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GMO authorisation in the EU: The Commission once again attacked for "undue delays"

Par Eric MEUNIER

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On 17 October 2014, EuropaBio, Fefac and Coceral filed a complaint to the European Ombudsman, Emily O'Reilly, regarding the delay in the authorisation procedures concerning twenty applications for GMOs. This complaint occurs while the European bodies are close to an agreement on the GMO opt-out proposal, an agreement supposedly aimed at "unblocking" the GMO authorisation process.

The Ombudsman's website does mention the case but does not provide detailed information [1]. The small amount of information that is provided states that the complaint concerns allegations of maladministration by the European Commission of the GMO applications. The European Commission is accused of having breached its duties relating to a "reasonable time-limit for taking decisions". The Ombudsman's office told Inf'OGM [2] that the plaintiffs are EuropaBio (European Association for Bioindustries), the European Feed Manufacturers' Federation (FEFAC) and the European association representing the trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply (Coceral).

The three associations consider that the European Commission has badly administered twenty applications of GMOs for import, food and feed under regulation 1829/2003 by causing "illegal and unreasonable delays". They claim that the "Commission should put to vote in the relevant committee and/or adopt a formal decision on the twenty pending applications and abstain from causing any such delays in the authorisation process in the future".

The Ombudsman's office told Inf'OGM that they had only published limited information so far as the case is ongoing. They added that they have already "inspected the relevant files in the Commission" and that they are "waiting for the Commission's opinion on the allegations which they should submit by the end of January 2015". At the time of publication of this article, Inf'OGM was still expecting requested comments from Fefac, Coceral and EuropaBio.

A new complaint for an old request

An initial case had been filed in court by BASF in 2008 to complain about the European Commission's delay on BASF Amflora potato application [3]. This case was stopped before the

clock, the authorisation being given on March 2010 [4]. The authorisation was finally cancelled by the Court of Justice of the European Union (CJEU) in December 2013, the court having considered that the Commission had broken the law by not consulting the member states [5].

A second case was filed by Pioneer in April 2010: it concerned a delay in the application process of genetically modified maize TC1507. The CJEU finally considered that the European Commission was at fault but did not condemn it. Two months later, following this decision of justice, the Commission submitted a proposal of authorisation of TC1507 maize to member states [6].

In June 2014, EuropaBio wrote on its website that the applications of 21 GMO were "delayed illegally", a delay representing 44 years (sic) [7] [8]. The complaint to the Ombudsman is likely to concern twenty of those 21 GMOs [9]. Three of the applications are renewal applications, meaning that the three GMOs are currently authorised in the EU until the final decision is taken.

Finally, on 17 October 2014, the same day the complaint to the Ombudsman was filed, some organisations representing industry (including two of the plaintiffs) published a press release stating they had "urged the EU Barroso Commission today not to delay authorization of 8 new varieties of genetically modified grain" [10], but without mentioning the complaint to the Ombudsman.

Following the CJEU's decision in the Pioneer's case, Inf'OGM wrote that the industry associations could "mobilise to pressure the European Commission as happened previously in 2011 with the EuropaBio report". In this report, EuropaBio complained about the delay in scientific risk assessment and the voting procedure and requested that the system be updated. Less than a year after the CJEU's decision, the Ombudsman is the body involved this time.

The complaint's timing raises some questions. It comes at a time when the talks between the European Parliament, the Council and the Commission on the GMO opt-out have almost reached an agreement. This GMO opt-out has always been pushed forward by the European Commission as a way to "unblock" the GMO authorisation procedure. However, such an agreement [11] paves the way to more and more GMO authorisations being given in a near future. This situation should please industry. But their complaint to the Ombudsman suggests that the industry might have some doubts about the European Commission's willingness to stop delaying the authorisation procedures. They therefore chose the Ombudsman as a way to put more pressure on the European Commission in order to make sure the authorisations will indeed be given in a short timescale.

Delay in the authorisation procedure: what's going wrong?

Each application for a GMO must go through different steps of a procedure. First, it must be "scientifically" evaluated by the European food safety authority (EFSA) which must assess the risks from the use of the GMO. If EFSA's opinion is positive, the European Commission proposes a decision on which Member states vote twice (if needed), respecting the qualified majority procedure. In case no qualified majority is reached, the final decision is up to the Commission.

Each step of the procedure (except the member states' vote) has a legally defined delay. But the procedure can be stalled if discussions are needed on the risk assessment between the European expert body and the industry applicants. European law (decision 1999/468, article 5) states that in the case of no qualified majority at a first meeting of the member states, the Commission is to

present the proposal a second time "without delay". This wording (without delay) was the one raised by Pioneer to complain about the European Commission on its maize TC1507 application. In this second round, if no qualified majority is reached, the final decision will be taken by the European Commission, as already explained. The European Commission has a delay of a maximum of three months to do so. This delay is rarely respected and this is the reason for the complaint to the Ombudsman.

- [1] http://www.ombudsman.europa.eu/en/cases/caseopened.faces;jsessionid=D0A93F70BFACD7FAD743F595117C455F
- [2] Email exchanges with Inf'OGM on 9 and 10 December.
- [4] Order of the Court of justice of the European union, 9 june 2010, point 13
- [7] EuropaBio has chosen to add up the alleged delays for all the applications a method that recalls ISAAA's tactic of adding the surface area of GM crops cultivation for every year since 1996.
- [8] http://www.europabio.org/sites/default/files/position/europabio_undue_delays_update_june_2014_0.pdf
- [9] For cultivation, the GMOs are: maize MON810 (renewal), maize GA21, maize 59122, maize Bt11, maize TC1507. For import, food and feed, the GMOs are: maize NK603, maize MON863, cotton MON531, cotton MON1445, cotton MON531*MON1445, cotton MON88913, maize MON87460, rapeseed Gt73 (renewal), cotton T304-40, maize T25 (renewal), soybean MON87708, soybean MON87705, soybean 305423, soybean BPS-CV127-9, soybean MON87769 and cotton GHB614*LL25

[10] The eight GMOs are: maize MON87460, rapeseed GT73, soybean 305423, soybean MON87708, soybean MON87705, soybean BPS-CV127-9, maize T25 and cotton T304-40, http://www.coceral.com/data/1413540729EU Food Feed Chain Joint Press Release urgent EC decision GM import authoriza

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