Mid term review of EU Ombudsman's verdict regarding DG SANTE's pesticide decision-taking methods.

(PAN Europe survey, published April 2017).

Summary.

PAN Europe in 2013 submitted a complaint to the EU Ombudsman regarding the massive (mis)use of a so-called 'confirmatory data' regime in the approval of pesticides. In case of observed high risks for the environment (birds, mammals, arthropods, fish, etc.) industry was granted the opportunity to submit additional information to show that those high risk do not exist, AFTER approval of their chemical. And industry was granted the same opportunity in case of lacking data, even if the data were a legal condition (data requirement) for approval. Pesticide Regulation 91/414 didn't have a provision on confirmatory data (CD) and the derogation on CD was entirely illegal; pesticide Regulation 1107/2009 only allowed a strictly limited use of CD, only if new requirements were established during the evaluation. Nevertheless the use of CD remained a standard approach by DG SANCO/SANTE for almost every pesticide and again far beyond the legal boundaries. The EU Ombudsman in 2016 condemned the wide use of CD, ordered DG SANTE to change their practices and apply the law strictly. In two years time DG SANTE has to submit a report to the Ombudsman to show that they indeed changed practices. PAN Europe takes a look after one year by evaluating the decisions taken after February 2016.

The conclusion is that DG SANTE did not change their practices in the year after the Ombudsman's verdict and proceeded with their illegal regime of confirmatory data (CD).

Introduction.

- **Pesticide Regulation 1107/2009, art 6.f:**

submission of further confirmatory information to Member States, the Commission and the European Food Safety Authority, (the Authority), where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge;

- **Ombudsman's verdict, Feb 2016:**

The Commission's report should, in particular,
(i) show that the confirmatory data procedure is used restrictively, and strictly in line with the applicable legislation;
(ii) show, with regard to those active substances out of the ten examined in this case in relation to which the confirmatory data still needs to be assessed, that the Commission completed and updated that assessment without delay;
(iii) show that the Commission has considered whether all confirmatory data should systematically be subject to an EFSA peer review (and whether the ad hoc Guidance document concerning the evaluation of confirmatory data should be amended accordingly). In the event that the Commission decides that EFSA peer reviews concerning confirmatory data need not be systematic, the report should give reasons for that position;
(iv)show that the Commission has reviewed its approach to the definition of mitigation measures and that its approval decisions include further requirements which reflect EFSA's conclusions;
(v) show how the Commission has implemented the Ombudsman's proposal that, in the event that the FVO makes findings of non-compliance with the terms of an approval decision on an active substance in one Member State, it checks, without delay, whether there is similar non-compliance in other Member States; and
(vi) show how the Commission has implemented the Ombudsman's proposal that, if the Commission decides to withdraw or amend an approval, it ensures that this is duly reflected at Member State level without delay.

Analysis.

- **Mid-term review PAN Europe, February 2017**.

PAN Europe collected 14 decisions of DG SANTE from Eur-Lex, http://eur-lex.europa.eu/homepage.html , on synthetic chemicals from February 2016 on and analysed them on two elements (see Table below). Analysed is if the decisions are strictly in line with the Regulation and if the definition of mitigation measures is changed.

A general (but rather useless) justification by DG SANTE in their decisions is: "In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information."

Pesticide approval + date	Confirmatory data	Strict in line with the Reg.? (CD ONLY if: new requirements established during the evaluation; or as a result of new scientific and technical knowledge)	"Pay particular attention" category	Mitigation definition changed/ further requirements introduced in decision that reflect EFSA's conclusions?
Acibenzolar-S-methyl 17-03-2106	The applicant shall by 1 June 2017 submit to the Commission, the Member States and the Authority confirmatory information as regards the relevance and reproducibility of the morphometric changes observed in the cerebellum of foetuses linked to exposure to acibenzolar-S-methyl and whether these changes may be produced via an endocrine mode of action. The information to be submitted shall include a systematic review of the available evidence assessed on the basis of available guidance (e.g. EFSA GD on Systematic Review methodology, 2010).	NO, on ED effects (no new requirement; no new scientific insight; 5.8.3 data requirements* and ** NO on review (no new requirement; 1.4, data requirements*)	In this overall assessment Member States shall pay particular attention to: (a) the risk for consumers via food intake; (b) the protection of operators and workers; (c) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.	NO, EFSA concludes that gloves are needed for operators, that a 20-meter buffer zone is needed for aquatic organisms
Benzovindiflupyr, 10-02-2016	The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities; (2)the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification; (3) the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit to the Commission, the Member States and the Authority the information requested under points (1) and (2) by 2 September 2016 and the information requested under point (3) within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.	1. toxicity impurity: NO (no new requirement; 1.4. data requirements*) 2. batches: NO (no new requirement; 1.11, data requirements) 3. drinking water: NO (no new requirement; 8.8/8.7 data requirements)	In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.	NO EFSA concludes that drift mitigation measures, comparable to a 10-meter buffer zone, should be out in place.
Cyantraniliprole 24-08-2016	The applicant shall submit to the Commission, Member States and the Authority confirmatory information (***) as regards the effect	Drinking water: NO (no new requirement;	In this overall assessment Member States shall pay particular attention to: (a) the	NO, Bees, aquatic,

	of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.	8.8/8.7 data requirements)	risk to operators; (b) the risk to aquatic organisms, bees and other non-target arthropods; (c) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses; (d) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate.	groundwater, etc. no mitigation definition.
Ethofumesate 25-08-2016	No CD requested (despite 12 (!!) data gaps), including possible genotoxic impurities, batches and endocrine disrupting properties (OECD-tests proposed). Even a CAoC! Pesticide used for toxicity testing not representative.	- (why not ED effects this time?; why not genotoxic impurities?)	In this overall assessment Member States shall pay particular attention to: — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.	NO. (10-20 meter buffer zone concluded by EFSA)
I**sofetamid 25-08-2016**	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1)the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities; (2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification; (3)the effect of water treatment process chlorination on the nature of residues, including the potential for the formation of chlorinated residues that may be formed from residues present in surface water, when surface water is abstracted for drinking water. The applicant shall submit the information requested under points (1) and (2) by 15 March 2017 and the information requested under point (3) within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.	1. batches: NO (1.11, data requirements); 2. batches ecotoxicity: NO (1.11 data requirements); 3.drinking water: NO (8.8/8.7 data requirements);	In this overall assessment Member States shall pay particular attention to the risk to operators, workers and aquatic organisms, in particular fish. Conditions of use shall include risk mitigation measures, where appropriate.	NO (EFSA concludes: operators should wear coveralls and PPE-gloves)
Lambda-cyhalothrin, 04-02-2016	The applicants shall submit confirmatory information as regards: 1. a systematic review to assess the evidence available as regards potential sperm effects linked to exposure to lambda-cyhalothrin using guidance available (e.g. EFSA GD on Systematic Review methodology, 2010); 2. toxicological information to assess the toxicological profile of the metabolites V (PBA) and XXIII (PBA(OH)). The applicants shall submit those information to the Commission, the Member States and the Authority by 1 April 2018. (26 data gaps!).	1. sperm effects: NO (1.4, data requirements) 2. tox profile metabolites: NO (1.2/1.3, data requirements) (Endocrine mode of action no reason for OECD-testing?)	In this overall assessment Member States shall pay particular attention to the: (a) protection of operators, workers and bystanders; (b) metabolites potentially formed in processed commodities; (c) risk to aquatic organisms, mammals and non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate.	NO (EFSA concludes: Personal protective equipment (PPE) during mixing and loading (gloves, as well as broad brimmed headwear for hand-held application in orchards), and

				during application (gloves, hood and visor/broad brimmed headwear, coverall and sturdy footwear) (Also: still acute and chronic risk for fish at maximum mitigation measures)
Metsulfuron-methyl **02-02-2016**	The applicant shall submit to the Commission, the Member States and the Authority by 30 September 2016 confirmatory information as regards the genotoxic potential of the metabolite triazine-amine (IN-A4098) to confirm that this metabolite is not genotoxic and not relevant for risk assessment	1. genotox metabolite: NO (1.2, data requirements)	In this overall assessment Member States shall pay particular attention to: — the protection of consumers, — the protection of groundwater, — the protection of non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate	NO (EFSA concludes: a 20-meter buffer zone is needed to protect non-target plants)
Picolinafen **25-08-2016**	No CD requested (8 data gaps, among which reproductive effects on mammals, a CAoC, a critical area of concern, meaning an approval cannot be granted if the law is followed)	-	In this overall assessment Member States shall pay particular attention to: — the impurities in the technical active substance; — the protection of mammals, especially of large herbivorous mammals; — the protection of non-target terrestrial plants; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of aquatic organisms, especially of algae. Conditions of use shall include risk mitigation measures, where appropriate.	NO (EFSA: none identified)
Pinoxaden **15-03-2016**	The applicant shall submit confirmatory information as regards: (a) a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in ground water; (b) the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in point (a) by 30 June 2018 and the information set out in point (b) within six months from the notification of the	1. analysis metabolites: NO (4.2, data requirements); 2. relevance of metabolites: YES (5.8.1, data requirements)	In this overall assessment Member States shall pay particular attention to the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite M2 in vulnerable zones,	NO (EFSA: none identified - despite 2 CAOC on herb. mammals and algae)

	classification decision under Regulation (EC) No 1272/2008 of the European Parliament and of the Council(2) concerning pinoxaden.		where appropriate.	
Thifensulfuron-methyl **25-08-2016**	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the absence of genotoxicity of metabolites IN-A4098 and its derivative IN-B5528, IN-A5546 and IN-W8268; (2) mechanistic data to rule out an endocrine mediated mode of action for mammary gland tumours; (3) the risk to aquatic organisms from thifensulfuron-methyl and metabolite IN-D8858 and the risk to soil organisms from metabolites IN-JZ789 and 2 acid 3 triuret; (4)the relevance of the metabolites IN-A4098, IN-L9223 and IN-JZ789 if thifensulfuron-methyl is classified as reprotoxic category 2 under Regulation (EC) No 1272/2008 of the European Parliament and of the Council(2) and the risk that those metabolites contaminate groundwater. The applicant shall submit the information requested under point (1) by 31 March 2017, under points (2) and (3) by 30 June 2017 and under point (4) within six months after the notification of the classification decision concerning thifensulfuron-methyl.	1. genotoxicity metabolites: NO (1.2 data requirements) 2. endocrine action NO (no new requirement; no new scientific insight; 5.8.2 data requirements) 3. risks aquatic/soil metabolites 4. relevance metabolites YES and pollution groundwater NO (no new requirement; 1.2/5.8.1 data requirements)	In this overall assessment Member States shall pay particular attention to: — the protection of groundwater; — the protection of non-target plants and aquatic organisms. Conditions of use shall include risk mitigation measures and the obligation to monitor the groundwater, where appropriate	NO (EFSA concludes that no-spray zones up to 15 meter are necessary to protect non-target plants)
Thiabendazole **30-01-2017**	The applicant shall submit by 31 March 2019 to the Commission, the Member States and the Authority confirmatory information regarding Level 2 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of thiabendazole.	NO, on ED effects (no new requirement; no new scientific insight; 5.8.3 data requirements*); (the CAoC concerning compliance of batches was ignored in the decision)	In this overall assessment Member States shall pay particular attention to: — the protection of operators and consumers, — the protection of groundwater, — the control of waste water from post-harvest uses. Conditions of use shall include risk mitigation measures, where appropriate.	NO (EFSA concludes, wearing PPE for operators; waste water post-harvest needs to be collected and treated)
Sulfuryl fluoride **16-02-2017** (decision on confirmatory data; change of conditions of approval)	The notifier shall submit to the Commission, Member States and the Authority monitoring data on tropospheric concentrations of sulfuryl fluoride every fifth year, starting from 30 June 2017. The limit of detection for the analysis shall be at least 0,5 ppt (equivalent to 2,1 ng sulfuryl fluoride/m^3 of tropospheric air). *NB. EFSA feels that CD submitted by the applicant are insufficient; EFSA also concluded that applicant refused to submit data on air pollution and global warming*	**Second CD!!** Because of insufficient data submitted: NO, no new requirement, it was an old requirement already	In this overall assessment, Member States must pay particular attention to: — the risk posed by inorganic fluoride through contaminated products, such as flour and bran that remained in the mill machinery during fumigation, or grain stored in silos in the mill. Measures are required to ensure that only products complying with the existing MRLs enter the food and feed chain; — the risk to operators and the risk to workers, such as when re-entering a fumigated structure after aeration. Measures are required to ensure	NO (EFSA pr 2010: a 10-meter exclusion zone is needed around the fumigation structure to protect bystanders; Use of PPE for operators; Removing contaminated floor)

			that they wear self-containing breathing apparatus or other appropriate personal protective equipment; — the risk to bystanders by applying an appropriate exclusion zone around the fumigated structure. Conditions of authorisation shall include risk mitigation measures, where appropriate	
Oxyfluorfen **18-02-2017** (decision on confirmatory data; change of conditions of approval)	No CD requested (while EFSA concludes to a high risk for aquatic org., CAoC)	-	In this overall assessment, Member States must pay particular attention to: — operator safety and ensure that conditions of use impose the application of adequate personal protective equipment where appropriate, — the risks to aquatic organisms, earthworm-eating mammals, soil-living macro-organisms, non-target arthropods and non-target plants. Conditions of authorisation shall include risk mitigation measures such as no-spray buffer zones and drift reducing nozzles and shall provide for respective labelling of plant protection products. Those conditions shall include further risk mitigation measures, where appropriate.'	NO (EFSA concludes: PPE needed for operator; 5-meter no-spray zone for non-target arthropods; 5-meter no-spray zone for non-target plants
Oxathiapiprolin **10-02-2017** **New substance**	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities; (2)the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification. The applicant shall submit the information requested under points (1) and (2) by 3 September 2017.	1. batches and impurities: NO 2. batches and toxicity: NO	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxathiapiprolin, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.	NO EFSA none identified

(*) Data requirements: COMMISSION REGULATION (EU) No 283/2013, of 1 March 2013, setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.
(**) 5.8.3. Endocrine disrupting properties

If there is evidence that the active substance may have endocrine disrupting properties, additional information or specific studies shall be required:

— to elucidate the mode/mechanism of action,

— to provide sufficient evidence for relevant adverse effects.

Studies required shall be designed on an individual basis and taking into account Union or internationally agreed guidelines, in the light of the particular parameters to be investigated and the objectives to be achieved.
(***) Several data requirements mention additional studies. They should have been discussed with the RMS at the time of drafting dossiers or earlier and not be left to EFSA to identify.

Conclusion:

1. The Ombudsman verdict ordered DG SANTE to use confirmatory data (CD) strict in line with the Regulation; however in 20 out of the 22 cases (91%) analysed, SANTE kept on violating the rules.

2. The Ombudsman verdict ordered DG SANTE to change the definition of the mitigation measures and include further requirements which reflect EFSA's conclusions; however in 14 out of the 14 cases (100%) analysed, SANTE didn't change the definition nor included conclusions published by EFSA.