SFDA response to EU comments

	EU request	SFDA Comments
1	The EU would kindly request to be assured that this new procedure would not lead to any trade disruptions of current trade from EU Member States towards to the KSA.	The purpose of the new document is to regulate the import of goods to the KSA. In addition, the procedure in this new document is similar to the current practice. However, it has been expanded to include products of animal origin, grains and crop yields.
2	the EU would seek clarifications on when this procedure will be applicable and if this procedure only applies to new applications for countries/establishments currently not exporting to the KSA one or more products listed within the scope of this notified procedure.	The procedure in this new document will be applicable 29/10/2021. It only applies to new applications for establishments currently not exporting to the KSA one or more products listed within the scope of this notified procedure.
3	The notified document does not specify what the SFDA would decide in relation to countries that currently have food plants approved for export to the Kingdom of Saudi Arabia, but never have been audited by the system.	The procedure in this new document will not apply on food plants already approved by the SFDA for export to the Kingdom of Saudi Arabia. In addition, countries that have an approved competent authority will provide the SFDA with list of approved establishments by their side to be approved by SFDA.
4	Will the official control bodies of the above-mentioned countries have to undergo an approval procedure for products that can currently be sent to the KSA market, or only for new types of animal products?	Products that can currently be sent to the KSA market from approved establishments do not have to apply with the new procedure. Official control bodies of the have to undergo an approval procedure for new types of food products.
5	It would be useful to clarify if the mutual recognition process that currently applies for EU competent authorities is proposed to be replaced by the process set out in the WTO notification.	The mutual recognition process that currently applies for EU competent authorities will not be replaced by the process set out in the WTO notification.
6	It would also be useful to clarify if it is planned that EU establishments currently approved by SFDA need to re-apply for approval, complete detailed forms, require site visits and pay again fees etc. under the process proposed in the WTO notification.	The EU establishments currently approved by SFDA do not need to re-apply for approval.
7	the EU would kindly request to receive the weblinks where this complete and updated information can be found for each of the products mentioned in the scope of this approval process mentioned in the notified draft text.	Updated information can be found on the following link: https://www.sfda.gov.sa/en/list_countries_products
8	With regard to the scope, the EU noted that the scope in the notified draft text has significantly been expanded in comparison to the current practice. For example, establishments exporting processed fruits and vegetables and establishments exporting grains and crop yields have been added. The EU would like to point out that this new requirement for these products is creating additional burdens	This document aims to verify the procedures carried out by the competent control authority in the country of origin, which paves the way for assigning the competent authority the responsibility of approving plants interested in exporting their products to Saudi market.

	affecting exports of these products to the KSA. In line with the WTO SPS Agreement, the EU would like to request KSA to provide its risk analysis that demonstrates that these additional import requirements for these products can be justified.	
9	As the EU is a Union of 27 countries with sanitary and Phytosanitary measures laid down in harmonised EU legislation and implemented in all EU Member States, therefore the EU would like to request to foresee the option (if the EU wishes to do so) to make a single application to the KSA for a group of interested EU Member States to export to the KSA a product under the scope of this application procedure.	The SFDA will consider this suggestion if the EU wishes to do so.
10	the EU would like to request to allow for a sufficiently long transition period to implement this process to avoid any unnecessary trade restrictions, or market access requests are seen.	The procedure in this new document will be applicable 29/10/2021. In addition, the procedure in this new document is similar to the current practice. However, it has been expanded to include products of animal origin, grains and crop yields.
11	the EU is requesting when this process is intended to be implemented and how much time countries/establishments will be granted to complete this procedure taking into account that authorities in the KSA need to make an assessment of all applications received before an approval will be granted.	The procedure in this new document will be applicable 29/10/2021. It only applies to new applications for establishments currently not exporting to the KSA one or more products listed within the scope of this notified procedure.
12	The EU would kindly request to receive an indicative timing of all the steps in the approval procedure and an indicative timing to finalise this procedure from the start of the application until the approval of the country/establishment granted to export food products to the KSA.	This will depend on the status of each establishments and the fulfilments of the required documents tanking into account the official communication timing via the MOF.
13	The EU would request the KSA to put a procedure in place, which allows for a transparent, swift and smooth processing of all the steps in the procedure to be finalised in a short and reasonable period without undue delays. Could the KSA confirm that it has put in place all resources needed to handle this procedure effectively and smoothly in a short period of time?	The procedure in this new document is similar to the current practice which was implemented since 2015 and it only applies to new applications for establishments currently not exporting to the KSA one or more products listed within the scope of this notified procedure.
14	The EU would like to receive a clarification on which products are covered under each of the general products headings mentioned within the scope.	At the mean time the classification for products is if the general product is the main ingredient in the product intended for export .
15	The EU would like to seek clarification as follows: the EU understands that breast milk substitutes (BMS) are a subcategory of milk and its products and would like to seek clarification if the control authority is approved for BMS are they granted approval for milk and its products also or vice	In this case no, if the control authority is approved for BMS are they need to apply for milk and its products to be granted approval and vice versa. The commodity regulation is listed in section 5, however we will take this comment into consideration.

	versa? There is no commodity regulation listed within the scope. Are Food for Special Medical Purpose (FSMP) products and nutritional supplements exempted or fall under milk and its products?	Food for Special Medical Purpose (FSMP) products and nutritional supplements are exempted.
16	*The competent control authority that is responsible for food safety in the exporting country and seeks an approval must be from a country that is not subject to a temporary ban on the import of its food products.'* The EU would like to suggest to delete this requirement. The EU believes that this requirement unnecessarily blocks a request from a country which is subject to a temporary ban imposed by the KSA. The temporary ban in place might also not have link to the product for which the competent authority wants to file an application towards the KSA. Instead, the application by a competent authority from a country subject to a temporary ban should be accepted by the Authorities of the KSA. The application should contain information which demonstrates that the temporary ban in place can be lifted or modified to allow safe imports of the food product(s) included in the application.	If a country wants to file an application towards KSA for a product not subject to a temporary ban, then this statement do not apply. This statement will be amended.
17	The EU would also like to request on which web link of the KSA an updated list can be found of countries/establishments which are subjected to a temporary ban.	Updated information can be found on the following link: https://www.sfda.gov.sa/ar/decisions?keys=&tags=All
18	*1.Application and 2. Submission of the Regulations and Control Authority Evaluation Form::* In order to facilitate the process and to eliminate any unnecessary burden and to shorten the procedure, the EU would like to kindly request to eliminate these 2 first steps and to combine it with step N° 3 whereby the applicant authority submits immediately a completed evaluation form to KSA relevant authorities. In addition, as mentioned above, to increase transparency and predictability, the EU would invite KSA to provide an indicative timeline for each of the steps in the process as well as an overall indicative timing finalizing the application procedure.	This point will be taken into consideration.
19	*5. Inspection Fees:* Reference is made to a GSO in this section. The EU would like to reiterate that GSOs are not transparent as these are not freely available while these are used as an import condition by the KSA. The EU would like to request to the KSA that its import conditions related to sanitary and Phytosanitary measures are transparent and freely available. In addition, if	Saudi Arabia would like to notify that most of the EU standards are compatible with the Saudi standards, with the exception of the following: • GSO 2500 "Additives Allowed for Use in Foodstuffs" • GSO 1016 " Microbiological criteria for • food products"

	the KSA would consider the GSO requirements to be equivalent to the relevant EU requirements, the procedure would be easier to apply for EU countries. Could the KSA confirm that this would be possible?	In addition, currently Saudi Arabia is working on the main differences between the Saudi and European standards in regards to the two standards mentioned above, and will be shared once finalized.
20	Under this point *inter alia* requirements are mentioned that must be followed by establishments interested in exporting food products to the KSA. For establishments exporting aquaculture products, "Best Aquaculture Practices (BAP)" are listed. Information available on the Internet shows that the BAP standards are about appropriate and sustainable fish farming and that they are created by the Global Aquaculture Alliance (GAA) - a non-profit international trade association dedicated to the development of responsible aquaculture. On the website of this organisation (link https://www.bapcertification.org/Standards) standards can be found for aquaculture farms, hatcheries and nurseries, feed plants and seafood processing plants. KSA is kindly requested to clarify whether the use of the above-mentioned standards by fish establishments processing aquaculture products will have to be verified by the veterinary services of the exporting country, or perhaps certified by accredited certification bodies according to BAP standards.	The use of the BAP standards by fish establishments processing aquaculture products do not have to be verified by the veterinary services of the exporting country.
21	The EU veterinary services do not have the competence to approve and certify quality systems implemented by food establishments being under their supervision. However, the EU would like to point out that a high level of food safety and plant/animal health conditions is applied in all EU Member States under EU harmonised legislation, for all food producing establishments, including for establishments exporting aquatic aquaculture products. All these food establishments are under the supervision of the competent authority in the EU.	
22	Therefore, the EU would like to request that the BAP is optional and that the EU official control system can be accepted as equivalent to guarantee the safety of the aquaculture products exported to the KSA.	The BAP is applied in Saudi establishments.
23	It is not clear whether the indicated amount applies to all plants, regardless of their number, i.e. whether it is a total amount, which establishments will have to contribute in the event of a system control / audit or is it to be paid separately from each site?	The indicated amount applies to any new food establishment seeking an approval by the SFDA and requires a technical team visit according to the notified procedure.

24	The EU seeks also some clarifications as follows: Will this fee apply to every facility exporting to KSA? For companies with several facilities exporting to KSA, this will be a significant cost if this fee is required for each of its establishments. If the facility is not inspected, will the fee be waived or refunded? Will the fee revenue only be used for inspections and, if so, will there be mechanisms in place to fee diversion to other parts of the SFDA budget?	The fee applies to any new food establishment seeking an approval by the SFDA and requires a technical team visit according to the notified procedure.
25	The EU would like to request to delete the requirement of such a fee as it is considered not in line with international commitments. The EU has discussed this in the past with KSA upon which the EU was grateful that the requirement of inspection fees was deleted at that time by the KSA.	The fee requirement was issued by the Board of Directors for Inspection Services. However, you may consider sending this request officially to the SFDA.
26	The EU is very concerned that the KSA proposes in its notified text to request again these high fees which are considered not equitable in relation to any fees charged on like domestic products or products originating in any other country and are considered higher than the actual cost of the service. In addition, the CODEX Guideline CAC/GL 26-1997[1] states clearly *'The costs incurred in undertaking an assessment, including all travel costs, costs of technical experts and auditors or inspectors, and costs of support staff should normally be borne by the competent authority of the importing country except as may otherwise be agreed.*. As this fee requirement, as noted in the draft notified text of KSA, is perceived a serious barrier to trade, the EU is kindly requesting to delete this requirement.	The fee requirement was issued by the Board of Directors for Inspection Services. However, you may consider sending this request officially to the SFDA.
27	the EU would like to highlight that the audit costs, related to approval of countries/establishments of agri-food carried out by the EU in any trading partner, including for the KSA, are covered by the EU. Consequently, the EU would call for the KSA to apply a reciprocate treatment of EU countries and establishments. Could the KSA confirm to agree to this reciprocal treatment for the EU countries and to delete the request for paying inspection fees?	The fee requirement was issued by the Board of Directors for Inspection Services. However, you may consider sending this request officially to the SFDA.
28	The EU's understanding is that the SFDA carries out such an audit to verify the functioning of the official inspection and certification systems. As part of such a visit, some establishments (but not all that would like to be approved by SFDA) will be visited to serve as an example to verify the effectiveness of the official control system (=system control). Could the KSA confirm that this is the approach as notified in the draft notified text?	If the SFDA visits some establishments, those establishment should fulfill the fee requirement because there will be possibility for approval. However, once the competent authority is approved then the procedure for approving interested establishments will be by providing the SFDA with a list of approved establishments by the competent authority in the country, those establishments are not required to pay, as no visit is required.

29	The EU would be very concerned in case that each establishments, that would like to export to the KSA, needs to undergo an inspection by SFDA.	This will differ in terms weather the competent authority in the specific country approved or not. And weather the product require an import permit or not.
30	The EU would also like to suggest to include in the text the possibility to foresee virtual technical visits if physical visits cannot take place with a view to not unnecessarily prolong the application process. Could this be confirmed by the KSA?	The SFDA may conduct a virtual technical visit if physical visits cannot take place.
31	In section 6 a reference is made to a technical visit of SFDA experts to the exporting country in order to verify that the application for approval meets the technical regulations and health requirements approved by the KSA. If this visit is necessary, it may include various facilities such as establishments, laboratories, quarantine facilities, livestock farms and other bodies responsible for inspection. In our opinion, it is important to clarify which party covers the costs of such a visit (e.g. costs of transport, accommodation, meals, interpreters, etc.).	Yes the visit may include various facilities such as establishments, laboratories, quarantine facilities, livestock farms and other bodies responsible for inspection. However, the fee is only required from export establishments.
32	As referred to above, the CODEX Guideline CAC/GL 26-1997[3] states clearly *'The costs incurred in undertaking an assessment, including all travel costs, costs of technical experts and auditors or inspectors, and costs of support staff should normally be borne by the competent authority of the importing country except as may otherwise be agreed.'*. and *'The costs incurred by the competent authority of the exporting country, in supporting the assessment, for support staff and technical experts in the exporting country should normally be borne by the competent authority of the exporting country except as may otherwise be agreed.'* Could the KSA confirm that it would apply this international CODEX Guideline with regard to the cost covering of an audit?	The fee requirement was issued by the Board of Directors for Inspection Services. However, you may consider sending this request officially to the SFDA.
33	The EU would like to suggest to include a timeframe upon which a draft report is sent to the audited country. A reasonable period would be within 30 days. Upon receipt of this draft report, the EU would suggest to allow for the competent authorities to provide comments within 30 days on this report before it becomes a final report where the comments received are included. The EU would like to be assured that also here the CODEX Guideline CAC/GL 26-1997 with regard to reporting is followed.	The challenge is the time consumed during official sending as it cannot be estimated, however the SFDA will consider including the timeframe in the procedure.
34	*Approval of Control Authority:*	The challenge is the time consumed during official sending as it cannot be estimated, however the SFDA will consider including the timeframe in the procedure.

	The EU would kindly request to include in the procedure a timeframe for approving the control authority and listing of the associated establishments.	
35	On paragraph: *Third: Procedures for approving establishments* In section 1 a link is provided to the specimen forms according to which establishments interested in exporting to the KSA market should be reported. The document "Form to update the list of approved establishments for Diary Products" contains the following attestation: "… competent authority confirms that the following establishments fulfil the SFDA *Food Hygienic Requirements (here),* the SFDA.FD 1694 standard" *General Principles Of Food Hygiene* " , and the SFDA.FD 21 technical regulation "*Hygienic Regulations For Food Plants* *And Their Personnel"* - in relation to the above, KSA is kindly requested if the SFDA.FD standards are equivalent to the EU legislation.	Saudi Arabia would like to notify that most of the EU standards are compatible with the Saudi standards, thus, in regards to the food hygiene related measures the EU legislation is equivalent to the SFDA.FD standards.
36	The EU would kindly request to set a time bound process for the SFDA for listing the establishments once the control authority provides the list.	The challenge is the time consumed during official sending as it cannot be estimated, however the SFDA will consider including the timeframe in the procedure.
37	In addition, the document should clarify that, if there is no approved control authority listed on the SFDA website and the control authority does not want to seek approval, a single establishment can be approved for export to the KSA. It is also unclear on what parts of sections 5-7 the control authority is to participate in and why the Health Certificate Form is only found in this section? If the control authority is approved, is there a Health Certificate exemption? The EU would kindly request the KSA to provide further clarifications on this aspect and to make it clear in the process described.	Yes, if there is no approved control authority listed on the SFDA website and the control authority does not want to seek approval, a single establishment can be approved for export to the KSA.. For sections 5-7 the control authority's role is to assure that the establishment seeking approval fulfills the requirements stated in this documents. There is no exemption from the health certificate for the products that require it according to the KSA Import conditions. This will be clarified in the document.
38	The EU would be grateful to receive also clarifications on following: regarding paragraph three section 1 should the list of establishments be the same as the one sent in reference with paragraph two section 5 in order for the establishments to be approved and listed for import or once the control authority is granted an approval, could the list then be extended?	yes the list can be extended
39	In case the procedure under point paragraph three section 2 is possible and there is/are only one or a few establishment/s interested in exporting food products to the KSA, is it then possible to avoid the procedure for the approval of the control	Yes it is possible to avoid the procedure for the approval of the control authority. for all products within the scope.

	authority? And if yes, for which products, all within the scope or only some of them like fish, dairy, honey, etc.?	
40	On paragraph: *Four. List of Approved Establishments:* The EU would kindly request to include a set timeframe for updating the list of approved establishments. Furthermore, the EU would like to request to include in the process that the SFDA will notify the control authority prior to a removal from the list of approved establishments.	The SFDA will consider including the timeframe in the procedure.
41	The title of the questionnaire in Annex 1 to the notified document is considered misleading as it suggests that the questionnaire can only be completed by countries for which export of meat and poultry meat and their products to the Kingdom of Saudi Arabia were previously allowed. Therefore, it is not clear whether countries that the SFDA has not approved for the export of meat and meat products (including poultry) may apply for export authorisation for other animal products (e.g. dairy products, egg products, etc.). If the export acceptance for meat and meat products takes place in the same way as for other products of animal origin, it seems reasonable to correct the title of the questionnaire accordingly.	The title of the questionnaire will be changed accordingly.
42	Annex 3 of the notified document only contains the form relating to fish establishments. It is suggested that the Saudi provision should include specimen change notification forms for all food establishments (i.e. separately for meat establishments, separately for dairy plants, fish plants and honey packaging plants). Above forms are currently available at the link: https://www.sfda.gov.sa/en/forms?keys=&date%5Bmin%5D=&date%5Bmax%5D=&tags=1 .	All forms will be attached to the document.