on monitoring plans – May 2020

THE POOLED SELF-MONITORING PLANS HAVE DEMONSTRATED THEIR USEFULNESS

To monitor the quality and feed safety, OQUALIM has set up a pooling approach for monitoring actions based on the risk of contamination of feed materials and finished products. All of these initiatives have one final objective : managing quality, safety and traceability from the feed materials intended for the feed of livestock, in order to better guarantee the health quality of the animal products.

Aims of the pooled self-monitoring plans :

- Define a sufficient self-monitoring plan at the profession level.
- Monitor the quality of the feed materials used in the territory, by providing a real-time overview to the participants with the possibility of individual reactions in the event of an alert.
- Be an observatory for substances that are undesirable for feed.

The strengths of the system recognised by all players and beneficiaries :



Monitoring modalities focusing on the exploitation of pooled self-monitoring results on feed materials and finished products, carried out by companies in a pooled framework with the continuous search for efficiency



Very high levels of monitoring achievement, which show the backing and strong acceptance of professionals for the system and its operations. A history of over 10 years of operations, based on stable relationships between partners



Clear targets and monitoring modalities supported by a good level of formalisation of monitoring rules and procedures

Good monitoring coverage thanks to the massive participation of premixes and complete or supplementary compound feed manufacturers



A key involvement of laboratories in the system, which is based on conventions and documented requirements



Centralised databases, with secure access, that provide results monitoring to each participating company



An alert system for the community in the event of detection corresponding to a first category hazard



Dynamic internal communications for the system, with the diffusion of regular operational reports



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OQUALIM is an association whose aim is to provide solutions to help meet health security and animal feed quality challenges.

The association coordinates the collective approach by the French animal nutrition sector in terms of quality and health security of animal feed. It has two main objectives : health security and compliance with both public and private specifications. To achieve these objectives, it has constructed two tools : pooled self-monitoring plans and the certification of animal feed plants with the RCNA (Animal Nutrition Certification Reference).

OQUALIM

41 ^{bis} boulevard la Tour-Maubourg 75007, Paris - France <u>www.oqualim.com</u> contact@oqualim.fr +33 (0)144 186 355

Tangible achievements carried out with the professional feed manufacturer environment :

- Participation in the monitoring of the health quality of French cereals and oilseed sector, in partnership with the sector monitoring plans. Monitoring in line with the regulatory changes and specific needs of animal species, as you can see in the mycotoxin articles in the central pages,
- Data available to feed European studies, as in 2019 for dioxins (article on the last page),
- Active participation in the national platform of surveillance of the food chain (SCA Platform), which notably enabled participation in the assessment of the salmonella monitoring system

(OASIS assessment by the ANSES as part of the ONDES working group) ; the results of the study will be published in 2020, but the findings on the system's efficiency are already encouraging and provide constructive ideas for moving forward,

• Exploratory analyses targeted on elements that are unregulated in feed according to the specific concerns of the animal production sectors.

Objectives that have been fully achieved by the plans serving manufacturers of premixes and compound feed, for the overall benefit of the health quality of animal products.

Céline Ravel

Your contacts OQUALIM :

Céline Ravel Manager c.ravel@oqualim.fr

Cécile Bouveret Quality Officer c.bouveret@oqualim.fr





Very satisfactory results in 2019

The monitoring of mycotoxins is a major issue in feed. As part of the Feed plan, the monitoring concerns not only mycotoxins for which there is a maximum regulatory level in feed (aflatoxins B1, rye ergot), but also those for which recommendations exist at a European level (deoxynivalenol or DON, zearalenone, ochratoxin A, T-2 and HT-2 toxins and fumonisins). In 2019, over 1,700 analyses were carried out on feed materials (46 % concerning DON), and 274 on finished products (24 % concerning DON).

Mycotoxin results obtained on feed materials as part of the Feed plan in 2019

	Compliant result *	Result to be monitored**	Non-compliant result***	TOTAL
Aflatoxin	125	0	0	125
DON	716	77	0	793
Ergot	58	0	0	58
Fumonisins	201	8	0	209
Ochratoxin	14	0	0	14
T2-HT2	49	3	0	52
Zearalenone	425	35	0	460

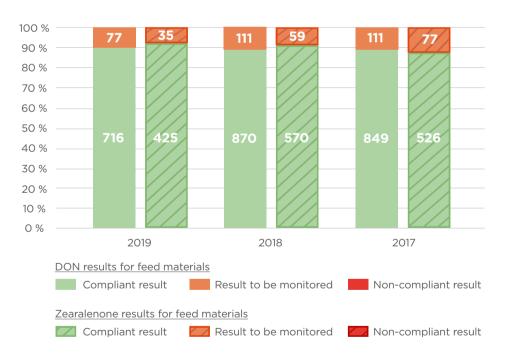
 $\ast\,$ Results below the maximum authorised level in human food or 2/3 of the maximum level authorised in feed

 $\ast\ast$ Results above or equal to the maximum authorised level in human food or 2/3 of the maximum level authorised in feed

*** Results above the maximum authorised or recommended level in feed

Overall, the results were very satisfactory, as in previous years. No "red" results were recorded in 2019.

A few "orange" results were obtained for T2-HT2 (3 results or around 6 %), for fumonisins (8 results or around 4 %) and above all for DON (77 results or around 10 %). These results show an overall stability over 3 years. A slight improvement has been noted for zearalenone.



DON and zearalenone results for feed materials

A revision to the regulatory requirements at the European level

At the European level, projects are being undertaken to revise the regulatory requirements for mycotoxins to take into account emerging mycotoxins. With regard to human food, the regulatory draft on ergot and ergot alkaloids should enter into force on 1st July 2021, that on tropane alkaloids should apply for the 2022 harvest and discussions are on-going for the T2-HT2 toxins and DON. These changes will probably have repercussions on feed. Given the thresholds defined for some "feed materials - mycotoxin" couples, declassifications of batches and redirection to feed plants are to be expected.

Whilst human food is directly impacted by these regulatory changes, modifications are also to be expected in feed. The European projects cover most mycotoxins : fumonisins, DON, zearalenone, T2 – HT2 toxins and ergot sclerotia. The main objective is to reduce the maximum levels.

For the DON, the Authorities are moving towards a significant decrease in the recommended levels for all species in order to include the modified forms of DON (15aDON, 3aDON, DON3G). A single value for the DON would be provided instead of a threshold per type of DON. In feed, the ratio selected by the Authorities between the single DON on the one hand, and the total DON and its modified forms on the other would be 0.69. The maximum levels would be reduced by the same proportions... From a technical viewpoint, this reasoning based on a single ratio has not convinced French scientists. According to the results of the ARVALIS study, it would not be possible to apply a single correction factor, in a reliable way. Whilst correlated, the proportion of modified forms compared to the DON varies according to the toxin, crop and year¹.

From a monitoring viewpoint, data from OQUALIM's plans shows that these new thresholds would lead to the emergence of "orange" and "red" signals for the DON. In addition, the authorities also intend to reduce the NOEL² for the DON for different species : pig, poultry and fish.

Moreover, beyond the thresholds and quantitative values set, the European Commission is also discussing changes in the concepts used in feed. Some Member States question whether to change the maximum recommended levels in compound feed to regulatory maximum limits. If this is envisaged for compound feed, the European experts would retain the recommendation level for feed materials in order to optimise the available resources. These changes may cause problems for feed, as the processes do not enable mycotoxins to be eliminated.

OQUALIM's role in response to these developments

OQUALIM intervenes at the pre-regulatory level. The European experts build on the data transmitted by Member States to propose the regulatory thresholds and assess the feasibility of the proposals. Plan data may, therefore, be mobilised in this context to anticipate the difficulties and share, at a European level, the problems that these revised thresholds would cause.

After the publication of the new regulatory requirements, an increase in monitoring across the chain will be required, with the addition of exploratory aspects for the new subjects. OQUALIM's plans could integrate this new data and respond to these new requirements.

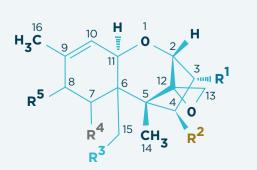
> Blandine Markwitz, Bruno Barrier-Guillot (Intercéréales), Béatrice Orlando (Arvalis)

¹B. Orlando et al. Occurrence of modified forms of DON in cereals and identification of factors that modulate their proportion compared to the DON ² NOEL : Non Observed Effect Level

Emerging and modified mycotoxins

In Europe, the climatic conditions favour the contamination by Fusarium type fungi for which the main toxins, fumosinins, type A trichothecenes (T2 and HT2), type B trichothecenes (deoxynivalenol (DON)) and zearalenone) are regulated or are subject to recommendations in food and feed. However, the Fusarium also produces other toxins such as beauvericin, enniatins (A, A1, B and B1), apicidin and aurofusarin, which are less well described and unregulated, called emerging mycotoxins. Projects are on-going to study their prevalence and toxicity. The regulations do not include all of the modified forms of mycotoxins including fungi metabolites (15aDON, 3aDON, NIV...) or the forms modified by the host plants such as DON3G.

Native and metabolite DON mycotoxin produced by fungus.



	R1	R2	R3	R4
Deoxynivalenol	ОН	н	ОН	ОН
3-aceryl-DON	OAc	н	ОН	он
15-aceryl-DON	он	н	OAc	он
Nivalenol	он	он	он	он
Fusarenone-X	он	OAc	ОН	ОН



Since 2006, the recommendation no. 2006-576 (EC) concerning the presence of deoxynivalenol (DON) in products intended for feed is the benchmark for professionals in the assessment and monitoring of the health quality of feed. The maximum recommended levels for compound feed were defined based on the EFSA opinion to preserve the health and well-being of animals as well as the economic situation of breeders. Thus, exceeding these thresholds could lead to adverse consequences both on the economic performance of breeders and on animal health.

The recommendations established in 2006 did not include the modified forms of DON (15aDON, 3aDON, DON3G). To take into account the inherent risks of these modified forms, the European Commission intends to lower the guide values currently in force. This could concern feed materials (decrease from 8,000 to 5,500 μ g/kg), corn co-products (from 12,000 to 8,000 μ g/kg) and compound feed (from 5,000 to 3,500 μ g/kg for most species). For feed intended for pigs, the threshold would be decreased even further going from 900 μ g/kg to 500 μ g/kg.

We propose here to compare the summary of 10 years of OQUALIM data collected via the plans with these proposals and discuss the introduction of these new thresholds.

Impact of the new thresholds on compliance of feed

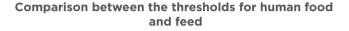
0.2 % 99.8 % 0.1 % Cereals 5500 µg/kg 0.7 % 98.8 % Corn co-products 0.5 % 8000 µg/kg .0.2 % Compound feed 99.8 % 0% (except pig) 3500 µg/kg + 9 % non-compliance 86 % Feed for pig 500 µg/kg 70 % 75 % 80 % 85 % 90 % 95 % 100 %

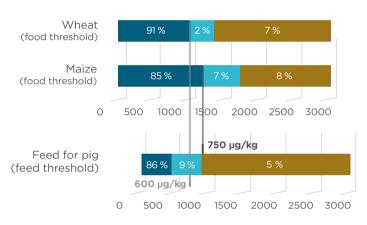
Results of analysis DON OQUALIM below the proposed threshold
Results between the proposed and the current threshold
Results above the current regulatory threshold

The establishment of new DON thresholds for cereals, corn co-products and compound feed (for most species) will no doubt not have an impact. Very few results currently measured exceed the values for the new thresholds. However, specific vigilance must be paid to the pig industry, due to the reduction in the DON threshold for compound feed and the lack of consistency between the thresholds for feed materials and compound feed.

On the one hand, the reduction in the threshold for pig feed from 900 to 500 μ g/kg would multiply by 3 the proportion of "unacceptable" samples exceeding the threshold, going from 5 to 14 % of samples.

On the other hand, the thresholds selected for cereals intended for feed remain too high to guarantee compliance of the new thresholds in compound feed intended for the pig industry. It should be noted that the values selected for cereals intended for food have only just arrived.





Below the proposed threshold

Included between the proposed threshold and the current threshold
Above the current regulatory threshold

Pig feed ration = 60 % of cereals

New wheat threshold in human food = $1,000 \mu g/kg$ (currently $1,250 \mu g/kg$)

Simulation of the feed threshold for pigs : 1,000 x 0.60 = $600 \mu g/kg \rightarrow$ non-compliant with the new feed threshold for pigs

New threshold but in human food = $1,250 \mu g/kg$ (currently 1,750 $\mu g/kg$)

Simulation of the feed threshold for pigs : 1,250 x 0.60 = **750 \mug/kg \rightarrow** non-compliant with the new feed threshold for pigs

Very sensitive to the presence of conventional mycotoxins and mainly fed with cereals, pigs could be particularly sensitive to emerging mycotoxins such as the modified forms of DON.

Pooling of data outside of the plan

OQUALIM proposes to animal nutrition players to pool all "dormant" data that is usable and can be valued outside of the existing pooled self-monitoring plans, such as routine analyses carried out as an addition to the plans, regulatory analyses (gatekeeping), exploratory analyses on emerging substances, or related to the context (crisis management, industrial accidents...).

Tangibly, for mycotoxins, for example, the animal nutrition players have analysis forms which show the results for the DON and for its modified forms : 15aDON, 3aDON, DON3G. The pooling of these data outside of the plans could provide the profession with a better overview for animal health, in a context of changing regulations.

Pooling of mycotoxin data "outside of plans" could be subject to specific contextual requests, reinforcing the monitoring pressure on new harvests for increased monitoring in the event of favourable climatic factors.

The pooling of data "outside of plans" aims to supplement the monitoring system of contaminants in feed materials for feed in pooled self-monitoring plans. It adds to the information on emerging contaminants or those that affect product quality without having a health impact during exceptional events (weather, technological accidents...).

Voluntary companies may access the overall, anonymous results for all couples [type of mycotoxin X products] to which they contribute. At the end of each participation period, a summary of the off-plan data will be made available to the participants.

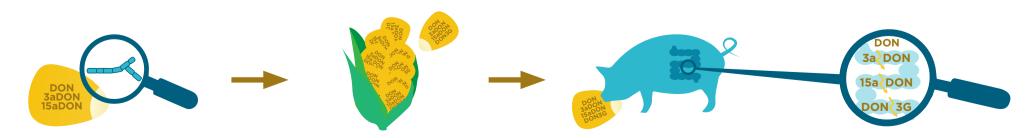
For this first "test" launch campaign (2019-2020) for a duration of 18 months, the participation in the Pooling of Data Outside of the Plan is free. All "dormant" Mycotoxin data outside of the plan generated since 1st January 2019, that is usable and can be valued may be sent within this framework. To date, the pooling of the data outside of plans includes 11 participants (9 companies and 2 associations).

For more information, please visit our page dedicated to the pooling of data outside of plans on our new website <u>www.oqualim.com</u>

Cécile Bouveret

Amandine Spiandore, Valérie Bris

DON and modified forms



A fungus produces mycotoxins such as the DON and its modified forms : 3aDON, 15aDON. The plant sets up defence mechanisms. For example, it adds a sugar to the mycotoxin: DON3G (DON-3-glucoside). The pig consumes grains containing the DON and its modified forms.

During digestion, the sugar or acetyl split. The quantity of DON present in the intestinal lumen will be greater than that measured in the grain.

DIOXINS, TOWARDS A CHANGE IN MAXIMUM REGULATORY LEVELS

Dioxins and PCBs come from thermal and industrial processes, such as waste incineration, the metal industry, the chemicals industry, energy... and natural sources, such as volcanoes, forest fires and storms.

The term "dioxins" is used to designate polychlorinated dibenzo-p-dioxins (PCDD) and polychlorinated dibenzofurans (PCDF). 210 molecules (or congeners) have been counted in this family, including 17 with proven toxicity.

PCBs (polychlorinated biphenyls), are a group of chemical compounds comprising 209 different molecules (or congeners). Amongst all of these molecules, 12 have toxic properties similar to dioxins, leading to the name PCB-DL (dioxin-like).

After having been deposited in the soil, plants or water, these chemical contaminants are absorbed by the animals via their feed, accumulate in fats and enter the food chain. It is estimated that over 90 % of human ingestion of dioxins and PCBs comes from the food chain, mainly through meat, dairy products, fish and seafood.

Levels of dioxins and PCBs (in the form of weighted amounts of WHO-TEQ¹) are today regulated.

Following a reassessment of the risk for humans and animals by EFSA², the European Commission wanted to reduce the regulatory levels for dioxins and PCB-DL in some products. **The feed sector alerted the European Commission about these proposals that do not appear to be compatible, for some inflows, with the background levels observed ground and wanted to provide data to supplement the EFSA's opinion.** Within this framework, through FEFAC³, the French feed trade unions were asked to contribute.

Thus, **OQUALIM's pooled self-monitoring "Feed" and "Supplements" plans have been a precious source of information.** The results of these plans, after compilation and being made anonymous, were supplied to EFSA.

- ¹ WHO-TEQ World Health Organization Toxic Equivalence
- ² EFSA European Food Safety Authority
- ³ FEFAC European Feed Manufacturers' Federation

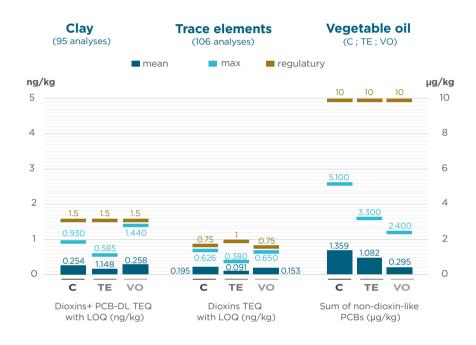
For feed, fish products (oils, fishmeal), plant oils and fats, clays and trace elements have been identified by the sector as being critical to meeting the proposed reductions based on the study of the results of the 2017 and 2018 plans. Some batches of these products may exceed the initial reduced maximum level proposals.

This revision to maximum levels has not yet been decided as beyond the constraints related to "background" levels of dioxins in some products, there are also technical difficulties related to analysis methods and detection limits.

Note that over the last 2 years, no alerts for dioxins, PCB-DL and PCB other than dioxin-like PCBs have been launched as part of the "Feed" and "Supplements" Plans.

Claire Laurent

Report on the 2019 "Feed" and "Supplements" plans, Dioxins and PCB results





Definition of the professional thresholds for the qualification of results

In addition to monitoring regulated pesticides and identifying emerging risks, OQUALIM also makes proposals on the interpretation of the results obtained.

Whilst the maximum residue limits (MRLs) are defined by regulations on conventional harvested products, there are no regulatory MRLs for products that can only be used as ingredients for feed. Regulation (EC) No 396/2005 stipulates that when MRLs for transformed and/ or compound products have not been set, the applicable MRLs are those provided for the product(s) from which they are produced and indicated in appendix 1 taking into account the changes in pesticide residues due to the transformation and/or mixing process. However, whilst the regulation stipulates that specific concentration or dilution factors may be added to the list in appendix VI, nothing has been published to date.

Monitoring and identification of emerging risks

Pesticide residues are subject to monitoring under OQUALIM's "Conventional Feed", "Milk Replacer" and "Organic" plans. Screening of 200 or 500 molecules, including some that are specific to some feed materials, is carried out. In order to guarantee the necessary homogeneity of the research carried out, OQUALIM has defined a minimum shared list of 99 pesticides that all referenced laboratories must analyse. The laboratories supplement this list with molecules of their choice, notably allowing the identification of emerging risks.

OQUALIM's plans are reviewed each year by a group of experts that conduct a risk analysis including the latest news : regulatory monitoring, alerts, history, etc.

In the absence of positioning by the Authorities on the issue, **OQUALIM has proposed transfer coefficients to assess the health quality of these products within a sector approach.** These coefficients were defined using the database of the German Federal Risk Analysis Institute (BfR) which compiles transformation factors. These professional qualification thresholds are publicly presented by the association each year as feedback from monitoring results, in the presence of the French Authorities. Similarly, in the absence of the publication of thresholds applicable to the organic sector, the Profession was required to establish its own result qualification rules, based on the values recommended in 2001 by the Bundesverband Naturkost Naturwaren (BNN). For example, following the upcoming ban of chlorpyrifos and chlorpyrifos methyl, monitoring for these pesticides will be reinforced, in order to obtain data on the contamination and persistence of these molecules.

In 2019, 377 analyses were carried out on conventional feed materials, representing 148,733 results, with : 99 % of samples "compliant" or "to be monitored", with an increase in "to be monitored" results compared to previous years. This matter will be monitored by the expert groups responsible for managing these plans.

To date, we can conclude that feed materials generally comply with the regulations with only 1 % of non-compliant samples.

■ Marie Foucrier, Blandine Markwitz