[redacted] (ENV)

Subject: FW: Meeting with Mr [redacted] (Bayer Crop Science)
Attachments: 140316-Background note ED.docx; 140317-Global Results Trade effects.docx

Importance: High

From: [redacted] [mailto:[redacted]@gffa-wirtschaft.de]
Sent: Monday, March 17, 2014 4:10 PM
To: FALKENBERG Karl (ENV)
Subject: WG: Meeting with Mr [redacted] (Bayer Crop Science)

Lieber Karl,
I am writing to you to seek your agreement to meet with Mr [redacted], Director Public and Government Affairs Europe of Bayer Crop Science. We spoke some time ago over a beer after tennis about the issue at stake. But I fear that this is too serious to be left there.
I would therefor like to suggest to you to meet Mr [redacted], whom I am advising on institutional matters. He would like to see you to draw your attention to a potential trade conflict arising from EU legislation on plant protection products and to explain his position on the Commission`s impact assessment on criteria for endocrine disruptors . He had some time ago a useful exchange of view with [redacted] on the same subject.
For your information I add a short note about the relevant EU legislation and its potential conflict with the WTO SPS Agreement. I also include the summary from a study about the potential trade impact of EU regulations on Endocrine Disruptors.
I am sure that with your trade background you will agree that it is better to solve trade problems before they evolve into a fully-fledged formal dispute. I would therefor appreciate if you could find some time to meet with Mr [redacted]. I would be pleased to hear from you or that you would respond directly to Mr [redacted].

Address :
[redacted]
Bayer Crop Science
Square de Meeus 40
Belgium – 1000 Brussels

Tel: +32 2550 [redacted]
Fax: +32 2550 [redacted]
Mobil: +32 475 [redacted]
E-mail: [redacted]@bayer.com

Herzliche Grüße

[redacted]
Koordinator

Global Forum for Food and Agriculture Berlin e.V.

Claire-Waldoff-Straße 7
10117 Berlin

Kontakt
(+49 30 2007[redacted]
(Mobil + 32493[redacted])
@ [redacted]@gffa-wirtschaft.de
ü www.gffa-wirtschaft.de

GFFA Berlin e.V.

Bitte drucken Sie diese E-Mail nicht, wenn es nicht notwendig ist.

The context:

- EU Regulation No. 1107/2009, which governs the registration of plant protection products, establishes several hazard-based "cut-off" criteria that essentially exclude certain categories of products from consideration for normal authorization for use in the EU. For such products, the EU would not perform a risk assessment (see Article 4.1 and Annex II, paragraph 3.6). It would simply delist them due to their intrinsic properties without taking into account important risk factors such as level of exposure. As a result, It can be expected that widely used substances – such as those classified as endocrine disruptors under the current proposal of the European Commission (DG Environment) – would to be delisted when their current registration expires. **For products delisted due to the hazard-based cut-off criteria, the residue limit will be set at 0.01 mg/kg.**

- MRLs and import tolerances are established under separate legislation, EU Regulation 396/2005. The regulatory decision-making process under this regulation is nominally risk-based, rather than hazard-based. Nevertheless, there are fears that for products delisted under Regulations 1107/2009 due to the cut-off criteria, the **EU may ignore the normal risk assessment process and automatically reset all MRLs and import tolerances at the default level – 0.01 mg/kg.**
- **This is in contradiction to agreed principles under the WTO SPS Agreement.** Article 5 of the Agreement requires a risk assessment, respectively an "Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection".

Our position:

- We agree that regulatory systems around the world need to provide adequate protection for consumers, animals and the environment and we believe that existing, well developed regulatory approaches around the world that are based on risk assessments do provide such protection. Pesticides are already heavily regulated, including on their potential to cause ED-related effects.
- We support a risk-based assessment and risk management approach based on sound scientific principles (especially exposure elements) to carefully weigh the risks and benefits in order to reach balanced and proportionate decisions on a case-by-case basis.
- We recognize that there is still considerable debate the issue of endocrine disruption. Therefore the industry is committed to support further meaningful research in this area. It is important that regulatory processes address possible endocrine related adverse effects within a risk assessment and risk management framework.
- The cooperation of industry, government and farmers in managing risks before and after the market authorization of pesticides is a well-established practice. To enhance adherence to good stewardship practices, industry acknowledges the need for farmer

training and cooperates with extension services and farmer organizations to provide such training.

- We have always been committed to ensuring that the products of our members in the chemical and crop protection industries can be used safely. Companies invest significant resources in testing and evaluating the safety of products, including assessing the potential for endocrine related risks. We stand ready to continue working with governments and other stakeholders to ensure that the regulation of pesticides is based on a risk assessment and risk management approach that is grounded in sound scientific principles.

Potential Trade Effects on World Agricultural

Exporters of European Union Regulations on Endocrine Disruptors

Global Results

Summary results of the combined MRL/trade database review for all E.U. imports and each major global region are below, in million Euros.11 Detailed results for seventy-five countries supplying over €50 million each of these commodities are provided in a separate volume.

The commodities identified in this study which could be affected by the regulation account for approximately 60% of the value of all E.U. imports of agricultural products. 12 Potentially affected commodities are imported from every global region, and from developed, developing and least-developed countries.

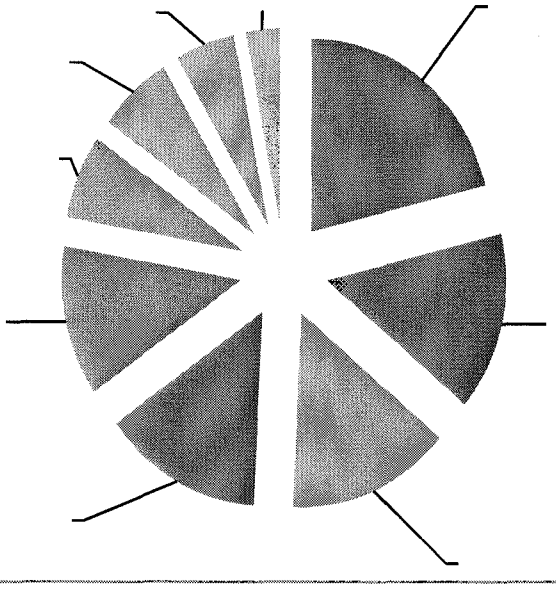
E.U. Imports of Covered Commodities Million €, 2012

Vegetables, € 3,525

Sugar, € 2,046

Fruit and Nuts, € 13,795

Cocoa, € 4,336



Cereals, € 4,613

Vegetable Oil, € 8,222

Coffee, Tea and Spices, € 9,470

Animal Feed Ingredients, € 9,780

Oilseeds and Groundnuts, € 9,574

Tariff Chapter	Imports from World
	€ Million Jan-Dec 2012
Fruit and Nuts	€ 13,795
Animal Feed Ingredients	€ 9,780
Oilseeds and Groundnuts	€ 9,574
Coffee, Tea and Spices	€ 9,470
Vegetable Oil	€ 8,222
Cereals	€ 4,613
Cocoa	€ 4,336
Vegetables	€ 3,525
Sugar	€ 2,046
Total	€ 65,362

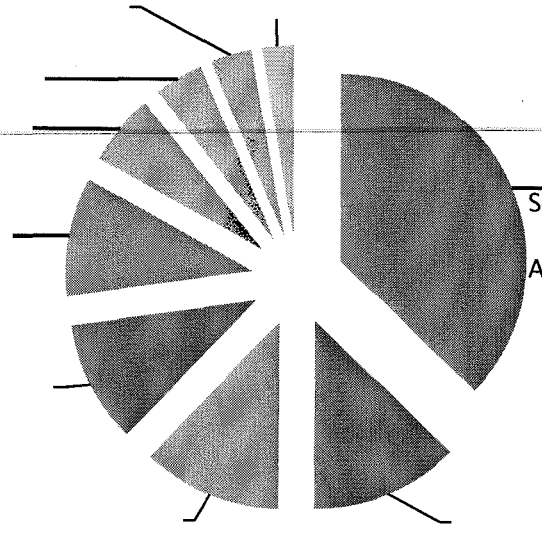
E.U. Imports of Covered Commodities by Region Million €, 2012

Oceania, € 2,345

Central Asia, € 1,870

North Africa and Middle East, € 2,881

East and South Asia € 3,987



South and Central America, € 24,324

North America and Caribbean, € 6,697

Non-E.U./EFTA Europe, € 6,911

Sub-Saharan Africa, € 7,915

Southeast Asia, € 8,432

Region	Imports from World
	Million Euro, Jan - Dec 2012
South and Central America	€ 24,324
Southeast Asia	€ 8,432
Sub-Saharan Africa	€ 7,915
Non-E.U./EFTA Europe	€ 6,911
North America and Caribbean	€ 6,697
East and South Asia	€ 3,987
North Africa and Middle East	€ 2,881
Oceania	€ 2,345
Central Asia	€ 1,870
Total	€ 65,362

[redacted] (ENV)

From: HANSEN Bjorn (ENV)
Sent: 21 May 2014 22:21
To: [redacted]
Subject: Re: AW: Our recent meeting

Dear[redacted]

I Do not have any such agreements - I would see that I would categorise the information you send us as CBI and would not disclose it. I Was hoping the exercise could be kept rather informal.

On the classification work itself. I would see you would assess the two or three AISs which you have chosen because you think they would fulfil the WHO definition, and/or the leaked DG ENV criteria, but are not Cat 1 or 2 CMRs (in your own self classification or in Annex VI of CLP). We would then review your judgement based on the relent data you supply.

Greetings

Bjorn

Sent from my iPhone

On 21 May 2014, at 20:16, "[redacted]" [redacted]@bayer.com> wrote:

> Dear Bjorn,
> thanks for the clarification, we are in the process of picking 2-3 a.i.s for a classification exercise trough you. Any idea, how long that would tentatively take ? Would you have a specimen of a secrecy agmt draft available to have it looked at by our legal department (internal requirement) ?
> Best regards
> [redacted]
>
> **Von:** Bjorn.HANSEN@ec.europa.eu [mailto:Bjorn.HANSEN@ec.europa.eu]
> **Gesendet:** Dienstag, 20. Mai 2014 21:26
> **An:** [redacted]
> **Betreff:** RE: Our recent meeting
>
> Dear[redacted]
>
> Apologies for the delay in replying.
>
> Firstly – the review – it would be internal. I see my unit doing it, maybe with some help from JRC and clearly involving SANCO. I also see this as informal, simply to bring the discussion on a specific case. But I am open to hear if you have other views.
>
> Secondly – here is the link:
>
> http://www.panna.org/sites/default/files/2013.06.11%20EDC_Recommendation%20Commission%20Draft_0.pdf
>
> Greetings,
>
> Bjorn

From: [redacted] [mailto:[redacted]@bayer.com]
Sent: Tuesday, May 06, 2014 11:10 AM
To: HANSEN Bjorn (ENV)
Subject: Our recent meeting

Dear Bjorn,
I just wanted to come back on some topics we discussed recently. You offered to evaluate 1-2 of our products under confidentiality agmt. With respect to their ED classification, following the criteria you are proposing. We are in the process of selecting 2 products now, but I have been asked by my colleagues, who exactly will do the evaluations ? DG Envi or DG Sanco, or who in particular. Maybe an external body ?

We are still trying to find the criteria you are now proposing in the internet, but are not really successful. Maybe you could send us the link in order to be sure that we have the right site ?

Best regards
[redacted]