**REGULATORY AFFAIRS COMMITTEE**

**ZOOM MEETING:** <https://us06web.zoom.us/j/81925155980?pwd=eGtwUzYxdlpqaVNDNWlFV212RTRxQT09>

**Tuesday 14th November 2023 – 3.00 – 5.00 pm CET**

**MINUTES**

1. **Welcome, anti-trust statement and adoption of the agenda**

The Chair, B. Loberant (SuperMeat), welcomed the participants and especially S. ten Hoeve who recently joined Meatable (see **Annex I**), who were reminded of the anti-trust rules (see **Annex II**). The agenda was adopted with an additional topic to be discussed under item 5: recent changes in the US Food & Drug Administration (FDA).

1. **Adoption of minutes of previous Committee meeting, 29th August 2023**

The minutes of the 29th August 2023 call (see **Annex III**) were approved.

1. **Updates from sub-committees**

Further to a presentation delivered by C. Rey (secretariat) (see **Annex IV**), with clarifications added by H. Lester (Gourmey), L. Racault (Nestlé) and V. Teloni (MosaMeat) who participated in EFSA’s 18th October ad hoc meeting, the following topics were discussed:

* EFSA’s survey on future applications for authorisation of cell-culture derived products: It was reminded that members of Cellular Agriculture Europe, EuropaBio and Food Fermentation Europe have until 8th December to inform EFSA how many dossiers shall be submitted between 2024 and 2026. Like N. Baldwin, Committee members noted that EFSA was losing its patience. V. Teloni indicated that the EFSA staff present at the 18th October ad hoc meeting[[1]](#footnote-1) asked similar questions in response to stakeholders’ observations on the unnecessary delays at completeness check level. In N. Baldwin and C. Kalk (Meatable)’s view, EFSA needs help to anticipate the future workload and have the appropriate resources.

**Actions:**

* **All members to inform the secretariat directly how many dossiers they intend to submit at EU level and when before 1st December. All responses will be aggregated and treated confidentially.**
* **Secretariat to remind all members in writing (Done on 20th November) and at the 27th November extraordinary General Meeting.**
* EFSA’s *ad hoc* meeting with industry representatives on cell culture-derived foods and food ingredients: H. Lester stressed that EFSA welcomed Cellular Agriculture Europe’s comments on the current version of the Novel Foods Guidance[[2]](#footnote-2). It also appeared that the EFSA staff was defensive on the three associations’ request for more in-depth pre-submission advice. The EFSA staff stressed during the meeting that the assessment of the safety of an apple fruit cell culture biomass[[3]](#footnote-3) as a novel food took three years: the applicant had to re-submit an entirely new dossier as the initial version of its application dealt with the apple cell culture biomass together with Isomaltulose. H. Lester pointed that such delay could have been avoided with a robust and in-depth pre-submission dialogue. On the other hand, its seems that EFSA is adamant to preserve its impartiality and independence. EFSA thus fears it could be seen as partial if it gives advice on the studies that should be conducted.

V. Teloni then added that EFSA was reluctant to answer the Cellular Agriculture Europe delegation’s question on the notification of “studies” that are no longer considered as “studies” since the update of the Authority’s questions and answers on its Practical Arrangements[[4]](#footnote-4).

L. Racault also underlined that EFSA did not answer clearly the delegation’s question on DIAS or PDCAAS for the assessment of protein quality. N. Baldwin indicated that other EFSA Panels had worked on protein quality and expressed the wish to have an overview of the Authority’s work on the matter. C. Kalk submitted the idea to possibly team-up with institutes like ILSI[[5]](#footnote-5) on the issue.

**Actions:**

* **Cellular Agriculture Europe, EuropaBio and Food Fermentation Europe to work together on a joint follow-up letter (In progress**[[6]](#footnote-6)**).**
* **Secretariat to draft a follow-up letter for EFSA (Done[[7]](#footnote-7)).**
* **Regulatory Affairs Committee members to share all relevant information about EFSA’s work on protein quality.**
* Risk management measure for apple fruit cell culture biomass as a novel food: The members’ discussed EFSA’s assessment as well as the Novel Foods working group labelling considerations and noted that the authorised amount was low.

**Actions:**

* **Secretariat to monitor the outcome of the 22nd November SCoPAFF meeting.**
* **Secretariat to explore the appropriateness of preparing a statement on the possible authorisation of the apple cell culture biomass with the Communications Committee (Done[[8]](#footnote-8)).**
* BeneMeat’s Feed Materials Register[[9]](#footnote-9) announcement: H. Lester stressed that BeneMeat’s entry was categorised as a product or by-product obtained by fermentation using microorganisms, inactivated resulting in absence of live microorganisms (category 12). In a call organised with BeneMeat together with the Good Food Institute Europe to express the cellular agriculture sector’s concerns on the possible detrimental consequences of their hasty and inexact announcement, BeneMeat first confirmed that their categorisation was correct and then asked for strategic advice on the food safety data they would need to prepare for an assessment.
1. **EU matters**

Following a presentation delivered by C. Rey (see **Annex V**), B. Loberant expressed the wish for association to be more (pro)active in Romania and suggested that this request is discussed at Board level.

**Action: Secretariat to share the Regulatory Affairs’ concerns on Romania with the Board (Done on 21st November).**

1. **Non-EU matters**

Following a presentation delivered by C. Rey (see **Annex VI**), the following topics were discussed:

* + Singapore Food Agency Roundtable on Novel Foods Regulations: B. Loberant informed the group that two members of the EFSA were physically present at the Roundtable. H. Lester also indicated that the UK Food Standards Authority delegate was of the view that, when scaffolds are used in the manufacturing process, the latter shall be assessed and authorised separately.
	+ FAO Stakeholder roundtable meeting on cell-based food production and precision fermentation: V. Teloni reminded that the meeting was co-organised by the FAO and China’s National Center for Food Safety Risk Assessment (CFSA). Mosa Meat and Gourmey were invited to deliver presentations together with other companies and experts. The event, which consisted of 10 to 15 presentations was followed by a tasting of cultivated chicken.

**Action: Secretariat to monitor the report of that meeting.**

* + UK: N. Baldwin was of the view that the press article and announcement of a fast-track procedure was premature.
	+ US FDA committee – recent changes: B. Loberant informed the group that SuperMeat recently had a meeting with the US FDA, whose team has been significantly reshuffled. This seems to result in philosophical and methodological changes. It also seems that the FDA has received around thirty submissions; which has an impact on their workload and might generate backlog, especially since GRAS notifications shall have precedence over the application for cell-cultured products approval. In addition, this would also mean that the FDA would have less time for dialogues with individual companies.
1. **AOB**
	* Cellular Agriculture Europe’s extraordinary general meeting: members were invited to register to the 27th November virtual meeting.
	* C. Kalk informed members about recent changes in the Meatable regulatory affairs team and explained that S. ten Hoeve would be the company’s main interlocutor within the Committee. The whole Committee and the secretariat warmly thanked C. Kalk for his knowledge, expertise and for the good collaboration.
2. **Next meeting**

This item was not discussed.

B. Loberant thanked all participants, the secretariat and closed the call.

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1. See <https://www.efsa.europa.eu/en/events/ad-hoc-meeting-industry-representatives-1>. [↑](#footnote-ref-1)
2. See <https://www.efsa.europa.eu/en/efsajournal/pub/6555>. [↑](#footnote-ref-2)
3. See <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00488?search=apple>. [↑](#footnote-ref-3)
4. See <https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements>. [↑](#footnote-ref-4)
5. See <https://ilsi.eu/>. [↑](#footnote-ref-5)
6. Post meeting note: a joint call with EuropaBio, Food Fermentation Europe is scheduled on 1st December. [↑](#footnote-ref-6)
7. See <https://docs.google.com/document/d/1moVKyfkDvnJArgYvzj9EQ-o2SBbU6j07/edit?usp=sharing&ouid=101759161577690989103&rtpof=true&sd=true>. [↑](#footnote-ref-7)
8. See <https://docs.google.com/document/d/1Z-UUybZ9whIILHFdltcpN0X0qwWsAwlR/edit?usp=sharing&ouid=101759161577690989103&rtpof=true&sd=true> [↑](#footnote-ref-8)
9. See <https://www.feedmaterialsregister.eu/register>. [↑](#footnote-ref-9)