European Ombudsman

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Against which European Union (EU) institution or body do you wish to complain?

European Commission

What is the decision or matter about which you complain? When did you become aware of it? Add annexes if necessary.

EU Health Directorate DG SANCO is using a special regime for the approval of active substances of pesticides, called "confirmatory data". This regime allows approval of an active substance while data gaps are still present and allows the applicants (industry) to submit the required studies for this data gap in a later phase when the substance is already on the market and released in the environment. Even when Food Authority EFSA concludes to "high risks" for the environment (birds, bees, mammals, etc), Commission approves the substance and offers the applicants a second chance of proving the risk is acceptable.

Pesticide Directive 91/414 (soon the first approvals will be done based on the new pesticide Regulation 1107/2009) has no reference to "confirmatory data" but DG SANCO constructed this new 'invention' of "confirmatory data" at implementation level in Brussels comitology. We stumbled on this "confirmatory data" regime in a case on the pesticide Chlorpyrifos early summer 2011 but only became fully aware of the extend and impact of "confirmatory data" when we analysed the approval of a sample of 10 active substances in our 2012-report Resubmission (attached). In 10 out of 10 cases we analysed (page 10/11 of the report) the "confirmatory data" regime was used. It appears, looking at more approvals, that "confirmatory data" regime is used on a routine basis.

In the new Regulation 1107/2009 there is mentioning of "confirmatory data" under special conditions, but since all decisions were still based on the old Directive 91/414, we are not able to analyse how this new provision will be used.

What do you consider that the EU institution or body has done wrong?

We feel that this "confirmatory data" regime is an infringement of Article 5 of Directive 91/414/EEC. Data are missing or data are indicating a high risk and still Commission expects that the substance doesn't have any harmful effects for humans and/or unacceptable influence on the environment.

Article 5 must in our opinion be understood as requiring that – at least for one representative use - there is sufficient documentation to show on the basis of a scientifically reliable risk assessment that this use is safe in relation to all relevant risks.

The wording in article 5(1) that it “may be expected” that plant protection products fulfil the requirements in Article 5(1) cannot in our opinion justify inclusion of an active substance in Annex I if there is only an uncertain or theoretical *possibility* that a product containing the active substance can be acceptable.

Furthermore the "confirmatory data" regime disrespects the "high level/standard of protection" the pesticide Directive 91/414 and Regulation 1107/2009 provide for and disrepects the precautionary principle:

Recital 8 of Directive 91/414 states: Whereas the provisions governing authorization must ensure a high standard of protection, which, in particular, must prevent the authorization of plant protection products whose risks to health, groundwater and the environment and human and animal health should take priority over the objective of improving plant production;

Recital 8 of Regulation 1107/2009 states: The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.

By using the "confirmatory data" regime, DG SANCO exposes people to potential harmful risks and the environment many times to high risks, as determined by Food Authority EFSA.

We illustrate the infringement by a few examples. First one is the pesticide active substance, Bitertanol. The decision of Commission can be found on the internet, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:327:0049:0055:EN:PDF

In recital No. (7) of the decision it is stated that: “It has appeared from the various examinations made that plant protection products containing bitertanol may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular as regards the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve bitertanol in accordance with Regulation (EC) No 1107/2009”.

However, in recital No. (9) it is stated that: "Without prejudice to the conclusion that bitertanol should be approved, it is, in particular, appropriate to require further confirmatory information".

In the Annex of this decision the "confirmatory information" is specified:

"The applicant shall submit confirmatory information as regards:

(1) the toxicological relevance of the impurities BUE 1662, thus referred to for confidentiality reasons, and 3-chlorophenoxy compound;

(2) the acute and short-term risk to granivorous birds;

(3) the long-term risk to granivorous mammals;

(4) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin;

(5) the possible impact of the variable isomer-ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and the environmental risk assessment.

The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (1) by 30 June 2012, the information set out in points (2), (3) and (4) by 31 December 2013 and the information set out in point (5) two years after the adoption of specific guidance.

Food Authority EFSA identified a high risk to birds and mammals for Bitertanol (http://www.efsa.europa.eu/en/scdocs/doc/1850.pdf) and one would expect Commission to conclude to an unacceptable influence on the environment. On the contrary, Commission concludes to NO unacceptable influence. Commission doesn't draw this conclusion based on additional data, but allows the applicants to submit additional data/information a few years later, after the approval, with an uncertain outcome. We feel it must be a requirement that all data necessary for a scientific reliable risk assessment for birds and mammals is available before the inclusion in Annex I.

Food Authority EFSA also identified a "critical area of concern" in the same opinion on Bitertanol for the impurities. Again Commission concludes to NO harmful effects on humans while additional data still need to be generated and submitted in future. We feel data on the toxicology of these impurities should be available before inclusion in Annex I.

In a large range of Commission decisions, similar wording is used as in recital (7) and (9) of the decision on Bitertanol. The 'confirmatory data" of course differ for every substance. The "confirmatory data" can be anything what is not finalised or lacking or were EFSA concludes to high risks; just for illustration reasons we add another example, the substance Oryzalin where recital (7) of Decision: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:060:0012:0016:EN:PDF reads:

"Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions.

- Therefore, it is necessary that the specification of the technical material, as commercially manufactured, be confirmed by appropriate analytical data, including information on the relevance of the impurities, which for confidentiality reasons are referred to as impurities 2, 6, 7, 9, 10, 11, 12.

- The relevance of the test material used in the toxicity dossiers should be confirmed in view of the specification of the technical material and information confirming the risk assessment for aquatic organisms should be requested.

- Provided that oryzalin becomes classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1) as 'suspected of causing cancer', the Member States concerned shall request the submission of further information confirming the relevance of the metabolites OR13 (2) and OR15 (3), and the corresponding groundwater risk assessment". The inclusion is therefore on condition that the notifier provides further studies to confirm the risk assessment for impurities, aquatic organisms, and potentially the relevance of metabolites and groundwater risk.

Article 5 of Directive 91/414, the most crucial provision of the Directive, is violated by Commission on a very large scale.

What, in your view, should the institution or body do to put things right?

Claim 1.

We demand DG SANCO to immediately stop making use of the "confirmatory data" regime. This regards any approval done under the old Directive 91/414 but certainly also (future) approvals under the new Regulation 1107/2009.

For the new pesticide Regulation 1107/2009 we feel the situation on "confirmatory data" is very clear. Art.6 summes up the conditions and restrictions to which an approval may be subject to. Art.6 makes it perfectly clear that it is a matter of conditions and not future studies. Only Art. 6.i tends to talk about future studies but this only refers to monitoring. We feel the conditional approvals made under the "confirmatory data" regime are the more unjustified given the obligation to make use of the precautionary principle under Art.1 (4). In case of scientific uncertainty the precautionary principle should be used.

Claim 2 .

Given the fact that Food Authority EFSA in many cases identified high risks for the environment as well as lacking data on potential toxic metabolites or impurities, we are of the opinion an approval in these cases is unjustified. However since the "confirmatory data" are used almost on a routine basis, it is most likely DG SANCO will continue these practices in future, potentially by misinterpreting Art.6.f of Regulation 1107/2009. It all starts with the applicant delivering required studies to the Rapporteur Member State. The Rapporteur Member State then needs to make a "completeness check" decision on the studies and reports delivered by the applicant and in many cases in a later phase of risk assessment it appears the dossier is not complete. Also it could be the case that the quality of industry studies is low and the study should be repeated, but this is generally only discovered in a later stage after the completeness check decision, mainly by Food Authority EFSA. A further case is that current academic science is generally not added by the applicant because they might not like the outcome of the studies of independent scientists and the Rapporteur Member State doesn't check this failure in the completeness check. We known the completeness check is done in a "bureaucratic" way, such as a simple administrative YES/NO

analysis on studies delivered, but not really studying them by experts. There even have been discussions among member states about this "bureaucratic" approach and the inappropriateness of it. We therefore additionally want DG SANCO to take a central role in the "completeness check" decision according to Art.9 of Regulation 1107/2009 (admissibility of the application) to prevent the massive use of "confirmatory data" in future or the use of another new derogation SANCO might develop in comitology. Our three (sub)claims are: DG SANCO should make detailed guidelines for the completeness check to make sure not only all required documents are submitted but also make sure the quality of the studies assessed is sufficient to be able to start the risk assessment. DG SANCO also should ensure that current academic science is part of the dossier and make sure that any additional studies needed based on concerns in the academic scientific literature are requested at the start of the risk assessment and not in a later phase. SANCO also should ensure that the decision on completeness will be made public to enable stakeholders to add information to the dossier and scrutinise the content of the dossier.

Have you already contacted the EU institution or body concerned in order to obtain redress?

Yes (please specify and submit copies of the relevant correspondence)

In June 2011 we wrote a letter to Health Commissioner Dalli and the short reply in July 2011 was that Commission legal services felt that "confirmatory data" regime was a condition according to art. 6(1) of Directive 91/414. We think this is not justified.

One of the conclusions of our Resubmission report was the wide use of 'confirmatory data" and our letter to Mr. Dalli beginning 2012 was answered in June 2012 with mainly general statement such as that the pesticide Regulation is among the strictest in the world but no detailed reply on the outcome of our report.

In September 2012 there was a meeting with several civil servants of DG SANCO. Some comments was given regarding the "confirmatory data" regime. One civil servant explained that data gaps could mean the experts do not agree or that in other cases the data are not fully robust. Another civil servant stated that DG SANCO has to make a balance between interests and that for this reason an approval is made while data gaps are still present.