thanks.

Regards,

Lyn Foster

Manager | Drugs and Therapeutic Substances
Community Protection | Trade Policy and Implementation

Australian Customs and Border Protection Service
5 Constitution Ave Canberra ACT 2601

phone: 02 6275 5963 | fax: 02 6229 3840

dts@customs.gov.au

community.protection@customs.gov.au

www.customs.gov.au

From: MARSHALL Laura
Sent: Wednesday, 24 October 2012 10:24 AM
To: FOSTER Lyn
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

FYI

Warm Regards,
Laura Marshall
Supervisor, IP Rights & Consumer Goods
Trade Policy & Implementation - Australian Customs and Border Protection Service

Ph: (02) 6275 6157 Fax: (02) 6229 3840
Email: laura.marshall@customs.gov.au or iprights@customs.gov.au

---

From: [redacted]
Sent: Tuesday, 23 October 2012 12:45 PM
To: [redacted]; bill.calder@health.wa.gov.au; [redacted]; Brett Herbert; brian.jones@act.gov.au; [redacted]; bwitherspoon@safefood.qld.gov.au; craig.shadbolt@foodauthority.nsw.gov.au; [IP Rights]; DAFF Food Incidents; Darryl Bourbour; DoHa generic email; Health Ops (Health); eric.johnson@dhhs.tas.gov.au; fay.jenkins@health.sa.gov.au; fiona.jones@health.vic.gov.au; Food Incident QLD; [redacted]; Gerard.Fitzsimmons@Health.gov.au; Glen Neal (glen.neal@mpi.govt.nz); glen.martin@health.sa.gov.au; Goodchild, Stan; [redacted]; MARSHALL Laura; Leigh Nind; Lyall, Chris; Miller, Craig; NSW Food Incident; olivia.mcquestin@dhhs.tas.gov.au; Oz Food Net; paul.dowsett@sa.gov.au; Peter Merell; Rob.Solomon@daff.gov.au; Spry, Zoe; Tegel, Marianne; tenille_fort@health.qld.gov.au; [redacted]; tracy.ward@nt.gov.au; [redacted], [redacted]; Wilson, Andrew; xavier.schobben@nt.gov.au; Yvette.Dethridge@aqis.gov.au
Cc: Food Incident Group; incident
Subject: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

GOVERNMENT-IN-CONFIDENCE

Dear NFIR team,

FYI – NSWFA have notified us of work they are carrying out on sports food supplements (post DMAA) and have sent through the attached information to share with you – please note this is NOT an incident notification, but has been kindly sent by NSWFA as a heads-up. Some testing is still being undertaken, however once the preliminary work is complete NSWFA have indicated they may wish to discuss with the NFIR team about the need to trigger the NFIRP.

Background
The main issue appears to be the continued innovation by the dietary sports industry in the USA reformulating products to include proprietary names of blended ingredients to confuse regulators and continue to supply poorly described ingredients in products that are not permitted and difficult to analyse for. Because of the health consequences the products have extensive health warnings on the labels due to the USA legal system. These labels are not in the form that would comply with the FSC and do not clearly disclose the levels of nutrients and other active substances per serve or per daily amount in many cases.

Once we hear anything further we will notify the NFIR team.

Kind regards

[redacted]

[redacted]
Assistant Manager Food Safety Section
Food Standards Australia New Zealand

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
[redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

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Unsolicited commercial emails MUST NOT be sent to the originator of this email.

[redacted]

From: [redacted]
Sent: Monday, 4 March 2013 10:38 AM
To: incident
Cc: [redacted]
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Thanks [redacted]. Whether it goes to FIG or SSIG depends on what decision we are looking for. If it is strategic then SSIG is not the correct forum. A science/technical based discussion would be SSIG. Thanks.
[redacted]

From: incident
Sent: Monday, 4 March 2013 10:23 AM
To: [redacted]
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

FYI- emails received from Lyn in Customs. I will work on the escalation document for an out of session topic for either SSIG or FIG now

Regards

[redacted]

From: FOSTER Lyn [mailto:lyn.foster@customs.gov.au]
Sent: Friday, 1 March 2013 2:15 PM
To: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi [redacted]

Thanks. I read the consumer advice form the links that [redacted] sent, however, I was wondering whether there would be a different advice for CRAZE in particular as it contains a methamphetamine analog rather than DMAA.

We are not able to control DMAA at the border when presented in a food type supplement as the DMAA itself is not subject to either Customs Regulations or the Criminal Code. CRAZE is different – due to the analog, we are able to seize it under our regulations and pass it to the AFP for action under the Criminal Code.

I'll follow up with Marianne Tegel as suggested as well.

Regards,

Lyn Foster

Manager | Drugs and Therapeutic Substances
Community Protection | Trade Policy and Implementation

Australian Customs and Border Protection Service
5 Constitution Ave Canberra ACT 2601

phone: 02 6275 5963 | fax: 02 6229 3840

dts@customs.gov.au

community.protection@customs.gov.au

www.customs.gov.au

From: incident [mailto:incident@foodstandards.gov.au]
Sent: Thursday, 28 February 2013 2:49 PM
To: FOSTER Lyn
Cc: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi Lyn,

Thanks for your email. [redacted] has already provided in her email to you below the current consumer advice which is available on our website and currently I am not aware of any plans to update this information at this stage. I have attached the most recent national communication on the product Craze to Food Incident Contact Officers (Laura Marshall is Customs contact member) which was circulated in November 2012 through the incident contact network for information.

As advised in the notification circulated, Marianne Tegel from the NSW Food Authority is happy to be contacted on their proposed actions and it may be appropriate to touch base with her on the overseas suppliers/ importers they have targeted.

In regard to recalls, FSANZ coordinates and monitors food recalls in Australia but does not enforce any recall action, conduct any testing or investigations. This is the role of the state and territory food enforcement agencies. FSANZ have not been advised by any state or territory authority regarding coordination of any recall associated with the product Craze.

The debrief referred to by [redacted] below covers internal operations matters and would not assist with addressing your enquiry. The policy development food/drug interface work between the TGA and FSANZ is an ongoing discussion at this stage.

I hope this information provides some assistance to you.

Kind regards
[redacted]

[redacted] | **Project Officer**

Food Safety Section

55 Blackall Street, Barton, ACT 2600
PO Box 7186, Canberra BC, ACT 2610

t [redacted] |

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From: [redacted]
Sent: Wednesday, 27 February 2013 12:52 PM
To: 'FOSTER Lyn'
Cc: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

Hi Lyn

Thanks for your email – apologies for not replying sooner, I was on leave and away for work too. I actually am not working directly in incident management at the moment as I've moved temporarily into another Section at FSANZ. However, I've cc'd in the incident team in the Food Safety Section and they'll be able to follow up with the states and territory health authorities and let you know if there's any additional consumer advice; the current advice we have on our website is here and the info on the TGA scheduling decision is here . There has also been a debrief on the DMAA incident and it may be useful for you to be aware of the outcomes of the debrief. If you require a direct contact in the incident team please contact [redacted] (incident secretariat) at [redacted]

Hope this helps,

[redacted]
Senior Scientist
Strategic Science International and Surveillance Section
Chief Scientists Branch

Food Standards Australia New Zealand
55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
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From: FOSTER Lyn [mailto:lyn.foster@customs.gov.au]
Sent: Friday, 22 February 2013 2:53 PM
To: [redacted]
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Importance: High

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Sent: Wednesday, 24 October 2012 10:24 AM
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Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

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Laura Marshall
Supervisor, IP Rights & Consumer Goods
Trade Policy & Implementation - Australian Customs and Border Protection Service

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Email: laura.marshall@customs.gov.au or iprights@customs.gov.au

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To: [redacted]; bill.calder@health.wa.gov.au; [redacted]; Brett Herbert; brian.jones@act.gov.au; [redacted]; bwitherspoon@safefood.qld.gov.au; craig.shadbolt@foodauthority.nsw.gov.au; [IP Rights]; DAFF Food Incidents; Darryl Bourbour; DoHa generic email; Health Ops (Health); eric.johnson@dhhs.tas.gov.au; fay.jenkins@health.sa.gov.au; fiona.jones@health.vic.gov.au; Food Incident QLD; [redacted]; Gerard.Fitzsimmons@Health.gov.au; Glen Neal (glen.neal@mpi.govt.nz); glen.martin@health.sa.gov.au; Goodchild, Stan; [redacted]; MARSHALL Laura; Leigh Nind; Lyall, Chris; Miller, Craig; NSW Food Incident;

olivia.mcquestin@dhhs.tas.gov.au; Oz Food Net; paul.dowsett@sa.gov.au; Peter Merell; Rob.Solomon@daff.gov.au; Spry, Zoe; Tegel, Marianne; tenille_fort@health.qld.gov.au; [redacted]; tracy.ward@nt.gov.au; [redacted]; [redacted]; Wilson, Andrew; xavier.schobben@nt.gov.au; Yvette.Dethridge@aqis.gov.au
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GOVERNMENT-IN-CONFIDENCE

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[redacted]

From: [redacted]
Sent: Tuesday, 12 March 2013 5:37 PM
To: [redacted]
Cc: [redacted]
Subject: FSS committee paper [SEC=IN-CONFIDENCE]

Yo Team,

Please find attached the draft paper SPORTS SUPPLEMENTS CONTAINING PROHIBIT SUBSTANCES for the FSS committee HERE. I look forward to your feedback as this document is just a start. I am happy for someone from incidents to take over if that is a more suitable approach going forward.

Thanks
[redacted]

[redacted]
Senior Food Scientist

55 Blackall Street, Barton, ACT 2600
PO Box 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

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IN-CONFIDENCE

AUTHORITY IN CONFIDENCE

FOOD SAFETY STRATEGIC STEERING COMMITTEE
18 March 2013

SPORTS SUPPLEMENTS CONTAINING PROHIBITED SUBSTANCES

PURPOSE

That the Strategic Steering Committee:

(a) **discuss** the Australian Customs and Border Protection Service (Customs) concerns regarding national communication messages and the development of educational material to inform consumers of the risks of drinking CRAZE.

(b) **agree** to the development of a FSANZ strategy which draws together activities being under taken in the policy development area (legislative review), enforcement activities (ISC) and communication and articulates the purpose of these activities and FSANZ's role.

1. ISSUES

- Australian government agencies and state and territory authorities are currently undertaking a number of activities in an attempt develop and implement an effective whole-of-government management and control system for products that are not clearly a food or a medicine.
- The contact from Customs highlighted the lack of awareness within and across key agencies about these activities.
- Can more be done by FSANZ to promote interagency coordination and consultation to control and manage the risks associated with consumption of these products?

2. BACKGROUND

Since 2010 FSANZ has coordinated a number of national responses, under the National Food Incident Response Protocol, to manage the supply of foods and supplements that have been adulterated with prescription medications and drugs.

The roles and responsibilities of national, state and territory regulatory authorities and enforcement agencies has been blurred and sometimes confused, inhibiting effective management and control at the border and post-border of these types of products.

Recently representatives from Customs, Stacey Ward (Manager Communication and Media – File note on discussion with Stacey 25.2.13) and Lyn Foster (Manager, Drugs & Therapeutic Substances) have contacted FSANZ expressing their concerns about the lack of a national coordinated effort to develop communication messages about the risks of consuming CRAZE (which has been tested and found to contain an analogue of DMAA and is a border controlled substance (methamphetamine) under the Criminal Code (C'wth)). Stacey and Lyn were not aware of the interagency activities currently under way. Customs currently have 30 consignments of this product on hold at the border.

3. PROPOSED APPROACH

(a) In the appropriate internal FSANZ forum development a FSANZ strategy which draws together all activities being under taken in the policy development area (legislative

review), enforcement activities (ISC) and communication and articulates the purpose of these activities and FSANZ's role (for example, a map of current activities).

(b) Establish a single log of activities to centralise information on the progress and coordination of various activities involving FSANZ.

(c) Facilitate an interagency meeting (teleconference or face-to-face) to share information on the status of work underway on the broader food:medicine interface issues.

(d) Anything else?

4. DISCUSSION POINTS

Can FSANZ contribute to the development of an interagency consultation and coordination group (government to government) to oversee the policy development, operational matters and communication of responsibilities, public health and safety issues and response to the adulteration and fraudulent behaviour of suppliers and retailers of this type of product?

Is it possible to have a national strategy to manage and control the supply and sale of these products and have a joint communication plan and educational material to inform consumers and medical professionals of the dangers of consuming these types of products?

Prepared by: FSS

Project team: N/A

Exec Sponsor: Melanie Fisher

[redacted]

From: [redacted]
Sent: Monday, 18 March 2013 1:18 PM
To: [redacted]
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi [redacted]

Interesting however consider this excerpt from an email to Melanie & Incident team (last year)

Melanie
Sorry about the delay in getting back. The advice I have been given by our pharmaceutical chemists is that phenylisobutylamine is not a derivative or a precursor of amphetamine, it cannot be used to make amphetamine and vice versa; phenylisobutylamine has some pharmacological effect however it's very reduced compare to amphetamine.
Regards
Tony
Dr Tony Gill | MBBS MPH FAFPHM AFACHSM | Acting Principal Medical Adviser | TGA Executive | Therapeutic Goods Administration | PO Box 100, WODEN ACT 2606 | [redacted]

The email from Tony Gill (TGA/chair Medicines Scheduling Committee) stands in stark contrast to the advice received by customs from the AFP (below).

NB. N,α-diethylbenzeneethanamine and phenylisobutylamine are one in the same

Cheers

[redacted]

From: [redacted]
Sent: Monday, 18 March 2013 12:22 PM
To: [redacted]
Subject: FW: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi [redacted],
As discussed – this is in the email traffic highlighted below.

'*CRAZE, as you know, contains N,α-diethylbenzeneethanamine and the AFP advised us that they consider this to be an analogue of the border controlled substance methamphetamine under the Criminal Code (C'wth). Accordingly, Customs and Border Protection have been seizing this product and transferring it to the AFP*'.

Lyn Foster
Manager | Drugs and Therapeutic Substances
Community Protection | Trade Policy and Implementation
Australian Customs and Border Protection Service

Regards,
[redacted]

[redacted]

From: FOSTER Lyn [mailto:lyn.foster@customs.gov.au]
Sent: Friday, 1 March 2013 2:15 PM
To: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi [redacted],

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I'll follow up with Marianne Tegel as suggested as well.

Regards,

Lyn Foster

Manager | Drugs and Therapeutic Substances
Community Protection | Trade Policy and Implementation

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5 Constitution Ave Canberra ACT 2601

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From: incident [mailto:incident@foodstandards.gov.au]
Sent: Thursday, 28 February 2013 2:49 PM
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Cc: incident
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In regard to recalls, FSANZ coordinates and monitors food recalls in Australia but does not enforce any recall action, conduct any testing or investigations. This is the role of the state and territory food

enforcement agencies. FSANZ have not been advised by any state or territory authority regarding coordination of any recall associated with the product Craze.

The debrief referred to by [redacted] below covers internal operations matters and would not assist with addressing your enquiry. The policy development food/drug interface work between the TGA and FSANZ is an ongoing discussion at this stage.

I hope this information provides some assistance to you.

Kind regards
[redacted]

[redacted] | **Project Officer**

Food Safety Section

55 Blackall Street, Barton, ACT 2600
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[redacted] |

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Sent: Wednesday, 27 February 2013 12:52 PM
To: 'FOSTER Lyn'
Cc: incident
Subject: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
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Hope this helps,

[redacted]

Senior Scientist
Strategic Science International and Surveillance Section
Chief Scientists Branch

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From: FOSTER Lyn [mailto:lyn.foster@customs.gov.au]
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Laura Marshall
Supervisor, IP Rights & Consumer Goods
Trade Policy & Implementation - Australian Customs and Border Protection Service

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From: [redacted]
Sent: Tuesday, 23 October 2012 12:45 PM
To: [redacted]; bill.calder@health.wa.gov.au; [redacted]; Brett Herbert; brian.jones@act.gov.au; [redacted]; bwitherspoon@safefood.qld.gov.au; craig.shadbolt@foodauthority.nsw.gov.au; [IP Rights]; DAFF Food Incidents; Darryl Bourbour; DoHa generic email; Health Ops (Health); eric.johnson@dhhs.tas.gov.au; fay.jenkins@health.sa.gov.au; fiona.jones@health.vic.gov.au; Food Incident QLD; [redacted]; Gerard.Fitzsimmons@Health.gov.au; Glen Neal (glen.neal@mpi.govt.nz); glen.martin@health.sa.gov.au; Goodchild, Stan; [redacted]; MARSHALL Laura; Leigh Nind; Lyall, Chris; Miller, Craig; NSW Food Incident; olivia.mcquestin@dhhs.tas.gov.au; Oz Food Net; paul.dowsett@sa.gov.au; Peter Merell; Rob.Solomon@daff.gov.au; Spry, Zoe; Tegel, Marianne; tenille_fort@health.qld.gov.au; [redacted]; tracy.ward@nt.gov.au; [redacted], [redacted]; Wilson, Andrew; xavier.schobben@nt.gov.au; Yvette.Dethridge@aqis.gov.au
Cc: Food Incident Group; incident
Subject: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]
Importance: High

GOVERNMENT-IN-CONFIDENCE

Dear NFIR team,

FYI – NSWFA have notified us of work they are carrying out on sports food supplements (post DMAA) and have sent through the attached information to share with you – please note this is NOT an incident notification, but has been kindly sent by NSWFA as a heads-up. Some testing is still being undertaken, however once the preliminary work is complete NSWFA have indicated they may wish to discuss with the NFIR team about the need to trigger the NFIRP.

Background
The main issue appears to be the continued innovation by the dietary sports industry in the USA reformulating products to include proprietary names of blended ingredients to confuse regulators and continue to supply poorly described ingredients in products that are not permitted and difficult to analyse for. Because of the health consequences the products have extensive health warnings on the labels due to the USA legal system. These labels are not in the form that would comply with the FSC and do not clearly disclose the levels of nutrients and other active substances per serve or per daily amount in many cases.

Once we hear anything further we will notify the NFIR team.

Kind regards

[redacted]

[redacted]
Assistant Manager Food Safety Section
Food Standards Australia New Zealand

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
[redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

A safe food supply which supports the health of people in Australia and New Zealand

UNCLASSIFIED

This email message and any attached files may be protected information under section 16 of the Customs Administration Act 1985 (CA Act) and may also contain information that is confidential, and/or subject to legal professional privilege.

The content of this email is intended only for use by the individual or entity to whom it is addressed.

If you ARE the intended recipient, and are subject to an undertaking provided under section 16 of the CA Act, you must not use or further disclose the information within this email except for the purpose for which it was provided to you or otherwise as required or authorised by law.

[redacted]

From: [redacted]
Sent: Wednesday, 24 April 2013 5:53 PM
To: [redacted]
Cc: News@health.gov.au; Media; [redacted]; May, Peter
Subject: Fwd: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

[redacted]

FYI and for action as necessary.

Sent from my iPad

Begin forwarded message:

From: <News@health.gov.au>
Date: 24 April 2013 4:58:57 PM AEST
To: [redacted]
Cc: [redacted]
Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

[redacted]

That is definitely not an official TGA statement on that bodybuilding forum.

In fact I am advised that Driven Sports Craze does not fall within the regulatory responsibilities of the TGA, and that Food Standards Australia New Zealand (FSANZ) would be a better contact point to assist.

I've cc'd [redacted] at Food Standards.

Regards,

Neil

Neil Branch
Media Adviser

Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi

I have included below an email we sent earlier this month. We are still getting the odd enquiry, so would appreciate your advice.

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

[redacted]
F: +61 (0) 2 6222 4308

E: [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: [redacted]
Sent: Monday, 8 April 2013 1:09 PM
To: 'Kay.McNiece@health.gov.au'
Cc: [redacted]
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Dear Kay

I have been asked to contact you in regards to a supplement called 'Craze' which ASADA has received a number of queries about.

A number of the queries have cited a supposed response from the TGA on a bodybuilding forum (http://www.bodybuildingforums.com.au/training-and-exercise/3464-craze-now-illegal-in-australia-4.html).

I have extracted the response and copied this below for your convenience. Before we develop our own response, we were hoping to check with you that this is in fact a bona-fide TGA response?

Any assistance would be greatly appreciated.

Yours sincerely

[redacted]

TGA

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The TGA are responsible for the regulation of medicines which are typically products in capsule and tablet format that make therapeutic claims on the label.

[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

[redacted]
Fax: +61 (0) 2 9763 0373
[redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

[redacted]

From: [redacted]
Sent: Friday, 26 April 2013 2:47 PM
To: 'News@health.gov.au'; [redacted]'
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

No worries Neil.

[redacted]– I will give you a call to discuss.

[redacted]
Public Affairs Officer

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
[redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

A safe food supply which supports the health of people in Australia and New Zealand

From: Neil.Branch@health.gov.au [mailto:Neil.Branch@health.gov.au] **On Behalf Of** News@health.gov.au
Sent: Friday, 26 April 2013 2:45 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

No [redacted], I thought they would contact you direct.

[redacted] can you please deal direct with [redacted] and cc me into any suggested lines. Thanks.

Regards,

Neil Branch
Media Adviser

Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]
To: <News@health.gov.au>,

Date: 26/04/2013 14:38
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi Neil

Did you hear back from FSANZ?

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

T: [redacted]
F: +61 (0) 2 6222 4308

E: [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: Neil.Branch@health.gov.au [mailto:Neil.Branch@health.gov.au] **On Behalf Of** News@health.gov.au
Sent: Wednesday, 24 April 2013 5:04 PM
To: [redacted]
Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

I just got Lorraine's out of office email - am now forwarding this to Saffron.

Neil

_____
Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: News/Health
To: [redacted]
Cc: [redacted]
Date: 24/04/2013 16:58
Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]
Sent by: Neil Branch

[redacted],

That is definitely not an official TGA statement on that bodybuilding forum.

In fact I am advised that Driven Sports Craze does not fall within the regulatory responsibilities of the TGA, and that Food Standards Australia New Zealand (FSANZ) would be a better contact point to assist.

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Neil Branch
Media Adviser

_____
Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]>
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi

I have included below an email we sent earlier this month. We are still getting the odd enquiry, so would appreciate your advice.

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

T: [redacted]
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E: [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

Note to media: Unless otherwise agreed, the information contained in this email is for background and is not for attr bution.

From: [redacted]
Sent: Monday, 8 April 2013 1:09 PM
To: 'Kay.McNiece@health.gov.au'
Cc: [redacted]
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Dear Kay

I have been asked to contact you in regards to a supplement called 'Craze' which ASADA has received a number of queries

about.

A number of the queries have cited a supposed response from the TGA on a bodybuilding forum (http://www.bodybuildingforums.com.au/training-and-exercise/3464-craze-now-illegal-in-australia-4.html).

I have extracted the response and copied this below for your convenience. Before we develop our own response, we were hoping to check with you that this is in fact a bona-fide TGA response?

Any assistance would be greatly appreciated.

Yours sincerely

[redacted]

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As a result, the importation of Driven Sports Craze into Australia would see the product seized by Customs officials due the presence of this prohibited import ingredient present in the formulation.

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Businesses or persons supplying Driven Sports Craze within Australia are liable to action from the relevant Food Authority Enforcement Branch in each State as Driven Sports Craze is a powder product that you add water to before consuming. These types of products are generally considered to be foods.

The TGA are responsible for the regulation of medicines which are typically products in capsule and tablet format that make therapeutic claims on the label.

_____
[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

****

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

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[redacted]

From: [redacted]
Sent: Friday, 26 April 2013 4:25 PM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]
Can you check with [redacted] too please re [redacted] request.
Regards
[redacted]

sent from my Telstra NEXTG™ handset

From: Media <Media@foodstandards.gov.au>
Sent: Friday, 26 April 2013 3:37 PM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

I just spoke to [redacted] from ASADA about this email. He wants to check with us whether we issued the response which was copied onto the body building forum (also copied below).

I told him that we definitely haven't issued any public statement but that I would check to see whether we had responded to any enquiries about craze.

He simply wants to know whether the below words have come from us (as the TGA said it wasn't them). I know, it's probably highly unlikely but just need to confirm.

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Thanks

[redacted]
Public Affairs Officer

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

A safe food supply which supports the health of people in Australia and New Zealand

From: [redacted]
Sent: Wednesday, 24 April 2013 5:53 PM
To: [redacted]
Cc: News@health.gov.au; Media; [redacted]; May, Peter
Subject: Fwd: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

[redacted]

FYI and for action as necessary.

Sent from my iPad

Begin forwarded message:

> **From:** <News@health.gov.au>
> **Date:** 24 April 2013 4:58:57 PM AEST
> **To:** [redacted]
> **Cc:** [redacted]
> **Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]**
>
> [redacted]
>
> That is definitely not an official TGA statement on that bodybuilding forum.
>
> In fact I am advised that Driven Sports Craze does not fall within the regulatory responsibilities of the TGA, and that Food Standards Australia New Zealand (FSANZ) would be a better contact point to assist.
>
> I've cc'd [redacted] at Food Standards.
>
> Regards,
>
> Neil
>
> Neil Branch
> Media Adviser
>
> Media Unit
> Australian Government Department of Health and Ageing
> Media enquiries: 02 6289 7400

Email: news@health.gov.au

From: [redacted]
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi

I have included below an email we sent earlier this month. We are still getting the odd enquiry, so would appreciate your advice.

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

T: [redacted]
F: +61 (0) 2 6222 4308

E: [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: [redacted]
Sent: Monday, 8 April 2013 1:09 PM
To: 'Kay.McNiece@health.gov.au'
Cc: [redacted]
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Dear Kay

I have been asked to contact you in regards to a supplement called 'Craze' which ASADA has received a number of queries about.

A number of the queries have cited a supposed response from the TGA on a bodybuilding forum (http://www.bodybuildingforums.com.au/training-and-exercise/3464-craze-now-illegal-in-australia-4.html).

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[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

[redacted]

From: [redacted]
Sent: Friday, 26 April 2013 4:51 PM
To: [redacted]
Cc:
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [DLM=For-Official-Use-Only]
Attachments: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]; FOR INFORMATION- Sports Supplements/Craze- actions undertaken by NSW Food Authority [DLM=For-Official-Use-Only]; Attachment 1 - Draft Post Incident Log 01082012.docx

Hi [redacted],

The only enquiry incident have responded to was from Customs in February but we merely outlined the status of the DMAA incident and suggested they speak to NSW Food Authority as a food enforcement agency. Attachment 1 is the email I sent to Customs and the other attachments were previously provided to them so I don't believe the response below on the blog site was from the incident team.

Wendy left for the day a short while ago so I am unable to ask [redacted] if she provided any response to any other enquiry but will follow up with her on Monday for you if that is ok?

Regards
[redacted]

From: Media <Media@foodstandards.gov.au>
Sent: Friday, 26 April 2013 3:37 PM
To: [redacted]>
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

I just spoke to [redacted] from ASADA about this email. He wants to check with us whether we issued the response which was copied onto the body building forum (also copied below).

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[redacted]
Public Affairs Officer

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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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---

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Cc: News@health.gov.au; Media; [redacted]; May, Peter
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[redacted]

FYI and for action as necessary.

Sent from my iPad

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> **Date:** 24 April 2013 4:58:57 PM AEST
> **To:** [redacted]
> **Cc:** [redacted]>
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Neil

Neil Branch
Media Adviser

_____
Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]>
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

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Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

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PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

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[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

[Draft]

Post Incident Activity Log	
Incident Name and Number:	**2012-01: Sports supplements containing DMAA and other prohibited substances**
Stand-down date:	**16 July 2012**
Date of Log update:	**01 August 2012**
Agencies engaged in post incident activities: ☐ NSW ☐ VIC ☐ WA ☐ QLD ☐ SA ☐ TAS ☐ ACT ☐ NT ☐ AQIS ☐ Customs ☒ TGA ☐ OzFoodNet ☒ FSANZ	

Action	Agency Responsible	Timeframe	Status / Comments
Final decision released for DMAA to be scheduled under Appendix C	TGA	1 August 2012	**TGA DMAA final scheduling decision 1 August 2012** Published 1 August 2012
Liaise with DoHA with regards to a communications media release on the 1st of August if the decision to make DMAA a scheduled substance is made.	FSANZ	For release once the scheduling decision is made	1 August 2012 media release finalized and posted on the FSANZ website. Additionally circulated to all Agency Food Incident Controllers on 1 August 2012.
Provide test results from product tested in QLD	Queensland Health/FSANZ	ASAP	Circulated with Situation report 6/final
ISC food/medicine interface paper to be drafted by FSANZ	FSANZ	For their next teleconference (estimate to be in August)	Ongoing

[redacted]

From: [redacted]
Sent: Friday, 26 April 2013 4:52 PM
To: [redacted]
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [DLM=For-Official-Use-Only]

Thanks [redacted] – no worries, Monday is fine.

Have a good weekend.

[redacted]
Public Affairs Officer

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

A safe food supply which supports the health of people in Australia and New Zealand

---

From: [redacted]
Sent: Friday, 26 April 2013 4:51 PM
To: [redacted]
Cc: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [DLM=For-Official-Use-Only]

Hi [redacted],

The only enquiry incident have responded to was from Customs in February but we merely outlined the status of the DMAA incident and suggested they speak to NSW Food Authority as a food enforcement agency. Attachment 1 is the email I sent to Customs and the other attachments were previously provided to them so I don't believe the response below on the blog site was from the incident team.

Wendy left for the day a short while ago so I am unable to ask [redacted] if she provided any response to any other enquiry but will follow up with her on Monday for you if that is ok?

Regards
[redacted]

From: Media <Media@foodstandards.gov.au>
Sent: Friday, 26 April 2013 3:37 PM
To: [redacted]>
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

I just spoke to [redacted] from ASADA about this email. He wants to check with us whether we issued the response which was copied onto the body building forum (also copied below).

I told him that we definitely haven't issued any public statement but that I would check to see whether we had responded to any enquiries about craze.

He simply wants to know whether the below words have come from us (as the TGA said it wasn't them). I know, it's probably highly unlikely but just need to confirm.

TGA

The product Driven Sports Craze was recently tested by the National Measurement Institute (NMI) on behalf of the Australian Sports Anti-Doping Authority (ASADA).

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Methamphetamine contains the stereoisomer Levomethamphetamine which is a prohibited import substance under Customs legislation.

As a result, the importation of Driven Sports Craze into Australia would see the product seized by Customs officials due the presence of this prohibited import ingredient present in the formulation.

As a result, the importation of Driven Sports Craze into Australia is a Customs matter.

Businesses or persons supplying Driven Sports Craze within Australia are liable to action from the relevant Food Authority Enforcement Branch in each State as Driven Sports Craze is a powder product that you add water to before consuming. These types of products are generally considered to be foods.

The TGA are responsible for the regulation of medicines which are typically products in capsule and tablet format that make therapeutic claims on the label.

Thanks

[redacted]
Public Affairs Officer

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From: [redacted]
Sent: Wednesday, 24 April 2013 5:53 PM
To: [redacted]
Cc: News@health.gov.au; Media; [redacted]; May, Peter
Subject: Fwd: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

[redacted]

FYI and for action as necessary.

Sent from my iPad

Begin forwarded message:

From: <News@health.gov.au>
Date: 24 April 2013 4:58:57 PM AEST
To: [redacted]>
Cc: [redacted]>
Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

[redacted]

That is definitely not an official TGA statement on that bodybuilding forum.

In fact I am advised that Driven Sports Craze does not fall within the regulatory responsibilities of the TGA, and that Food Standards Australia New Zealand (FSANZ) would be a better contact point to assist.

I've cc'd [redacted] at Food Standards.

Regards,

Neil

Neil Branch
Media Adviser

Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi

I have included below an email we sent earlier this month. We are still getting the odd enquiry, so would appreciate your advice.

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

T: [redacted]
F: +61 (0) 2 6222 4308

E: [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: [redacted]
Sent: Monday, 8 April 2013 1:09 PM
To: 'Kay.McNiece@health.gov.au'
Cc: [redacted]
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Dear Kay

I have been asked to contact you in regards to a supplement called 'Craze' which ASADA has received a number of queries about.

A number of the queries have cited a supposed response from the TGA on a bodybuilding forum (http://www.bodybuildingforums.com.au/training-and-exercise/3464-craze-now-illegal-in-australia-4.html).

I have extracted the response and copied this below for your convenience. Before we develop our own response, we were hoping to check with you that this is in fact a bona-fide TGA response?

Any assistance would be greatly appreciated.

Yours sincerely

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[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

****

IMPORTANT

The information contained in this e-mail message and any attached files may be confidential information and may also be the subject of legal professional privilege. It remains the property of the Australian Sports Anti-Doping Authority (ASADA). If you are not the intended recipient,
any use, disclosure, retransmission or copying of this e-mail is unauthorised. If you have received this e-mail in error, you are requested to notify the sender immediately
by reply e-mail and delete the original e-mail together with any attachments.

****

[redacted]

From: [redacted]
Sent: Friday, 26 April 2013 4:54 PM
To: [redacted]
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

As discussed earlier, I'm checking with others here about this and whether this may have come from us. At this stage it's looking highly unlikely but I will confirm for you on Monday when a staff member is back in the office.

Cheers

[redacted]
Public Affairs Officer

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
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A safe food supply which supports the health of people in Australia and New Zealand

From: Neil.Branch@health.gov.au [mailto:Neil.Branch@health.gov.au] **On Behalf Of** News@health.gov.au
Sent: Friday, 26 April 2013 2:45 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

No [redacted], I thought they would contact you direct.

[redacted] can you please deal direct with [redacted] and cc me into any suggested lines. Thanks.

Regards,

Neil Branch
Media Adviser

Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]
To: <News@health.gov.au>,
Date: 26/04/2013 14:38
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi Neil

Did you hear back from FSANZ?

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

T: [redacted]
F: +61 (0) 2 6222 4308

E: [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: Neil.Branch@health.gov.au [mailto:Neil.Branch@health.gov.au] **On Behalf Of** News@health.gov.au
Sent: Wednesday, 24 April 2013 5:04 PM
To: [redacted]
Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

I just got [redacted] out of office email - am now forwarding this to [redacted].

Neil

_____
Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: News/Health
To: [redacted]>,
Cc: [redacted]
Date: 24/04/2013 16:58
Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]
Sent by: Neil Branch

[redacted],

That is definitely not an official TGA statement on that bodybuilding forum.

In fact I am advised that Driven Sports Craze does not fall within the regulatory responsibilities of the TGA, and that Food Standards Australia New Zealand (FSANZ) would be a better contact point to assist.

I've cc'd [redacted] at Food Standards.

Regards,

Neil

Neil Branch
Media Adviser

_____
Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]>
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi

I have included below an email we sent earlier this month. We are still getting the odd enquiry, so would appreciate your advice.

Regards
[redacted]

[redacted]

Communication and Media Manager
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F: +61 (0) 2 6222 4308

E [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: [redacted]
Sent: Monday, 8 April 2013 1:09 PM
To: 'Kay.McNiece@health.gov.au'
Cc: [redacted]
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Dear Kay

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I have extracted the response and copied this below for your convenience. Before we develop our own response, we were hoping to check with you that this is in fact a bona-fide TGA response?

Any assistance would be greatly appreciated.

Yours sincerely

[redacted]

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[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

****

IMPORTANT

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

[redacted]

From: [redacted]
Sent: Monday, 29 April 2013 9:25 AM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]
Attachments: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi [redacted],

Are you aware of any other responses being made to any enquiries regarding 'Craze' other than the response we provided Customs (attached)?

Regards
[redacted]

From: [redacted]
Sent: Friday, 26 April 2013 4:25 PM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]
Can you check with [redacted] too please re [redacted] request.
Regards
[redacted]

sent from my Telstra NEXTG™ handset

From: Media <Media@foodstandards.gov.au>
Sent: Friday, 26 April 2013 3:37 PM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

I just spoke to [redacted] from ASADA about this email. He wants to check with us whether we issued the response which was copied onto the body building forum (also copied below).

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From: [redacted]
Sent: Wednesday, 24 April 2013 5:53 PM
To: [redacted]
Cc: News@health.gov.au; Media; [redacted]; May, Peter
Subject: Fwd: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

[redacted]

FYI and for action as necessary.

Sent from my iPad

Begin forwarded message:

> **From:** <News@health.gov.au>
> **Date:** 24 April 2013 4:58:57 PM AEST
> **To:** [redacted]>
> **Cc:** [redacted]>
> **Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]**
>
> [redacted],
>
> That is definitely not an official TGA statement on that bodybuilding forum.
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> In fact I am advised that Driven Sports Craze does not fall within the regulatory responsibilities of the TGA, and that Food Standards Australia New Zealand (FSANZ) would be a better contact point to

assist.

I've cc'd [redacted] at Food Standards.

Regards,

Neil

Neil Branch
Media Adviser

_____
Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi

I have included below an email we sent earlier this month. We are still getting the odd enquiry, so would appreciate your advice.

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

T: [redacted]
F: +61 (0) 2 6222 4308

E: [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

Note to media: Unless otherwise agreed, the information contained in this email is for background and is not for attr bution.

From: [redacted]
Sent: Monday, 8 April 2013 1:09 PM
To: 'Kay.McNiece@health.gov.au'
Cc: [redacted]
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Dear Kay

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[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

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[redacted]

From: [redacted]
Sent: Monday, 29 April 2013 10:42 AM
To: [redacted]
Cc: [redacted]; incident
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]
Attachments: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi [redacted],
The discussion thread on the site starts with a blogger stating that they got the information from the TGA (interesting). Below is a link to the discussion I had with Customs and I have included Stacey's contact details if you want to ask her if they have an official statement on the product.

F:\FSANZ Common\Emerging Food Safety Issues\Ongoing issues\multiple year issues\CRAZE – file note

Stacey Ward | Manager Communication and Media
Australian Customs and Border Protection Service
P: 02 6275 6065 | M: 0401 044 310
E: stacey.ward@customs.gov.au
W: www.customs.gov.au

If FSANZ has not provided comment then only other agencies that may have provided this type of insight are Customs, the Federal Police or NSW FA. Stacey has spoken to the Feds communications area on this matter (see in file note).

Here is another website on the issue - http://patrickarnoldblog.com/craziness-over-craze/

Sorry I have on other information I can contribute.

Regards,
[redacted]

UNCLASSIFIED

From: [redacted]
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Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

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[redacted]
Public Affairs Officer

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[redacted]

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Sent from my iPad

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> **From:** <News@health.gov.au>
> **Date:** 24 April 2013 4:58:57 PM AEST
> **To:** [redacted]>
> **Cc:** "[redacted]>
> **Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]**
>
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>
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>
> I've cc'd [redacted] at Food Standards.
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> Regards,
>
> Neil
>
> Neil Branch
> Media Adviser
>
> _____
> Media Unit
> Australian Government Department of Health and Ageing
> Media enquiries: 02 6289 7400
> Email: news@health.gov.au

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[redacted]

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The TGA are responsible for the regulation of medicines which are typically products in capsule and tablet format that make therapeutic claims on the label.

[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

[redacted]

From: [redacted]
Sent: Monday, 29 April 2013 12:11 PM
To: [redacted]
Cc: [redacted]; incident
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Thanks [redacted].

Yep very interesting indeed.

I'll let ASADA know that it wasn't us and suggest he contacts the agencies you mention below.

[redacted]
Public Affairs Officer

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

FOOD STANDARDS Australia New Zealand
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---

From: [redacted]
Sent: Monday, 29 April 2013 10:42 AM
To: [redacted]
Cc: [redacted]; incident
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted],
The discussion thread on the site starts with a blogger stating that they got the information from the TGA (interesting). Below is a link to the discussion I had with Customs and I have included Stacey's contact details if you want to ask her if they have an official statement on the product.

F:\FSANZ Common\Emerging Food Safety Issues\Ongoing issues\multiple year issues\CRAZE – file note

Stacey Ward | Manager Communication and Media
Australian Customs and Border Protection Service
P: 02 6275 6065 | M: 0401 044 310
E: stacey.ward@customs.gov.au
W: www.customs.gov.au

If FSANZ has not provided comment then only other agencies that may have provided this type of insight are Customs, the Federal Police or NSW FA. Stacey has spoken to the Feds communications area on this matter (see in file note).

Here is another website on the issue - http://patrickarnoldblog.com/craziness-over-craze/

Sorry I have on other information I can contribute.

Regards,
[redacted]

UNCLASSIFIED

From: [redacted]
Sent: Monday, 29 April 2013 9:25 AM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

Are you aware of any other responses being made to any enquiries regarding 'Craze' other than the response we provided Customs (attached)?

Regards
[redacted]

From: [redacted]
Sent: Friday, 26 April 2013 4:25 PM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]
Can you check with [redacted] too please re [redacted] request.
Regards
[redacted]

sent from my Telstra NEXTG™ handset

From: Media <Media@foodstandards.gov.au>
Sent: Friday, 26 April 2013 3:37 PM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

I just spoke to [redacted] from ASADA about this email. He wants to check with us whether we issued the response which was copied onto the body building forum (also copied below).

I told him that we definitely haven't issued any public statement but that I would check to see whether we had responded to any enquiries about craze.

He simply wants to know whether the below words have come from us (as the TGA said it wasn't them). I know, it's probably highly unlikely but just need to confirm.

TGA

The product Driven Sports Craze was recently tested by the National Measurement Institute (NMI) on behalf of the

Australian Sports Anti-Doping Authority (ASADA).

The results indicated that Driven Sports Craze was found to contain Alpha-Diethyl-Benzeneethamine which is a synonym for Methamphetamine.

Methamphetamine contains the stereoisomer Levomethamphetamine which is a prohibited import substance under Customs legislation.

As a result, the importation of Driven Sports Craze into Australia would see the product seized by Customs officials due the presence of this prohibited import ingredient present in the formulation.

As a result, the importation of Driven Sports Craze into Australia is a Customs matter.

Businesses or persons supplying Driven Sports Craze within Australia are liable to action from the relevant Food Authority Enforcement Branch in each State as Driven Sports Craze is a powder product that you add water to before consuming. These types of products are generally considered to be foods.

The TGA are responsible for the regulation of medicines which are typically products in capsule and tablet format that make therapeutic claims on the label.

Thanks

[redacted]
Public Affairs Officer

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

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---

From: [redacted]
Sent: Wednesday, 24 April 2013 5:53 PM
To: [redacted]
Cc: News@health.gov.au; Media; [redacted]; May, Peter
Subject: Fwd: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

[redacted]

FYI and for action as necessary.

Sent from my iPad

Begin forwarded message:

> **From:** <News@health.gov.au>
> **Date:** 24 April 2013 4:58:57 PM AEST
> **To:** [redacted]>
> **Cc:** "[redacted]>
> **Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]**

[redacted],

That is definitely not an official TGA statement on that bodybuilding forum.

In fact I am advised that Driven Sports Craze does not fall within the regulatory responsibilities of the TGA, and that Food Standards Australia New Zealand (FSANZ) would be a better contact point to assist.

I've cc'd [redacted] at Food Standards.

Regards,

Neil

Neil Branch
Media Adviser

_____
Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]>
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi

I have included below an email we sent earlier this month. We are still getting the odd enquiry, so would appreciate your advice.

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

T: [redacted]
F: +61 (0) 2 6222 4308

E: [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: [redacted]
Sent: Monday, 8 April 2013 1:09 PM
To: 'Kay.McNiece@health.gov.au'
Cc: [redacted]

Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Dear Kay

I have been asked to contact you in regards to a supplement called 'Craze' which ASADA has received a number of queries about.

A number of the queries have cited a supposed response from the TGA on a bodybuilding forum (http://www.bodybuildingforums.com.au/training-and-exercise/3464-craze-now-illegal-in-australia-4.html).

I have extracted the response and copied this below for your convenience. Before we develop our own response, we were hoping to check with you that this is in fact a bona-fide TGA response?

Any assistance would be greatly appreciated.

Yours sincerely

[redacted]

TGA

The product Driven Sports Craze was recently tested by the National Measurement Institute (NMI) on behalf of the Australian Sports Anti-Doping Authority (ASADA).

The results indicated that Driven Sports Craze was found to contain Alpha-Diethyl-Benzeneethamine which is a synonym for Methamphetamine.

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[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

****

[redacted]

From: [redacted]
Sent: Monday, 29 April 2013 12:21 PM
To: [redacted]
Cc: 'news@health.gov.au'
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

Just to confirm that FSANZ did not issue that response/statement on that forum.

The only other agencies that may have provided this type of insight are Customs, the Federal Police or NSW Food Authority.

I hope that helps.

[redacted]
Public Affairs Officer

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

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---

From: [redacted]
Sent: Friday, 26 April 2013 4:54 PM
To: [redacted]
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

As discussed earlier, I'm checking with others here about this and whether this may have come from us. At this stage it's looking highly unlikely but I will confirm for you on Monday when a staff member is back in the office.

Cheers

[redacted]
Public Affairs Officer

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

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From: Neil.Branch@health.gov.au [mailto:Neil.Branch@health.gov.au] **On Behalf Of** News@health.gov.au
Sent: Friday, 26 April 2013 2:45 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

No [redacted], I thought they would contact you direct.

[redacted] can you please deal direct with [redacted] and cc me into any suggested lines. Thanks.

Regards,

Neil Branch
Media Adviser

_____
Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]>
To: <News@health.gov.au>,
Date: 26/04/2013 14:38
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi Neil

Did you hear back from FSANZ?

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

T: [redacted]
F: +61 (0) 2 6222 4308

E [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: Neil.Branch@health.gov.au [mailto:Neil.Branch@health.gov.au] **On Behalf Of** News@health.gov.au
Sent: Wednesday, 24 April 2013 5:04 PM
To: [redacted]
Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

I just got [redacted] out of office email - am now forwarding this to [redacted].

Neil

Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: News/Health
To: [redacted]
Cc: [redacted]>
Date: 24/04/2013 16:58
Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]
Sent by: Neil Branch

[redacted],

That is definitely not an official TGA statement on that bodybuilding forum.

In fact I am advised that Driven Sports Craze does not fall within the regulatory responsibilities of the TGA, and that Food Standards Australia New Zealand (FSANZ) would be a better contact point to assist.

I've cc'd [redacted] at Food Standards.

Regards,

Neil

Neil Branch
Media Adviser

Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]>
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi

I have included below an email we sent earlier this month. We are still getting the odd enquiry, so would appreciate your advice.

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

T: [redacted]
F: +61 (0) 2 6222 4308

E: [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: [redacted]
Sent: Monday, 8 April 2013 1:09 PM
To: 'Kay.McNiece@health.gov.au'
Cc: [redacted]
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Dear Kay

I have been asked to contact you in regards to a supplement called 'Craze' which ASADA has received a number of queries about.

A number of the queries have cited a supposed response from the TGA on a bodybuilding forum (http://www.bodybuildingforums.com.au/training-and-exercise/3464-craze-now-illegal-in-australia-4.html).

I have extracted the response and copied this below for your convenience. Before we develop our own response, we were hoping to check with you that this is in fact a bona-fide TGA response?

Any assistance would be greatly appreciated.

Yours sincerely

[redacted]

TGA

The product Driven Sports Craze was recently tested by the National Measurement Institute (NMI) on behalf of the Australian Sports Anti-Doping Authority (ASADA).

The results indicated that Driven Sports Craze was found to contain Alpha-Diethyl-Benzeneethamine which is a synonym for

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Methamphetamine contains the stereoisomer Levomethamphetamine which is a prohibited import substance under Customs legislation.

As a result, the importation of Driven Sports Craze into Australia would see the product seized by Customs officials due the presence of this prohibited import ingredient present in the formulation.

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[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

[redacted]

From: [redacted]
Sent: Tuesday, 30 April 2013 4:55 PM
To: [redacted]; May, Peter
Cc: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]
Attachments: RE: Head up - Sports Food Supplements [SEC=UNCLASSIFIED]

Hi [redacted]
I also found my file note F:\FSANZ Common\Emerging Food Safety Issues\Ongoing issues\multiple year issues\CRAZE – file note (it was in the text of the first email) and another email from Lyn Foster (Customs) attached –
Thanks. I read the consumer advice form the links that Barbara sent, however, I was wondering whether there would be a different advice for CRAZE in particular as it contains a methamphetamine analog rather than DMAA. We are not able to control DMAA at the border when presented in a food type supplement as the DMAA itself is not subject to either Customs Regulations or the Criminal Code. CRAZE is different – due to the analog, we are able to seize it under our regulations and pass it to the AFP for action under the Criminal Code.

Regards,
[redacted]

UNCLASSIFIED

From: [redacted]
Sent: Monday, 29 April 2013 10:42 AM
To: [redacted]
Cc: [redacted]; incident
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]
The discussion thread on the site starts with a blogger stating that they got the information from the TGA (interesting). Below is a link to the discussion I had with Customs and I have included Stacey's contact details if you want to ask her if they have an official statement on the product.

F:\FSANZ Common\Emerging Food Safety Issues\Ongoing issues\multiple year issues\CRAZE – file note

Stacey Ward | Manager Communication and Media
Australian Customs and Border Protection Service
P: 02 6275 6065 | M: 0401 044 310
E: stacey.ward@customs.gov.au
W: www.customs.gov.au

If FSANZ has not provided comment then only other agencies that may have provided this type of insight are Customs, the Federal Police or NSW FA. Stacey has spoken to the Feds communications area on this matter (see in file note).

Here is another website on the issue - http://patrickarnoldblog.com/craziness-over-craze/

Sorry I have on other information I can contribute.

Regards,
[redacted]

UNCLASSIFIED

From: [redacted]
Sent: Monday, 29 April 2013 9:25 AM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

Are you aware of any other responses being made to any enquiries regarding 'Craze' other than the response we provided Customs (attached)?

Regards
[redacted]

From: [redacted]
Sent: Friday, 26 April 2013 4:25 PM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]
Can you check with [redacted] too please re [redacted] request.
Regards
[redacted]

sent from my Telstra NEXTG™ handset

From: Media <Media@foodstandards.gov.au>
Sent: Friday, 26 April 2013 3:37 PM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

I just spoke to [redacted] from ASADA about this email. He wants to check with us whether we issued the response which was copied onto the body building forum (also copied below).

I told him that we definitely haven't issued any public statement but that I would check to see whether we had responded to any enquiries about craze.

He simply wants to know whether the below words have come from us (as the TGA said it wasn't them). I know, it's probably highly unlikely but just need to confirm.

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Thanks

[redacted]
Public Affairs Officer

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
[redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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---

From: [redacted]
Sent: Wednesday, 24 April 2013 5:53 PM
To: [redacted]
Cc: News@health.gov.au; Media; [redacted]; May, Peter
Subject: Fwd: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

[redacted]

FYI and for action as necessary.

Sent from my iPad

Begin forwarded message:

> **From:** <News@health.gov.au>
> **Date:** 24 April 2013 4:58:57 PM AEST
> **To:** [redacted]>
> **Cc:** [redacted]
> **Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]**
>
> [redacted],

That is definitely not an official TGA statement on that bodybuilding forum.

In fact I am advised that Driven Sports Craze does not fall within the regulatory responsibilities of the TGA, and that Food Standards Australia New Zealand (FSANZ) would be a better contact point to assist.

I've cc'd [redacted] at Food Standards.

Regards,

Neil

Neil Branch
Media Adviser

_____
Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi

I have included below an email we sent earlier this month. We are still getting the odd enquiry, so would appreciate your advice.

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

[redacted]
F: +61 (0) 2 6222 4308

[redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: [redacted]
Sent: Monday, 8 April 2013 1:09 PM
To: 'Kay.McNiece@health.gov.au'
Cc: [redacted]
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Dear Kay

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I have extracted the response and copied this below for your convenience. Before we develop our own response, we were hoping to check with you that this is in fact a bona-fide TGA response?

Any assistance would be greatly appreciated.

Yours sincerely

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[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

[redacted]
Fax: +61 (0) 2 9763 0373
[redacted]

[redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

[redacted]

From: [redacted]
Sent: Wednesday, 1 May 2013 9:46 AM
To: [redacted]; May, Peter; [redacted]
Cc: [redacted]
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted], no – I have no further insight into where that information came from.

[redacted]
Acting Communication Manager

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

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---

From: [redacted]
Sent: Tuesday, 30 April 2013 4:31 PM
To: May, Peter; [redacted]
Cc: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]
Below and attached is some corro on the topic. In the email traffic attached there is an email from Lyn Foster where she provides some detail - *CRAZE, as you know, contains N,α-diethylbenzeneethanamine and the AFP advised us that they consider this to be an analogue of the border controlled substance methamphetamine under the Criminal Code (C'wth). Accordingly, Customs and Border Protection have been seizing this product and transferring it to the AFP.*

It is obvious that the Feds and Customs have been working together on this matter.

However I am not sure if there is a link but DMAA has been subject to a FSANZ coordinated national food incident response. The details are here - F:\FSANZ Common\Incident Response\Incidents 2012\2012 - 01 Sports supplements containing DMAA and other prohibited substances
The scheduling for DMAA is here - http://www.tga.gov.au/industry/scheduling-decisions-1207-interim.htm

Schedule 9 - New entry
1,3-dimethylamylamine
SUSMP Index - New cross-reference entries
DMAA
See 1,3-dimethylamylamine
4-methylhexane-2-amine
See 1,3-dimethylamylamine

I have copied [redacted] in on this email as they may have other details I am not aware of, such as the working group on the food:medicine interface. Also I am not sure if [redacted] tracked down the 'information source' of concern below.

I hope this information is of assistance.

Regards,
[redacted]
(I am on leave from today and will be back in the office on Monday 13 May)

[redacted]
Senior Food Scientist

55 Blackall Street, Barton, ACT 2600
PO Box 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

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UNCLASSIFIED

From: [redacted]
Sent: Monday, 29 April 2013 10:42 AM
To: [redacted]
Cc: [redacted]; incident
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted],
The discussion thread on the site starts with a blogger stating that they got the information from the TGA (interesting). Below is a link to the discussion I had with Customs and I have included Stacey's contact details if you want to ask her if they have an official statement on the product.

F:\FSANZ Common\Emerging Food Safety Issues\Ongoing issues\multiple year issues\CRAZE – file note

Stacey Ward | Manager Communication and Media
Australian Customs and Border Protection Service
P: 02 6275 6065 | M: 0401 044 310
E: stacey.ward@customs.gov.au
W: www.customs.gov.au

If FSANZ has not provided comment then only other agencies that may have provided this type of insight are Customs, the Federal Police or NSW FA. Stacey has spoken to the Feds communications area on this matter (see in file note).

Here is another website on the issue - http://patrickarnoldblog.com/craziness-over-craze/

Sorry I have on other information I can contribute.

Regards,
[redacted]

UNCLASSIFIED

From: [redacted]
Sent: Monday, 29 April 2013 9:25 AM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted],

Are you aware of any other responses being made to any enquiries regarding 'Craze' other than the response we provided Customs (attached)?

Regards
[redacted]

From: [redacted]
Sent: Friday, 26 April 2013 4:25 PM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]
Can you check with [redacted] too please re [redacted] request.
Regards
[redacted]

sent from my Telstra NEXTG™ handset

From: Media <Media@foodstandards.gov.au>
Sent: Friday, 26 April 2013 3:37 PM
To: [redacted]>
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]

I just spoke to [redacted] from ASADA about this email. He wants to check with us whether we issued the response which was copied onto the body building forum (also copied below).

I told him that we definitely haven't issued any public statement but that I would check to see whether we had responded to any enquiries about craze.

He simply wants to know whether the below words have come from us (as the TGA said it wasn't them). I know, it's probably highly unlikely but just need to confirm.

TGA

The product Driven Sports Craze was recently tested by the National Measurement Institute (NMI) on behalf of the Australian Sports Anti-Doping Authority (ASADA).

The results indicated that Driven Sports Craze was found to contain Alpha-Diethyl-Benzeneethamine which is a synonym for Methamphetamine.

Methamphetamine contains the stereoisomer Levomethamphetamine which is a prohibited import substance under Customs legislation.

As a result, the importation of Driven Sports Craze into Australia would see the product seized by Customs officials due the presence of this prohibited import ingredient present in the formulation.

As a result, the importation of Driven Sports Craze into Australia is a Customs matter.

Businesses or persons supplying Driven Sports Craze within Australia are liable to action from the relevant Food Authority Enforcement Branch in each State as Driven Sports Craze is a powder product that you add water to before consuming. These types of products are generally considered to be foods.

The TGA are responsible for the regulation of medicines which are typically products in capsule and tablet format that make therapeutic claims on the label.

Thanks

[redacted]
Public Affairs Officer

55 Blackall Street, Barton, ACT 2600
PO BOX 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

A safe food supply which supports the health of people in Australia and New Zealand

---

From: [redacted]
Sent: Wednesday, 24 April 2013 5:53 PM
To: [redacted]
Cc: News@health.gov.au; Media; [redacted]; May, Peter
Subject: Fwd: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

[redacted]

FYI and for action as necessary.

Sent from my iPad

Begin forwarded message:

> **From:** <News@health.gov.au>
> **Date:** 24 April 2013 4:58:57 PM AEST
> **To:** [redacted]>
> **Cc:** [redacted]
> **Subject: Re: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]**

[redacted],

That is definitely not an official TGA statement on that bodybuilding forum.

In fact I am advised that Driven Sports Craze does not fall within the regulatory responsibilities of the TGA, and that Food Standards Australia New Zealand (FSANZ) would be a better contact point to assist.

I've cc'd [redacted] at Food Standards.

Regards,

Neil

Neil Branch
Media Adviser

_____
Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]
To: <news@health.gov.au>,
Date: 24/04/2013 14:58
Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi

I have included below an email we sent earlier this month. We are still getting the odd enquiry, so would appreciate your advice.

Regards
[redacted]

[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

T: [redacted]
F: +61 (0) 2 6222 4308

E: [redacted]
W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

From: [redacted]
Sent: Monday, 8 April 2013 1:09 PM
To: 'Kay.McNiece@health.gov.au'
Cc: [redacted]

Subject: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Dear Kay

I have been asked to contact you in regards to a supplement called 'Craze' which ASADA has received a number of queries about.

A number of the queries have cited a supposed response from the TGA on a bodybuilding forum (http://www.bodybuildingforums.com.au/training-and-exercise/3464-craze-now-illegal-in-australia-4.html).

I have extracted the response and copied this below for your convenience. Before we develop our own response, we were hoping to check with you that this is in fact a bona-fide TGA response?

Any assistance would be greatly appreciated.

Yours sincerely

[redacted]

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The TGA are responsible for the regulation of medicines which are typically products in capsule and tablet format that make therapeutic claims on the label.

[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

****

[redacted]

From: [redacted]
Sent: Wednesday, 1 May 2013 10:05 AM
To: [redacted]; May, Peter; [redacted],
Cc: [redacted]
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Likewise, I have no additional info re Craze.
Cheers
[redacted].

From: [redacted]
Sent: Tuesday, April 30, 2013 4:49 PM
To: [redacted]; May, Peter; [redacted]
Cc: [redacted]
Subject: RE: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Thanks [redacted],

The ISC food medicine interface working group has not met (or had any email correspondence) since September of last year. I don't have any information.

Regards, [redacted]

[redacted]
Section Manager – Scientific Strategy, International and Surveillance
Chief Scientist Branch

55 Blackall Street, Barton, ACT 2600
PO Box 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

From: [redacted]
Sent: Tuesday, 30 April 2013 4:31 PM
To: May, Peter; [redacted]
Cc: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]
Below and attached is some corro on the topic. In the email traffic attached there is an email from Lyn Foster where she provides some detail - *CRAZE, as you know, contains N,α-diethylbenzeneethanamine and the AFP advised us that they consider this to be an analogue of the border controlled substance methamphetamine under the Criminal Code (C'wth). Accordingly, Customs and Border Protection have been seizing this product and transferring it to the AFP.*

It is obvious that the Feds and Customs have been working together on this matter.

However I am not sure if there is a link but DMAA has been subject to a FSANZ coordinated national food incident response. The details are here - F:\FSANZ Common\Incident Response\Incidents 2012\2012 - 01 Sports supplements containing DMAA and other prohibited substances
The scheduling for DMAA is here - http://www.tga.gov.au/industry/scheduling-decisions-1207-interim.htm

Schedule 9 - New entry
1,3-dimethylamylamine
SUSMP Index - New cross-reference entries
DMAA
See 1,3-dimethylamylamine
4-methylhexane-2-amine
See 1,3-dimethylamylamine

I have copied [redacted] in on this email as they may have other details I am not aware of, such as the working group on the food:medicine interface. Also I am not sure if [redacted] tracked down the 'information source' of concern below.

I hope this information is of assistance.

Regards,
[redacted]
(I am on leave from today and will be back in the office on Monday 13 May)

[redacted]
Senior Food Scientist

55 Blackall Street, Barton, ACT 2600
PO Box 7186, Canberra BC, ACT 2610
t [redacted] | f +61 2 6271 2278
www.foodstandards.gov.au

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

A safe food supply which supports the health of people in Australia and New Zealand

UNCLASSIFIED

From: [redacted]
Sent: Monday, 29 April 2013 10:42 AM
To: [redacted]
Cc: [redacted]; incident
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted],
The discussion thread on the site starts with a blogger stating that they got the information from the TGA (interesting). Below is a link to the discussion I had with Customs and I have included Stacey's contact details if you want to ask her if they have an official statement on the product.

F:\FSANZ Common\Emerging Food Safety Issues\Ongoing issues\multiple year issues\CRAZE – file note

Stacey Ward | Manager Communication and Media
Australian Customs and Border Protection Service
P: 02 6275 6065 | M: 0401 044 310

E: stacey.ward@customs.gov.au
W: www.customs.gov.au

If FSANZ has not provided comment then only other agencies that may have provided this type of insight are Customs, the Federal Police or NSW FA. Stacey has spoken to the Feds communications area on this matter (see in file note).

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Sorry I have on other information I can contribute.

Regards,
[redacted]

UNCLASSIFIED

From: [redacted]
Sent: Monday, 29 April 2013 9:25 AM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted],

Are you aware of any other responses being made to any enquiries regarding 'Craze' other than the response we provided Customs (attached)?

Regards
[redacted]

From: [redacted]
Sent: Friday, 26 April 2013 4:25 PM
To: [redacted]
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

Hi [redacted]
Can you check with [redacted] too please re [redacted] request.
Regards
[redacted]

sent from my Telstra NEXTG™ handset

From: Media <Media@foodstandards.gov.au>
Sent: Friday, 26 April 2013 3:37 PM
To: [redacted]>
Subject: FW: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

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I told him that we definitely haven't issued any public statement but that I would check to see whether we had responded to any enquiries about craze.

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[redacted]
Public Affairs Officer

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---

From: [redacted]
Sent: Wednesday, 24 April 2013 5:53 PM
To: [redacted]
Cc: News@health.gov.au; Media; [redacted]; May, Peter
Subject: Fwd: Enquiries recieved by ASADA regarding 'Craze' supplement [SEC=UNCLASSIFIED]

[redacted]

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Sent from my iPad

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Cc: [redacted]
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Regards,

Neil

Neil Branch
Media Adviser

Media Unit
Australian Government Department of Health and Ageing
Media enquiries: 02 6289 7400
Email: news@health.gov.au

From: [redacted]
To: <news@health.gov.au>,
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[redacted]

Communication and Media Manager
Australian Sports Anti-Doping Authority

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F: +61 (0) 2 6222 4308

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W: www.asada.gov.au

PO Box 1744, Fyshwick, ACT, 2609

ASADA Hotline 13 000 ASADA (27232)

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Cc: [redacted]
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[redacted]
Senior Communications and Media Officer
Australian Sports Anti-Doping Authority

Phone: [redacted]
Fax: +61 (0) 2 9763 0373
Mob: [redacted]

Email: [redacted]
Web: www.asada.gov.au

Post: PO Box 3320, North Strathfield NSW 2137

ASADA Hotline: 13 000 ASADA (13 000 27232)

Escalation FSS **Version: 4/3/2013**

Substance	CRAZE- powdered sports supplement- contains *N,α-diethylbenzeneethanamine* .
Issue **Incident:** YES/**NO**	During the week commencing 25 February 2013, representatives from the Australian Customs and Border Protection Service (Customs) contacted FSANZ staff twice in relation to their concerns regarding CRAZE which is being imported. Australian Federal Police (AFP) advised Customs that they consider *N,α-diethylbenzeneethanamine* to be an analogue of the border controlled substance methamphetamine under the Criminal Code (C'wth). Accordingly, Customs have been seizing CRAZE which contains this analogue and referring it to the AFP. Customs currently have 30 consignments of CRAZE on hold which have entered Australia via air cargo and international mail which have tested positive for amphetamines. Customs are wondering whether there will be a recall of this product or if FSANZ is going to provide consumer advice relating to the health risks of consuming this food. In August 2012 the decision was made by the TGA to include 1, 3 dimethylamylamine or 4-methylhexane-2amine (DMAA) in Appendix C for the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)- *' a substance of such danger to health as to warrant prohibition of sale, supply and use'.* No incident, however this issue is closely related to the incident 2012-01: DMAA and other prohibited substances in sports supplements.
Original information sources	Lorraine Belanger and Wendy Chant spoke to Stacey Ward (Manager Communication and Media, Australian Customs and Border Protection Service) on 25/02/2013 regarding her concerns relating to the on-going issue of drugs in sports supplements and request for updated national communication on the issue. Incident mailbox also received an email from Lyn Foster (Manager, Drugs & Therapeutic Substances, Australian Customs and Border Protection Service) on 27/02/2013 wondering whether there would be different advice for CRAZE in particular as it contains methamphetamine analogue rather than DMAA. • File note on discussion with Stacey 25.2.13
Relevant background information on: • **risk** • **previous work** • **other (e.g. supply chain)**	**Customs current position (4/03/2013):** They are not able to control DMAA at the border when presented in a food type supplement as the DMAA itself is not subject to either Customs Regulations or the Criminal Code. CRAZE is different – due to the analogue, we are able to seize it under our regulations and pass it to the AFP for action under the Criminal Code. **DMAA background** • 1,3-dimethylamylamine (DMAA), also referred to as methylhexanamine, or 2-amino-4-methylhexane. • DMAA has been linked with increased blood pressure, headaches, vomiting, cerebral haemorrhage or

	stroke. It is a stimulant used in "party pills" and some pre-workout supplements. In Australia, a Northern Territory man is reported to have experienced psychoactive effects after consuming Jack3d, a pre-workout supplement containing DMAA. • On 15 June 2012, the NSW Food Authority triggered the National Food Incident Response Protocol (NFIRP) in order to formulate an agreed and uniform compliance/communication strategy nationally. •
FSANZ position and current management	DMAA was managed under the NFIRP which went into stand-down in July 2012. As part of the NFIRP, FSANZ assessed the safety of DMAA as an ingredient in food. • Final Situation Report (6) • DMAA Rapid Risk Assessment FSANZfinal_June • NSWFA circular to Food Contact officers for info - 28.11.2012
Consultation	**28 November 2012** NSW Food Authority communicated through the National Food Incident Response network the information they have gathered and their proposed action following their work on the product CRAZE. Testing conducted by the NSW Food Authority detected N,α-diethylbenzeneethanamine as present in the product CRAZE. An opinion from a forensic chemist at NSW Police has concluded that N,α-diethylbenzeneethanamine is a structural analogue of methyl amphetamine. To meet the definition of a prohibited drug under the NSW *Misuse and Trafficking Act 1985* the substance would need to have psychotropic properties. NSW Food Authority regarded CRAZE as unsuitable with health implications if the product was misused. Their primary concern is what constitutes a safe dose in relation to this product and at the very least its suitability. Following the test results and expert opinion, NSW Food Authority felt they were in a position to approach the importer requesting a recall of CRAZE. Marianne Tegel at the NSW Food Authority was happy to be contacted regarding the NSWFA proposed actions. **04/03/2013:** no recalls have been coordinated for DMAA containing products or specifically CRAZE in Australia
FSANZ future activities	• TGA/FSANZ food:medicine interface ongoing • TGA/FSANZ consultancy (Wynn Hannon) regarding when a product falls between the two agencies legislation. This will follow legal advice sought by TGA.
Standards/regulations/ permitted levels	Affected food standards: Standard 2.9.4 Formulated Supplementary Sports Food (FSSF). But also Standard 1.4.4 Prohibited Botanicals, Standard 1.5.1 Novel Foods. TGA decision to include DMAA under Appendix C. "Substances other than those in Schedule 9, of such danger to health as to warrant prohibition of sale, supply and use". ***The difference between Appendix C and Schedule 9***

	An Appendix C listing is where the sale, possession or supply of the poison is considered to constitute a potential public health hazard, but where the additional criminal sanctions associated with a Schedule 9 listing are considered unnecessary. Schedule 9 includes substances which may be abused or misused, where the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval from Commonwealth and/or State or Territory Health Authorities.
Information gaps	Following the circulation of information regarding NSW Food Authority's proposed actions (28.11.2012) FSANZ have not had any further communication with NSW Food Authority on the issue and no food recalls have been coordinated. A TGA/FSANZ consultancy addressing the TGA/FSANZ legislation, what TGA can and can't do and what comes under the Food Act is ongoing.
Consideration by FSANZ Strategic Steering Committees (SSC)	Not at this stage
Current Australian and New Zealand actions and management	NFIRP Participating Agencies agreed to maintain the current risk management approach of communicating to known distributors/suppliers/importers of the products advising them the products are unsuitable and to withdraw the products from the market place.
Current international actions and Management	New Zealand banned DMAA from all products with effect from 9 April 2012. The ban was affected under misuse of drugs legislation as DMAA is commonly used in party pills. The US Food and Drug Administration has issued warning letters to manufacturers and distributors of dietary supplements containing DMAA for marketing products for which evidence of the safety of the product had not been submitted to FDA. Canada classified DMAA as an unapproved drug under its Food and Drug Regulations, and recalled products containing the substance such as Jack3d and 1.M.R. Health Canada has also unequivocally stated that DMAA does not naturally occur in Geranium Maculatum Oil, Geranium oil from Pelargonium graveolens and Pelargonium Graveolens Flower Oil. While Sweden and Finland have joined Denmark in taking action against DMAA. In the US, a class action lawsuit filed against Nutrex Research over DMAA has been given the green light to proceed.
Fact Sheets and communication	• The current consumer advice on FSANZ website is here • Information on the TGA scheduling decision on FSANZ website is here

	• TGA final decision on scheduling: TGA website
Briefs/Minutes/QTBs	QTB DMAA Scheduling TGA MO 31.7.12as at 3 pm QTB- interim DMAA Scheduling TGA PSO Cleared 160712
Key internal folders	DMAA Incident: F:\FSANZ Common\Incident Response\Incidents 2012\2012 - 01 Sports supplements containing DMAA and other prohibited substances Additional sports supplements work post-incident: F:\FSANZ Common\Incident Response\Incidents 2012\Further sports supplements
FSANZ reports	DMAA food Incident notification DMAA Rapid Risk Assessment FSANZfinal June Final Situation Report (6) Draft Post Incident Log 01082012
Important links	
Issue closed: YES/NO	

Contact person: Steve Crossley

Initial contact officer: Lorraine Belanger/Wendy Chant/Incident mailbox

Notifying Section: FSS

Date of contact: 22/02/2013

Risk assessment co-ordinator: [ ]

Date notified to SSIG: [ ]

Executive Sponsor: [ ]

SSIG Recommendation:

• No action as there is no indication that this is likely to be an important emerging issue	
• Watching brief by collecting more information/data and then bring back to SSIG	
• Notify MGM, FIG and relevant stakeholders that this is clearly an emerged issue that we should follow up on as a priority and that there should be further data collection, evaluation and possibly escalation.	
• Other:	

SSIG Decision: (record SSIG decision here) [ ]

[1]**Decision by MGM**: [ ]
Strategic Steering Committee oversight: [ ]
FSANZ Issues Manager: [ ]

[1] Complete this box as required