APPENDIX I: TABLE A

Table on the impact of spraying genetically modified plants with a glyphosate-based herbicide

Study	Compound	Result
)Protein: malondialdehyde,	A second control of the second control of th
[SU/50]	ascorbate peroxidase,	
[~ 0.0 0]	glutathione reductase, and	
	catalase	
		Expressed differently (seed)
	glutamine synthetase,	
	glycinin subunit G1, and	
	glycine-rich RNA-binding	
	protein	
Bellaloui et al, (2008	<u> </u>	Protein elevated (seed)
[SU/51]	,1000,11	1 Total of Calca (Secur)
[50/51]	Oil	Reduced (seed)
	Oleic acid	elevated (seed)
Annual III	Linolenic acid	Reduced (seed)
	nitrogen assimilation, as	Reduced
	measured by in vivo nitrate	
	reductase	
	activity (NRA) in leaves.	
	roots, and nodules	
Bellaloui et al, (2009a		elevated (seed)
[SU/52]	Ji Totom	olovatou (300u)
[00/32]		
	Amino acids	elevated (not significant) (seed)
	Oil	Reduced (seed)
	Oleic acid	elevated (seed)
	Linolenic acid	Reduced (seed)
	Prolin	Elevated (seed)
***	nitrate reductase activity	Reduced
	(NRA)	
Bellaloui et al, (2009b	<u></u>	Reduced (seed)
[SU/53]		
Bott et al, (2008	root biomass and root	
[SU/54]	elongation	depressions of plant growth in the GR soybean cultivar
-		Valiosa strongly dependent on the selected culture
		conditions
	Shoot biomass	In soil culture, shoot biomass production declined by
		approximately 15–30% in glyphosate treated plants
		grown on an acidic Arenosol but not on a calcareous
		Loess sub-soil, while root biomass was not
		significantly affected
	nitrogen fixation	no effect of glyphosate application on nitrogen fixation
		as measured by acetylene reduction assay, soybean
		yield, or seed nitrogen content
		United to the state of the transfer



Study	Compound	Result
Cavalieri et al, (2012)		Roundup Original®, Roundup Transorb® and
[SU/4]	formulations on nutrient	Roundup WG® caused the greatest damage to nutrient
	accumulation and dry matter	accumulation and dry matter production. It was
		concluded that nutrient accumulation and dry matter
	1	production in the shoots of the soybean plants are
	0.71	affected by glyphosate application, even for GR
	1, ,	cultivars.
Duke et al, (2003)	daidzein	Elevated (seed)
[SU/2]		
Duke et al, (2012)	Plant mineral nutrition	Rigorous field studies on different soil types (including
(review) [SU/55]		those highly susceptible to inducing Mn or Fe
, , ,		deficiency in soybeans) are needed to resolve the issue
		of whether glyphosate might have adverse effects on
		mineral nutrition of GR crops.
Reddy et al, (2000)		Reduced (greenhouse)
[SU/56]	,	,
	chlorophyll content, root	no effect
[SU/57]	and shoot dry weight, or	
	nodule number	
		reduced by 21 to 28% 14 d LPOST
		Soybean recovered by 14 d.
	Seed protein	Reduced when two applications were made (seed)
Reddy et al, (2004)	AMPA, Shikimate,	Chlorosis, effects measured till 22 DAT
[SU/58]	glyphosate levels in plants	
Serra et al, (2011)		No effect
[SU/59]		V8 (20 days after application)
Greenhouse		
	N, Mn, Cu, Zn and Fe	reduced
	Nodes	reduced
	Dry mass	reduced
Zablotowicz et al	, seed nitrogen	reduced, when high doses of glyphosate were applied
(2007) [SU/60]		(seed)
Zobiole et al, (2010a	Number and weight of seeds	reduced by 25% and 13% (seed)
[SU/61]	per plant	
	17:1n-7 (not essentiell)	increased (by 30.3%) (seed)
	18:1n-9 (not essentiell)	increased (by 25%) (seed)
	linoleic acid (18:2n-6)	Decrease (2.3%) (seed)
	linolenic acid (18:3n-3)	Decrease (9.6%) (seed)
Zobiole et al, (2010b [SU/62]	Photosynthetic parameters	Decrease
	biomass production	Decrease
3100010-1100-1100	water absorption	Decrease
4 (100 / 100	photosynthesis	Decrease
	water use efficiency	Decrease
Zobiole et al, (2010c [SU/63]) Shoot and root dry biomass	Decrease
	Photosynthetic parameters	Decrease
	Micronutrients (Zn, Mn, Fe	Decrease
	Cu, B) in leaves	
		Decrease (but no effect on N)
	Mg, Ca, S)	

Study	Compound	Result
Zobiole et al, (2010d)		Linear decrease
[SU/64]	(A, SPAD, Fo, Fm)	
	(2, 222 - 2, 2 -	R1 growth stage
		→ long-term physiological impacts
	Macronutrients (N. P. K.	Decrease: effects in the following order: Ca > Mg >
	Mg, Ca, S)	nitrogen $(N) > S > K > P$
		Effects of single application in the following order:
	Mn, Cu, Mo, B)	Fe > Mn > cobalt (Co) > Zn > Cu > boron (B)> molybdenum (Mo)
		two applications: Fe > Co > Zn > Mn > Cu > Mo > B
	shoot, root and total	Reduced proportional to glyphosate dose.
	biomass dry weight	
Zobiole et al, (2010e) [SU/65]	photosynthetic rate	Severely decreased
-		RR2 more sensitive than RR1
	Leaf area and shoot biomass	Severely decreased
	production	
		RR2 more sensitive than RR1
Zobiole et al, (2010f	photosynthetic rate	1800 dose: reduction 33 and 31%.
[SU/66]		
	lignin and amino acid	Reduced (linear)
	height and total (shoot and	Reduced (linear)
	root) dry weight	
Zobiole et al, (2010g		reduced
[SU/67]) I toddio II siii soi	
	Ni concentration	reduced
	Chlorophyll (SPAD units)	Lower in RR soybean
	emerophyn (S1712 units)	Do wor in this soy oddin
		even lower when treated with glyphosate
		Chlorotic symptoms, non persistent
Zobiole et al, (2010h)	Fusarium spp	Increased in RR1 and RR2 soybean
RR1 and RR2 [SU/68]	obb.	
	Mn reducers /Mn oxidizers	Decreased in RR1; The greatest reduction in the ratio
	ratio	of potential Mn reducers Mn oxidizers occurred when
		glyphosate was applied at early (V2) compared with
		later growth stages (V4 and V6
	root and shoot dry weight	Decreased in RR1 and RR2 soybean
	Total of the first	
		Earlier glyphosate applications caused greater
		decreases in root dry weight
		Shoot dry weight of both varieties was most reduced
		when glyphosate was applied at the V6 growth stage
		and least at V4 and V2 stages, with the GR2 cultivar
		affected more than the GR1 cultivar (Fig. 6). In
		general, GR2 produced less biomass (shoot and root)
	The Control of the Co	than GR1 when glyphosate was not applied
Zobiole et al, (2011)	chlorophyll	decrease
RR1 and RR2 [SU/69]		
THE MICHAEL DOTON		

Study	Compound	Result
	macro and micronutrient	Decrease
	accumulation	All macro- and micronutrients, with exception of N and K, accumulated more in RR1 than RR2 (Figs. 2 and 3 and Table 1). This result may be an individual cultivar characteristic, but it suggests that the RR2 cultivar was inefficient in nutrient uptake and translocation or was unable to rapidly recover from potential chelating effects of glyphosate
		In the present experiment, glyphosate apparently remained active in soybean through R1 growth stage or later as indicated by decreased nutrient accumulation. It is known that glyphosate and its metabolites can remain within the plant until complete physiological maturity.
	Nodule dry weight and	Reduced tendency for late applications to have less effect than early applications
	number Shoot biomass	decrease
	Shoot blomass	higher percent reduction associated with late than with early glyphosate applications
	chlorosis	The new generation RR soybeans also showed undesirable glyphosate effects as "yellow flashing".
Zobiole et al, (2012) RR2 [SU/70]	photosynthetic rate	severely depressed
	macro- and micronutrient accumulations	Proportionally reduced as glyphosate rates increased and applications were delayed
		Macronutrient and all micronutrient concentrations except Cu were within the nutrient-sufficiency ranges for soybean
		Concentrations of Ca, Mg, S, and Cu were significantly ($p < 5\%$) lower in glyphosate-treated soybean yet all values were within the sufficiency ranges for those nutrient concentrations to provide acceptable soybean growth. Concentrations of P and Fe appeared to be increased by glyphosate.
	nodule number and dry weight	significantly decreased
	weight	In contrast with other results, a tendency was noted for reduced effects at late applications compared with early applications
	root dry weight	more severely depressed with glyphosate applied at V2 growth stage compared with V6 growth stage
	leaf area and shoot dry weight	More strongly decreased at the late growth stage than at the early stage

APPENDIX II – TABLE B

Table B: Summary of scientific literature showing the numerous plant constituents and chemicals which can have synergistic or combinatorial effects with the inserted Cry proteins/Bt toxins.

Publication	toxin	Factors which inflluence	Impact on	Impact on
		activity of Bt toxins	toxicty	selectivity
				(decrease in
				selectivity
				means risks for
				non-target
				organisms are
				enhanced)
Broderick et al,	Bt-toxins	Antibioticum Zwittermicin	+	?
(2003) [SU/71]				
Broderick et al.	Cry1 Ab	Microorganisms are part of toxic	+	?
(2006 [SU/11],		effects in the gut		
2009)				
Dubois and	CrylAb	Several bacteria	+	?
Dean (1995)		Spores from bacteria		
[SU/72]				
Hamshou et al,	Cry-Toxin	Lectines produced by	+	?
(2009) [SU/73]		solanaceae		
Huang et al,	Cry1 Ab	Activation of toxins by	+	?
(2002) [SU/74]		transferring it into plants		
Khalique &	Bt-toxins	pyrethroids	+	?
Ahmed, (2005)				
[SU/75]				
Kramarz et al,	CrylAb	cadmium and infestations with	+	
(2007) [SU/76]		nematodes in snails		
Kramarz et al.	Cry1Ab	infestation with nematodes in	+	-
2009 [SU/47]		snails		

i s for
200
s for
for

- 1
are
- Indiana and a second
ментини

APPENDIX III - APPENDED DOCUMENTS

PROCEDURAL DOCUMENTS ("PD")

TAB	DOCUMENT
1.	Monsanto Application EFSA-GMO-NL-2009-73 seeking authorisation of MON 87701 x MON 89788 for food and feed uses, import and processing under
	Regulation (EC) No 1829/2003: Part 2 (Summary)
2.	Opinions and Comments of the Member States
3.	Scientific Opinion on application (EFSA-GMO-NL-2009-73) for the placing on the market of insect-resistant and herbicide-tolerant genetically modified soybean MON 87701 x MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto ("the EFSA Opinion")
4.	Report of the meeting of the Standing Committee on the Food Chain and Animal Health held on 2 May 2012
5.	Commission Implementing Decision of 28 June 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 × MON 89788 (MON-877Ø1-2 × MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2012/347/EU)
6.	Testbiotech Request for internal Review sent on 6 August 2012 ("Request for Internal Review") and Covering letter
7.	European Commission Decision letter dated 8 January 2013 refusing Testbiotech's Request for Review of Commission Decision 2012/347 ("the Commission Decision")
8.	Commission Implementing Decision of 10 February 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 (MON-877Ø1-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2012/83/EU)
9.	Commission Decision of 4 December 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2008/933/EC)
10.	The Commission Decision as provided to ENSSER
11.	Sambucus' Cover Letter and Request for Internal Review
12.	The Commission Decision as provided to Sambucus
13.	TestBiotech Registration Document
14.	Testbiotech Statute/Articles of Association
15.	ENSSER's Statute/Articles of Association
16.	ENSSER's covering letter for the Request for Internal Review.
17.	Sambucus' Statute/Articles of Association
18.	ENSSER's Registration Document
19.	Sambucus' Registration Document

SUPPORTING DOCUMENTS ("SU")

TAB	DOCUMENT
1.	Monsanto Application EFSA-GMO-NL-2009-73 seeking authorisation of MON 87701 x MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003: Part 1 – ("the Technical Dossier")
2.	"Isoflavone, Glyphosate, and Aminomethylphosphonic Acid Levels in Seeds of Glyphosate-Treated, Glyphosate-Resistant Soybean", S. Duke, A. Rimando, P. Pace, K. Reddy, and R.J. Smeda, J. Agric. Food Chem 2003, 51, 340 -344 ("Duke et al (2003)")
3.	"Effects of Soy Phytoestrogens Genistein and Daidzein on Breast Cancer Growth" M.L. De Lemos, The Annals of Pharmacotherapy, 2001 September, Volume 35, ("De Lemos (2001)")
4.	"Acumlo de Nutrientes e Matéria seca na Parte Aérea de Dois Cultivares de Soja RR Sob Efeito de Formulacoes de Glyphosate - Nutrient and Shoot Dry Matter Accumulation of Two GR Soybean Cultivars under the Effect of Glyphosate Formulations" Cavalieri, Velini, Sã José, e Andrade, Planta Daninha, Viçosa-MG, v. 30, n. 2, p. 349-358, 2012 (Only summary provided as publication is only available in Spanish) ("Calalieri et al, (2012)")
5.	"Toxic Secondary Metabolite Production in Genetically Modified Potatoes in Response to Stress," Derek Matthews, Huw Hones, Paul Gans, Steven Coates and Lydia M.J. Smith, Journal of Agricultural and Food Chemistry ("Matthews et al, (2005)")
6.	"Proteomics as a Complementary Tool for Identifying Unintended Side Effects Occurring in Transgenic Maize Seeds As a Result of Genetic Modifications" Lello Zolla, Sara Rinalducci, Paolo Antonioli, and Pier Giorgio Righetti (2007), Journal of Proteome Research ("Zolla et al (2008)")
7.	"A simple question in a complex environment: How much Bt toxin do genetically engineered MON810 maize plants actually produce?" Breckling, B., Reuter, H. & Verhoeven, R. (2008) Implications of GM-Crop Cultivation at Large Spatial Scales. Theorie in der Ökologie 14. Frankfurt, Peter Lang, C. Then & A. Lorch, ("Then & Lorch, (2008)")
8.	"Transgene x Environment Interactions in Genetically Modified Wheat," Zeller SL, Kalinina O, Brunner S, Keller B, Schmid B (2010), PLoS ONE 5(7): e11405. doi:10.1371/journal.pone.0011405 ("Zeller et al, (2010)")
9.	"A mechanism of cell death involving an adenylyl cyclasePKA signaling pathway is induced by the Cry1Ab toxin of Bacillus thuringiensis", Xuebin Zhang, Mehmet Candas, Natalya B. Griko, Ronald Taussig, and Lee A. Bulla, Jr, (2006) www.pnas.org cgi_doi_10.1073_pnas.0604017103 ("Zhang et al, (2006)")
10.	"Signaling versus punching hole: How do Bacillus thuringiensis toxins kill insect midgut cells?" M. Soberon, S.S. Gill and A. Bravo, Cell. Mol. LifeSci. (2009) 1337-1349 ("Soberon, et al (2009)")
11.	"Midgut bacteria required for Bacillus thuringiensis insecticidal activity", Nichole A. Broderick, Kenneth F. Raffa, and Jo Handelsman, PNAS 2006;103;15196-15199 ("Broderick et al, (2006)")
12.	"Gut Bacteria Are Not Required for the Insecticidal Activity of Bacillus thuringiensis toward the Tobacco Hornworm, Manduca sexta", Paul R. Johnston and Neil Crickmore, Applied and Environmental Microbiology, Aug. 2009, p. 5094–5099 Vol. 75, No. 15 ("Johnston & Crickmore, (2009)")
13.	"From Commensal to Pathogen: Translocation of Enterococcus faecalis from the Midgut to the Hemocoel of Manduca sexta", Katie L. Mason, Taylor A. Stepien, Jessamina E. Blum, Jonathan F. Holt, Normand H. Labbe, Jason S. Rush,a Kenneth F. Raffa, and Jo Handelsmana, mBio 2(3):e00065-11. doi:10.1128/mBio.00065-11.

	("Mason et al, (2011)")
1 /	
14.	"Bacillus thuringiensis Cry1Ab Mutants Affecting Oligomer Formation Are Non-
	toxic to Manduca sexta Larvae" Nuria Jimenez-Juarez, Carlos Munoz-Garay, Isabel Gomez, Gloria Saab-Rincon, Juanita Y. Damian-Almazo, Sarjeet S. Gill, Mario
	Soberon, and Alejandra Bravo, the Journal of Biological Chemistry Vol. 282,
1.5	NO.29, pp. 21222-21229, July 20, 2007, ("Jiminez-Juares (2007)")
15.	"Synergistic Effect of the Bacillus thuringiensis Toxins CryIAa and CryIAc on the
	Gypsy Moth, Lymantria dispar", M. Kyong Lee, A. Curtiss, E. Alcantara and D. H.
	dean, Applied and Envionrmental Microbiology, Feb. 1996, p. 583–586 ("Lee et al,
3.6	(1996)")
16.	"Synergistic activity between Bacillus thuringiensis CrylAb and CrylAc toxins
	against maize stem borer (Chilo partellus Swinhoe)", P. Sharma, V. Nain, S.
	Lakhanpaul and P.A. Kumar, The Society for Applied Microbiology, Letters in
1 77	Applied Microbiology 51 (2010) 42–47 ("Sharma et al, (2010)")
17.	"Strategies to improve the insecticidal activity of Cry toxins from Bacillus
	thuringiensis" L. Pardo-Lo' pez, C. Munoz-Garay, H. Porta, C. Rodriguez-Almaza'
1.0	n, M. Sobero' n, A. Bravo, Elsevier (2009) ("Pardo-Lopez et al, (2009)")
18.	"Quantification of Bacillus thuringiensis Cry1Ab protein in tissues of YieldGard (MON810) corn hybrids tested at multiple field locations in India", S.P. Kamath, S.
AND THE PARTY OF T	Anuradha, H.S. Vidya, K.S. Mohan, Yelena Dudin, Elsevier (2010) ("Kamath et al,
19.	(2010)) "Risk assessment of GM stacked events obtained from crosses between GM events",
19.	A. De Schrijver, Y. Devos, M. Van den Bulcke, P. Cadot, M. De Loose, D. Reheul
	and M. Sneyers, (2006) Trends in Food Science & Technology xx (2006) 1e9
	Elsevier ("De Schrijver et al, (2006))
	Lisevici (De Sentifici et al, (2000))
20.	"Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical,
20.	Embryonic, and Placental Cells", Nora Benachour and Gilles-Eric Séralini, Chem.
	Res. Toxicol. 2009, 22, 97–105 ("Benachour et al, (2009)")
21.	"Glyphosate-Based Herbicides Produce Teratogenic Effects on Vertebrates by
	Impairing Retinoic Acid Signaling" Alejandra Paganelli, Victoria Gnazzo, Helena
	Acosta, Silvia L. Lopez and Andrés E. Carrasco, ACS Publications, (2010)
	("Paganelli et al, (2010)") (Only access to Summary)
22.	"Ultrastructural Morphometrical and Immunocytochemical Analyses of Hepatocyte
	Nuclei from Mice Fed on Genetically Modified Soybean", M. Malatesta, C
	Caporaloni, S. Gavaudan, M.B.L. Rocchi, S. Serafini, C. Tiberi, and G. Gazzanelli,
	Cell Structure and Function, 27: 173-180 (2002) ("Malatesta et al, (2002)")
23.	"Reversibility of hepatocyte nuclear modifications in mice fed on genetically
	modified soybean", M. Malatesta, C. Tiberi, B. Baldelli, S. Battistelli, E. Manuali,
	M. Biggiogera, European Journal of Histochemistry (2005) ("Malatesta et al,
	(2005)")
24.	"Hepatoma tissue culture (HTC) cells as a model for investigating the effects of low
	concentrations of herbicide on cell structure and function", M. Malatesta, F.
***************************************	Perdoni, G. Santin, S. Battistelli, S. Muller, and M. Biggiogera, Toxicology in
	Vitro, (2008) 1853-1860, Elsevier, ("Malatesta et al, (2008)")
25.	"Can a genetically-modified organism-containing diet influence embryo
	development? A preliminary study on pre-implantation mouse embryos", B.
	Cisterna, F. Flach, L. Vecchio, S.M.L. Barabino, S. Battistelli, T.E. Martin, M.
and the second s	Malatesta, M. Biggiogera, European Journal of Histochemistry, 2008; vol.52 issue
	4(October-December): 263-267("Cisterna et al, (2008)")
26.	"The Effect of Glyphosate on Potential Pathogens and Beneficial Members of
	Poultry Microbiota In Vitro", Awad A. Shehata, Wieland Schrodl, Alaa. A. AldinHafez
	M. Hafez · Monika Krüger, Springer, (2012) ("Shehata et al, (2012))
27.	"Glyphosate suppresses the antagonistic effect of Enterococcus spp. on Clostridium

	Botulinum" M. Krüger, A.A. Shehata, W. Schröder, A. Rodloff, Elsevier, 2013, ("Shehata et al, (2013)")
28.	"Mode of Action of Herbicidal Derivatives of Aminomethylenebisphosphonic Acid. Part II. Reversal of Herbicidal Action by Aromatic Amino Acids", G. Forlani,
	P. Kafarski, B. Lejczak, and P. Wieczorek, ("Forlani et al, (1997)")
29.	"Glyphosate in the Environment", S.M. Carlisle and J. T. Trevors, Water, Air, and Soil Pollution 39 (1988) 409-420, ("Carlisle & Trevors (1988)")
30.	"The effect of glyphosate on digestion and horizontal gene transfer during in vitro
	ruminal fermentation of genetically modified canola", T. Reuter, T.W. Alexander,
	T. Martinez, and T. McAllister, Journal of the Science of Food and Agriculture, J
	Sci Food Agric 87:2837-2843 (2007) ("Reuter et al, (2007)")
31.	Letter from EFSA dated 2011 which deals with a "Request for advice from DG Sanco to analyse the article on residues associated with GMO/maternal and fetal
	exposure in relation to a previous EFSA statement from 2007 as well as statements
	given during the GMO debate in January 2011 at the European Parliament by Mr.
	Seralini, and the ongoing public debate in general." ("the DG Sanco Letter")
32.	"Glyphosate-based herbicides are toxic and endocrine disruptors in human cell
	lines", Céline Gasniera, Coralie Dumontb, Nora Benachoura, Emilie Clair a, Marie-
	Christine Chagnonb, Gilles-Eric Séralini, Elsevier (2009) ("Gasniera et al,
	(2009)")
33.	"Detection of transgenic DNA in tilapias (Oreochromis niloticus, GIFT strain) fed genetically modified soybeans (Roundup Ready)", Tao Ran, Liu Mei, Wang Lei, Liu
	Aihua, He Ru & Sun Jie, Aquaculture Research, 2009, 40, 1350^1357 ("Ran et al,
	(2009)")
34.	"Fate of transgenic DNA and evaluation of metabolic effects in goats fed
	genetically modified soybean and in their offsprings", R. Tudisco, V. Mastellone,
	M. I. Cutrignelli, P. Lombardi-, F. Bovera, N. Mirabella, G. Piccolo, S. Calabro', L.
	Avallone and F. Infascelli, Animal, (2010) ("Tudisco et al, (2010)")
35.	"Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of
	cross-kingdom regulation by microRNA", Lin Zhang, Dongxia Hou, Xi Chen, Donghai Li, Lingyun Zhu, Yujing Zhang, Jing Li, Zhen Bian, Xiangying Liang,
	Xing Cai, Yuan Yin, Cheng Wang, Tianfu Zhang, Dihan Zhu, Dianmu Zhang, Jie
	Xu, Qun Chen, Yi Ba, Jing Liu, Qiang Wang, Jianqun Chen, Jin Wang, Meng
	Wang, Qipeng Zhang, Junfeng Zhang, Ke Zen1, Chen-Yu Zhang, Cell Research
	(2011) :1-20. ("Zhang et al, (2011))
36.	"A Bacillus thuringiensis Crystal Protein with Selective Cytocidal Action to Human
	Cells", Akio Ito, Yasuyuki Sasaguri, Sakae Kitada, Yoshitomo Kusaka, Kyoko
	Kuwano, Kenjiro Masutomi, Eiichi Mizuki, Tetsuyuki Akao, and Michio Ohba, Published, JBC Papers in Press, March 16, 2004, DOI 10.1074/jbc.M401881200
	("Ito et al, (2004)")
37.	"Mitogen-activated protein kinase pathways defend against bacterial pore-forming
	toxins", Danielle L. Huffman, Laurence Abrami, Roman Sasik, Jacques Corbeil, F.
	Gisou van der Goot, and Raffi V. Aroian, PNAS July 27, 2004, vol. 101 no. 30
	10995–11000 ("Huffman et al, (2004)")
38.	"Bacillus Thuringiensis var Israelensis Crystal q-Endotoxin: Effects on Insect and
	Mammalian Cells in vitro and in vivo", W.E. Thomas, D. J. Ellar J. Cell Sci. 60,
39.	181-197 (1983) (" Thomas & Ellar, (1983) ") "BT BRINJAL Event EE1The Scope and Adequacy of the GEAC Toxicological
37.	Risk Assessment Review of Oral Toxicity Studies in Rats", November 14, 2010, Dr
	Lou M Gallagher ("Gallagher, (2010)")
40.	"Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or
	with a glyphosate-based herbicide", R. Mesnage, E. Clair, S. Gress, C. Then, A.
	Székács and GE. Séralinia, Journal of Applied Toxicology,
	(wileyonlinelibrary.com) DOI 10.1002/jat.2712 ("Mesnage et al, (2012)")

41.	Letter from the Commission to Mr C. Then dated 11 November 2011, appending a letter from EFSA to the Commission in relation an application for authorisation of a
	genetically modified maize ("the Maize Letter")
42.	"The impact of altered herbicide residues in transgenic herbicide-resistant crops on
	standard setting for herbicide residues", Gijs A Kleter, John B Unsworth and
	Caroline A Harris, Sci, (wileyonlinelibrary.com) DOI 10.1002/ps.2128, (2011)
	("Kleter et al, (2011)")
43.	"Evaluation of stress- and immune-response biomarkers in Atlantic salmon, Salmo
	salar L., fed different levels of genetically modified maize (Bt maize), compared
	with its near-isogenic parental line and a commercial suprex maize", A Sagstad, M
	Sanden, Ø Haugland, A-C Hansen, P A Olsvik and G-I Hemre, Journal of Fish
	Diseases 2007, 30, 201–212, ("Sagstad et al, (2007)")
44.	"Effects of Feeding Bt MON810 Maize to Pigs for 110 Days on Peripheral Immune
	Response and Digestive Fate of the cry1Ab Gene and Truncated Bt Toxin", Maria
	C. Walsh, Stefan G. Buzoianu, Mary C. Rea,, Orla O'Donovan, Eva Gelencse',
	Gabriella Ujhelyi, R. Paul Ross, Gillian E. Gardiner, Peadar G. Lawlor, Plos One,
	(2012) ("Walsh et al, (2012))
45.	"Intestinal and Peripheral Immune Response to MON810 Maize Ingestion in
10.	Weaning and Old Mice", A. Finamore, M. Roselli, S. Britti, G. Monastra, R.
	Ambra, A. Turrini, E. Mengheri, Journal of Agricultural and Food Chemistry
	(2008) ("Finamore et al, (2008)")
46.	"Immunotoxicological studies of genetically modified rice expressing PHA-E lectin
10.	or Bt toxin in Wistar rats", Kroghsbo S, Madsen C, Poulsen M, Schröder M, Kvist
	PH, Taylor M, Gatehouse A, Shu Q, Knudsen I., U.S. National Library of Medicin,
	Toxicology. 2008 Mar 12;245(1-2):24-34. Epub 2007 Dec 17, ("Kroghsbo et al
	(2008)")
47.	"Increased response to cadmium and Bacillus Thuringiensis Maize toxicity in the
17.	snail helix aspersa infected by the nematode phasmarhabiditis hermaphrodita" P.
	Kramarz, A. de Vaufleury, P.M.S. Zygmunt, and C. Verdun, Environmental
	Toxicology and Chemistry, Vol. 26, No. 1, pp. 73–79, 2007 ("Kramarz et al,
	(2009)")
48.	"Pancreatic response of rats fed genetically modified soybean", J.A. Magana-
10.	Gomez, G.L. Cervantes, G. Yepiz-Plascenia and A.M. Calderon de la Barca,
	Journal of Applied Toxicology, J. Appl. Toxicol. 2008; 28: 217-226, ("Magana-
	Gomez et al, (2008)")
49.	"Glyphosate", Pesticide Action Network Asia & the Pacific, PANAP, November
.,,	2009, ("PANAP (2009)")
50.	"New insights on proteomics of transgenic soybean seeds: evaluation of differential
30.	expressions of enzymes and proteins", H. S. Barbosa, S. C. C. Arruda, R. A.
Warning and the same of the sa	Azevedo & M. A. Z. Arruda, Anal Bioanal Chem (2012) 402:299–314 ("Barbosa et
	al, (2012)")
51.	"Nitrogen Metabolism and Seed Composition As Influenced by Glyphosate
	Application in Glyphosate-Resistant Soybean", N. Bellaloui, R.M. Zablotowicz,
	K.N. Reddy and C.A. Abel, Journal of Agricultural and Food Chemistry, J. Agric.
	Food Chem. 2008, 56, 2765–2772 2765 ("Bellaloui et al, (2008)")
52.	"Effect of Glyphosate-Boron Application on Seed Composition and Nitrogen
• • • • • • • • • • • • • • • • • • • •	Metabolism in Glyphosate-Resistant Soybean", N. Bellaloui, H.K. Abbas, A.M.
	Gillen and C.A. Abel, Journal of Agricultural and Food Chemistry, J. Agric. Food
	Chem. 2009, 57, 9050–9056 ("Bellalui et al, (2009a)")
53.	"Effects of Glyphosate Application on Seed Iron and Root Ferric (III) Reductase in
] ,	Soybean Cultivars", N. Bellaloui, R.M. Zablotowicz, K.N. Reddy and C.A. Abel,
	Journal of Agricultural and Food Chemistry, J. Agric. Food Chem. 2009, 57, 9569—
	9574 ("Bellaloui et al, (2009b)")
54.	
74	"Glyphosate-induced impairment of plant growth and micronutrient status in

	glyphosate-resistant soybean (Glycine max L.)", Sebastian Bott, Tsehaye
	Tesfamariam, Hande Candan, Ismail Cakmak, Volker Römheld & Günter
	Neumann, Plant Soil (2008) 312:185–194 ("Bott et al, (2008)")
55.	"Glyphosate Effects on Plant Mineral Nutrition, Crop Rhizosphere Microbiota, and
55.	Plant Disease in Glyphosate-Resistant Crops" S. Duke, J. Lydon, W.C. Koskinen,
	T.B. Moorman, R.L.Chaney, and R. Hammerschmidt, Journal of Agricultural and
	Food Chemistry, (review) pubs.acs.org/JAFC ("Duke et al, (2012)")
56.	"Effect of Glyphosate on Growth, Chlorophyll, and Nodulation in Glyphosate-
30.	Resistant and Susceptible Soybean (Glycine max) Varieties", K. N. Reddy, R.E.
	Hoagland, R.M. Zablowitcz, Journal of New Seeds, Vol.2(3) 2000 ("Reddy et al,
	(2000)")
57.	"Glyphosate-resistant soybean response to various salts of glyphosate and
37,	glyphosate accumulation in soybean nodules", K. N. Reddy and R. M. Zablotowica,
	Weed Science, 51(4):496-502. 2003 ("Reddy et al, (2003)")
58.	"Aminomethylphosphonic Acid, a Metabolite of Glyphosate, Causes Injury in
56.	Glyphosate-Treated, Glyphosate-Resistant Soybean", K. R. Reddy, N. Reddy, A.M.
	Rimando and S.O. Duke, Journal of Agricultural and Food Chemistry, J. Agric.
	Food Chem. 2004, 52, 5139-5143 5139 ("Reddy et al, (2004)")
59.	"Glyphosate influence on nitrogen, manganese, iron, copper and zinc nutritional
J. J	efficiency in glyphosate resistant soybean", A. P. Serra, M.E. Marchetti, A.C. da
	Silva Candido, A.C. Ribeiro Dias, P.J. Christoffoleti, Ciência Rural, Santa Maria,
60	v.41, n.1, p.77-84, jan, 2011 ("Serra et al, (2011)")
60.	"Nitrogenase activity, nitrogen content, and yield responses to glyphosate in
	glyphosate-resistant soybean" R.M. Zablotowicz, K.N. Reddy Crop Protection 26
<u></u>	(2007) 370–376, Elsevier ("Zablotowicz et al, (2007)")
61.	"Glyphosate Affects Seed Composition in Glyphosate-Resistant Soybean", L. H. S.
	Zobiole, R. S. de Oliveira, JR, V. Visentainer, R. J. Kremer, N. Bellaloui, and T.
	Yamada, Journal of Agricultural and Food Chemistry, J. Agric. Food Chem. 2010,
62.	58, 4517–4522 (" Zobiole et al, (2010a) ") "Water use efficiency and photosynthesis of glyphosate-resistant soybean as
02.	affected by glyphosate", L.H. S. Zobiole, R.S. de Oliveira JR, R. J. Kremer, J.
63.	Constantin, C. M. Bonato, A. S. Muniz, ("Zobiole et al, (2010b)") "Glyphosate reduces shoot concentrations of mineral nutrients in glyphosate-
05.	resistant soybeans Zobiole et al", L. H. S. Zobiole, R. S. de Oliveira, JR, D.M.
	Huber, J. Constantin, C. de Castro, F.A. de Oliveira, A. de Oliveira Jr, Plant Soil
6.1	(2010) 328:57–69 ("Zobiole et al (2010c)")
64.	"Nutrient Accumulation and Photosynthesis in Glyphosate Resistant Soybeans is
	Reduced under Glyphosate Use", L. H. S. Zobiole, R. S. de Oliveira, JR, R. J.
	Kremer, A.S. Muniz, A. de Oliveira Jr, Journal of Plant Nutrition, 33:1860–1873,
65	2010 ("Zobiole et al, (2010d)")
65.	"Glyphosate affects photosynthesis in first and second generation of glyphosate-
	resistant soybeans", L. H. S. Zobiole, R. J. Kremer, R. S. de Oliveira JR, and J.
66.	Constantin, Springer, 2010, ("Zobiole et al, (2010e)") "Glyphosate affects lignin content and amino acid production in glyphosate-
00.	resistant soybean", L. H. S. Zobiole, E. A. P. Bonini, R. S. de Oliveira JR, R. J.
	Kremer, O. Ferrarese-Filho, Acta Physiol Plant (2010) 32:831–837, ("Zobiole et
67.	al, (2010f)"), "Effect of glyphosate on symbiotic N2 fixation and nickel concentration in
0/.	glyphosate-resistant soybeans", L. H. S. Zobiole, R. J. Kremer, R. S. de Oliveira
	JR, J. Constantin, T. Yamada, C. Castro, F. A. Oliveira, J. Constantin, Applied Soil
60	Ecology 44 (2010) 176–180, Elsevier ("Zobiole et al, (2010g)")
68.	"Glyphosate affects micro-organisms in rhizospheres of glyphosate-resistant
	soybeans", L. H. S. Zobiole, R. J. Kremer, R. S. de Oliveira JR, J. Constantin,
	Journal of Applied Microbiology ISSN 1364-5072 ("Zobiole et al, (2010h)")

69.	"Glyphosate affects chlorophyll, nodulation and nutrient accumulation of "second generation" glyphosate-resistant soybean", L. H. S. Zobiole, R. J. Kremer, R. S. de Oliveira JR, J. Constantin, Pesticide Biochemistry and Physiology 99 (2011) 53–60 (Glycine max L.) ("Zobiole et al, (2011)")
70.	"Glyphosate effects on photosynthesis, nutrient accumulation, and nodulation in glyphosate-resistant soybean", L. H. S. Zobiole, R. J. Kremer, R. S. de Oliveira JR, J. Constantin, J. Plant Nutr. Soil Sci. 2012, 000, 1–12 ("Zobiole et al, (2012)")
71.	"Effect of Host Diet and Insect Source on Synergy of Gypsy Moth (Lepidoptera: Lymantriidae) Mortality to Bacillus thuringiensis subsp. kurstaki by Zwittermicin A", N. A. Broderick, R. M. Goodman, J. Handelsman, & K. F. Raffa ("Broderick et al, (2003)")
72.	"Synergism Between CryIA Insecticidal Crystal Proteins and Sports of Bacillus thuringiensis, Other Bacterial Spores, and Vegetative Cells Against Lymantria dispar (Lepidoptera: Lymantriidae) Larvae", N. R. Dubois and D.H. Dean, Environ. Entomol. 24(6): 17451-1747 (1995)("Dubois and Dean, (1995)")
73.	"Entomotoxic effects of fungal lectin from Rhizoctonia solani towards Spodoptera littoralis", M. Hamshou, E. J. M. Van Damme, and G. Smagghe, Fungal Biology Volume 114, Issue 1, January 2010, Pages 34-40 (Abstract Only) ("Hamshou et al, (2009)")
74.	"Survival of Kansas Dipel-Resistant European Corn Borer (Lepidoptera: Crambidae) on Bt and Non-Bt Corn Hybrids", F. Huang, L. Lawrent, L. Buschman, R. A. Higgins, and L. Huarong, Journal of Economic Entomology, 95(3):614-621. 2002 ("Huang et al, (2002)")
75.	"Compatibility of Bio-insecticide with Chemical Insecticide for Management of Helicoverpa armigera Huebner", F. Khalique and K. Ahmed, Pakistan Journal of Biological Science 8(3): 475-478, 2005 (("Khalique & Ahmed, (2005)")
76.	"Increased Response to Cadmium and Bacillus Thuringiensis Maize Toxicity in the Snail Helis Aspersa Infected by the Nematode Phasmarhabditis Hermaphrodita", P. E. Kramarz, A. de Vaufleury, P. M. S. Zygmunt and C. Verdun, Environmental Toxicology and Chemistry, Vol. 26, No. 1, pp. 73–79, 2007 ("Kramarz et al, (2007)")
77.	"Contributions of gut bacteria to Bacillus thuringiensis-induced mortality vary across a range of Lepidoptera", Nichole A Broderick, Courtney J Robinson, Matthew D McMahon, Jonathan Holt, Jo Handelsman and Kenneth F Raffa BMC Biology 2009, 7:11 ("Broderick et al (2009)")
78.	"Effects of infection with Nosema pyrausta on survival and development of offspring of laboratory selected Bt-resistant and Bt-susceptible European corn borers", M.D. Lopez, D. V. Sumerford, L. C. Lewis, Journal of Invertebrate Pathology 105 (2010) 248–253 ("Lopez et al, (2010)")
79.	"Avidin, a potential biopesticide and synergist to Bacillus thuringiensis toxins against field crop insects", Y.C. Zhu, J.J. Adamczyk Jr, S. West Southern Insect Management Research Unit, J Econ Entomol. 2005 Oct; 98(5):1566-71, Abstract only, ("Zhu et al, (2005)")
80.	"Synergistic effect of synthetic pyrethroids on the toxicity of Bacillus thuringiensis as shown by the biochemical changes in the sixth instar larvae of Tribolium castaneum", M. A. Saleem, N. Tufail, A. R. Shakoori, Pakistan Journal of Zoology [PAK. J. ZOOL.]. Vol. 27, no. 4, pp. 317-323. 1995 (Abstract Only) ("Saleem et al, (1995)")
81.	"Genetic Transformation of Crops for Insect Resistance: Potential and Limitations", H.C. Sharma, K.K. Sharma, J.H. Crouch, Critical Reviews in Plant Sciences, 23(1):47-72 (2004) ("Sharma et al, (2004)")
82.	"The Interactions between Soybean Trypsin Inhibitor and d-Endotoxin of Bacillus thuringiensis in Helicoverpa armigera Larva", J. Zhang, C. Wang, J. Qin, Journal

	of Invertebrate Pathology 75 , 259–266 (2000) (" Zhang et al, (2000) ")
83.	"Risk assessment of toxins derived from Bacillus thuringiensis—synergism, efficacy,
	and selectivity", C. Then, Environ Sci Pollut Res ("Then, (2009)")

AUTHORITIES ("AU")

TAB	DOCUMENT
1.	Regulation (EC) No 1289/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ("the GM Regulation")
2.	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
3.	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ("the Food Safety regulation").
4.	Case T-475/07 Dow AgroSciences Ltd v Commission, judgment of 9 September 2011
5.	Case T-13/99 Pfizer Animal Health v Council [2002] ECR II-3305
6.	Case T-70/99 Alpharma v Council [2002] ECR II-3495
7.	Case C-236/01 Monsanto Agricoltura SpA [2003] ECR I-8195
8.	Case T-326/07 Cheminova v Commission [2009] ECR II-2685
9.	Joined Cases C-189/02 P, C-205/02 P, C-208/02 P and 213/02 P <i>Dansk Rørindustri</i> A/S and Others v Commission [2005] ECR I-5425
10.	Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed, adopted on 24 September 2004, final edited version of 28 April 2006 ("the Risk Assessment Guidance")
11.	Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events, adopted on 16 May 2007 ("the Stacked Event Guidance")
12.	Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed EFSA Panel on Genetically Modified Organisms (GMO Panel) EFSA Journal 2010; 8(7):1700 ("the Allergenicity Opinion")
13.	Scientific Opinion, Guidance for risk assessment of food and feed from genetically modified plants ("the 2011 Guidance")