Clarification meeting – Members of the European Parliament, EFSA, Secrets Toxiques
Second session – September 3rd, 2021 – President : Mr. Claude Gruffat
Minutes – English version

Attendees:

Mr. Claude Gruffat, MEP, session's president

Mrs. Michèle Rivasi, MEP

Mr. Benoît Biteau, MEP

Mr. Manuel Bompard, MEP

Pr. Gilles-Eric Seralini, first author of the study « Toxic compounds in herbicides without glyphosate »

Mr. Philippe Piard, co-president of the NGO Secrets Toxiques

Mr. Dominique Masset, co-president of the NGO Secrets Toxiques

Mr. François Veillerette, board member of the NGO Secrets Toxiques

Mrs. Océane Mariel, APA for Mr. Benoit Biteau, MEP

Mrs. Merry Laballe, APA for Mr. Eric Andrieu, MEP

Mr. Lucas Trottmann, APA for Mr. Manuel Bompard, MEP

Mr. Charles-Maxence Layet, APA for Mrs. Michèle Rivasi, MEP

Mr. Jacques Loyau, APA for Mr. Claude Gruffat

Mr. Axel Singhofen, political advisor

Dr. Andy Battentier, campaign manager, Secrets Toxiques

Dr. Guilhem de Seze, Head of REPRO and Head of Delegation

Dr. Juliane Kleiner, ad interim Head of RASA

Dr. Suzanne Hougaard Bennekou, DTU (Denmark)

Dr. Tamara Coja, AGES (Austria)

Dr. Thorhallur Halldorsson, University of Iceland

Mrs. Manuela Tiramani, Head of Unit Pesticides Peer-Review (PREV)

Mr. Chris Lythgo, team leader chemistry and environmental Exposure (PREV)

Mrs. Mathilde Colas, team scientific coordination and administrative support (PREV)

Mrs. Victoria Villamar, Head of Unit Engagement and Cooperation (ENCO)

Mr. Christophe Wolff, institutional affairs (ENCO)

Excused:

- Mr. Eric Andrieu, MEP

Minutes

Claude Gruffat opens the meeting and thanks the participants. He suggests to directly dive into the questions in order to save time.

Guilhem de Seze indicates that he will chair EFSA's delegation for this meeting. He approves Claude Gruffat's suggestion and adds that in order to save time, participants should try to stay as synthetic as possible on the questions. He adds that he would like to keep some time at the end of the meeting to proceed to a synthesis and a conclusion, as one or two themes emerge as important throughout the questions.

Claude Gruffat approves and reminds that around 10 minutes are available by question. He specifies that some questions can be answered with a yes or a no. He asks the first question

Part 1. Long-term toxicity studies in the documents transmitted by EFSA on August 27th 2021

1st question: we proceeded to a demand of access to documents to which EFSA answered on August 27th. In these documents, we noticed the presence of studies on the formulations and studies on the declared active substance. However, we also noticed that no long-term toxicity study was performed on the formulations. Studies on formulations focus on the short-term effects of the products: skin or eyes irritation, acute toxicity, for instance.
If the analysis of the toxicity of formulations is the competence of Member States, why does EFSA only studies their short-term effects? In other words, what justifies the absence of long-term analysis of the formulations in EFSA's assessment reports, accounting for the fact that you mentioned in our last meeting that you knew that no long-term analysis was performed by Member States?

Guilhem de Seze proposes to break this question in subquestions. One subquestion is "how do we obtain the information on the toxic effects of the formulations?". Another subquestion is "Why are the industry not asked to test the whole formulation? Why are toxicity tests, acute as well as chronic toxicity not asked on the whole formulation, but only on its components, the different chemical composing the formulation?". Another subquestion is "With this approach, which is the one chosen by the law, to have data on individual components, first why does EFSA not obtain these data, and second why does EFSA not look at all data of all possible formulations?". And the last subquestion is present in the latter: "why is there no data on the chronic effect of co-formulants?"

He answers the first question: "Why is there no testing of the formulation taken as a whole?". He cites scientific, toxicological, risk assessment, economic and animal welfare reasons. He specifies that from few hundreds of possible constituents that go into the formulation of a pesticide product, it is theoretically possible to create tens of thousands, maybe hundreds of thousands of different formulations, that could eventually be found on the market. Some are known because they are on the market, some are not and industry will develop them according to the new products that they want to develop.

Hence, for pragmatic reasons, he says that the number of formulations to be tested is too big, and for reasons of available time, resources to invest, animal welfare. And even if all the possible formulations were tested, it is possible that a new formulation arrives on the market, for which there is no test done. Therefore, he says that the law requires to test individual components, and the toxicity of the mixture is estimated based on the toxicity of the single components.

Gilles-Eric Seralini says that he did not understand the answer. He says that EFSA could still ask the industry to test the long term effect of the representative formulation that is given to EFSA. He adds that about animal welfare, millions of animals will be exposed to the mixture, so it is better to test the mixtures on a few hundred animals. He asks what is the point of testing one substance, for instance glyphosate, alone, while the only exposure in real life will be the formulated product. He asks why EFSA tests one substance and not the formulation, so that the acceptable daily intake (ADI) is correctly deduced.

Guilhem de Seze answers that if there is a formulation in the dossier, it will be only one formulation. Even if the formulation is tested extensively for long term toxicity, different compounds could be added to the active substance later, and the data would not be available for these formulations.

Gilles-Eric Seralini insists that testing the formulation will still be more realistic than only testing one declared active substance. He specifies that he says “declared” as other more toxic compounds can be found in formulations, such as benzo(a)pyren, heavy metals, and polyoxyethanolamines. He repeats that it is for him better to test at least the representative formulation, and eventually restudy theoretically other formulations as EFSA usually proceeds. The purpose would be to have a realistic estimation of the ADI, which is for the moment only deduced from the declared active substance.

Guilhem de Seze says that there are other reasons, as he mentioned

Gilles-Eric Seralini says that he did not hear a scientifically acceptable reason

Guilhem de Seze asks to finish his answer. He explains that the exposure of consumers, operators, environment has to be accounted for because it will be to different fractions of the formulation. He claims that therefore studying the formulation is not the best sample to test, and that what is important is the knowledge of the toxicity of the different compounds that are in the formulation

Gilles-Eric Seralini denies

Guilhem de Seze says that this method is what the law asks for, asking for the data in particular on the active substance, which is invented to be toxic, and is therefore the one which carries the most risk in a product.

Gilles-Eric Seralini denies

Guilhem de Seze comes to the topic of impurities. He says that information about heavy metals have to be included in the dossiers, as well as information on co-formulants, even if chronic toxicity tests are not asked systematically in the dossiers because these data are obtained through other legislation like REACH or CLP. He mentions annex 3 of regulation 1107/2009 that lists the co-formulants banned in PPP formulations.

Gilles-Eric Seralini says that the only representativity is that of the mixture, with the cumulative effects of the products. He adds that in any case EFSA does not know all the impurities, the only representativity obtainable is the formulations provided by the industry.

Claude Gruffat says that the topic has been approached, that the discussion showed the difference of approaches to the analysis of toxicity of health and for the environment, and proposes to open the floor to questions, as four people are asking for speaking. He gives the floor to Benoît Biteau

Benoît Biteau makes the remark that the purpose of this meeting is to go forward, to make objective observations and find solutions to make progress. He says that the argument of animal welfare does not hold for him. As an ecologist, he perceives that massive use of pesticides are responsible for the loss of 70% of insect cohorts, and 40% of animals exposed to pesticides. He says that he has no problem that rats born in laboratory are used for experimentation if it avoids such losses.

He adds that Gilles-Eric Seralini is right to insist on the cocktail effect. An isolated molecule can be harmless and become harmful if it is mixed with co-formulants. He says that what we try to do here is to avoid a grave sanitary crisis, and asks Guilhem de Seze to be more constructive.

Claude Gruffat gives the floor to Michèle Rivasi

Michèle Rivasi notes that the confirmation has been given that there are no long-term studies on a type of formulations as a whole, but rather on each individual component. She asks to confirm this. She also asks who calculates the ADI, and if it is calculated only on the declared active substance, or on the whole formulation. She says that if the mixture multiplies by 100 or 1000 the toxicity, then the effect on users and the environment is underestimated.

Claude Gruffat gives the floor to Axel Singhofen

Axel Singhofen reminds that at the last meeting, Manuela Tiramani said that EFSA is supposed to analyse the product in the same way than member states[1]. But one representative formulation is an integral part of EFSA's evaluation and opinion. He noted that EFSA does not asks for tests on the whole formulation, and that if EFSA does not do it, it is not surprising that member states are not asking as well. He adds that the flaw seems to be that nobody ever evaluates a formulation as a whole. He understands the limits explained by Guilhem de Seze, but EFSA is supposed to study just one formulation, and not being able to assess all possible

[1] Manuela Tiramani adds, as a post-scriptum note : « Following the prescribed dual approach, EFSA is responsible to assess the a.s. and the representative formulation insofar it clarifies the potential of the a.s. in it. MSs are responsible of the authorisation of formulations to be put in the national market »

formulations is not a reason to not study the given formulation. If EFSA has the same obligations than member states, why doesn't it ask for tests on the representative formulation?

Claude Gruffat gives the floor to Andy Battentier

Andy Battentier says that he understands that not all possible formulations can be studied, but that EFSA's delegation mentioned at the last meeting that EFSA must study one representative formulation, that is however given in the assessment reports. Besides, this formulation is used to compute operators' exposure, skin or eye sensitisation. This formulation is eventually given to animals for 60 or 90 days acute toxicity tests on dogs or rats[2]. He does not understand the logic behind using the formulation only for short-term toxicity studies, and not for long-term toxicity studies. He asks how EFSA meets the regulation requirements, as it is supposed to study the cumulated and synergistic effects of at least one formulation, which is given to the agency.

Claude Gruffat gives the floor to Guilhem de Seze to answer the questions

Guilhem de Seze identifies that the first question is what studies are expected on co-formulants according to the legislation. He gives the floor to Tamara Coja to answer this question

Tamara Coja answers that it depends on the co-formulants, which are substances, chemicals regulated under REACH. Therefore, the requirements differ according to the tonnage brought per year on the European market. For co-formulants which are brought in over 1000 tons per year in the European market, an extensive data package is provided, which included carcinogenicity studies. Besides, information on co-formulants known by the applicant have to be provided by him in the authorisation dossier of the plant protection product. Besides studies on animal, more rapid ways of collecting information can be used, such as read across, grouping, QSAR, in vitro methodologies.

Claude Gruffat says that we deviate from the topic

Tamara Coja objects that what was asked was which information is available on co-formulants, and that it is the answer that she is giving.

Claude Gruffat says that what was asked was why there are no analysis and studies on complete formulations rather than on isolated molecules. He asks to come back to this primary question.

[2] Manuela Tiramani adds, as a post-scriptum note : « For mammalian toxicity, the studies requested on the representative formulation, according to the legal data requirements (Reg. (EU) 284/2013), are acute toxicity studies (oral, dermal, inhalation toxicity, skin and eye irritation and skin sensitisation, supplementary studies on the formulation/combination of formulations), data on exposure (operator, bystander, resident and worker exposure), dermal absorption studies and available toxicological data on co-formulants. Acute studies are only those testing a single dose. Sixty-90 days studies are sub-chronic toxicity studies »

Guilhem de Seze adds that Tamara Coja's answer is very relevant to the question of how the risk of complete formulations is assessed and answering to Michèle Rivasi's question. According to him, a central point of the discussion is "what information, which data are available on the toxicity of everything that comes with the active substances". He assumes that everybody in the meeting acknowledges that a lot is known on active substances and that the discussion is about co-formulants. As mixtures are not tested and that long term tests are not systematically asked, Tamara Coja's answer specifies that these long-term data come from other legislations. Specifically, REACH and other legislation create a list of unacceptable co-formulants, that are too toxic to be employed. This list is the annex 3 of regulation 1107/2009, which has been updated for the first time in April 2021.

He says that the debate should take place whether a positive list – a list of allowed co-formulants – would not be preferable to the current system of a negative list, which was a suggestion of a 2018 report of the European Commission's Scientific Advice Mechanism (SAM) Group of Chief Scientific Advisors, to which EFSA contributed.

Claude Gruffat suggests stopping discussing this question as 35 minutes have already passed and to move forward to question 2.

Part 2. The reevaluation of approbations and authorizations in the case of glyphosate

At any moment a market authorization can be withdrawn according to the evaluation of the knowledge upon the risks carried by a commercialized product. The presentation of studies and scientific proofs showing the dangerousness of a product can lead EFSA to intervene and to produce a negative opinion on the pursuit of the commercialization of a product

Claude Gruffat asks the 2nd question: In our last meeting, EFSA indicated that only iron and lead were among declared substances in the applicants' dossiers for the products analyzed by the Seralini-Jungers study. EFSA also indicated that other heavy metals and PAHs were not in these formulations. Does EFSA consider that there is a fraud, and will it reconsider its opinion on the studied representative formulations?

Guilhem de Seze says that it is a clear question and that Chris Lythgo, responsible of the question of analysis and exposure to pesticide is the most qualified to answer.

Chris Lythgo reminded that the Seralini-Jungers study was on herbicide products that were alternatives to glyphosate formulations so did not have glyphosate as declared constituents. He recalls that most of the compounds found in the products studied by Seralini & Jungers were not mentioned in the dossiers EFSA had received on the herbicide active substances that were indicated to be in the products investigated in this study. He suggests that the reason for this difference is that the formulations studied by Seralini and Jungers are different from the representative formulations assessed by EFSA. He suggests going to national authorities and is interrupted by a connection problem.

Claude Gruffat opens the floor to questions and calls Axel Singhofen

Axel Singhofen would like to come back to the previous point and says that his question will be strictly based on the regulation. Article 4-3 of regulation 1107/2009 gives the criteria for active substances authorization. In the paragraph 3-B, it is clearly said that the product must not have long-term effects on health, including cumulative and synergistic effects. And article 4-5 says that for the authorisation of an active substance, these criteria are met when at least a representative formulation has been studied. Finally, article 12-2 mentions that EFSA has to argue its opinion on whether the active substance meets the mentioned criteria. He understood that EFSA does this evaluation on the active substance, on the formulants of the formulation declared by EFSA, but does not make a global evaluation of the long-term effects of the mixture. It seems therefore that EFSA is not acting according to the law, and specifically according to what the CJUE says in the decision of October 1st 2019.

Guilhem de Seze says that in the last meeting, there was a discussion on the evaluation of cocktail effects, cumulated effects, and about the progresses that EFSA was leading on the matter. These progresses are described in the plan that has been published recently by the European Commission as well as how this will be implemented in the pesticide evaluations. Regarding the second question, on the fact that the legislation asks to test the representative formulation just like the other marketed formulations, this is what EFSA does. EFSA asks for the same data as those requested by member states for marketing authorizations. Indeed, the regulation asks less data on co-formulants than on the active substance, the reason being that the active substance is made to be toxic, whereas co-formulants are not. He says that this is the logic of the current regulation, and that this logic can be discussed, in particular whether enough data are asked, or if the suggestion of the SAM report from 2018 in which EFSA participated, to use a positive list of co-formulants, should be implemented.

Axel Singhofen repeats his question in English, citing the relevant legislation he quoted in his previous intervention (article 4-3, 4-5 and 12-2 of the regulation 1107/2009). He asks whether he understood correctly that EFSA is not testing or asking for tests on the formulation as a whole, but is looking for data on the co-formulants individually

Guilhem de Seze says that Axel Singhofen understood correctly, and that the legislation does not foresee EFSA to ask data on long-term toxicity of mixtures, even the representative one that is given. He says that besides, within the time frame of the peer review, EFSA has to consider what kind of testing is feasible. He gives the floor to Manuela Tiramani in order to give a more detailed answer.

Manuela Tiramani says that it has sense, in the legislator's view, to require only acute toxicity studies on the formulations. Because on the long-term, the fate of a mixture is not the same as what people will be exposed to just after the formulation has been sprayed in the environment. Hence, EFSA focuses on the different compounds, and importantly EFSA also focuses on the assessment of metabolites. The acute toxicity of the formulation is helpful for what the legislator had in mind to look at, for instance the operator's acute exposure. For the long-term cumulative effects, methodologies are under development, and EFSA has already made a lot of progress when it comes to dietary exposure, and cumulative assessment groups.

About the formulation, she mentions that everybody has the chance to comment on the available data during the public consultation. She mentions that EFSA is looking for all

information available on co-formulants and combined effects. Co-formulants of most concern are recently included in the negative list (Annex 3 of 1107/2009). She says that EFSA is putting a lot of attention on available alternative methodologies, such as for example the adverse outcome pathway, in order to evaluate these combined effects from the data available on the single chemicals. A lot of work has already been done, on many endpoints such as neurotoxicity, thyroid and cranofacial malformations

Claude Gruffat thanks Manuela Tiramani for her answer but reminds that what is of interest in this meeting is the long-term toxicity. He gives the floor to Gilles-Eric Seralini, and then Axel Singhofen.

Guilhem de Seze intervenes to stress that Manuela Tiramani's intervention was precisely about chronic toxicity, and the new alternative methods used to evaluate it.

Gilles-Eric Seralini says that EFSA can stop the evaluation and ask further tests to the industry, and that therefore, the argument that a timing has to be kept and does not allow for long-term studies is not defensible. He adds that EFSA eventually does its best to evaluate the long-term toxicity of mixtures with theoretical models, but that it is scientifically impossible to be accurate. And that therefore, it is the representative formulation that has to be assessed on the long-term, according to the law and what the CJEU said in its decision of October 1st, 2019. He considers unscientific to ask to REACH regulation data that it does not have.

While REACH does not provide data on all co-formulants, he considers that Chris Lythgo's answer showed that EFSA does not know the compounds of the representative formulation, as the compounds found in the Seralini-Jungers' study were not found in EFSA's dossiers. He considers that it is illegal to not test for the long-term effects of the representative formulation. He reminds that it is impossible to check industry's declarations that co-formulants are in the formulation intentionally or as impurities.

Manuela Tiramani wants to answer but **Claude Gruffat** asks Axel Singhofen to ask his question, followed by François Veillerette, and says that all questions will be answered at once.

Axel Singhofen says that to the best of his knowledge, data requirements also concern long-term data, on the contrary to what was said before. Besides, the CJEU decision refers to this regulation and affirms that information cumulative and synergistic effects on health and environment must be obtained by EFSA. He quotes a letter from the European Commission sent to NGOs, stating that the assessment of long-term health effects of plant protection products is required. So, while the Commission says that EFSA is responsible for assessment of the product through the assessment of the representative formulation, EFSA is saying here that it does not have to do it. And as Member States do the same thing than EFSA, they will not study it as well. He asks therefore if EFSA is saying that no one has to test for the long-term effects of the formulation.

Claude Gruffat gives the floor to François Veillerette

François Veillerette says that he understands that the way EFSA applies article 4-5 is not to test at least one formulation for its long-term effect, but to model its effects on the basis of the known effects of every component of the formulation. He asks EFSA to answer on whether he understood well. He supposes that EFSA uses for instance adverse outcome pathway. He wants to insist on the fact that this methodological choice is debatable. He agrees with Gilles-Eric Seralini when he says that testing chronic effects of at least one formulation would have been much more relatable. Therefore, he asks what has driven this methodological choice. He perceives a slide from regulation 1107/2009 as this choice of modelling has been made instead of in vivo testing on real representative formulations. Hence the choice is not only technical but political – however made outside of the political arena.

Claude Gruffat gives the floor to Guilhem de Seze for answers

Guilhem de Seze confirms that François Veillerette understood well EFSA's methodological approach, which is the same as the one of foreseen in various regulatory frameworks. . The EFSA approach is consistent with the kind of data asked by the legislator to industry applicants.

Claude Gruffat says that what is asked to EFSA is to study a real formulation, not a modelized one.

Guilhem de Seze says that EFSA evaluates the representative formulation in the same way as all other formulations have to be evaluated.

Claude Gruffat reiterates that a calculated formulation is not a real formulation

Guilhem de Seze says that the representative formulation is a real formulation and must correspond to a real or foreseen use if the active substance is not yet on the market. It cannot be just a theoretical model.

Claude Gruffat invites Guilhem de Seze to answer the rest of the questions

Guilhem de Seze says that when the evaluated active substance is already on the market, the rapporteur Member State makes sure that the formula is representative, meaning that it has a reality on the market.

Claude Gruffat gives the floor to Axel Singhofen

Axel Singhofen proposes questions to be answered one by one. He says that EFSA affirms that it is acting according to the law if it evaluates the representative formulation in its individual compounds but not as a whole.

Guilhem de Seze intervenes to says that modelling cumulative effects from the know effects of individuals components is a way to understand cumulative, combined effects. He says that EFSA developed methodologies in order to properly model cumulative effects.

Gilles-Eric Seralini says that these evaluations are nonetheless theoretical. He adds that all EFSA explained that it does not have access to all the data necessary for the modelling, as

some are not declared by industry and that REACH did not give access to all data on co-formulants. He cites the example of POEAs. He adds that moreover, EFSA cannot just assess the products theoretically and through modelling, as models need to be empirically verified, which is the basis of science. Therefore, not asking industry to proceed to the study of a representative formulation is what, according to him, create the bulk of damages to health and environment.

Claude Gruffat gives the floor to Michèle Rivasi

Michèle Rivasi says that the answer to our question has been given, as long-term effects of representative formulations are evaluated through a theoretical model based on known effects of individual substances. She considers that there is a difference in the interpretation of the law, as performed long-term studies are made through a model, and are not experimental in vivo studies. Besides some compounds are not declared by the industry and can amplify the toxicity of the mixture. She asks whether EFSA, when scientists will point that they found undeclared substances in commercialized products, will consider that there is a fraud, or whether it will consider that no toxic effect is added to the mixture that is sold in all Member States.

Claude Gruffat gives the floor to Guilhem de Seze

Guilhem de Seze says that with the three previous interventions, around 12 questions have been asked and that he does not know from where to start.

Gilles-Eric Seralini says that it is the same question, expressed differently

Guilhem de Seze insists that there are ten questions, so he asks what is the question that should be answered.

Claude Gruffat says that Gilles-Eric Seralini's question was about the studies provided by industry, on the products proposed for market authorization. How does EFSA obtain the studies, which studies EFSA has and are long-term studies of formulations available?

Guilhem de Seze says that it was Michèle Rivasi's question, and that he answered it. He specifies that the regulation does not require pesticides producers to generate long-term studies on complete formulations.

Gilles-Eric Seralini says that the regulation does

Guilhem de Seze continues and says that this is what the regulator decided and that EFSA works according to this. In this context, long-term effects of mixtures are done through modelling, through a molecular study of toxicity and of combination of these mechanisms. It says that EFSA's delegation already answered these questions.

Axel Singhofen says that EFSA has not answered. He cites the paragraph 115 of CJEU's decision "a plant protection product cannot be considered to satisfy the conditions (of article 4-3) if it exhibits any long-term carcinogenicity and toxicity". He cites paragraph 73 : "it is clear,

moreover from point 1.2 and 1.3 of the annex to commission regulation 284-2013, setting off the data requirements for plant protection products, that to obtain the authorization for plant protection products, there must be submitted any information on potentially harmful effects of a plant protection product, on human and animal health or on the environment, as well as known expected cumulative and synergistic effects caused by such interactions". He mentions that EFSA says that these data do not need to be submitted on the product as a whole.

He says that the MEPs' delegation is afraid that EFSA is not acting according to the law, while it is the key scientific institution providing the basis for approval. He mentions that moreover the Commission says that "it would be a misconception that long-term data on the assessment of health effects would not be required", and that EFSA is telling the MEPs' delegation that these data are not required and that they are just modelled.

Guilhem de Seze confirms that this is the case for the testing of mixture effects. He mentions the work of EFSA on modelling methodologies and the roadmap which the Commission and EFSA have published recently. He adds that the legislation does not foresee that EFSA asks data on the mixture and that the agency does not do it on its own.

Axel Singhofen says that it is a clear statement and that it is important that he and his delegation understand that it is the way EFSA reads the law.

Guilhem de Seze asks about the other questions on the available data on different constituents.

Claude Gruffat gives the floor to Michèle Rivasi

Michèle Rivasi asks if EFSA will review its opinion if other scientists show that other compounds such as PAH or heavy metals are found in the products sold in member states, or if it considers that it is a fraud as it was not declared by the applicant.

Guilhem de Seze gives the floor to Chris Lythgo

Chris Lythgo says that for the glyphosate replacement products, the information on the co-formulants is known, as well as the information declared on the impurities.

Michèle Rivasi says that it was not her question. She asks what happens if other scientists show that in the products, there are undeclared compounds, such as heavy metals or PAHs. Does EFSA take this into account? Is it the responsibility of EFSA or the one of Member States? Is there a fraud of the industry that did not declare these substances?

Chris Lythgo says that he does not know the answer whether there was a fraud because EFSA does not have the information on the co-formulants of these other products. He suggests contacting the Member States who authorised the products[3]. He says that EFSA has the contacts in the authorities that can provide these answers.

[3] Mathilde Colas adds, as a post-scriptum note : "During PAFF meeting, COM is regularly reminding MSs to declare illegal PPP use, as stated in Article 72 of Reg (EC) 1107/2009. According to Article 72, MSs have to lay

He also says that he considers that in the Seralini-Jungers study, the levels of PAHs and heavy metal are relatively low, and therefore it is plausible that these can be considered as impurities in the co-formulants. He says that it is possible that the regulatory authorities were aware of their presence, but that their assessment was that at these low levels they were not of concern. He adds that the Seralini-Jungers paper compares the concentrations found in the products with health-based standards for drinking water and this can be considered not the most relevant benchmark for a pesticide product. He says that other quality standards for heavy metals and PAHs such as those for fertilisers allow higher levels than drinking water standards. He concludes by confirming that EFSA had not asked for further information from the Member States.

Gilles-Eric Seralini wants to answer this technical point. He says that first, the presence of such toxic compounds was also observed in 2018 in glyphosate-based herbicides. He adds that gardeners can use the products of the 2020 study to grow their own vegetables, and that therefore they bio-accumulate in the field, in the garden, in the food. Therefore, comparing to the drinking water standards is accurate because these products can bio-accumulate in the water. He reminds that after the Lubrizol catastrophy of September 2019, the state was preoccupied for the presence of PAHs in the environment. The levels that were considered preoccupying were 1 million times lower than the concentration that was found in the products. He says that the pesticides in general may contribute to the general pollution through these products. And reminds that these products are not declared by industry. He asks whether EFSA asked back to the manufacturer if they had any analysis of these products in their representative formulations.

Chris Lythgo answers that EFSA did not contact the manufacturers of these products. He adds that the approval of the active substances in these products was based on an assessment of the information in the dossier, and that the applicant is expected to have provided information of all the components in that formulation, including unintentional compounds that can be there as impurities

Gilles-Eric Seralini asks if industry did not declare them

Chris Lythgo finishes his previous sentence and says that they [he probably refers to member states authorities] should have taken this information into account before authorising the products.

Gilles-Eric Seralini asks what happens if the products are already authorised

Chris Lythgo says that in this case this would possibly be an issue in the quality control of the manufacturers. He says that it is always possible that manufacturers put on the market something that does not comply with the registered specifications. He says that the

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down appropriate penalties for the infringements of this Regulation, including the illegal use of plant protection products.
Under Article 68 of Reg (EC) 1107/2009, MSs are required to carry out official controls to ensure compliance with the regulation.
At EU level, certain actions taken by OLAF are relevant to illegal PPPs".

specifications are based on the data in the dossier, which the Member States assess, and these specifications have to be safe, before products are authorised.

Claude Gruffat says that it is 10.30, and that all questions have been addressed in the previous exchanges. He proposes to have 10 minutes of additional questions, and then to proceed to the synthesis that was proposed by Guilhem de Seze. He gives the floor to Axel Singhofen

Axel singhofen wants to address the issue of whether a fraud is observed. He notes that EFSA said it will assess the active substance and the co-formulants of the representative formulation. He remarks that it is in the interest of the pesticide producer to send a representative formulation that is as innocuous as possible. He says that EFSA clarified that there is a difference between the representative formulation and the final ones. He asks if EFSA sees that companies send them as representative formulation the least harmful combination of products while the one that is finally commercialized contains other and more seriously problematic co-formulants.

Chris Lythgo says that the current framework gives the opportunity for that to be done but, and is interrupted by a connection problem.

Guilhem de Seze says that one representative formulation is mandatory in the dossier, and that it is the responsibility of the rapporteur Member State to check the reality of this representative formulation. He says that it is a point of attention for the rapporteur Member State. He calls Tamara Coja to answer in more details

Tamara Coja says that according to her experience, the representative formulation as submitted to EFSA in the dossier for active substance approval is also the formulation that is later on already available on the market of the respective Member States. Representative formulations included in a dossier for active substance approval are also formulations that are marketed in Member States. She thinks that the cherry-picking hypothesis is speculative, but that she does not know about it. She adds that Member States are confronted with formulations which also contain harmful co-formulants.

Axel Singhofen notes that on page 2 of the letter that was sent by EFSA, it is said that "while EFSA receives the application for approval, it does not have in its possession applications for the authorization of final plant protection products to be placed on the market, since it is not involved in the authorization process carried up at the national level". He also notes that in the same letter, it is also said "it follows that dossiers for approval or renewal of approval of an active substance submitted to EFSA, contain information regarding active substances in representative products rather than final products to be placed on the market in accordance with the authorization procedure". He finally notes that in the letter, a clear distinction is made between the representative and the final formulation, but that Tamara Coja just said that they are the same. He asks what is the current situation.

Tamara Coja says that she does not know which letter Axel Singhofen is reading

Axel Singhofen specifies that it is the letter received with the answer to the public access to documents request.

Tamara Coja says that she is disturbed when the distinction between a provisional, a representative, and a final formulation is made, and adds that there is in the end nothing is final and that therefore there is no final formulation. Formulations can be changed, and sometimes they have to be changed, as for instance when a co-formulant is not manufactured anymore or has been classified under REACH. She concludes by repeating that formulations are subject to changes and that requests are addressed to Member States for changes in formulations, and that certain data packages have to be provided when a request for formulation change is made.

Guilhem de Seze says that the wording of the letter might be confusing, but that the situation is clear. The formulation is representative at the moment when the dossier is submitted to EFSA. In the case of a re-authorization, the product is already on the market, and so the Member State will ensure that this representative formulation represents a reality and is actually used. For new substances, representative means: "at the step of development reached by the industrial, it is the formulation that he thinks he will put on the market, one of the formulations that he will put first on the market".

Claude Gruffat gives the floor to François Veillerette

François Veillerette wants to draw the discussion on the application of article 8-5 of regulation 1107/2009, which asks that academic scientific literature of the 10 years preceding the authorization renewal demand to be provided in the dossier. He says that these dossiers were expertized, and that this demand is never fulfilled, as between a few percentage up to 50, 60% of the literature only was present in the analyzed dossiers. He says that it might be a bias towards an underestimation of the risk as the information present in these studies are therefore not taken into account. He asks what how EFSA checks that the whole published literature, that can be easily found for instance through a PubMed research, is included in the dossiers.

Guilhem de Seze gives the floor to Manuela Tiramani

Manuela Tiramani says that the inclusion of literature is extremely important in our work. She says that guidance to support assessors, applicants, and the public to check how it was done was developed based on the provisions of regulation 1107/2009 , and that there is a clear methodology on how this process should be done[4]. She says that plenty of data gaps are mentioned in the conclusions of the assessments, in particular in the first years of implementation of the regulation. When a literature review is performed, there is a clear methodology for assessors, which must evaluate the criteria on which an applicant decided to exclude from or include some studies in the assessment. This is constantly checked and quite solid. She says that in case of a doubt concerning the presence of a proper literature review by the applicant, EFSA can run its own review. In any case, EFSA is always going back to the applicant if EFSA is not confident with the literature search provided.

[4] Manuela Tiramani adds, as a post-scriptum note : Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009, EFSA Journal 2011;9(2):2092 an EFSA participant sends in the meeting chat box the link to EFSA guidance xxxxxxx

Michèle Rivasi asks who establishes the ADI: EFSA or rapporteur Member States? She also asks if the ADI is computed on the basis of the declared active substance, and not on the mixture, as some co-formulants can be very toxic. She also asks whether EFSA, following the CJEU decision of October 1st, 2019 will change its practices concerning formulations, and that it will account for the whole products and not only the active substance. She mentions that in 2017, there was a controversy on glyphosate, that was considered toxic by the IARC but not by EFSA, as the former was considering the whole formulation, while the latter was focused on the active substance.

Guilhem de Seze gives the floor to Manuela Tiramani

Manuela Tiramani says that EFSA in collaboration with the Member States sets reference values for the active substance (Acceptable Daily Intake - ADI, acceptable operator exposure – AOEL, and acute reference dose – ARfD). For this, a complete database is used, data gaps are highlighted in the conclusions through open issues or critical areas of concern. Rapporteur Member States come to EFSA and other Member States with a proposal of ADI and other reference values (reported in the Draft Assessment Report), which is discussed, commented and in some cases also reviewed, and a (new) value is proposed.

In most cases, the basis for ADI is long-term toxicity, although other kind of studies might be used if they allow to identify and point out concerns. Such studies can be experimental studies and literature studies. In recent cases some concerns were highlighted on the basis of published literature. Based on this, EFSA adds an uncertainty factors related to the extrapolation of interspecies (animal to human) and intraspecies. This is what EFSA does in the frame of assessing the active substance[5]..

Claude Gruffat asks if Guilhem de Seze will answer the second question of Michèle Rivasi

Guilhem de Seze asks if the question can be repeated

Michèle Rivasi asks whether EFSA changed its way to see the toxicity of glyphosate in response to the CJEU decision of 2019, and the polemic between IARC and EFSA, as IARC said the glyphosate was carcinogenic but EFSA was saying the opposite, and that IARC was studying the product and EFSA was focused on the active substance. She asks whether EFSA reconsidered their methodology and if EFSA issued new guidelines to rapporteur Member States. She insists on the importance of the topic, as the authorization renewal process for glyphosate is ongoing.

Guilhem de Seze says that following the debates on glyphosate brought some changes in the regulatory framework, as for instance the new regulation on transparency (1381/2019) which brought a new way to prepare the dossiers, to set public consultations, to grant access to data. However, the regulation 1107/2009 has not changed, and it is the most important to define how the peer-review process is done, so EFSA continues to apply it in the same way.

He adds that in the case of the controversy, EFSA concluded that the most dangerous constituent in glyphosate-based products was one of the co-formulants, i.e. the polyethoxylated tallowamine. This was captured in EFSA's conclusions, and the Commission mandated EFSA for further assessment, which led EFSA to conclude on the necessity to further investigate the genotoxicity and carcinogenicity of POE-tallowamine. This further investigation led to exclude POE-tallowamines as possible co-formulants, and to include it in the annex new 3 of regulation 1107/2009

Gilles-Eric Seralini reminds that tallowamine is not a substance but a family of substances which can have from a few carbons to around forty carbons. He asks if this family of substances were declared in the formulations by industry.

Guilhem de Seze says that he does not know the representative formulation that was in the dossier evaluated by EFSA. As regards PPP formulations, co-formulants must be declared in the PPP dossier submitted to MSs by applicants

Gilles-Eric Seralini says that the answer is no in the detail of the dossier.

Guilhem de Seze says that any co-formulant, to be authorised in the market in a formulation or a pesticide product must be declared in the dossier that is submitted to Member States.

Gilles-Eric Seralini says that his team discovered the POEAs, and that they were not declared in the representative formulations EFSA had, which they obtained using transparency. He adds that the presence of carcinogenic PAHs was already shown in 2017-2018, which can explain the long-term effects. He asks Guilhem de Seze to check and give more details later.

He continues saying that this discovery changes considerably the ADI. EFSA has an interpretation of the law that is only theoretical, through modelling, but EFSA does not have all the compounds of the products, either because industry's fraud and do not declare them, either because REACH did not analyzed it because they are brought in the European market below the defined thresholds, either because there was no analysis at all from EFSA or from the industry. Therefore, EFSA cannot model something it does not know, or if it has to anticipate from a factor 10 or other…

However, his team made the experiments, comparing the effects of glyphosate or acetic acid alone regarding the effects of RoundUp, and found enormous differences on human cells, animal cells, and also in vivo. He says that a factor 1000 has to be accounted for in the definition of the ADI, which are currently false for him. He asks what EFSA thinks about this.

Guilhem de Seze says that as co-formulants, tallowamines had to be declared in the authorisation dossiers of the products. Therefore, Member States have seen it. And there was EFSA's assessment based on studies submitted by the applicant (https://ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/glyphosate/earlier-assessment_en), which led to forbid POE-tallowamine in all pesticides' formulations, as it is now inscribed to annex 3 of the regulation 1107/2009. He says that it brings back to a question that was discussed, about the potential deviations between the information in an applicant's dossier and what will be on the market, whether it is fraud

or non-compliance. He says that if any citizen, including the MEPs' delegation does a research that finds in a formulation that is on the market, concentrations of compounds that go above what has been declared, or undeclared compounds in concentrations above what is legally considered as an acceptable threshold for impurities (he cites the example of the level of impurities tolerated in the fertilizers or other products of large consumption such as detergents…), then a declaration has to be made to the Member State who authorized the pesticide product.

Gilles-Eric Seralini says that scientific publications are a declaration. And that NGOs are pointing at this problem. He adds that he thinks that the problem is general and asks what EFSA does with this information.

Guilhem de Seze says he does not know what to answer to the comment about the general aspect of the problem which falls in the remit of risk managers. He says that scientific data, proof are required.

Gilles-Eric Seralini says that when these compounds are found in 14 products that are representative of all products without glyphosate, it is a data. He asks EFSA's delegation whether they think they do not have a role in this system.

Guilhem de Seze answers that EFSA has a role if data are found on the active substance or the representative formulation that was given in the dossier submitted to EFSA. If Gilles-Eric Seralini considers that there is a problem of non-conformity of the product, then a declaration has to be submitted to the European Commission, that would ask EFSA to check the data, to check the problem. He adds that this is only in the case that what has been found concerns EFSA's work. On the opposite, if what has been found concerns marketed pesticide products that were authorized by the competent authorities of Member States, then Member States must be addressed, as EFSA does not have all the data on all possible co-formulants of products.

Gilles-Eric Seralini remarks that as representative formulations are confidential, and that EFSA takes time to give them, it is hard to make a declaration. He adds that EFSA could act on its own, and says to the Commission that it will proceed to a new study of these products and their approvals, from the representative formulation.

Guilhem de Seze says that it would require data that show that information given by an applicant is not conform to the reality of what is on the market. He adds that formally, the Commission must be addressed and give EFSA the right to proceed, but that if this information is brought to EFSA, the agency will get in touch with the Commission.

Gilles-Eric Seralini says that EFSA must know about scientific publication and act according to them.

Guilhem de Seze confirms that EFSA follows the scientific public literature, and that when studies bring reasons to doubt, to explore whether other toxicity phenomen mechanisms happen, the Commission is seized, typically by Member States, and the Commission seizes

EFSA. He says that this mechanism works and is often activated, as for instance on titanium dioxide most recently.

Claude Gruffat says that Guilhem de Seze talks about food and deviates from the topic of pesticides. He adds that the Seralini-Jungers study is alarming and that EFSA has not still seized itself, and that he does not understand why. He gives the floor to Andy Battentier

Andy Battentier says that EFSA has in its possession alarming studies. He mentions that two studies, Seralini-Jungers 2020 and Defarge et al. 2018 show the presence of arsenic, lead, and benzo(a)pyren. He notes that EFSA criticizes the choice to compare the concentrations found to drinkable water standards, but that it does not remove the fact that they said concentrations are significant, and that the presence of toxic compounds is systematic. Besides, on the last meeting, EFSA said that benzo(A)pyren is a model of carcinogenicity, and that it was out of question that this compound would be authorized in a pesticide. But benzo(A)pyren was found in authorized products.

When EFSA is asked whether it will react in front of these scientific information, you point at the Member States or the Commission. So, he deducts, as time was spent on this question and that no clear-cut answer was obtained, that EFSA will not react following the publication of Seralini-Jungers' study. He asks EFSA's delegation to confirm this.

Guilhem de Seze says that to seize the Commission, it would be necessary to have data that show that there are reasons to think that something on the market is not conform to the information that was given during the evaluation and authorization process, either on the active substance or on commercialized products.

Andy Battentier says that in the Seralini-Jungers study, these proofs are present, but that EFSA does not see them as sufficient.

Guilhem de Seze says that on benzo(A)pyren, what was said in the last meeting is that it cannot be a constituent of a pesticide product, as it is carcinogenic. It can be present as an impurity, as long as it stays under defined thresholds.

Gilles-Eric Seralini says that such thresholds do not exist

Guilhem de Seze says that there are acceptable thresholds, as impurities

Gilles-Eric Seralini answers that EFSA decides whether it is an impurity or not, and that its presence can be intentional

Guilhem de Seze says that its presence cannot be intentional, as it is carcinogenic. It cannot be authorized as a substance intentionally put in a pesticide product.

Claude Gruffat remarks that however, it cannot be there completely by chance

Guilhem de Seze says that it arrives in the product as an impurity, as it is the case in many industrial petroleum-based products.

Gilles-Eric Seralini agrees

Guilhem de Seze suggests taking a look at laundry detergents, and that probably PAHs will be found.

Gilles-Eric Seralini agrees and says that they are made from the same petrol.

Guilhem de Seze agrees and says that then, regulation defines acceptable thresholds for impurities, for different categories of products.

Claude Gruffat says that the meeting comes to an end and that there is no time to proceed to a conclusion, as it is 11. He thanks for the dialogue, although it has been observed that interpretations on the topic are very different. But he appreciates that it was possible to discuss them and to go forward. He says that he does not know if his delegation will contact EFSA again, that it is not planned but that if necessary, he is opened to continue the dialogue. He thanks all participants and Guilhem de Seze for leading EFSA's delegation.

Guilhem de Seze thanks for the meeting and open dialogue. He says that his delegation is open and interested in continuing the dialogue, for instance taking advantage of all the EFSA channels opened to civil society and EFSA's stakeholders. He also mentions the possibility of the Health and Environment and Food Safety Committee of the European Parliament (ENVI), and within the existing opportunities for NGOs.

Claude Gruffat thanks the translation services in this rather technical meeting and wishes everyone a good day.