

And who is Juliane Kleiner, EFSA's new science director?

Summary.

Juliane Kleiner worked for over 7 years for industry lobby group ILSI (International Life Sciences Institute) and developed and defended industry proposals to change the European risk assessment policy. She worked and published with many employees of chemical industry as well with a group of scientists who are in practice mainly industry consultants. In 2004 she moved to European Food Authority EFSA. While it is hard to imagine she suddenly will defend a neutral scientific position, evidence indeed shows she kept on supporting the same ILSI-ideas and kept on working with the same scientists/industry consultants, many of which managed to get a seat in EFSA panels in the same period she was at EFSA. While it is questionable she should be qualified for a position at EFSA at all, it is unbelievable she gets the most crucial position at EFSA just before this summer, the position of science director.



Juliane Kleiner has been working for industry lobby group ILSI (International Life Sciences Institute) from 1996 till 2004 as a 'senior scientist' when she moved to EFSA. She has been active in coordinating the ILSI EU-subsidised programme FOSIE (see publications in 2002/2003 in the Annex below) and she was 'responsible staff scientist' for the following 'task forces under the Scientific Committee (of ILSI) on food safety'¹ :

- food allergy
- natural toxins
- risk assessment of chemicals in food
- risk assessment for genotoxic carcinogens in food
- threshold of toxicological concern

ILSI tries to get their ideas accepted by governments and risk assessment institutes, all with only one objective, lowering costs for industry.



¹ ILSI Europe newsletter, Number 49, February 2003

Juliane Kleiner has worked at EFSA since March 2004, firstly in the Contaminants Unit, then as Senior Scientist of Scientific Expert Services and then as team leader of the Scientific Committee. She became head of the Scientific Committee Unit in March 2013 before taking up her post as Director of Science Strategy and Coordination on 16 May 2013 (text taken from the EFSA website²).

EFSA's new science director therefore, by working many years for industry lobby group ILSI, has actively supported and publicly defended industry positions on risk assessment and published opinions together with many industry employees. It is questionable therefore if she can take an independent position in EFSA on science. It is strange to note that EFSA didn't select a neutral person for this crucial position and also strange not having selected a person with a research background; Kleiner never published any experimental work. She takes the position from Hubert Deluyker, also with an industry background (worked for pharmaceutical company Pfizer), who will continue being an advisor to EFSA's director.

Looking at the studies Ms. Kleiner published (Annex D), the following picture emerges: In her ILSI-period she clearly defended industry positions and promoted industry-tools such as the existence of thresholds for carcinogens (Renwick, 2003), defended MOE, margin of exposure (Schilter, 2003), TTC (Kroes, 2004), the threshold of toxicological concern, defended the use of benchmark doses in risk assessment (Edler, 2002), supported attacks on current uncertainty factors for food standards (set by EFSA) (Kroes, 2002), defended the idea of 'substantial equivalence' for all kinds of food, not only GM (Dybing, 2002), promoting use of 'human relevance' tool (Barlow, 2002). These are all topics industry has been lobbying for in the last 10 years, several times with success. The misleading impression created in these studies is that this is (neutral) scientific work done by ILSI and that they try to get to a 'consensus' (FOSIE programme) among scientists.

She published these opinions with a lot of industry employees from Procter & Gamble, Coca Cola, Sudzucker, etc. but also with a group of ILSI-linked scientists such as Renwick, Boobis, Galli, Lhugenot and Kroes, with ILSI-consultants such as Susan Barlow (known from changing conclusions in her work for Philip Morris³) and with ILSI-linked civil servants such as Edler, Dybing and Schlatter. The scientists in the opinions misleadingly try to create the impression they represent neutral universities while in reality they have a long track record of supporting ILSI and industry (see for instance the PAN Europe report on TTC⁴), many of them have industry contracts. Boobis worked for many chemical and food companies⁵, Galli for cosmetics industry, Renwick for sweeteners industry, Lhugenot for the paper and board industry⁶, Schlatter for flavouring industry⁷, etc.

By using these smokescreens many people in EU Commission and EFSA might have genuinely believed for a long time ILSI and these people promoted sound science and regulators didn't understand they are working for industry agenda with the mission to reduce costs for chemical industry.

² <http://www.efsa.europa.eu/en/staffdirectory/staff/julianekleiner.htm>

³ Elisa K. Tong, MD; Lucinda England, MD and Stanton A. Glantz, Changing Conclusions on Secondhand Smoke in a Sudden Infant Death Syndrome Review Funded by the Tobacco Industry, PEDIATRICS Vol. 115 No. 3 March 2005

⁴ [PAN report on TTC](#)

⁵ [PAN report on TTC](#)

⁶ [PAN report on TTC](#)

⁷ [PAN report on TTC](#)

This part of Juliane Kleiner's career should already be enough to disqualify her for a position at EFSA, let alone for the position of the science director. It is hard to believe a person just changes her mind on all these topics after defending them for over 7 years and take a neutral position -as required- at EFSA.

And evidence shows indeed that she didn't change her mind and kept on promoting industry agenda while working for EFSA. Publications (see Annex in the period after 2004) show that she keeps on promoting a threshold for genotoxics (Barlow, 2006), promoting MOE (margin of exposure) (Barlow, 2006), TTC (Kroes, 2005), even in 2009 (Pratt, Barlow, 2009), promoting the assumption of 'substantial equivalence' (Houdebine, 2008), risk-benefit tools (ILSI's FOSIE programme and Bottex, 2008), all of them industry 'babies'. She keeps on writing articles with the same ILSI-people such as Barlow, Schlatter, Benford, Kroes, Dybing, all people biased towards industry interest and many of them trying to infiltrate in EFSA panels and working groups to further promote the industry tools.

Juliane Kleiner also has a remarkable preference in her publications for EFSA-people with a link to industry or ILSI. She published in 2008 with Diana Banati (now ILSI director), with EFSA employee Bernhard Bottex (like her worked many years for ILSI) and with David Carlander (part of ILSI-taskforce as an EFSA-employee, and who later on moved from EFSA to industry). From 2008- 2010 she was observer⁸ at the EU-subsidised ILSI project EURECA.

EFSA made a big mistake and again shows they have a long way to go to get to a neutral position in risk assessment on food.

Annex I. Articles published by Juliane Kleiner.

2009:

- Article promoting industry tools (MOE and TTC) and supporting industry's position on thresholds for genotoxics:

Publication⁹ with Susan Barlow (industry consultant, worked for ILSI, evidence of scientific misconduct for cigarette industry) and John Christian Larsen, Danish food expert with strong links to ILSI¹⁰.

2008:

- Article¹¹ with German Hildegard Przyrembel (worked in 2004 for German risk assessment institute BfR) on another industry tool, the risk benefit of food consumption (industry started an FP7 programme on this tool, called BRAFO)
- Article¹² on cloning of animals assuming 'substantially equivalence' of food,

⁸ EFSA website, declaration of interest of Juliane Kleiner

⁹ Pratt I, Barlow S, Kleiner J, Larsen JC. The influence of thresholds on the risk assessment of carcinogens in food., *Mutat Res.* 2009 Aug;678(2):113-7.

¹⁰ [PAN report on TTC](#)

¹¹ Przyrembel H, Kleiner J., What is a benefit in relation to food consumption? *Toxicol Lett.* 2008 Aug 15;180(2):72-4

¹² Louis-Marie Houdebine, Andra's Dinnye's, Diana Banati, Juliane Kleiner and David Carlander, Animal cloning for food: epigenetics, health, welfare and food safety aspects, *Trends in Food Science & Technology* 19 (2008) S88eS95

With EFSA colleagues Diana Banati (now ILSI director) and David Carlander (member of ILSI-taskforce while working for EFSA; now director of advocacy, Nanotechnology Industries Association –revolving doors case-).

- Article¹³ on risk-benefit discussion of food (industry promoted tool), With Bernhard Bottex (ILSI-employee (ex-colleagues) and now also at EFSA), Benford (UK civil servant with strong ILSI-links) and David Carlander (ILSI-link; now Nanotech Industries).

2006:

- Article¹⁴ (conference outcome) of a joint EFSA-ILSI conference on genotoxic substances. The article gives a certain spin towards the conference and tries to undermine existing EU policy on genotoxics (ALARA) and substitute it for the industry tool MOE.

Written with Susan Barlow (ILSI, changing conclusion for cigarette industry), with Renwick, Dybing, Edler, Schlatter, Kroes, all of them with a strong link to ILSI, as well as Muller (Procter & Gamble) and Wurtzen (Coca Cola).

2005:

- Article¹⁵ promoting industry tool TTC, With Renwick and Kroes (both having a long track record of supporting ILSI¹⁶).

2004:

- Article¹⁷ promoting industry tool TTC with a range of ILSI-people and industry-biased scientist, also employees from Nestle (Schilter) and Coca Cola (Wurtzen).

2003:

- Article¹⁸ with industry group (Danone, Nestle, Numico) and ILSI to promote a risk assessment tool for botanicals, mainly MOE approach
- Article¹⁹ as a result of FP-programme FOSIE promoting all usual industry tools and positions, threshold for genotoxics, questioning the uncertainty factor of 100 used for

¹³ Bernard Bottex, Jean Lou C.M. Dorne, David Carlander, Diane Benford, Hildegard Przyrembel, Claudia Heppner, Juliane Kleiner and Andrew Cockburn, Risk-benefit health assessment of food - Food fortification and nitrate in vegetables, Trends in Food Science & Technology 19 (2008) S113eS119

¹⁴ Barlow S, Renwick AG, Kleiner J, Bridges JW, Busk L, Dybing E, Edler L, Eisenbrand G, Fink-Gremmels J, Knaap A, Kroes R, Liem D, Müller DJ, Page S, Rolland V, Schlatter J, Tritscher A, Tueting W, Würtzen G., Risk assessment of substances that are both genotoxic and carcinogenic report of an International Conference organized by EFSA and WHO with support of ILSI Europe., Food Chem Toxicol. 2006 Oct;44(10):1636-50.

¹⁵ Kroes R, Kleiner J, Renwick A., The threshold of toxicological concern concept in risk assessment., Toxicol Sci. 2005 Aug;86(2):226-30.

¹⁶ [PAN report on TTC](#)

¹⁷ Kroes R, Renwick AG, Cheeseman M, Kleiner J, Mangelsdorf I, Piersma A, Schilter B, Schlatter J, van Schothorst F, Vos JG, Würtzen G; European branch of the International Life Sciences Institute., Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet., Food Chem Toxicol. 2004 Jan;42(1):65-83. Review

¹⁸ Schilter B, Andersson C, Anton R, Constable A, Kleiner J, O'Brien J, Renwick AG, Korver O, Smit F, Walker R; Natural Toxin Task Force of the European Branch of the International Life Sciences Institute., Guidance for the safety assessment of botanicals and botanical preparations for use in food and food supplements., Food Chem Toxicol. 2003 Dec;41(12):1625-49.

ADI, increase burden for regulators (demand mode of action), introduce probabilistic modelling, etc.

With all 'usual suspects' from ILSI, Renwick, Barlow, Boobis, Dybing, Kroes, Edler and industry representatives from Unilever, Procter & Gamble and Nestle.

2002:

- Article²⁰ on the use of epidemiology studies in risk assessment, questioning the uncertainty factors and proposing loopholes in exposure calculations (excluding people with genetic predisposition), with Coca Cola..

Part of FOSIE, an EU subsidised ILSI programme to develop industry risk assessment tools.

- Article²¹ on exposure on contaminants through food, saying current (EFSA) approach is over conservative and promoting a tiered approach with probabilistic modelling,

With ILSI-linked scientists (Kroes), Procter & Gamble and Red Bull employees.

- Article²² on various industry tools and positions, TTC, thresholds, benchmark dose, probabilistic modelling,

With ILSI-linked scientists (Edler, Renwick), Ajinomoto and Coca Cola.

- Article²³ promoting derogation for novel foods, macronutrients and whole foods from risk assessment and promoting the GM-tool of 'substantial equivalence',

With ILSI-linked scientists (Boobis, Dybing, Renwick, Schlatter) and Syngenta and Nestle-employees.

- Article²⁴ discussing in-vitro testing for risk assessment use,

With ILSI-linked scientists (Boobis, Lhugenet) and Unilever and Sudzucker employees.

- Article²⁵ on use of animal testing in risk assessment, promoting among others the industry tool 'human relevance', enabling disqualification of adverse outcomes of animal studies.,

¹⁹Renwick AG, Barlow SM, Hertz-Picciotto I, Boobis AR, Dybing E, Edler L, Eisenbrand G, Greig JB, Kleiner J, Lambe J, Müller DJ, Smith MR, Tritscher A, Tuijtelars S, van den Brandt PA, Walker R, Kroes R., Risk characterisation of chemicals in food and diet. *Food Chem Toxicol.* 2003 Sep;41(9):1211-71

²⁰ van den Brandt P, Voorrips L, Hertz-Picciotto I, Shuker D, Boeing H, Speijers G, Guittard C, Kleiner J, Knowles M, Wolk A, Goldbohm A., The contribution of epidemiology. *Food Chem Toxicol.* 2002 Feb-Mar;40(2-3):387-424.

²¹ Kroes R, Müller D, Lambe J, Löwik MR, van Klaveren J, Kleiner J, Massey R, Mayer S, Urieta I, Verger P, Visconti A., Assessment of intake from the diet., *Food Chem Toxicol.* 2002 Feb-Mar;40(2-3):327-85. Review.

²² Edler L, Poirier K, Dourson M, Kleiner J, Mileson B, Nordmann H, Renwick A, Slob W, Walton K, Würtzen G., Mathematical modelling and quantitative methods., *Food Chem Toxicol.* 2002 Feb-Mar;40(2-3):283-326.

²³ Dybing E, Doe J, Groten J, Kleiner J, O'Brien J, Renwick AG, Schlatter J, Steinberg P, Tritscher A, Walker R, Younes M., Hazard characterisation of chemicals in food and diet. dose response, mechanisms and extrapolation issues., *Food Chem Toxicol.* 2002 Feb-Mar;40(2-3):237-82. Review.

²⁴ Eisenbrand G, Pool-Zobel B, Baker V, Balls M, Blaauboer BJ, Boobis A, Carere A, Kevekordes S, Lhugenet JC, Pieters R, Kleiner J., Methods of in vitro toxicology., *Food Chem Toxicol.* 2002 Feb-Mar;40(2-3):193-236. Review.

²⁵Barlow SM, Greig JB, Bridges JW, Carere A, Carpy AJ, Galli CL, Kleiner J, Knudsen I, Koëter HB, Levy LS, Madsen C, Mayer S, Narbonne JF, Pfannkuch F, Prodanchuk MG, Smith MR, Steinberg P., Hazard identification by methods of animal-based toxicology., *Food Chem Toxicol.* 2002 Feb-Mar;40(2-3):145-91. Review.

With industry-linked scientists (Boobis, Galli), a consultant with evidence of scientific misconduct (Barlow) and Red Bull, Roche and Unilever employees.

2001:

- Article²⁶ claiming DNA in food from GM-crops is harmless, With Sudzucker and Procter & Gamble employees.

²⁶ Jonas DA, Elmadfa I, Engel KH, Heller KJ, Kozianowski G, König A, Müller D, Narbonne JF, Wackernagel W, Kleiner J., Safety considerations of DNA in food., Ann Nutr Metab. 2001;45(6):235-54. Review.