

## Code of conduct for the interview

2023 2 October

### Aim of the interview

- This interview is a necessary process to avoid unnecessary elevation of cultivated food concerns by those with malicious intent and to help cultivated foods gain public trust and understanding
- JACA is currently the only organization capable of representing the industry and communicating with the regulatory community when the safety of cultivated foods becomes a hot topic in Japan
- JACA is in the process of encouraging the MHLW to set up a consultation system for direct communication with individual companies through regulatory agencies and politicians, but this effort is a time-consuming process
- Unfortunately, this is currently the only conceivable way for cultivated food developers to inform the MHLW about your products' safety, by contributing to the Safety Report that JACA is trying to create. This is, in addition, the only way for companies to contribute to MHLW's development of regulatory guidance for the industry

### Interview process

- The interview will be set by JACA admin and conducted between Vireo and the Interviewee
- There are three types of information handled within your company. **When Vireo interviews your company, the information provided by your company is only (ii) and (iii).**
  - (i) Trade secrets at a level that cannot be shared with Vireo/JACA even under the three-party NDA - **You need to eliminate (i) from the interview answers or censor it with "black stripes"**
  - (ii) Information that cannot be shared with competitors but may be included in materials submitted to the ministry (we call it  $\beta$  report) - **You need to highlight it with "yellow" to differentiate it from (iii)**
  - (iii) Information that may be disclosed as industry views (your claims based on third-party literature, etc.) in order to improve the transparency of the industry (we call this an  $\alpha$  report)
- In the interview, your company should **clearly specify which information is (ii)/ should be included in  $\beta$  report and which information is (iii) / should be included in  $\alpha$  report**, so that (ii) and (iii) are not confused in any case
- Vireo may suggest that you change the categorization of certain information if the information cannot logically be explained as a trade secret
- We know several companies have already contributed to similar projects in other countries

(like the project in Korea that Upside Foods mentioned in our general catch up meeting). You may share with us the output of similar projects in which you have been involved to reduce the cost of contributing to our project

- Vireo will provide a summary of the interview to the Interviewee which will mark information that would be included in the  $\alpha$ - or  $\beta$ -reports. Interviewees will have 10 days to review and approve or modify the information, or change the categorization of certain information

### **Benefits for the Interviewee**

- This interview process decreases your actual cost of entry into Japan by sharing with the government in advance any potential safety points of concern that may arise when your product enters the country. Therefore, it is in company's best interest to share as much detail as possible to the project
- We recommend you to categorize your "methodologies on how to secure the safety of cultivated food" as much as possible to the  $\alpha$  report, since it will be then reviewed by JACA domestic companies, which are familiar with the local Food Sanitation Law, etc. and ultimately published as the 'Views on cultivated food safety advocated by the domestic cellular agriculture industry'. In other words, the safety methodologies taken within your company categorized in the  $\alpha$  report would be endorsed by a group of Japanese companies, with a high reputation in Japan, and shared with the domestic community

### **Method of Information Disclosure**

- The interview will cover possible **Hazard Characterization, Similar Presence** of the Hazard in other food products, **Risk Characterization, Risk Mitigation Control Measures, Testing Control Measures** for cultivated food products (depending on cell type and animal species) that you are developing, and **HACCP and other quality control measures that you are actually taking**
- Disclosure of **Hazard Characterization** may directly or indirectly include manufacturing steps and substances used for cultivated food products at your company. You can make the information high level as much as possible, if the information is deep enough to understand the possibility of the hazard. We can also anonymize/generalize the process description when we reflect it in the  $\alpha$  report or just categorize your information into  $\beta$  report. In order to avoid disclosing the most important trade secrets which should be categorized as (i), for example, instead of describing the process itself in detail, if the justification for the safety of the process can be explained by certification by a third-party organization, it is possible to use the statement "The process is in accordance with international standards called XXX" or "The product was prepared in accordance with

standards called XXX in Japan" instead.

- **Similar Presence** can be disclosed if the example is not tied to other companies' trade secrets.
- As for **Risk Characterization, Risk Mitigation Control Measures, Testing Control Measures**, any safety standards that you can provide are critical for MHLW to support the conclusion that cultivated food is safe, since there are not so many quantitative/qualitative descriptions about the testing and control methods and thresholds for potentially hazardous substances. You can focus on just disclosing the logic of why the risk can be explained as small and indicate that raw data exists to support the logic. For example, if the logic is based on GRAS or other regulations, you can just mention that. For another example, if allergenicity risks are included in the interview question, and there is data on the allergenicity of your product that has been tested, instead of disclosing the tested data itself, you may share only the fact that "a company has tested XX-based cultivated food product for allergenicity using XX test method and it was negative," and the raw data of the test results are not shared as your essential trade secret categorized as (i). The existence of the raw data to support and the information to show the quality of the data is more important than the actual raw test result when we generalize the Risk Mitigation Control Measures, Testing Control Measures, and safety standards. It is also welcome to reference any academic research to explain the safety of the product.
- If you would like to use the Virtual Data Room to limit us to only see the data / cannot DL or copy the data, we can consider the option as well