EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B – Sustainability
The Director (acting)

Brussels
AGRI B4/EG/ant/agri.b.4(2024)799233

Subject: Application of ETKO Ekolojik Tarim Kontrol Org Ltd Sti for its recognition under the EU organic compliance scheme (Article 46(2) of Regulation (EU) 2018/848)

Dear Mr Akyüz,

I would like to inform you about the state of play of your request for recognition submitted in OFIS on 13 October 2023 (Ref. Ares(2023)7019390) pursuant to Article 46(4) of Regulation (EU) 2018/848([1]).

DG AGRI has examined the technical dossier for recognition.

In accordance with Article 1(2) of Regulation (EU) 2021/1698[(2)], the technical dossier must contain the information listed in this provision in one of the official languages of the Union. DG AGRI is of the opinion that the technical dossier submitted by your control body does not contain all of the information that is necessary to ensure that the criteria set out in Article 46(2) of Regulation 2018/848 for the recognition have been met. The information submitted by your control body is partially incomplete and unsatisfactory. Please find a list of specific remarks in the Annex to this letter.

Please address the questions in Annex and submit the requested information within 3 months from the date of sending of this letter, directly in the OFIS2 application ([3]). Please submit only the information strictly relevant for replying to the requests mentioned in the Annex. For any documents you may revise, please ensure that you

([1]) Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1)

([2]) Commission Delegated Regulation (EU) 2021/1698 of 13 July 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with procedural requirements for the recognition of control authorities and control bodies that are competent to carry out controls on operators and groups of operators certified organic and on organic products in third countries and with rules on their supervision and the controls and other actions to be performed by those control authorities and control bodies (OJ L 336, 23.9.2021, p. 7).

([3]) Please note that you application will be re-opened in OFIS as soon as this letter is sent in order to allow your Control Body to upload the requested information.

Mr Mustafa AKYÜZ
Managing Director
ETKO Ekolojik Tarim Kontrol Org Ltd Sri
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clearly indicate the correspondence between the questions asked in the Annex and the answers provided by your control body.

Once the information has been received, it will be verified again whether the information required under Article 1(2) of Regulation (EU) 2021/1698 is complete, up-to-date and satisfactory and whether, therefore, the criteria set out in Article 46(2) of Regulation 2018/848 have been met. If the outcome of this verification is positive, the Commission services will propose to include your control body in the list of control authorities and control bodies recognised under the compliance scheme, established via an amendment of Commission Implementing Regulation (EU) 2021/1378 ([4]) to be adopted in accordance with the examination procedure referred to in Article 55(2) of Regulation (EU) 2018/848.

In case part of the information submitted by your control body in reply to this letter is considered incomplete, outdated or unsatisfactory, a partial recognition of your control body for those product categories for which your application is considered meeting the criteria set out in Article 46(2) of Regulation (EU) 2018/848 will be proposed by the Commission services. You will be informed accordingly. The remainder of your request will be treated when the necessary information has been received from your control body and the possible recognition for that part might be delayed, depending on requests received from other control authorities and control bodies (see next paragraph).

In case the information submitted by your control body in reply to this letter is still considered incomplete, outdated or unsatisfactory, you will be informed accordingly. This might delay your possible recognition, with the consequence that your control body may not be recognised before 1 January 2025. This will depend on the number and complexity of technical dossiers submitted by other control authorities and control bodies and, if relevant, the additional information submitted by them as a result of remarks received from DG AGRI, that DG AGRI will need to examine.

If no reply to this letter is received by the abovementioned deadline, we will conclude that you have withdrawn your request for recognition and your file will be closed. However, you will be able to submit a new request for recognition at any time.

I would also like to inform you that, in assessing your technical dossier, the co-reporter Member States in copy of this letter received your application for examination in accordance with Article 3(6) of Regulation (EU) 2021/1698.

Yours sincerely,

Michael PIELKE

([4]) Commission Implementing Regulation (EU) 2021/1378 of 19 August 2021 laying down certain rules concerning the certificate issued to operators, groups of operators and exporters in third countries involved in the imports of organic and in-conversion products into the Union and establishing the list of recognised control authorities and control bodies in accordance with Regulation (EU) 2018/848 of the European Parliament and of the Council (OJ L 297, 20.8.2021, p. 24)

c.c.: IOAS accreditation body (info@ioas.org; aldana@ioas.org; nentcheva@ioas.org)
MS co-reporters (MT, PL)

Annex

1. We have the following questions and remarks concerning the documents submitted in section "7. Certification procedure" and "8. Control measure" of your technical dossier ([5]):

   a) Please clarify the role of each of these documents, and for who they are intended (e.g. inspectors, operators, …). Please also specify how the documents relate to each other, as some contain similar information.

   b) These documents contain legal and procedural references to various organic schemes including the EU organic equivalence scheme (referred to in your documents as 'IACB'), the EU organic compliance scheme, the US NOP and IFOAM. This makes the documents difficult to read which risks creating uncertainty for the users of the procedures. Your accreditation body (AB) recorded a similar concern and Opportunity For Improvement (OFI) in section 7.13 of your Office Assessment regarding ETKO's procedure TI09 Investigation of Irregularities. Please submit the revised procedures that concern only your future operations for the purpose of the EU compliance import regime.

   c) We welcome the approach you have taken in indicating the references to EU legislation in various sections of the documents referenced above. Please be informed that, despite these detailed references, they are not all up-to-date, correct or complete. For example:

      i) Article 34(2) of Regulation (EU) 2018/848, cited in OP04 section 5.4.4.1.2 and in GP30 section 3.4.1.3 is applicable to operators within the EU and not to operators in third countries to be certified by control authorities and control bodies to be recognise under Article 46 of Regulation (EU) 2018/848.

      ii) in the second part of section 5.5.5.3 of OP04 reference is made to Section 6 of Annex III of Regulation (EU) 2018/848. This paragraph concerns the rules that apply for the reception of products once they enter the Union.

   Please review the documents to ensure they are up-to-date, correct and complete. You can find the relevant legal texts on the EU organic website ([6]) as well as by searching through the EU legislation portal EUR-Lex ([7]). Please ensure that you consider all the amendments to the legal acts applicable to your possible future operations as a control body recognised under Article 46 of Regulation (EU) 2018/848.

2. According to Article 1(2)(b) of Regulation (EU) 2021/1698, the technical dossier must contain an indication of the organic products the CB intends to import into the Union during the first year of activity following recognition, together with their Combined Nomenclature (CN) codes and organised by category of products. In the CN codes provided in "3. Overview of activities" of your technical dossier, we have identified some errors:

([5]) Document numbers OP04, OP02 and GP30

([6]) https://agriculture.ec.europa.eu/farming/organic-farming/legislation_en#trade

([7]) https://eur-lex.europa.eu/homepage.html

	CN codes not applicable to the category requested
Category A	1515 and 2103

Please verify the attribution of the product codes to the product categories, correct as appropriate, and provide a revised indicative list of activities.

In addition, we would kindly ask you to address the question in column D concerning the following product codes requested:

A	B	C	D
Category A	0904	Pepper of the genus Piper	Production in Türkiye?
Category A	0906	Cinnamon and cinnamon-tree flowers	Production in Türkiye?
Category A	0907	Cloves (whole fruit, cloves and stems)	Production in Türkiye?

Lastly, for product category G you have listed one CN code (code 3301 – essential oils). Your document OP04 (in section 5.1 and 5.2.6) seems to suggest ETKO's intention to also certify "cotton, not carded or combed" and "plant-based traditional herbal preparations" under product category G. Kindly please confirm whether our understanding is correct. If you are considering certifying all three products during the first year of activity following the recognition by the Commission, please update the above-referenced list of CN codes.

3. Under sub-point (ii) of Article 1(2)(c) of Regulation (EU) 2021/1698, the technical dossier must contain a description of the control body's IT management system. The purpose of this information is to ensure, *inter alia*, that your control body has set up an appropriate IT system, for instance to store, monitor and cross-check data received from your operators or through controls, and that appropriate documents are available to your inspectors. We take note that your Accreditation Body has positively assessed your IT management system, and that you have provided document "ETKO Record Control procedure" as part of your technical dossier. However, this document provides too few details to understand how the system operates. Please provide a more detailed description of ETKO's IT management system together with specific evidence to show that your IT management system is capable of managing the above-mentioned elements and any other elements covering your operations as a control body under the compliance scheme.
4. Article 1(2)(d) of Regulation (EU) 2021/1698 states that the technical dossier must contain the certification procedures, detailing in particular the procedures for granting or rejecting, suspending or withdrawing the certificate referred to in point (b)(i) of Article 45(1) of Regulation (EU) 2018/848. We could not find detailed descriptions of the certification procedures in the documents provided, notably as regards the procedures for rejecting, suspending or withdrawing certificates. We note that reference is made on several occasions to GP15 which was not, however, included. Please provide evidence detailing the procedures for granting or rejecting, suspending or withdrawing the certificate.
5. According to Article 1(2)(f) of Regulation (EU) 2021/1698, the control body (CB) must provide documents proving that the criteria set out in Article 46(2) of

Regulation (EU) 2018/848 are fulfilled. Please provide documentation proving that ETKO is a legal entity established in a Member State of the EU or a third country.

6. Article 1(2)(g) of Regulation (EU) 2021/1698 requires that the technical dossier contains the procedures describing in detail the functioning and the implementation of the control measures to be set up in accordance with that Regulation. Given the concern raised under point 1b above, it was not always clear to us which rules would apply under the EU compliance regime. In addition to addressing the request under point 1b, please ensure that your procedures reflect all the following provisions of Regulation (EU) 2021/1698:
    a. Article 10: points 1(b) and 1(c), point 1(d) sub-points (iv) to (ix), points 2, 3 and 4 as concerns check for the certification of operators;
    b. The risk assessment called for under Article 11(3) and further details as regards the methods and techniques for the requirements established in Articles 11(4) and 11(5);
    c. The methods and procedures for sampling as set out in paragraphs (3) and (4) of Article 12;
    d. Article 14(1) point (d) on written records of controls and Article 14(2) on the countersignature of the inspected operators;
    e. Article 16 paragraphs (1) to (5) concerning the verification of consignments intended for import into the Union;
7. According to Article 1(2)(f) of Regulation (EU) 2021/1698, the technical dossier must contain documents proving that the criteria set out in Article 46(2) of Regulation (EU) 2018/848 are fulfilled. Accordingly, please provide evidence demonstrating how ETKO intends to comply with the requirements under point (c) of Article 46(2) of Regulation (EU) 2018/848 and specifically how it will ensure staff performing controls and other actions are free from any conflict of interest, and that the operators are not inspected by the same inspectors for more than 3 years consecutively.
8. Thank you for the Catalogue of Measures submitted in section "7. Certification procedure" and in section "8. Control measures" of your technical dossier in line with Article 1(2), point (h) of Regulation (EU) 2021/1698. Please:
    a. clarify the statement on page 1: "*For regulation of the EU, ETKO uses the uniform national catalogue of measures*".
    b. note that, according to the table on page 1 of the Catalogue of Measures, your CB has chosen not to include in major NCs the "*prohibition to import for placing on EU market*" from the measures proposed in point 2 of Annex IV part A of Regulation (EU) 2021/1698 despite the potential, according to your proposed Catalogue, for a repeated minor NC to become a major NC (page 2). Whilst this is acceptable, we would like to recall that ETKO may also need to consider in such circumstances whether Article 23 of that Regulation applies.
    c. explain how the measures in the column "consequences" of the table on page 1 of ETKO's proposed Catalogue of Measures will be implemented to ensure a standard approach by ETKO's inspectors. Please provide further details of the enforcement actions ETKO intends to apply for each NC including, if applicable, any escalation of sanctions, for example in case of repeated NCs.
    d. update the list of examples of major NCs provided on page 3 of the proposed Catalogue to include the complete set of elements referred to in Part B of

Annex IV of the above Regulation, including the missing example "*Significant deviation between input and output calculation (mass balance)*", as these are all mandatory.

e. provide additional clarifications as regards the following points:

   i. "*Presence of unauthorized substances on the farm and storage*" is considered a minor NC: would this be the case in all circumstances/ types of holdings (e.g. on a fully organic holding)?
   ii. How the assessment would be carried out to differentiate between the major NC "*Use of inputs which are not allowed by the regulations*" and the critical NC: "*Intentional use of non-authorized substances or products within the scope of the Regulation (EU) 2018/848*"?
   iii. The consideration for establishing "*Non-organic product labelling and sale as organic*" as a major NC and "*Intentional mixing organic with in-conversion or non-organic product*" as a critical NC.

f. provide evidence of the procedures established to address the requirements under Articles 22 and 23 of Regulation (EU) 2021/1698.

9. Article 1(2)(i) of Regulation (EU) 2021/1698 and Annex I to this Regulation state that a witness audit report for each category of products must be included in the assessment report. You have provided three witness audits, in line with your request for recognition for three products categories: A, D and G.

   a. The witness audit for product category D was carried out on 28.06.21 which is in line with section 3 of Annex I Part B of the above Regulation. However, we understand it concerns an operator "*planning to do packing and trading of organic products*". Packing and trading are actions that do not fall under the definition of "processing" contained in point 73 of Article 3 of Regulation (EU) 2018/848, which excludes packaging and labelling operations. Please provide a valid witness audit for category D on an operator whose activities include processing.

   b. The witness audit for product category G was carried out, according to the witness audit report submitted, at a: "*company manages organic and non organic products, and is certified according to the TR organic regulation, Cosmos and NOP by ETKO*" and indicates that the company: "*processes through maceration, distillation and extraction (this last process applies only for cosmetic products)*". It is further stated that: "*processing room for extraction, visited during the audit, was out of the scope as the extraction process is used to produces cosmos certified products*" and that the witness audit took place at a time when: "*no processing activity of organic products in place, only extraction of conventional products. Organic raw material and final product present on stock*.". Based on these elements we would ask you to please clarify which of the operators' activities (e.g., maceration, distillation or extraction, for which purpose) ETKO aims to certify once recognised under Article 46 of Regulation (EU) 2018/848, and how this was addressed during the audit.

10. According to Article 1(2)(j) of Regulation (EU) 2021/1698, the CB is required to provide proof that it has notified its activities to the relevant authorities of the third country concerned as well as its undertaking to respect the legal requirements

imposed on it by the authorities of the third country concerned. You have enclosed two documents issued by your AB in section “9. Proof(s) of notification per country” of your technical dossier. We are unable to accept these as proof of ETKO’s notification to the Turkish authorities of its intention to become a recognised control body specifically in accordance with Article 46 of Regulation (EU) 2018/848. In addition, we did not find any undertaking concerning the respect of legal requirements. Please provide evidence meeting these two requirements.

11. ETKO’s website currently lists in a very clear manner all the operators certified by your control body at the webpages indicated in your technical dossier in section “1. Administrative information”. In accordance with Article 1(2)(k) of Regulation (EU) 2021/1698, please provide further details demonstrating how you plan, once recognised, to meet the requirements established in Article 17 under point (a).