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Dear Mr. Leggett, Dear Ms. Guven

CropLife Canada and CropLife America understand from our sister associations that you are holding a meeting of the country missions in Brussels to discuss the EU consultation process on their Impact Assessment Roadmap for Endocrine Disruptors. CropLife Canada and CropLife America are the trade associations which represent the manufacturers, developers, formulators and distributors of crop protection products, pest control products and plants with novel traits in Canada and the United States. We very much appreciate your engagement in this process, because of the influence this consultation and subsequent impact assessment will have on the regulation of our compounds within the EU. The EU regulation will not only affect growers in the EU, but will have a significant impact on growers in Canada and the United States, and will likely influence the regulatory approach adopted around the globe. For this reason, we would be grateful if you would consider our perspective on the EU Roadmap, and the effect the EU regulatory approach will likely have on the Canadian and US food and agriculture industry should you choose to provide public comment to the EU.

EU regulation 1107/2009 diverges from the risk based regulatory approach in both the US and Canada because it relies on hazard based cut off to remove products which have been "categorized" as endocrine disruptors from the EU market. In addition, such compounds will have a default MRL or import threshold of 0.01mg/kg, a 'de facto' zero. Achieving such a low MRL is difficult and testing to this low level is subject to false positives. Thus the potential impact on Canadian agricultural exports to the EU is estimated at €1.49 billion, on US exports it is €4.29 billion - or 40% of current US agricultural exports to the EU¹. This is a conservative estimate because endocrine disruptors is only one of seven categories which Regulation 1107/2009 regulates using hazard based market cut-offs.

Because use of these compounds could trigger rejection at port, this regulation effectively restricts the suite of compounds Canadian and US growers can use on their crops. Growers of bulk commodities rarely know where their commodities will be shipped, thus they aim to meet the most stringent market requirements. In this case it would be the EU's MRL. The net effect is to restrict the use of compounds registered for use in the US and Canada because they have been banned in the EU. This undermines the regulatory cooperation underway between Canada and the US to jointly assess chemistries. It essentially results in wasted resources to register tools for farmers that they cannot use. Restricting the suite of compounds available for use by farmers also

¹ <http://www.dtbassociates.com/docs/EUregsEndocrineDisruptorsTradeEffects2-2014.pdf>

compromises resistance management practices, could increase reliance on older chemistries, and will cause difficulties in achieving maximum yield per acre – an important consideration for sustainable agricultural production and land use conservation. It also impacts the pesticide industry directly through sales of products into these markets, which in turn impacts jobs and investment.

Unfortunately, none of the four scenarios being proposed within the EU Roadmap for the impact assessment of ED criteria include a risk assessment option. The scenarios focus entirely on different versions of defining the hazard. The word “criteria” has become synonymous with “categories”, when we believe “criteria” should reflect the entire framework used to assess crop protection products, including an exposure and risk assessment. This is in line with current practices in the US and Canada and the use of data generated through the US’s Endocrine Disrupter Screening Program. Where “negligible exposure” is proposed to be replaced by “negligible risk” in Option B this would be done by derogation which is an entirely unpredictable and potentially political decision making process and thus arbitrary and not proportional. Such an approach does not facilitate, and may actually discourage new product development and investment in research and development as the costs are not justified by the probability of success in reaching the market.

CLC and CLA believe it is inappropriate to define any compound as an “endocrine disrupter” because endocrine disruption does not necessarily lead to an adverse effect. Compounds, both natural and manmade, are in constant interaction with our endocrine system, and adversity only occurs when the dose or exposure is sufficient. Coffee is an endocrine disrupter, as is wine and ibuprofen². Whether or not they exert an adverse effect on the endocrine system is entirely dependent on how much of these we consume and over what period of time. Pesticides undergo extensive regulatory testing and evaluation to define both exposure and hazard. They are data-rich compounds therefore there are far fewer uncertainties about their effects. This makes them far easier to assess in a risk assessment context. However, because the EU approach stops at hazard identification, it does not allow the use of all this scientific information to characterize the hazard (such as severity, irreversibility and so forth), or to factor exposure into their assessment. The EU system is therefore unable to discriminate effectively between substances of concern and substances which are not.

Unlike the US, the EU approach also lacks a screening process to prioritize existing compounds for further testing and evaluation and to ensure that those which pose the biggest potential risk are evaluated first. As there are at least 10,400 chemicals (pesticidal and industrial) in commerce, this is a serious deficit. By using hazard based cut offs, or market bans the EU fails to recognize the fact that compounds which are potentially hazardous can none the less be used safely. Thus it risks removing compounds from the market which are vital to agricultural production but which also protect human and animal health by eradicating harmful infections or infestations in the crop that in themselves are dangerous contaminants. One such example are the triazole fungicides which effectively control diseases like fusarium head blight in cereals, and without which can result in mycotoxins in our food supply.

Canada and the US have invested considerable effort, as part of the NAFTA Technical Working Group (TWG) and the Regulatory Cooperation Council (RCC) process, to harmonizing our approaches to regulating pesticides in order to avoid trade disruption and barriers, while still being protective of human health and the environment. For pesticides these harmonization efforts occur at both the regulatory and technical level. Both the Canadian and US regulatory approaches are consistent with the WTO SPS agreement which specifies the use of a risk based approach to regulation that does not go beyond what is necessary to protect human health or the environment. A recent legal analysis has concluded that the EU approach runs counter to the WTO SPS agreement. It is entirely unclear how Canada or the US could achieve similar harmonization with the EU in the

² The screening of everyday life chemicals in validated assays targeting the pituitary–gonadal axis
H. Tinwell ↑, S. Colombel, O. Blanck, R. Bars Regulatory Toxicology and Pharmacology 66 (2013) 184–196

regulation of crop protection products, and one which does not conflict with our own harmonization effects under NAFTA.

In conclusion, we support the use of a scientific risk assessment to regulate our products as the most comprehensive and precautionary method of protecting human health and the environment. We support the US EPA Endocrine Disrupter Screening Program³ because it enables prioritization and screening of compounds and utilizes the most up to date science available in a comprehensive risk based framework. A hazard based approach is not justifiable either on scientific grounds or as sufficiently protective of human health or the environment and thus our public comments to the EU consultation process will reflect our concern regarding the lack of a risk assessment option within the four scenarios, reflect the fact that it is possible to regulate compounds effectively using a comprehensive and scientific risk assessment, and that the US EPA program offers huge benefits as a model approach for enabling prioritization and screening approaches to ensure substances of possible concern are flagged early, and tested rapidly. We would be grateful if Canada and the US would consider input into the EU public consultation on the Roadmap, to highlight the concerns and difficulties with the proposed scenarios and within Regulation 1107/2009.

Sincerely,



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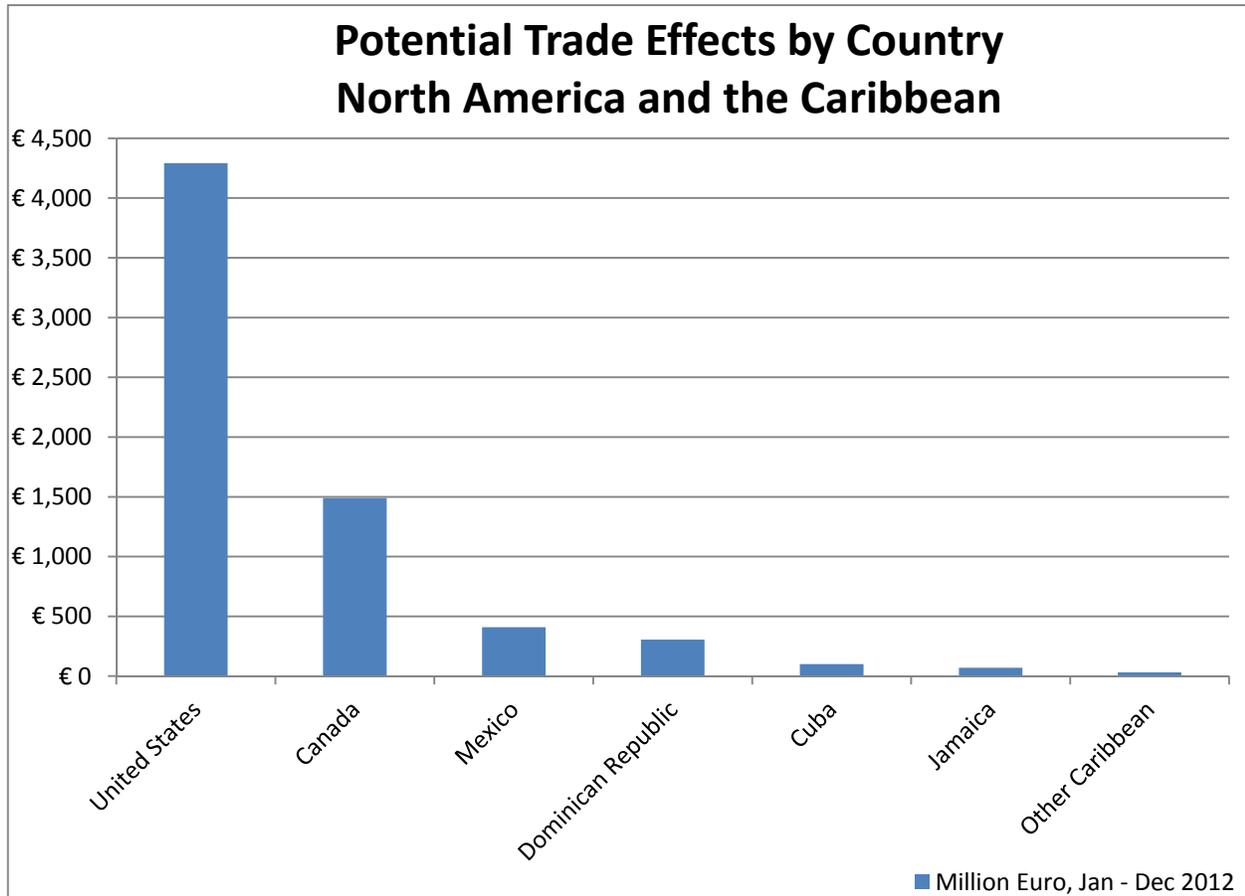
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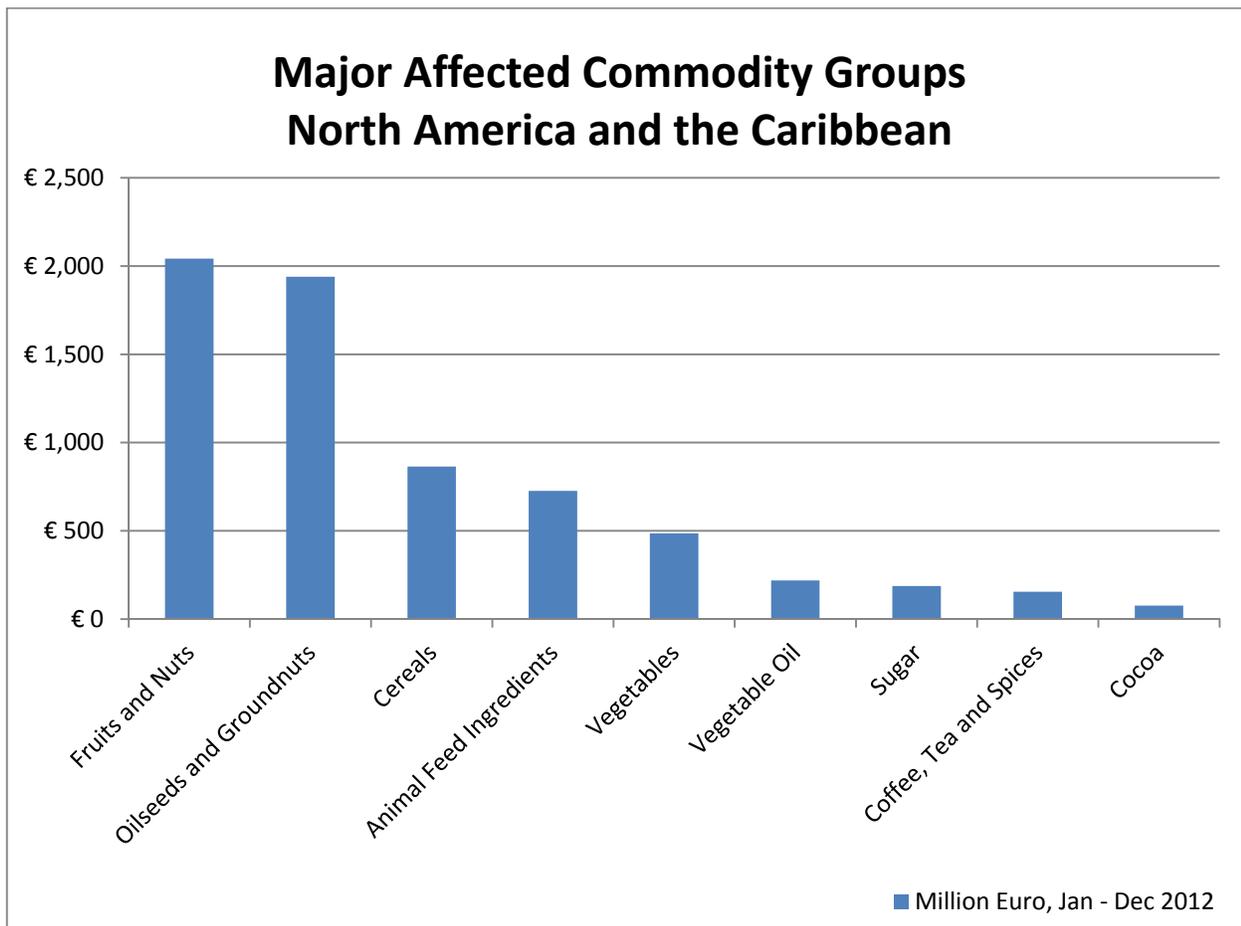
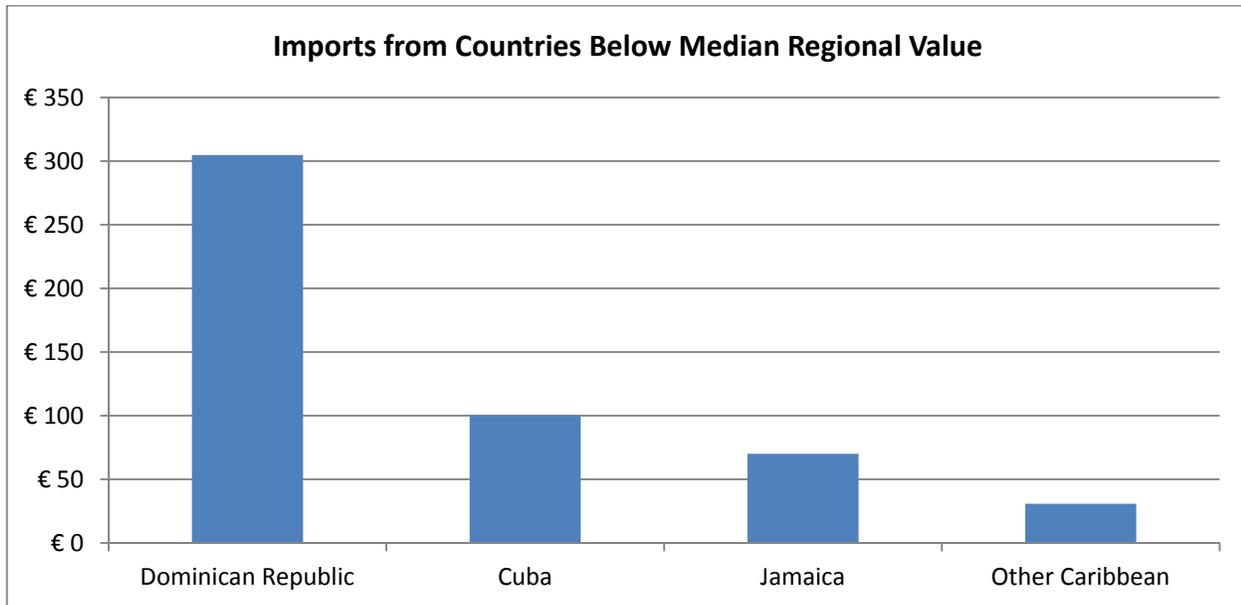
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³ <http://www.epa.gov/endo/>

APPENDIX 1: Results for North America and the Caribbean

The North America and Caribbean region supplies the E.U. with €6.7 billion of commodities that may be affected by cut-off criteria in Regulation 1107/2009. The graphs below show the value of all covered commodities imported by the E.U. for each country in the region and the major commodity groups comprising these imports.





The North American and Caribbean region supplies approximately 10% of E.U. imports of raw and semi-processed agricultural commodities, although its position among regional suppliers has declined sharply over the last twenty years. Changes in E.U. agricultural and regulatory policies have led to

declines in volumes of U.S. corn and soy imports, although this has been partially offset by increases in imports of tree nuts from the U.S. and oilseeds from Canada. The table below shows E.U. imports of these commodities from the world, from North America and Caribbean countries and the percentage of imports from the world supplied by the region.

Commodity Group	Million Euro, Jan - Dec 2012		Percent
	E.U. Imports from World	From North America and Caribbean	
Fruit and Nuts	€ 13,795	€ 2,042	15%
Oilseeds and Groundnuts	€ 9,574	€ 1,939	20%
Cereals	€ 4,613	€ 865	19%
Feed Ingredients	€ 9,780	€ 726	7%
Vegetables	€ 3,525	€ 486	14%
Vegetable Oil	€ 8,222	€ 220	3%
Sugar	€ 2,046	€ 188	9%
Coffee, Tea and Spices	€ 9,470	€ 155	2%
Cocoa	€ 4,336	€ 77	2%
Total	€ 65,362	€ 6,697	10%

APPENDIX 2: IMPACT ON CANADIAN EXPORTS TO THE EU

CANADA - 2012 Exports to E.U. of Potentially Affected 4-digit HTS Commodities (€ 1,489,861,380)

7 - Vegetables	€ 180,782,506
703 - Onions etc.	€ 125,291
706 - Carrots, etc	€ 417
708 - Leguminous Veg	€ 98,666
709 - Veg NESOI fresh	€ 462,064
710 - Veg Frozen	€ 557,251
712 - Veg Dried	€ 222,780
713 - Veg Dried Shelled	€ 179,315,607
714 - Cassava etc	€ 430
8 - Fruits and Nuts	€ 82,984,364
801 - Coconuts, Brazil/Cashew	€ 502
802 - Tree Nuts	€ 739,704
804 - Dates/figs	€ 379
805 - Citrus fresh/dried	€ 256
806 - Grapes fresh/dried	€ 64,218
807 - Melons	€ 4,024
808 - Apples/Pears	€ 965,051
809 - Apricots/Cherry/Peach	€ 6,017,813
810 - Fruit NESOI	€ 1,200,278
811 - Fruit/Nuts frozen	€ 73,556,616
813 - Fruit dried	€ 435,523
9 - Coffee, Tea, Spices	€ 2,115,644
901 - Coffee	€ 983,005
902 - Tea	€ 776,721
903 - Matte	€ 3,240
904 - Pepper	€ 21,527
905 - Vanilla bean	€ 58,919
906 - Cinnamon	€ 5,207
909 - Anise, etc	€ 21,128
910 - Ginger, etc	€ 245,897

17 - Sugar	€ 8,548
1701 - Cane/Beet Sugar	€ 8,282
1703 - Molasses	€ 266
18 - Cocoa	€ 17,684

10 - Cereal Grains	€ 436,706,725
1001 - Wheat	€ 403,503,943
1002 - Rye	€ 118
1003 - Barley	€ 17,306
1004 - Oats	€ 67,136
1005 - Maize	€ 398,689
1006 - Rice	€ 2,188
1008 - Buckwheat etc.	€ 32,717,345
12 - Oilseeds and Groundnuts	€ 653,842,740
1201 - Soybeans	€ 512,887,813
1202 - Groundnuts	€ 71,214
1204 - Flaxseed	€ 9,982,414
1205 - Rapeseed	€ 77,540,639
1206 - Sunflower Seed	€ 74,005
1207 - Oilseed NESOI	€ 26,044,426
1208 - Oilseed Flour	€ 614,100
1209 - Sowing Seeds	€ 21,822,562
1210 - Hop Cones	€ 3,838
1212 - Locust Beans	€ 3,724,776
1213 - Cereal Straw	€ 1,317
1214 - Other Forage	€ 1,075,636
15 - Vegetable Oils	€ 32,155,446
1508 Peanut Oil	€ 123
1509 - Olive Oil	€ 12,345
1510 - Olive Residue Oil	€ 46,850
1511 - Palm Oil	€ 157
1512 Sun/Saf/Cotton Oil	€ 2,768
1513 Coconut Oil	€ 1,827
1514 - Rapeseed Oil	€ 28,974,651
1515 - Veg Oil NESOI	€ 3,032,286
1516 - Animal/Veg Hydrogenated	€ 7,214
1521 - Veg Waxes	€ 77,225

1801 - Cocoa Beans	€ 371
1803 - Cocoa Paste	€ 1,939
1804 - Cocoa Butter	€ 1,576
1805 - Cocoa Powder	€ 13,798
23 - Animal Feed Ingredients	€ 101,247,723
2302 - Cereal Bran	€ 140,960
2303 - Starch/Sugar Residue	€ 11,152,411
2304 - Soya Meal	€ 31,096,006
2306 - Veg Oilcake NESOI	€ 19,271,147
2308 - Veg Waste/Feed	€ 491,028
2309 - Animal Feed Preps	€ 39,096,171

APPENDIX 3: IMPACT ON UNITED STATES EXPORTS TO THE EU

UNITED STATES – 2012 Exports to E.U. of Potentially Affected 4-digit HTS Commodities (€ 4,292,301,972)

7 - Vegetables	€ 195,793,705
701 - Potatoes	€ 5,171
702 - Tomatoes	€ 88,910
703 - Onions etc.	€ 399,132
704 - Cabbages	€ 2,093,009
705 - Lettuce	€ 1,996,916
706 - Carrots, etc	€ 4,044,391
707 - Cucumbers	€ 32
708 - Leguminous Veg	€ 1,617,252
709 - Veg NESOI fresh	€ 8,753,091
710 - Veg Frozen	€ 978,159
712 - Veg Dried	€ 30,569,016
713 - Veg Dried Shelled	€ 109,360,575
714 - Cassava etc	€ 35,888,051
8 - Fruits and Nuts	€ 1,606,088,899
801 - Coconuts, Brazil/Cashew	€ 531,800
802 - Tree Nuts	€ 1,333,299,887
803 - Bananas	€ 45,129
804 - Dates/figs	€ 10,912,677
805 - Citrus fresh/dried	€ 37,499,060
806 - Grapes fresh/dried	€ 103,160,910
807 - Melons	€ 76,339
808 - Apples/Pears	€ 15,829,685
809 - Apricots/Cherry/Peach	€ 20,417,755
810 - Fruit NESOI	€ 23,329,146
811 - Fruit/Nuts frozen	€ 8,219,703
813 - Fruit dried	€ 52,595,920
814 - Citrus/Melon peel	€ 170,888

9 - Coffee, Tea, Spices	€ 27,182,229
901 - Coffee	€ 10,329,283
902 - Tea	€ 9,138,857
903 - Matte	€ 30,034
904 - Pepper	€ 4,474,623
905 - Vanilla bean	€ 698,744
906 - Cinnamon	€ 176,743
907 - Cloves	€ 3,321
908 - Nutmeg/Mace	€ 385,378
909 - Anise, etc	€ 23,743
910 - Ginger, etc	€ 1,921,503
10 - Cereal Grains	€ 384,731,221
1001 - Wheat	€ 298,017,918
1003 - Barley	€ 62,591
1004 - Oats	€ 19,096
1005 - Maize	€ 36,123,280
1006 - Rice	€ 38,544,019
1007 - Sorghum	€ 2,910,331
1008 - Buckwheat etc.	€ 9,053,986
12 - Oilseeds and Groundnuts	€ 1,275,758,558
1201 - Soybeans	€ 951,515,411
1202 - Groundnuts	€ 62,893,055
1203 - Copra	€ 70,860
1204 - Flaxseed	€ 3,048,734
1205 - Rapeseed	€ 9,564,646
1206 - Sunflower Seed	€ 61,040,152
1207 - Oilseed NESOI	€ 7,045,412
1208 - Oilseed Flour	€ 961,437
1209 - Sowing Seeds	€ 156,437,969
1210 - Hop Cones	€ 16,337,784
1212 - Locust Beans	€ 4,295,431
1213 - Cereal Straw	€ 56,903
1214 - Other Forage	€ 2,490,764

15 - Vegetable Oils	€ 168,225,491
1507 - Soya Oil	€ 1,054,455
1508 - Peanut Oil	€ 1,674,238
1509 - Olive Oil	€ 300,609
1510 - Olive Residue Oil	€ 37,174
1511 - Palm Oil	€ 46,478
1512 - Sun/Saf/Cotton Oil	€ 948,644
1513- Coconut Oil	€ 901,155
1514 - Rapeseed Oil	€ 35,741,849
1515 - Veg Oil NESOI	€ 116,682,781
1516 - Animal/Veg Hydrogenated	€ 8,317,476
1521 - Veg Waxes	€ 2,520,632
17 - Sugar	€ 21,131,715
1701 - Cane/Beet Sugar	€ 6,586,099
1703 - Molasses	€ 14,545,616
18 - Cocoa	€ 5,110,511
1801 - Cocoa Beans	€ 238,335
1802 - Cocoa Shells/Husks	€ 443
1803 - Cocoa Paste	€ 1,250,454
1804 - Cocoa Butter	€ 442,729
1805 - Cocoa Powder	€ 3,178,550
23 - Animal Feed Ingredients	€ 608,282,643
2302 - Cereal Bran	€ 1,534,281
2303 - Starch/Sugar Residue	€ 34,419,111
2304 - Soya Meal	€ 314,544,195
2306 - Veg Oilcake NESOI	€ 7,323,743
2308 - Veg Waste/Feed	€ 61,649,065
2309 - Animal Feed Preps	€ 188,812,248