Neutral Citation Number: [2024] EWHC 614 (Admin)

Case No: AC-2022-LON-003434

IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 19/03/2024

Before :

MR JUSTICE CALVER

- -

Between :

The King	**Claimant**
on the application of	
GUILIN GFS MONK FRUIT CORPORATION	
- and -	
FOOD STANDARDS AGENCY	**Defendant**
- and -	
FOOD STANDARDS SCOTLAND	**Interested Party**

- -
- -

David Scannell KC, Malcolm Birdling (instructed by **Covington & Burling LLP**) for the **Claimant**
Brendan McGurk (instructed by **Food Standards Agency**) for the **Defendant**

Hearing dates: Thursday 29 February 2024

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JUDGMENT

This judgment was handed down by the Judge remotely by circulation to the parties' representatives by email and release to The National Archives. The date and time for hand-down is deemed to be 10:00 on Tuesday 19 March 2024.

Mr Justice Calver :

Introduction

1. Monk fruit (Siraitia grosvenorii) is a small, round fruit from the melon family. It is primarily cultivated in the southern and eastern provinces of China, where it is known as "luo han guo". It is known for its sweetness, a characteristic that comes from the presence of various mogrosides in the flesh of the fruit.

2. Guilin GFS Monk Fruit Corporation ("the Claimant") is a world-leading producer and manufacturer of monk fruit products, including monk fruit decoctions. It has an estimated market share of around 50% of the global monk fruit ingredient market. These decoctions can be made from fresh or dried monk fruit and are consumed as hot and cold teas and infusions, and as an ingredient in other foodstuffs such as soups, stews, desserts, sauces, baked goods and breakfast cereals. The skin and seeds of the fruit are not usually consumed. In parallel to its food use, monk fruit decoctions are also used for various purposes in traditional Chinese medicine, particularly for coughs and sore throats.

3. The Claimant brings a claim for judicial review of the joint decision dated 8 September 2022 ("**the Decision**") of the Food Standards Agency ("**FSA**") and Food Standards Scotland ("**FSS**") (collectively, "**the Agencies**"), made pursuant to Article 4 of retained Regulation (EU) 2015/2283 ("**the Novel Foods Regulation**") and retained Regulation (EU) 2018/456, as amended by the Novel Food (Amendment) (EU Exit) Regulations 2019/702 ("**the Implementing Regulation**"). By the Decision, the Agencies concluded that monk fruit decoctions constitute 'novel food' within the meaning of Article 3(2)(a) of the Novel Foods Regulation. The Claimant challenges the Decision.

4. Food business operators ["**FBOs**"] are responsible for verifying whether or not a food that they intend to place on the market within Great Britain falls within the scope of the Novel Foods Regulations. This matters because if a food is found to be non-novel, no scientific assessment is required and the food may immediately enter the market, whereas a novel food must undergo scientific safety checks.

5. Where a food business operator is unsure whether its product might be deemed novel it must formally consult with the Agencies in accordance with Article 4 of the Novel Foods Regulation.

6. When the Agencies are consulted in this way, in order to determine whether something is "novel food" for the purposes of the Novel Food Regulation, the relevant question is whether it was "used for human consumption to a significant degree within the EU or the United Kingdom before 15 May 1997". It is common ground in the present case that that is the relevant test which the Agencies had to apply.

The relevant legislation

7. The relevant definition of a "novel food" in the case of monk fruit is set out in Article 3(2)(a) of the Novel Foods Regulation. This provides:

"(a) 'novel food' means any food that was not used for human consumption to a significant degree within the EU or the United Kingdom before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:

…

(iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the EU or United Kingdom and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

— traditional propagating practices which have been used for food production within the EU or United Kingdom before 15 May 1997; or

— non-traditional propagating practices which have not been used for food production within the EU or United Kingdom before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances …"

8. The procedure for the determination of whether a food constitutes a novel food is found in Article 4 of the Novel Food Regulation. Article 4 of provides as follows:

"***Procedure for determination of novel food status***

1. Food business operators must verify whether or not the food which they intend to place on the market within Great Britain falls within the scope of this Regulation.

2. Where they are unsure whether or not a food which they intend to place on the market within Great Britain falls within the scope of this Regulation, food business operators must consult the Food Safety Authority. Food business operators must provide the necessary information to the Food Safety Authority to enable it to determine whether or not a food falls within the scope of this Regulation."

9. The Implementing Regulation lays down rules for the implementation of Article 4 of the Novel Foods Regulation, concerning in particular the consultation process to determine whether or not a food falls within the scope of that Regulation.

10. In particular, Article 4 of the Implementing Regulation provides for the submission of a "consultation request" as follows:

"Content and presentation of a consultation request

1 The consultation request shall be submitted electronically to the recipient Member State and shall consist of the following:

a a cover letter;

b a technical dossier;

c supporting documentation;

d an explanatory note clarifying the purpose and relevance of the submitted documentation.

2 The cover letter referred to in paragraph 1(a) shall be drafted in accordance with the template provided in Annex I.

3. The technical dossier referred to in paragraph 1(b) shall contain the information necessary to enable the recipient member state to conclude on the novel food status…"

11. It follows that the technical dossier should contain the information necessary to enable the Agencies to reach a conclusion on the question whether the food was "used for human consumption to a significant degree within the EU or the United Kingdom before 15 May 1997".

12. Article 5 then sets out procedures for the Member State's expeditious verification of the validity of a consultation request:

"**Procedures for verifying the validity of a consultation request**

1. *The recipient Member State shall without delay verify whether the consultation request complies with the requirements of Article 4.*
2. *Where the food business operator submits insufficient information in the consultation request, the recipient Member State shall request the food business operator to provide additional information or make the relevant updates to the consultation request within the time period specified by the recipient Member State.*
3. *The consultation request shall be considered not valid where:*
    a. *the food business operator does not provide requested additional information or updated consultation request within the period specified by the recipient Member State;*
    b. *the submitted additional information is insufficient to conclude that the consultation request is valid.*
4. *The recipient Member State shall decide on the validity of the consultation request and without delay inform the food business operator, the other Member States and the Commission of the decision. Where the consultation request is considered not valid, the recipient Member State shall provide the reasons for that conclusion."* (emphasis added)

13. It follows that the Agencies must consider the dossier and supporting information, and must request additional information from the FBO if they consider that insufficient information under Article 4 has been submitted to validate the consultation request. That is reinforced by Article 6:

"**Procedures for evaluating a valid consultation request**

1. *The recipient Member State shall conclude on the novel food status of a food within 4 months from the date on which it decided on the validity of the consultation request.*
2. *Where the recipient Member State identifies that it does not have sufficient evidence to decide on the novel food status of a food, it may request the food business operator to provide additional information. The period of that request shall be determined together with the food business operator.*
3. *Without prejudice to paragraph 4, a request for additional information referred to in paragraph 2 shall not extend the time period referred to in paragraph 1.*
4. *In duly justified cases, the recipient Member State may extend the time period referred to in paragraph 1 by a maximum of 4 months. The Food Safety Authority shall inform the food business operator, and the appropriate authority of their decision and shall provide justification.*

5. *On concluding on the novel food status of a food, the recipient Member State shall without delay notify the food business operator, and the appropriate authority of the decision and shall provide justification in accordance with Article 7 of this Regulation."*

14. It follows that if the Agencies request additional information from the FBO to decide on the novel status of a food, they must reach a decision within a maximum of 8 months.

15. Article 7 makes clear that the Agencies have a statutory duty to provide reasons for their decision:

"**Information on the novel food status and publication**

1. *The notification referred to in Article 6(5) of this Regulation shall include the following:*

…

b. a statement indicating whether the food concerned is novel, not novel or not novel only in food supplements;

c. reasons justifying the statement referred to in point (b)…"

Guidance

16. The European Commission has published guidance to assist in the determination of whether there is "human consumption to a significant degree" of the relevant food within the meaning of Article 3(2)(a) of the Novel Food Regulation (the "**Guidance"**).

17. The Guidance does not purport to be exhaustive and states "*[t]his document does not provide an exhaustive list of relevant criteria to be considered for determination of the novel food status… In fact, each product has to be evaluated on a case-by-case basis. A specific criterion might be not applicable in one case but of significant value for another product.*"

18. When assessing evidence as to whether something is novel, the guidance recognises (in paragraph 1.1) that:

> "*Whilst there may be occasions when a history of consumption to a significant degree for a product is unequivocal (e.g. by provision of extensive sales data), given the timescales since the entry into force of Regulation (EC) No 258/97, it should be emphasised that as it is as such evidence would now be 12-15 years old this will not always be the case and the "whole picture" needs to be examined. This document therefore also details possible alternative sources of information which could be used to determine "consumption to a significant degree".*"

19. It should be noted that with the passing of time since the Guidance was first published, it would now be more accurate to refer to evidence being 25 years old, rather than 12-15 years old.

20. In addition to difficulties of proof caused by the passage of time, the Guidance also recognises that import or distribution lists may not accurately describe the purpose for which the specific product has been sold/imported (food, cosmetics, medicinal products, animal feed) and so it is reasonable that all available data and information from a wide variety of sources should be taken into account in establishing whether the test is satisfied, which could include invoices, recipes, cookbooks and catalogues. The Guidance cautions, however, that only food uses can be taken into account in establishing whether a specific product has been used for human consumption to a significant degree within the Community (or the UK) before 15 May 1997 or not.

21. Paragraph 1.4 of the Guidance makes the following observation (which, as shall be seen, is reflected in the wording of the Decision):

> "*Generally, the more a food has been used the easier it should be to demonstrate a significant degree. However, the quantities consumed may vary significantly dependent on the type of food, e.g. spices, herbs or some berries may be used in smaller amounts than bread, cereals or flour. The assessment as to whether a food has been used for human consumption to a significant degree before May 1997 should therefore be based on typical levels of consumption for specific product categories*". (emphasis added)

22. In paragraph 2 of the Guidance it is provided that:

> "*In order to assist interested parties to assess the novel food status of a particular product and, if necessary, to ensure that all relevant information is made available to Competent Authorities the attached decision tree and questionnaire should be followed. The use of the decision tree and questionnaire should also indicate to interested parties when the evidence that they have available is unlikely to be sufficient to demonstrate that the produce has been consumed to a significant degree prior to 15 May 1997.*"

23. The Decision Tree and Questionnaire are intended, therefore, to assist FBOs (described as "Interested Parties") to understand the evidence that they need to submit to the Agencies in order to demonstrate that the produce has been consumed to a significant degree prior to 15 May 1997. The Questionnaire contains the following explanatory note:

> "*1. In order to assist interested parties as regards the conclusion on the novel food status of a particular product, it is recommended to fill in the table(s) below, which aim to most adequately describe the foodstuff and, where appropriate, include additional confirmatory information.*

> *2. Interested parties should use Table 3 (below) to detail the nature of evidence provided to support evidence of a history of consumption.*
>
> *3. In case of doubt about the novel food status, interested parties may send the information to a relevant Member State's Novel Food Competent Authority for review.*" (emphasis added)

24. Table 3 concerns "Evidence of a history of consumption". It is attached at *Appendix 1* to this Judgment.

25. It can be seen that it provides for "*possible weightings*". As the Guidance makes clear, each product has to be evaluated on a case by case basis, depending on the evidence adduced in support of the FBO's case that its product has been consumed, as a food, to a significant degree prior to 15 May 1997. The whole picture needs to be examined and there are several alternative possible sources of information which may be relied upon. Comprehensive sales information in the form of invoices prior to 1997 detailing the sale of the product as food will naturally be very good evidence in support of the FBO's case. However, the guidance recognises that such evidence might very well be difficult to obtain by reason of the passage of time.

26. The Guidance accordingly recognises that there will be other types of supporting evidence which demonstrate consumption of the product, as a food, to a significant degree prior to 1997. That supporting evidence may be good, bad or indifferent, depending upon its nature. All that Table 3 makes clear is that in principle there are other types of evidence, such as the types set out therein[1], which can support the claim of a history of significant consumption pre-1997. But Table 3 plainly cannot be interpreted in such a way as to treat those types of evidence which can amount to supporting evidence as being necessarily inferior to those types of evidence (invoices, pre-1997) which are considered to be very good or good evidence. It all depends on the nature and extent of the supporting evidence adduced. This is an important point in the context of the present case as I shall explain below.

Submission of the Claimant's dossier of evidence; interaction with the Agencies pre-Decision

27. Between 2018 and 2020 the Claimant began gathering evidence, and putting together a dossier, to support its case that monk fruit had been used for human consumption to a significant degree within the UK before 15 May 1997. It found that there was limited sales information in the form of sales invoices pre-dating 1997 for monk fruit or monk fruit decoctions in the EU. But as Mr. Thorrold, the Claimant's General Manager of Sales and Marketing, states in his first witness statement on behalf of the Claimant at [29-30]:

> "*This was not surprising: the regulatory consultants and I were searching for 20-year-old sales records, where local tax and*

[1] Such as import/export documents; catalogues; sales brochures; personal testimonies; magazine articles; recipe books and other (unspecified) types of evidence.

> *company law typically only requires companies to keep records for 6–7 years. In addition, the records we sought dated from before mass digitisation of sales records, so there were no electronic "back-up" files to search. Ultimately, a number of certificates of origin were located from a Chinese exporter who was exporting processed foods containing monk fruit decoctions from mainland China to the EU prior to 1997… they are dated 1998-2000…*
>
> *30. The regulatory consultants and I believed that the existence of these certificates of origin from 1998 onwards, when considered alongside the quantitative survey data, in the context of "the whole picture" supporting significant consumption prior to 1997 (discussed below), suggests that there was trade of processed food containing monk fruit decoctions to the EU prior to 1998.*"

28. In addition to these certificates of origin, Mr. Thurrold explains at [32] that a considerable volume of data from consumers and FBOs were collected by the Claimant, namely:

    a. *Evidence from a <u>qualitative</u> study (carried out in 2018) with 71 participants in the UK, Ireland, Netherlands and France with Chinese FBOs, such as Chinese supermarkets, wholesalers, distributors, importers and monk fruit consumers. The study comprised face-to-face interviews and some email follow-up. The study yielded 31 signed affidavits and 29 signed questionnaires. This evidence confirmed that monk fruit, and processed food containing monk fruit decoctions as an ingredient, was sold in specialty supermarkets and consumed in the UK/EU for many years before 15 May 1997;*

    b. *Evidence from 1,153 questionnaires as part of a systematic <u>quantitative</u> population sample survey (carried out in 2020) of people living in the UK of Chinese origin or descent about their personal purchase of monk fruit and processed foods containing monk fruit decoctions, and their preparation and consumption of monk fruit decoctions as food (before 1997 and to the present time in the UK/EU). This data evidences, by extrapolation[2], the annual consumption of millions of servings of monk fruit decoctions as food in the UK/EU before 1997;*

    c. *Evidence from a survey of types of monk fruit products sold in supermarkets in the UK/EU. This evidence shows that a broad range of monk fruit products are sold in the UK/EU, including whole monk fruits, as well as processed products containing monk fruit decoctions. The evidence from the 2018 study confirms that such a wide range of monk fruit products have been sold in the UK/EU since before 1998; and*

[2] According to the Claimant, by extrapolating data from the 2020 UK study to the entire UK population in 1996 there can be an estimation of the total number of Chinese people consuming monk fruit in the UK in 1996. The extrapolation only considered answers from those who were resident in the UK before 1997 and who were 35 years of age or older at the time of the UK 2020 Study. From that subset, 43% (118 people) consumed monk fruit decoctions as food in beverages and 41% (111 people) consumed the decoctions in soups and stews. Based on average consumption patterns, it was estimated that 5.2 million servings of monk fruit products were consumed as food in 1996 alone. Projecting further backwards in time, it was estimated that 56.4 million servings of monk fruit decoctions were consumed as food between 1980 and 1996.

d. *Other signed declarations and statements (in addition to those gathered during the 2018 study referenced at a. above) from restaurant owners, FBOs and the London Chinatown Chinese Association, attesting to the sale and/or consumption of monk fruit and monk fruit decoctions as food in the UK/EU before 1997.*

29. In addition to this evidence, the Claimant also collected the following further categories of evidence:

    i. Cooking recipes, featuring monk fruit decoctions, by way of a sample of the many recipes available before 15 May 1997. These recipes include directions for preparing a variety of foods with monk fruit decoctions including monk fruit beverages (various hot tea decoctions and cold beverages), soups and stews, as well as other foods such as watery desserts and porridge.

    ii. Interview and questionnaire responses confirming that monk fruit decoctions were used in restaurants in the EU before 1997. Over 55% of the people who were interviewed and filled out questionnaires confirmed that beverages and other foods made with monk fruit decoctions were offered or used in restaurants at that time (some respondents were restaurant owners themselves).

30. On 14 October 2021 the Claimant submitted a Consultation Request containing its dossier of evidence under Article 4 of the Retained Novel Foods Regulation.

31. Having had no feedback on its dossier at all, on 16 December 2021 the Claimant emailed the FSA with a request to "*update us on the recent dossier article 4 submission we submitted in October 2021 on monk fruit decoctions and timelines and next step*." Mr. Jacobs, Senior Policy Adviser of the FSA, emailed the Claimants on the same day to inform them that the FSA was considering the information provided and stating that it appeared that the Claimant had applied for a novel food determination under Article 3(2)(a)(ii) of the Novel Foods Regulation, when it should have applied under sub-paragraph 3(2)(a)(iv). The Claimant corrected this the following day, stating that it was a typographical error.

32. On 5 January 2022, Miss van Tonder, former policy advisor in Novel Foods at the FSA, sent an internal email to the other policy advisors within the FSA and FSS of the proposed next steps of the FSA in relation to the Claimant's consultation request:

    "…

    2. *We spoke with Legal for clarification on the meaning of 'human consumption to a significant degree'. They confirmed that there isn't a specific answer to this question in any of the published guidance, but they did provide us with some relevant guidance from a previous judgment, copied below. This rather suggests that consumption among one ethnic group could be sufficient evidence for an Art 4 determination.*

        • *The judgment of the European Court suggests that <u>it is the quantity of the food consumed that must be significant rather than the number of people who</u>*

consumed it. I therefore do not think there is any strong legal support to suggest that consumption must have been widespread geographically or by a majority population in any one EU Member State or the UK.

• However, when determining whether the quantity consumed is significant, I do think that the number of people is a relevant consideration. In other words, it could be argued that the amount of food consumed by a very small number of people (such as a single household) could never be sufficient to be considered a significant quantity, and therefore not amount to consumption to a significant degree, for the purposes of the legislation."

33. Nine days later, on 14 January 2022, Miss van Tonder sent a further email internal to the FSA and FSS members after they had spoken, in which she stated:

"Hi all
Thanks for your time earlier.
As requested, I have summarised our opinion below

- *We believe the application does not demonstrate significant HoC[3] in UK/EU prior to May '97 and therefore consider MF[4] to be novel*
- *We believe the evidence provided is limited for several reasons:*
  - *The sample groups for both the qual and quant studies are too small to be considered significant*
  - *The earliest invoice provided is from 30th April 1998*
  - *The two recipes provided are from 1999 and 2005*
- *We acknowledge that MF has historically been used within a specific ethnic group (Chinese communities) and is unlikely to have been consumed by 'core populace'. However, this is not our main consideration, and we believe stressing this point in our determination could set a challenging precedent for future Article 4s. We do not have reason to believe there is a food safety risk with MF, which would be covered by General Food Law*
- *Ultimately, none of the evidence provided by the applicant meets the 'very good evidence' criteria outlined in the guidance doc*

Please can you send your final opinion by ***COP Tuesday 18th January****."*
(underlining added)

34. It appears therefore that the Agencies considered the quantitative and qualitative studies to be too small in terms of their samples, but in any event the application ultimately was bound to fail because the evidence in the dossier did not come within the "very good evidence" criterion in table 3 of the guidance (invoices detailing the sale of food). It appears therefore that the Agencies were viewing Table 3 in the Guidance as imposing hierarchical categories of evidence.

35. This conclusion is reinforced by the email from the FSA in Wales, in reply to Ms van Tonder's email four days later on 18 January 2022 in which it stated:

> "*We agree with the Novel Foods Team determination that the Monk Fruit notification does not demonstrate human*

[3] History of consumption
[4] Monk fruit

consumption to a significant degree within UK/EU before 15 May 1997 and therefore consider Monk Fruit to be novel. We also agree that the evidence provided by the applicant pre 1997 does not meet the "very good evidence" criteria outlined [in the Guidance"]…

We would also like to clarify our approach to Article 4 notifications and how we establish history of consumption with the Novel Foods Team to ensure a consistent approach going forward." (emphasis added)

36. It can be seen that the FSA in Wales also viewed Table 3 in the Guidance as imposing rigid criteria and that since the dossier did not contain invoices showing sales pre-1997, it did not amount to very good evidence of a HoC.

37. Mr Joshua Evans of the FSS also replied to Miss van Tonder's email of 14 January 2022 by email dated 19 January 2022 in the following terms:

"Good afternoon Monique,

Apologies for not getting back sooner. We agree with the determination that the dossier does not demonstrate 'very good evidence' of a significant HoC within the EU before the 15th of May 1997 and is therefore novel.

When contacting the applicant, we will need to outline our reasoning and give some thought to how they may question our rationale. I have written a couple of these points:

• The content comprises supporting evidence, but no definitive evidence such as 1997 sales information.

• These originate from Chinese supermarkets and communities throughout the EU and UK. This means monk fruit would fall both under a specific population group (not part of a normal diet by the average population, used by specific population groups only) and limited availability (not widely available to consumers in common food stores/supermarkets)

I can understand not wanting to stress the point about traditional communities. However, this leaves us with the lack of 1997 evidence as our key point. It is clear that there were significant amounts of monk fruit being imported as early as 1998. It's not unreasonable that since businesses take some time to reach this level of imports that there likely would have been consumption before 1998. Since we agree this is not 'very good evidence' to prove a HoC, this will set a precedent for future Art. 4 requests that we should consider.

It seems that regardless of the evidence applicants present, unless it includes comprehensive sales information from before May 15th 1997, it will never qualify as 'very good evidence'. There is a major advantage to this position as it is well supported by both the guidance and legislation, but we would need to maintain this with future Art. 4 requests. If we receive a request which presents compelling evidence that their product was being sold widely, was in common use and was easily available in 1998 (or even late 1997) but they cannot produce sales information from prior to May 15th 1997, they should be deemed novel. Especially as time progresses, the ease of

producing the required sales information becomes increasingly difficult for operators.

Again, we agree with the determination and believe this is the position we should take, but it is good to recognise some of the restrictions this does bind us to for future requests." (emphasis added)

38. Consistently with the responses of the FSA and the FAS in Wales, the FSS also viewed Table 3 in the Guidance as imposing rigid hierarchical criteria and considered that because the Claimant's dosser did not contain invoices/sales receipts evidencing sales pre-15 May 1997, it did not demonstrate very good evidence of a significant HoC and the food was *therefore* novel. However, it sounded a word of warning that this inflexible position could not necessarily be adopted as a precedent for *future requests*.

39. It is to be noted that at this stage, the Agencies had still not verified the Claimant's application under Article 4 as a valid application. They had apparently decided, however, that the application should fail, despite (i) not taking any advice on the statistical validity of the quantitative and qualitative samples and (ii) not seeking any further, clarificatory information from the Claimant.

40. On 19 January 2022 the FSA's Regulated Product Approval Team ("**RPAT**") were advised that validation checks could commence on the Consultation Request.

41. In paragraph 32 of her witness statement, Ms van Tonder states that a meeting took place on 26 January 2022 between the Agencies and the Claimant, the Claimant wanting to have a "get to know session" and to discuss timeframes following validation for a status determination. She states that there was also a discussion concerning confidentiality of certain parts of the dossier supplied in support of the consultation.

42. On 27 January 2022 the RPAT sent a request for further information to the Claimant as it was unclear to the FSA what parts of their dossier they asserted to be confidential and their justification for this. The FSA received a response on 3 February 2022 that the Claimant would be uploading an amended dossier to cater for this.

43. On 12 March 2022 the Claimant uploaded an amended consultation application dated 8 March 2022. The FSA acknowledged by email dated 14 March 2022 that this had been received but informed the Claimant that it did not know when it would be in position to respond to the Claimant's request for confidentiality.

44. On 29 March 2022 the Claimant sent an email to the FSA stating as follows:

> "*…Since some of the evidence MFC have supplied in the dossier does not fit easily into existing guidance granularity for ranking and weighting the evidence for significant consumption, we would like to share a note (attached PDF) showing considerations about the different forms of evidence gathered and how this may be categorised in terms of significant consumption, especially in regards to monk fruit decoctions.*

Also attached is a worksheet with what we call the "totality tool" which the note is based on.

The intention here is not to provide new evidence as an annex to the dossier, but more of a stand-alone ancillary document that we hope you will find useful in your assessment process of monk fruit decoctions under an article 4 submission…

Looking forward to hearing back from you on outcomes of the validation soon."

45. Validation took place on 4 April 2022. By article 6(1) of the Implementing Regulation the Agencies now had 4 months from this date (ie until 4 August 2022) to conclude on the novel food status of monk fruit. Despite the fact that, as the Claimant stated, no new evidence as such was being submitted, Ms van Tonder responded by email dated 4 April 2022 as follows:

"*I can confirm that your application has been validated by FSA England and Wales and is pending validation by Food Standards Scotland (FSS). Thank you for sharing these two additional documents. For our team and the other nations to consider these documents, they will need to be formally submitted. If the additional information is submitted, our team and the other nations will need to review the new evidence. There is likely to be some extension to the process as a result, which we will agree with you. The extent of the delay would be determined by the amount and complexity of the new information you have provided, but we would endeavour to minimise it.*

Please let us know how you would like to proceed."

46. The Claimant responded on the same day, 4 April 20222, as follows:

"*A few brief questions:*

1.If you do review these new documents (just several pages about the grading/ ranking of significant consumption) – are we talking about a delay of just 1 or 2 weeks?

2. Or if longer than that, can we submit these latest documents after validation and if so what happens – will it add a "stop clock" to the 4 months assessment period (in the past this did not add stop clocks)?

3. With regard to waiting for the Scottish response. If they do not agree to validation will you take a majority decision and agree validation or what happens here?

4. You mentioned in the teleconference a few months ago that during validation a lot of work was expended to understand the

> *new approaches to significant consumption in the dossier and therefore that the actual assessment period would be shorter than that. While we realise that you cannot give a definitive or legally binding answer here, could you give us some idea on the timeline? Is it likely to be a month or 2 or do you think it will likely to 4 months or may even need an extension beyond that? (accepting that this answer is not a commitment in any way by the FSA).*"

47. Ms van Tonder responded to the Claimant's email the following day, 5 April, by inserting her answers into the Claimant's email under each of its paragraph numbers as follows:

> "*1.This will be a delay of two weeks minimum. It is difficult to provide an exact estimate, especially as we have Easter this month and a few members of the wider team have leave booked.*"
>
> *2. <u>Further evidence can be submitted after validation</u>. There is no 'stop clock', but understandably any new evidence submitted will add time to the assessment period.*
>
> *3. FSS are agreeing to validation…*
>
> *4. We expect it to be within the 4-month period and don't anticipate it running over this period. However, we cannot give specific guarantees about the time that will be required.*" (emphasis added)

48. Since the delay was only likely to be "two weeks minimum" which took account of Easter leave booked by staff members, it is apparent that there was little to consider by way of "new" evidence.

49. On 10 May 2022 the Agencies provided written confirmation to the Claimant that its revised consultation request was regarded as valid under the Implementing Regulation. It now had 4 months within which to determine the application.

50. As explained above, the Agencies had already recorded their conclusion by email in January 2022 that "*the dossier does not demonstrate 'very good evidence' of a significant HoC within the EU before the 15th of May 1997 and is therefore novel*".

51. It is not particularly surprising therefore to see Ms van Tonder recording on 20 May 2022 in an internal email to each of the agencies only 10 days after validation had taken place, that "*I've outlined the key points for reaching our decision on MF below this can help provide some context for the ministerial notifications. I've also attached the decision this has been through our legal and FSS legal.*"

52. She then set out in the same internal email the Agencies' rationale for the Article 4 outcome (namely that the fruit was novel) as follows:

"…

3. The evidence provided includes official documents (including 6 sales invoices from after 1997 and two recipes also from after this date), quantitative study, qualitative study, a population model based on this data, FBO signed affidavits and questionnaires, signed documents by non-FBO experts in consultation with FBOs and first hand field research.

4. Later the applicant provided an accompanying note to summarise the evidence provided and a proposed weighting of their evidence against the suggested ranking in the FSA guidance document.[5]

5. The EFSA guidance states that 'evidence should be based on robust reliable information and data taken from referenced sources'. We do not believe there is adequate evidence of this nature included in the dossier. The only official (and independent) data is from after 1997 and the majority of data submitted has been carried out by the applicant and is based on estimates and word of mouth.

6. In addition to this, the guidance specifies that 'Only food uses can be taken into account'. We understand that monk fruit is traditionally used in Chinese medicine and as a sweetener (with a previous novel determination in the EU as a food additive in 2019). We are not sufficiently convinced that the applicant has shown significant HoC of monk fruit as a food.

7. We are open to new approaches and types of evidence and understand that official documents from ~25 years ago may be limited. However, we do not believe the body of evidence submitted is significantly compelling to unequivocally demonstrate the required significant HoC prior to 1997."

53. This last point was no doubt intended to alleviate Mr. Evans' concern about reliance upon the absence of pre-1997 sales receipts/invoices, which would set a difficult precedent for future requests. By this stage therefore, the Agencies had agreed that the fruit should be declared novel and they had a stated rationale for that view. I reject the submission of Mr. McGurk, counsel for the FSA, that "these views were plainly preliminary views". They were much more than that: the decision had effectively already been taken.

54. It will be recalled that on 14 January 2022 Ms Van Tonder had emailed the Agencies summarising their mutual opinion that the Monk Fruit application did "*not demonstrate HoC in UK/EU prior to May 1997 and therefore they considered it to be novel*". This was because:
We believe the evidence provided is limited for several reasons:

[5] This confirms that no new evidence as such was provided on 29 March 2022, as the Claimant had stated.

a. *The sample groups for both the qual and quant studies are too small to be considered significant*
b. *The earliest invoice provided is from 30th April 1998*
c. *The two recipes provided are from 1999 and 2005*

55. However, on 25 May 2022 she recorded the feedback on the quantitative and qualitative studies that she had received from the FSA's Social Sciences and Statistics experts. They suggested that she was wrong:

> "*they consider the sample sizes and data collection methods to be robust and don't see any immediate issues with using this kind of data as supporting evidence. However, they were unable to advise on whether they consider the data to be suitable for further use in population modelling.*"

56. This naturally caused the Agencies some difficulties with their conclusion, expressed as early as January 2022, that this evidence was "limited" in terms of its support of the Claimant's application.

57. The Social Science team stated as follows:

> "*Overall from a Social Science perspective this looks robust to me in terms of approach and also sample sizes. I've added a few comments below on the 2 different studies. I would say they are robust in terms of drawing conclusions about monk food consumption in the timeframes – but would check with the other teams in terms of robustness using the sample sizes for population modelling.*
>
> *EU 2018 qualitative study:*
>
> *- 71 participants is robust qualitatively overall across the 4 EU countries. However there were only 26 participants in UK. This is still a decent number of qual interviews to make conclusions and through qualitative analysis and to inform quant study, but I wouldn't suggest using the percentages for UK only with a base size of 26.*
>
> *- Therefore I think this study is robust to draw conclusions about the consumption of monk fruit and is indicative of consumption as a trend to inform the quant study*
>
> *- One other comment on this, is that the participants were FBOs (rather than consumers) so may skew results higher, and can't generalise to wider Chinese population*
>
> *2020 UK quantitative study*

- Over 1153 ppts overall – this is a decent sample size and is robust, 756 identified as Chinese which is also a large sample size

- The report details various sample groups, e.g. 344 UK chinese participants living in UK before 1997 (of which 182 consumers of monk fruit as food), 274 age 35+ chinese UK residents before 1997 (of which 151 consume as food). I think this is still robust in terms of drawing conclusions (e.g. proportions of consumers who consume monk fruit in different ways). However I would check with stats/economics teams re the sample sizes used for population modelling

- Only participants who confirmed they consume monk fruit as food nowadays were invited to answer questions on retrospective consumption of monk fruit decoctions as beverages or soups in the UK over time. So someone may have consumed before 1997 but not nowadays (but that would just be a higher % back in pre-1997 so not an issue for the purpose of this exercise) – however this is fine from my POV as it mentions the importance of selecting people who have been consuming monk fruit continuously over time to consider aspects of past consumption and recall reliably (informed by qual)

I hope this helps – overall from a Social Science perspective I don't see any issues in terms of using the data as supporting evidence and the research is robust and reliable – I would just caveat with a couple of my points above and check whether the data modelling part of it is robust." (emphasis added)

58. It is plain that the Social Sciences Team considered the Claimant's quantitative and qualitative studies to be reliable and robust overall.

59. The comments of the Statistics team were attached in a separate document to Ms van Tonder's email. It appears from those comments that the Statistics team:

    (1) had not been provided with the entire dossier report because they stated, for example:

        "*1. General comment on statistics… I can not find a detailed description of how the study chose the sample that was selected (or self-selected) and it would be good to know such details. Is this detailed elsewhere in the report?*

    (2) (as one would expect) had questions about how the figures in the extrapolated growth model were calculated:

        2. P.4: The proportion 0.43 of Chinese population consuming monk fruit tea is given as 0.43. The authors then multiply this value by the estimated Chinese population in 1996 (183,400 – according to P.7) to obtain the number of monk

fruit tea consumers. This may be the best estimate, but it disregards the uncertainty in the proportion estimate. This could be given as a 95% confidence interval based upon 1000 people in the sample, for example, p=0.43, 95% CI: 0.40-0.46, referring to 73,000 – 85,000 MF tea consumers.

(3) did not have the purpose of the statistical exercise explained to them, which was to assess whether there was evidence of significant consumption pre-May 1997:

11. i.e. Why the emphasis on the 1996 Chinese population and consumption of MF if the survey was taken in 2020? Are the authors not looking to future projected consumption of MF?

60. In her covering email of 25 May 2022, Miss van Tonder stated as follows regarding these comments of the Statistics team:

"*Stats have done quite a comprehensive review of the modelled data and put together some comments in the attached document. A lot of this is quite technical (for me, anyway!) but it definitely seems like there are some concerns about the data model and data collection methods which put into question its overall accuracy and reliability. One of the comments highlights that this study was commissioned by the applicant and has not been independently reviewed. This calls into question the reliability of both the data and the claims made in the report.*

This seems aligned with some of the concerns we've discussed and that I summarised in my previous email." (emphasis added)

61. Ms van Tonder's observations seem slanted against the Claimant. The Statistics team were simply raising queries, and seeking further clarification of a sort that one would naturally expect from an extrapolated exercise of this nature. It is going too far to say that they were "putting into question the overall reliability" of the modelled data. Likewise, it is going too far to state that "*One of the comments highlights that this study was commissioned by the applicant and has not been independently reviewed"* and that "*this calls into question the reliability of both the data and the claims made in the report*". In fact, the Statistics Team were simply raising a query in relation to a particular table in the dossier as follows:

"*P.10: The parameter values given in the table (b-f) are from a 2020 unpublished study. Are the authors of this study the same authors of this report? Given these two factors, how reliable is this data, especially as the 2020 report has not been independently reviewed? Have you seen this 2020 report? It looks like an essential document to support the authors' claims. Indeed, these parameter values support much of the numerical claims of the authors. What about uncertainty around these estimates?*"

62. These are queries which the statisticians are raising in order to get comfort about the Claimant's approach. To take these queries out of context in order to support a conclusion

that the entirety of the claims made in the Claimant's dossier/report have been "called into question" is unreasonable and, as Mr. Scannell KC (counsel for the Claimant together with Malcolm Birdling) submitted, appears designed to support the conclusion which the Agencies had already reached.

63. The Claimant's application had only been validated two weeks earlier, on 10 May 2022. There was therefore plenty of time (until 10 September 2022) for the Agencies to raise these queries with the Claimant and seek its response. But they chose not to do so, despite Ms van Tonder having confirmed to the Claimant in her email of 5 April 2022 (above) that "*further evidence can be submitted after validation.*" It follows that the Claimant was entirely in the dark as to these so-called "concerns" of the Agencies' Statistics team.

64. Instead, two months later on 25 July 2022, Ms van Tonder sent the monk fruit notification for clearance to each of the Agencies. Ms van Tonder states in her witness statement that clearance was received in September 2022 and the decision, dated 8 September 2022, was communicated to the Claimant, refusing its application. It was also sent to the Minister for information[6]. In the Decision the Agencies expressly relied upon the alleged lack of an independent review of the Claimant's studies.

65. The Agencies concluded that the evidence presented was insufficient to demonstrate human consumption to a significant degree in the UK or EU before 15 May 1997. Thus, they determined monk fruit to be novel.

The Decision and the reasons given for the Decision

66. I consider that the reasoning contained in the Decision is consistent with the correspondence (above) leading up to it. The material parts of the Decision are as follows:

> "*The FSA and FSS have concluded that the evidence presented is insufficient to demonstrate human consumption to a significant degree in the UK or EU before 15 May 1997.*
>
> …
>
> ***Reasons statement:***
>
> *(1) The FSA and FSS were provided with limited evidence of a history of consumption within the UK or EU for monk fruit decoctions and there is insufficient reliable and robust information to demonstrate consumption to a significant degree before 15 May 1997.*
>
> *(2) The EU guidance on significant history of consumption (HoC) is relevant to the FSA and FSS consideration of the status of a novel food, as the principles in the EU law are consistent to those that apply in the UK under retained EU Regulations. The guidance states that evidence 'should be based on robust, reliable information and data taken from referenced sources'. The FSA and FSS have found there is insufficient evidence of this nature included in the dossier.*
>
> *(3) The FSA and FSS have reviewed the quantitative and qualitative studies and concluded they appear to be robust in terms of their sample sizes and data collection methods. However, these studies only amount to 'supporting evidence',*

[6] See paragraph 25 of the witness statement of Georgina Finch dated 2 January 2024.

as defined in the guidance, and are not sufficient in themselves to demonstrate a significant HoC.

(4) The FSA and FSS had some concerns regarding the data collection method for the applicant's population model, resulting in potential issues with its accuracy and reliability. This model was commissioned by the applicant and has not been independently reviewed.

(5) FSS and the FSA are open to considering different approaches to determining a significant HoC. However, the FSA and FSS do not consider that the supplementary information provided with this application demonstrates that the total evidence is sufficient.

(6) Independent data provided are sales invoices and recipes, both of which date from after 15 May 1997. Other data provided was based on estimates and personal testimonies from those purchasing and/or selling monk fruit prior to 1997, collated by the applicant. These originate from a specific population group, specifically Chinese supermarkets and communities in parts of the EU and UK. Whilst these estimates and personal testimonies did not indicate atypical quantities of consumption of monk fruit, this evidence cannot be verified by an independent source and therefore is not sufficiently robust and reliable to demonstrate a significant[7] HoC.

(7) The guidance specifies that 'only food uses can be taken into account'. The FSA and FSS do not consider the evidence of EU importers, as referenced on sales receipts (dated after May 1997) and mentioned by participants, to be strong enough evidence to demonstrate a significant[8] HoC as defined above and in the guidance, since this does not necessarily demonstrate this led to sale for human consumption of monk fruit as a food.

(8) *The FSA and FSS are aware that there are a number of potential uses for monk fruit. For example, monk fruit is traditionally used in Chinese medicine and more recently, outside of the EU and UK as a food additive to impart a sweet taste in food. The limited evidence presented has not been clearly demonstrated as being exclusively for food uses. The applicant has not shown a significant HoC of monk fruit as a food within the EU or the UK before 15 May 1997.*"

67. I have numbered the paragraphs of the Decision for ease of reference. The following is apparent from the terms of the Decision.

68. The Agencies sought to apply the Guidance. By paragraph (3) of the Decision, the Agencies accept that the Claimant's quantitative and qualitative studies are robust in terms of sample size and data collection methods. They had to accept this in view of the feedback on the quantitative and qualitative studies that they had received from their Social Sciences and Statistics experts on 25 May 2022.

69. The Agencies then state "*However, these studies only amount to 'supporting evidence', as defined in the Guidance, and are not sufficient in themselves to demonstrate a significant HoC.*" It is clear from this that the Agencies are applying Table 3 to the Guidance rigidly.

[7] Emphasised in the original
[8] Emphasised in the original

Instead of considering "the whole picture" in the light of the evidence submitted by the Claimant, the Agencies instead have looked at Table 3 and seen that these studies do not fall within the "possible weighting" columns of "very good" or "good" evidence (because they do not consist of invoices detailing sale of monk fruit pre-1997). They have then classified them as amounting "only" to "supporting evidence" "as defined in the Guidance". This sentence makes clear that the Agencies consider anything other than invoices pre-1997 to be an inferior type of evidence as a category, amounting only to supporting evidence, which is not sufficient in itself to demonstrate a significant HoC. In other words, the supporting evidence must support some other, stronger form of evidence (invoices pre-1997). Indeed, consistently with this, in her witness statement at paragraph 51 Ms van Tonder states "*… this was categorised as "supporting evidence" to reflect the fact that it was not very good or good and not sufficiently independent.*"

70. The Agencies also state in Paragraph (5) of the Decision that they "*do not consider that the supplementary information provided with this application demonstrates that the total evidence is sufficient."* This is a clumsily and opaquely worded sentence. Ms van Tonder does not explain what was meant by "supplementary information" in her witness statement, and nor do any of the other witnesses, save for Mr. Evans. He states in paragraph 53 of his witness statement that this "*was a reference to the further information provided by the Claimant at a later stage in the process. This included the aforementioned 'Totality of evidence' tool which presented an argument that when taken as a whole the evidence was sufficient.*" If so, it adds nothing of any significance for the purposes of the present analysis.

71. Paragraph (4) of the Decision refers to the fact that the Claimant's model had not been "*independently reviewed*". There is no requirement in the legislation or the guidance for independent verification of the evidence submitted, which may consist of types of evidence which the Agencies would not expect to be independently verified, such as personal testimonies. In any event, this requirement of independent verification was something that Ms van Tonder latched onto in the manner set out in paragraphs 61-62 above. Despite the Agencies having some 3 ½ months to raise this issue with the Claimant and obtain its response, they chose not to do so but instead to issue their decision without seeking any clarification about this matter, and then to purport to rely upon it in the Decision rejecting the application.

72. It is apparent from paragraph (6) of the Decision that the Agencies' requirement that the Claimant's studies should be independently reviewed is tied in with its consistent thinking in the run up to the taking of the Decision that the Claimant's dossier does not demonstrate 'very good evidence' of a significant HoC within the EU before the 15th of May 1997 by reason of the absence of invoices/sales receipts evidencing sales of monk fruit as a food pre-May 1997, which it considered to be the only robust and reliable evidence capable of demonstrating a significant HoC.

73. I say this because in paragraph (6) of the Decision the Agencies refer to "*independent data*" being provided in the form of sales invoices and recipes but they state that they are dated from after 15 May 1997. They state that the "*other data*" provided of consumption of monk fruit as a food, which it was recognised consisted of pre-1997 data, was based upon estimates and

personal testimonies[9]. Whilst these estimates and personal testimonies did not indicate atypical quantities of consumption of Monk Fruit – in other words, the last sentence of paragraph 1.4 of the Guidance was satisfied[10] - the Agencies state that this evidence "*cannot be verified by an independent source and therefore is not sufficiently robust and reliable to demonstrate a significant HoC.*" Once again, the Agencies are imposing a requirement of independent verification of the pre-1997 evidence submitted by the Claimant, which does not appear in the legislation or the Guidance, and they therefore reject the Claimant's studies out of hand as not being "sufficiently robust and reliable to demonstrate a *significant* HoC." This is despite the fact that the Guidance expressly recognises that "*the 'whole picture' needs to be examined*" on the basis that "*extensive sales data*" will not always be available given the timescales involved, and that "*possible alternative sources of information*" may be used "*to determine "consumption to a significant degree"*.

74. The word "significant" is italicised in paragraph (6) of the Decision. It is not clear why the Agencies considered that the lack of independent verification of the Claimant's evidence led to a conclusion that there was not a "significant" history of consumption in circumstances where the sample sizes were admittedly robust. Nor do the Agencies explain what form this independent verification should take. It is apparent that the Agencies considered that it could not be provided by the evidence of other, unconnected named importers, distributors or sellers of monk fruit during the relevant period, as there was ample such material, there being 71 named individuals painting the same picture as to the scale and scope of consumption in the EU prior to 1997; nor, it seems, could it be from the overall results of a statistically valid quantitative survey. It is, moreover, difficult to see how personal testimony can be independently verified: as the Claimant pointed out in its submissions, such a requirement would frequently render personal testimony redundant. It appears that this reference to independent verification is probably intended to be another reference to the flawed requirement for "very good" or "good" evidence in the form of invoices/sales receipts pre-1997, instead of merely "supporting evidence" in order for the application to succeed.

75. In short, I accept the Claimant's submission that the Agencies sought to fit the Claimant's qualitative and quantitative evidence into the categories referred to in Table 3 of the Guidance, as though that provided a template of evidence to be applied rigidly in all cases. Having found the evidence to be based on "*estimates*" and "*personal testimonies*", they categorised it as falling within the group "*Expert Knowledge – Personal Testimonies*" and consequently assigned it a pre-determined weighting of "*Supporting Evidence*", which was then necessarily deemed insufficient to establish a significant HoC pre-1997.

Agencies' post-Decision explanation of their reasons

76. Because the Agencies have adduced witness evidence on this application supposedly to "elucidate" their reasoning in the Decision; to explain that they considered all of the evidence submitted by the Claimant in support of its application in the round; and to explain that they did not rigidly apply the "very good", "good" and "supporting evidence" criteria in the

[9] These "personal testimonies" consist of witness evidence from named importers, distributors or sellers of monk fruit during the relevant period and survey data from those consuming monk fruit during the relevant period.

[10] "*The assessment as to whether a food has been used for human consumption to a significant degree before May 1997 should therefore be based on typical levels of consumption for specific product categories."*

guidance, it is instructive to look at what they told the Claimant in the period after the Decision was taken. It can be seen that, consistently with the pre-Decision correspondence and consistently with the above analysis of the reasoning which is contained in the Decision, in their post-Decision responses the Agencies continued to seek to fit the Claimant's evidence into the categories referred to in Table 3 of the Guidance, as though that provided a template of evidence to be applied rigidly in all cases, rather than assessing that evidence as a whole.

77. First, the Agencies sent the Claimant's solicitors a Response to their Pre-Action Protocol letter[11] ("**PAP response**") on 4 November 2022, two months after they published their Decision. It is a highly significant document.

78. In the PAP response, the Agencies stated in particular as follows, under the heading "The reasons for Decision":

> "*17. The FSA and FSS relied upon the EU Guidance … The EU Guidance states that evidence "should be based on robust reliable information and data taken from referenced sources." The FSA and FSS found that there was insufficient evidence of this nature included in the dossier of supporting evidence. They considered the quantitative and qualitative studies submitted with the dossier but concluded they only amounted to 'supporting evidence', as defined in the EU Guidance, and were not sufficient in themselves to demonstrate a significant History of Consumption ("HoC").*
>
> *19. Your LoC sets out the documentation provided in your client's dossier, including certificates of origin for export purposes postdating May 1997. That alone, as your client will be aware, is no evidence at all of a History of Consumption prior to the relevant date. That evidence cannot, then, be relied upon by reference to unverifiable witness evidence of the Chinese community in the EU. Even if it was verifiable, it would not be evidence of human consumption to a "significant degree" in the EU either. The Regulation presupposes that there will be objective and verifiable documentary evidence available prior to May 1997. Whilst the EU guidance states that given the time since the implementation of the Regulation that this need not be extensive, some objective, verifiable documentary evidence prior to May 1997 is required. The failure of your client to produce any such objective data is fatal to its Consultation Request. The FSA and FSS, having considered the totality of the evidence (in line with the "whole picture" approach), did not, in their assessment, accept, as a matter of fact, that there was a sufficient degree of consumption of monk fruit decoctions in the EU or UK before 15 May 1997."*

[11] Which the Claimant's solicitors had sent on 14 October 2022

79. Under the heading "Grounds of Challenge" the response continues:

> "*29. The Decision is crystal clear as to why the evidence in your client's dossier could at most be said to be 'supporting' as explained in the EU Guidance. That guidance makes clear that 'very good evidence' (if the purpose, i.e. food use, is indicated) will exist where there is 'comprehensive sales information' and 'invoices etc. detailing sale of food, including evidence of large quantities of sale in the EU.' There is no or no material objective evidence that pre-dates 15 May 1997, and certainly not that shows the purpose of the sale was food use. There is not even 'good evidence' to that effect as explained in the EU Guidance.*
>
> *30. It is plainly wrong to seek to equate sample qualitative surveys with 'very good evidence' as defined in Table 3. In particular, asking a sample of people is doing little more than aggregating personal testimonies, where testimonies are at most 'supporting evidence' in the EU Guidance.*"

80. In paragraphs 31-33 of the response to the PAP, the Agencies further stated as follows:

> "*31. Moreover, your client's complaint that "it is not explained how (for example) import or export data relating to imports and exports that took place more than 25 years ago could not be verified or how the data recorded on sales invoices from before 1997 could now be verified and/or why such data ought to be preferred to (as in this case) robust survey data corroborated by signed testimonials from named and contactable consumers, traders and representative organisations." These complaints are again without foundation and bound to be rejected:*
>
> *…*
>
> *b. Second, the LoC's complaint seems to be attacking the evidential standards adopted by the EU Guidance and which have been applied by the FSA/FSS. But such a challenge would be hopeless; there is no basis upon to challenge the standard of proof that has been adopted as against a threshold date (15 May 1997) which is very obviously a significant time ago. The evidential threshold is deliberately high (in order to establish that safety assessments are not required) and it is incapable of challenge;*
>
> *c. Third, the burden of proof is on your client and the person seeking to show a history of consumption to a significant degree. That your client is not able to do this, again, reveals the dearth of 'very good' or even 'good' evidence available to support that claim. Seeking to corroborate sales information post-dating with*

> *personal testimonies and quantitative survey analysis is being deployed by way of legal alchemy. If the basi[c] sales data doesn't exist or does not pass muster for the relevant period, neither it, not personal testimonies can be elevated to 'very good evidence' since that is to use merely supporting evidence to enable post-dating sales information to pull itself up by its own bootstraps.*
>
> …
>
> *32. [Your client]has no evidence remotely approximating very good evidence, try as it might to elevate supporting evidence to very good evidence."*
>
> *33…*
>
> *c. The evidence was considered and the FSA/FSS rightly concluded that it was no better than supporting evidence, as defined."* (emphasis added)

81. This is the clearest possible evidence that the Agencies reached the Decision by applying Table 3 of the Guidance as though it set out rigid, hierarchical categories of evidence, namely "very good", "good" and merely "supporting". Only evidence in the first category (or possibly the first and second categories), that is pre-1997 sales data, is deemed sufficient by them. Evidence in the latter category ("supporting") is deemed insufficient. Moreover, if the sales data post-dates 1997, then adding to it "supporting evidence" as defined in Table 3, such as personal testimonies, will not turn it into "very good" evidence. That would allow post-dated sales data to "pull itself up by its own bootstraps". The Agencies are belittling the Claimant's survey evidence and it is clear that they are suggesting that such evidence could never amount to sufficient evidence or corroborative evidence of personal testimonies because only pre-1997 sales data could do that. That is clearly erroneous.

82. Unsurprisingly, Mr. McGurk did not seek to support this legally erroneous reasoning, which is to the effect that:

    (i) the evidentiary requirements of the test for novelty under the Novel Foods Regulation could not be met in the absence of pre-15 May 1997 sales data and

    (ii) personal testimonies and quantitative survey analysis were categorically incapable of demonstrating a significant history of consumption unless supported by objective verifiable documentary evidence pre- 15 May 1997, namely sales data.

83. This reasoning, which one sees in the Decision (albeit worded in a somewhat less strident manner), is erroneous and there is no warrant for it in the legislation. Indeed, as observed above, the Guidance itself expressly cautions that because evidence of sales data pre-1997 would now be 12-15 years' old (and now some 25 years' old), it may not be possible to adduce sales data evidence and instead "*the whole picture needs to be examined*", with "*alternative sources of information*".

84. Mr. McGurk did not have an answer to this, other than to say that at the time when the Response to the PAP was served the claim was put "on a very different basis", in particular on the basis of irrationality. But that is not an answer to this point, as in the Response to the PAP the Agencies are nonetheless explaining the reasoning for their Decision. In any event, the claim was not put on a very different basis in the Claimant's solicitors' pre-action protocol letter dated 14 October 2022. The same three grounds of challenge were advanced which were advanced before this court. In particular the Claimant's solicitors alleged errors of law as follows:

> "*The Decision explains that the quantitative and qualitative studies accompanying the dossier were insufficient to establish a significant history of consumption because, while robust in terms of their sample sizes and data collection methods, the studies only amounted to "supporting evidence", as defined in the Guidance.*
>
> *This is incorrect. There is, in fact, no basis in either the Novel Food Regulation, Implementing Regulation or the Guidance for the FSA and FSS to classify the qualitative and quantitative studies as only amounting to 'supporting evidence'.* [Ground 1]
>
> *The next reason identified in the Decision relates to the other data which were submitted along with the dossier. The FSA and FSS appears to accept that this indicated "typical" use in Chinese communities in the UK and the EU, but nevertheless to have rejected it on the basis that it could not be verified by an independent source.*
>
> *This, too, seeks to impose an evidential test which has no basis in either the Novel Food Regulation, Implementing Regulation or the Guidance. Neither the Guidance nor Regulations impose any requirement that evidence must be capable of being "verified by an independent source". Indeed, "personal testimonies" are specifically referred to as acceptable evidence in the Guidance. This reason, too, was premised on a material misdirection as to the standard of evidence required.* [Ground 2]
>
> *Finally, the FSA and FSS comment that "[t]he limited evidence presented has not been clearly demonstrated as being exclusively for food uses." This is a plain misdirection as to the relevant test. An applicant does not need to demonstrate that the substance was used "exclusively" as a food. The only relevant question for the FSA/FSS is that posed by the Regulation itself, which is whether the food was "used for human consumption to a significant degree within the EU or UK before 15 May 1997*". [Ground 3]

85. The conclusion in paragraphs 82-83 above is further reinforced by the terms of the Agencies' Summary Grounds of Resistance which they served on 16 January 2023 in response to the

Claimant's claim for judicial review dated 2 December 2022 (which was accompanied by its Statement of Facts and Grounds).

86. The Claimant advanced (and continues to advance) three grounds of judicial review, with the permission of Swift J on 1 November 2023 as follows[12]:

Ground 1: The Agencies erred in concluding that the evidentiary requirements of the test for novelty under the Novel Foods Regulation could not be met in the absence of pre-15 May 1997 sales invoices and/or sales data: *i.e.*, it applied a bright-line evidential standard with no foundation in the statute, but which was said to be derived from the Guidance.

Ground 2: The Agencies erred in concluding that personal testimonies (no matter whether they were signed or sworn, or how clear, specific and detailed, and however much they were corroborated by other such testimonies) were categorically incapable of demonstrating a significant history of consumption unless they could be verified by an (undefined) "*independent source*". Again, that approach is not mandated, or permitted, by the statutory test.

Ground 3: The Agencies erred in concluding that it was necessary to demonstrate that monk fruit was consumed "*exclusively for food uses*" (*i.e.*, again, applying a bright-line evidential standard with no foundation in the statute).

87. By their Summary Grounds of Resistance, the Agencies defended the reasoning in their Decision by invoking the same erroneously rigid approach to their assessment of the Claimant's evidence. They stated that the Claimants' survey evidence did not fall into the "very good" or "good" category of evidence (no pre-May 1997 sales data) in Table 3 and therefore it was necessarily insufficient to demonstrate a significant degree of consumption as a food before May 1997:

> "*21. …The basic point is that if there was a "significant degree" of consumption prior to May 1997, one would assume that there would be primary documentary evidence of sales / import / export from that period demonstrating the same, such evidence constituting 'robust, referenced sources'. And there is no such evidence.*
>
> *22. It was therefore entirely reasonable for the Defendants to conclude, in accordance with the Commission's approach, that: (i) this was at best "supporting evidence" as distinct from "Very Good" or "Good" evidence; and therefore (ii) insufficient on its own to demonstrate a significant degree of consumption as a food before May 1997. Nor was it unreasonable for the FSA and FSS not to treat the quantitative and qualitative surveys as 'referenced sources' or "Very Good Evidence" akin to comprehensive sales information. Nothing in the Novel Foods Regulation, the Implementing Regulation or the Guidance required them so to do: it was reasonable and rational for them*

[12] Mr. Scannell KC confirmed that the Claimant no longer also pursues an irrationality argument.

> *to consider that only primary documentary evidence of sale or import, such as would demonstrate that monk fruit decoctions were being acquired for sale as a food, would constitute sufficiently robust and referenced sources of evidence, or akin to the "Very Good Evidence" as classified in the Guidance. Taking the approach that it did was not contrary to the 'bigger picture' approach and the evidence was looked at in the round.*" (emphasis added)

The Agencies' witness evidence

88. It was against this background that the Agencies then served no fewer than four witness statements (out of seven in total) in which their witnesses purport merely to "*elucidate the reasons for the Decision*"; "*to further explain and clarify the intended meaning of the words in the Decision*". They further submit that this evidence "*shows there was no misunderstanding or misapplication of the test* [for determining whether monk fruit was a novel food]." The Claimant submits, however, that this witness evidence seeks *ex post facto* to alight on new or different reasons for concluding that monk fruit is a novel food which were not in the Decision and that to the extent this witness evidence seeks to do so, it is inadmissible.

89. The parties agreed on the test which the court applies in determining whether or not to allow such *ex post facto* witness evidence to be adduced in respect of the reasons for an administrative decision.

90. In *South Buckinghamshire District Council v Porter (No. 2)* [2004] 1 WLR 1953 at §36, in a passage which has been applied generally in public law cases, Lord Brown stated as follows:

> "*'The reasons for a decision must be intelligible and they must be adequate. They must enable the reader to understand why the matter was decided as it was and what conclusions were reached on the "principal important controversial issues", disclosing how any issue of law or fact was resolved. Reasons can be briefly stated, the degree of particularity required depending entirely on the nature of the issues falling for decision. The reasoning must not give rise to a substantial doubt as to whether the decision-maker erred in law, for example by misunderstanding some relevant policy or some other important matter or by failing to reach a rational decision on relevant grounds. …* "

91. As Chamberlain J recently explained in *Inclusion Housing Community Interest Company v Regulator of Social Housing* [2020] EWHC 346 (Admin):

> *78. So far as ex post facto reasons are concerned, the authorities draw a distinction between evidence elucidating those originally given and evidence contradicting the reasons originally given or providing wholly new reasons: Ermakov, pp. 325-6. Evidence of the former kind may be admissible; evidence of the latter kind is generally not. Furthermore, reasons proffered after the commencement of proceedings must be treated especially carefully,*

because there is a natural tendency to seek to defend and bolster a decision that is under challenge: Nash, [34(e)]. …

92. This formulation encapsulates the relevant principles from a long and settled line of authorities which apply the Court of Appeal's decision in *R. v Westminster City Council Ex p. Ermakov* [1996] 2 All ER 302 (CA) at 309 per Hutchison LJ:

> "*The affidavits of Mr Lodge and Mr Humphreys did not merely correct, amplify or explain the reasons given in the decision letter—they put forward entirely new reasons, completely at odds with those given in the letter. Moreover, they put forward those new reasons five or six months after the decision letter had been sent and, of course, only after judicial review proceedings had been launched.*
>
> *It is well established that an obligation, whether statutory or otherwise, to give reasons for a decision is imposed so that the persons affected by the decision may know why they have won or lost and, in particular, may be able to judge whether the decision is valid and therefore unchallengeable, or invalid and therefore open to challenge.*"

And at 315:

> *(2) The court can and, in appropriate cases, should admit evidence to elucidate or, exceptionally, correct or add to the reasons; but should, consistently with Steyn LJ's observations in Ex p Graham, be very cautious about doing so. I have in mind cases where, for example, an error has been made in transcription or expression, or a word or words inadvertently omitted, or where the language used may be in some way lacking in clarity. These examples are not intended to be exhaustive, but rather to reflect my view that the function of such evidence should generally be elucidation not fundamental alteration, confirmation not contradiction. Certainly there seems to me to be no warrant for receiving and relying on as validating the decision evidence—as in this case—which indicates that the real reasons were wholly different from the stated reasons. It is not in my view permissible to say, merely because the applicant does not feel able to challenge the bona fides of the decision-maker's explanation as to the real reasons, that the applicant is therefore not prejudiced and the evidence as to the real reasons can be relied upon. This is because, first, I do not accept that it is necessarily the case that in that situation he is not prejudiced; and, secondly, because, in this class of case, I do not consider that it is necessary for the applicant to show prejudice before he can obtain relief. Section 64 requires a decision and at the same time reasons; and if no reasons (which is the reality of a case such as the present) or wholly deficient reasons are given, he is prima facie entitled to have the decision quashed as unlawful.*

> *(3) There are, I consider, good policy reasons why this should be so. The cases emphasise that the purpose of reasons is to inform the parties why they have won or lost and enable them to assess whether they have any ground for challenging an adverse decision. To permit wholesale amendment or reversal of the stated reasons is inimical to this purpose. Moreover, not only does it encourage a sloppy approach by the decision-maker, but it gives rise to potential practical difficulties. In the present case it was not, but in many cases it might be, suggested that the alleged true reasons were in fact second thoughts designed to remedy an otherwise fatal error exposed by the judicial review proceedings. That would lead to applications to cross-examine and possibly for further discovery, both of which are, while permissible in judicial review proceedings, generally regarded as inappropriate. Hearings would be made longer and more expensive.*
>
> *(4) While it is true, as Schiemann J recognised in Ex p Shield, that judicial review is a discretionary remedy and that relief may be refused in cases where, even though the ground of challenge is made good, it is clear that on reconsideration the decision would be the same, I agree with Rose J's comments in Ex p Carpenter that, in cases where the reasons stated in the decision letter have been shown to be manifestly flawed, it should only be in very exceptional cases that relief should be refused on the strength of reasons adduced in evidence after the commencement of proceedings. Accordingly, efforts to secure a discretionary refusal of relief by introducing evidence of true reasons significantly different from the stated reasons are unlikely to succeed.*" (emphasis added)

93. If the witness evidence seeks to alter, contradict or recast the reasons in the Decision, then that witness evidence will be inadmissible: see for example *R (City of Westminster) v Transport for London* [2018] EWHC 2402 (Admin) at [60][13].

94. In *Nash v Chelsea College of Art and Design* [2001] EWHC 538 (Admin) at [34], Stanley Burnton J (as he then was) sought to summarise the principles applicable to this issue (which he subjected to one correction in his subsequent decision in *R(B) v Merton LBC* [2003] 4 All ER 280 at [42] and which I have incorporated into point (i) below):

> *34. In my judgment, the following propositions appear from the above authorities:*

[13] Mr. McGurk contended that the court should accept the evidence of the Agencies' witnesses unless there is documentary or other objective evidence that is inconsistent with the Agencies' evidence which cannot sensibly be explained away: *R (Shasha) v Westminster City Council* [2017] P.T.S.R. 306 at [42]. Whilst I consider that the correct approach in a case such as the present is that set out in *Ermakov* and *Nash,* the application of either test in the present case leads to the same result.

(i) Where there is a statutory duty to give reasons as part of the notification of the decision[14], so that (as Law J put it in Northamptonshire County Council ex p D) 'the adequacy of the reasons is itself made a condition of the legality of the decision', subsequent evidence of the reasons will normally only be allowed if that evidence is merely elucidatory of those reasons.

(ii) In other cases, the Court will be cautious about accepting late reasons. The relevant considerations include the following, which to a significant degree overlap:

(a) Whether the new reasons are consistent with the original reasons.

(b) Whether it is clear that the new reasons are indeed the original reasons of the whole committee.

(c) Whether there is a real risk that the later reasons have been composed subsequently in order to support the tribunal's decision, or are a retrospective justification of the original decision. This consideration is really an aspect of (b).

(d) The delay before the later reasons were put forward.

(e) The circumstances in which the later reasons were put forward. In particular, reasons put forward after the commencement of proceedings must be treated especially carefully. Conversely, reasons put forward during correspondence in which the parties are seeking to elucidate the decision should be approached more tolerantly.

95. The starting point is that the reasons in the Decision should speak for themselves. The fact that the Agencies felt the need to adduce evidence from no fewer than four witnesses in order supposedly to "elucidate" the reasons in the Decision leads me to evaluate that evidence in an especially cautious manner. Moreover, the witness statements were made in December 2023 and January 2024, being some 15 months after the Decision was published. Those statements need to be carefully scrutinised as there is indeed a temptation in a case such as this to seek, *ex post facto*, to rationalise and bolster the decision under challenge. The key points made in those statements are as follows.

96. In his witness statement dated 10 January 2024 Mr Shaun Jacobs, senior policy advisor in Novel Foods for the FSA states in particular as follows:

"23… Table 3 [in the Guidance] was not used in isolation, nor did we regard it as imposing definitions of types of evidence within a rigid framework.

…

26. No precondition or threshold rule was applied by us during the decision-making that unless personal testimonies could be

[14] As in the instant case

> *independently verified or corroborated, they could not amount to evidence of a sufficient history of consumption. The FSA did not (i) apply any pre-condition such that only very good or good sales information would be sufficient to demonstrate a history of consumption or (ii) did not apply a rule whereby if an application only submitted 'supporting evidence' only, such an application would never on its own be capable of demonstrating a history of consumption to a sufficient degree…*
>
> *27. Whilst neither the legislation nor the Guidance require independent verification and this was not a pre-condition imposed by us … we did not impose a verifiability requirement…"*

97. Yet this is precisely what the Agencies did according to the reasons in the Decision:

> *"… these estimates and personal testimonies cannot be verified by an independent source and therefore [are] not sufficiently robust and reliable to demonstrate a significant HoC" and*
>
> *"However these studies only amount to 'supporting evidence' as defined in the guidance and are not sufficient in themselves to demonstrate a significant HoC").*

Indeed, this is what the Agencies did according to their own account of their reasoning in their Response to the PAP (see [78]-[81] above). The Agencies also adopted the same approach in the correspondence in the run up to its decision which is set out in [32]-[62] above.

98. Paragraph 48 of the witness statement of Miss van Tonder dated 10 January 2024 is to similar effect:

> *"The Guidance was useful in giving generalised indications for categorising the evidence but neither myself nor my colleagues felt bound by this and did not accept nor dismiss evidence solely due to the nature of the category as described at Table 3. There was not a rigid application of the Table in that way. We looked at all the evidence submitted originally and even allowed further information to be provided within the four-month period between validation and determination to give the Claimant every opportunity to provide as much good or very good evidence as possible in order to persuade us that there was a history of human consumption to a significant degree pre-May 1997."*[15]

99. Again, the first two sentences of this paragraph set out above are belied by the pre-Decision correspondence, the reasons in the Decision itself and the post-Decision explanation of the Agencies' reasoning. Indeed, an insight into the rigid way in which the Agencies applied the

[15] In fact, no new evidence as such was supplied by the Claimant, as is explained in paragraph 44 above.

Guidance is revealed in paragraph 49 of Ms van Tonder's witness statement when she goes on to state that "*There was no pre-1997 evidence nor indeed any evidence from the two categories of evidence which would have been given the greatest weight*" and, as for the Claimant's quantitative and qualitative survey evidence, she again reveals (in paragraph 51) the erroneous way in which the Agencies' assessed this evidence: "*this was categorised as 'supporting evidence' to reflect that it was not very good or good and not sufficiently independent.*"

100. The other witness statements are all to like effect and the same points apply. Thus, in her witness statement dated 2 January 2024 Miss Finch, a senior policy advisor for Regulated Products in FFS, states:

> *"I agree with Joshua Evans statement in that although we had regard to the guidance, the evidence is always considered on a case by case basis as the totality of the evidence will be different in each case. In reaching a decision there was no hard edge approach in respect of the nature of the evidence provided. For example, although the invoice provided was post May 1997 we considered that the volumes may indicate this was not the first export albeit there was no indication that the export was for food use."*

101. As is set out in paragraph 37 above, on 19 January 2022 Mr. Evans sent an email to Ms van Tonder, which included his conclusion on behalf of the FSS that: "*We agree with the determination that the dossier does not demonstrate 'very good evidence' of a significant HoC within the EU before the 15th of May 1997 and is therefore novel."* In other words, "very good evidence" (sales data pre-15 May 1997) is a pre-condition or a requirement for the establishment of a significant HoC. There was none in this case and therefore Monk Fruit was novel. That conclusion was consistent with the wording of paragraph (3) of the Decision (see paragraph 66 above). That the Agencies imposed this as a requirement or pre-condition is made abundantly clear in their unequivocal response to the PAP, which is repeated here for convenience:

> *"29. The Decision is crystal clear as to why the evidence in your client's dossier could at most be said to be 'supporting' as explained in the EU Guidance. That guidance makes clear that 'very good evidence' (if the purpose, i.e. food use, is indicated) will exist where there is 'comprehensive sales information' and 'invoices etc. detailing sale of food, including evidence of large quantities of sale in the EU.' There is no or no material objective evidence that pre-dates 15 May 1997, and certainly not that shows the purpose of the sale was food use. There is not even 'good evidence' to that effect as explained in the EU Guidance".*

102. Yet contradicting this, in paragraph 27 of his witness statement dated 10 January 2024 Mr Evans now states, in stark contrast:

> *"Whilst 'very good evidence' is not necessarily a requirement for every case and such evidence is not treated as a pre-condition to a finding of non-novelty we did consider this a relevant early*

> *observation, as the presentation of 'very good evidence' would be more compelling and have clearly demonstrated non-novelty but in the instant case there was not that clarity overall for the Food Safety Authority to be satisfied."*

103. This goes well beyond being elucidatory or clarifying evidence. And he concludes at paragraph 47 as follows, inconsistently with the Decision and with the documentary evidence both before and after the Decision had been taken:

> *"Therefore FSS and FSA (as with every Article 4 consultation) considered this application in the round, on it's own merits, facts and evidence. This was done in view of the Guidance, which provides general indications of how certain forms of evidence could be weighed. However my colleagues and I were fully aware this was not binding and we were free to evaluate the evidence on it's own strength. In line with this I did not (nor did my colleagues) dismiss or accept evidence out of hand due to it's nature."*

104. I consider that those passages of these four witness statements, where the Agencies' witnesses seek to re-write the reasoning contained in the Decision in the (different) manner which I have described, so as to give a version of the reasoning in the Decision which cannot stand with the wording of that document itself, as well as the Agencies' explanations of their reasoning *pre* and *post* Decision, are accordingly inadmissible.

Conclusions

105. It accordingly follows from the analysis above that I accept Mr. Scannell KC's submission that the Decision is legally erroneous as set out in Grounds 1 and 2 of the claim for Judicial Review[16], namely:

> Ground 1: The Agencies erred in concluding that the evidentiary requirements for the test of novelty under the Novel Foods Regulation could not be met in the absence of pre-15 May 1997 sales invoices and/or sales data.
>
> Ground 2: The Agencies erred in concluding under the Novel Foods Regulation that personal testimonies were incapable of demonstrating a significant history of consumption unless they could be verified by an "*independent source*".

106. This only leaves Ground 3, which is an allegation that the Agencies misdirected themselves as to the relevant test and accordingly erred in concluding that it was necessary to demonstrate that monk fruit was consumed "*exclusively for food uses*" (*i.e.*, again allegedly applying a bright-line evidential standard with no foundation in the statute). While an applicant's evidence must of course demonstrate a significant history

[16] Whilst it had no bearing on this court's judgment, it is interesting to note that, as this court was informed by the parties, the FSA of Ireland took a similar decision (based on similar reasoning) to the Agencies in the present case. The Claimant challenged that decision before the Irish Courts and the FSA consented to the quashing of that decision.

of consumption of the relevant food *as a food*, it need not demonstrate that monk fruit was consumed "*exclusively for food uses*".

107. This ground is concerned with the paragraphs (7) and (8) of the Agencies' reasons in the Decision as follows:

> *"(7) The guidance specifies that 'only food uses can be taken into account'[17]. The FSA and FSS do not consider the evidence of EU importers, as referenced on sales receipts (dated after May 1997) and mentioned by participants, to be strong enough evidence to demonstrate a significant[18] HoC as defined above and in the guidance, since this does not necessarily demonstrate this led to sale for human consumption of monk fruit as a food.*
>
> *(8) The FSA and FSS are aware that there are a number of potential uses for monk fruit. For example, monk fruit is traditionally used in Chinese medicine, and more recently outside the EU and UK as a food additive to impart a sweet taste in food. The limited evidence presented has not been clearly demonstrated as being exclusively for food uses. The applicant has not shown a significant history of consumption."*

108. Paragraph 1.5 of the Guidance provides that :

> *"Regulation (EC) No 258/97 exclusively covers foods and food ingredients. Therefore, only food uses can be taken into account in establishing whether a specific product has been used for human consumption to a significant degree within the Community before 15 May 1997 or not. Furthermore, the demonstrated use should relate to the specific food in question.*
>
> *Products that have been used for their medicinal effects/as a drug or as cosmetics (for example, traditional restorative remedies, plant based medicinal products, traditional Chinese medicine, toothpaste) do not indicate that this product was used as food."*

109. In the Agencies' Detailed Grounds of Resistance it is said that:

> *"71. Section 1.5 of the Guidance deals with 'Intended purpose' and states that the previous Novel Foods Regulation "exclusively covers foods and food ingredients. Therefore, only food uses can be taken into account in establishing whether a specific product has been used for human consumption to a significant degree within the Community before 15 May 1997 or*

[17] This is an express reference to paragraph 1.5 of the Guidance.
[18] Emphasised in the original

> *not. Furthermore, the demonstrated use should relate to the specific food in question. Products that have been used for their medicinal effects/as a drug or as cosmetics (for example, traditional restorative remedies, plant based medicinal products, traditional Chinese medicine, toothpaste) do not indicate that this product was used as a food." The Decision was using the word 'exclusively' in the same way.*
>
> *72.This is clarified in a number of the FSA/FSS statements. Ms Van Tonder states that "When stating 'exclusively for food use' the FSA was emphasising that only the food use was relevant to the novel status determination before it." The evidence had to relate monk fruit's consumption as a food (para 56). See also Jacobs, para 31 and Finch, para 26."*

110. Mr. Jacobs refers in his witness statement to the "clumsy wording" in the Decision in this regard, but he and Ms Finch both assert that the Agencies intended to emphasise that only food use was relevant to the novel status determination.

111. The Claimant contends, however, that this is not what the Decision says. It maintains that the actual statement in the Decision, that the evidence "*has not been clearly demonstrated as being exclusively for food uses*", was to the effect that the mixed use of monk fruit necessarily precluded a finding of non-novelty, not that when the evidence was separated out it could not be concluded that there was enough food-consumption evidence. This is, maintains Mr. Scannell, a further impermissible *ex-post facto* attempt to contradict the contemporaneous reasons.

112. The way in which the reasoning in paragraph (8) of the Decision is worded is that *"[t]he limited evidence presented has not been clearly demonstrated as being exclusively for food uses*." In reaching this conclusion, it is clear from paragraph (7) of the Decision that the Agencies have relied upon their erroneous assessment of the quality of the evidence presented, namely that it is "limited" by reason of their erroneous approach to the test (as to whether the food was used for human consumption to a significant degree pre-15 May 1997). They therefore only refer to evidence in the form of "sales receipts", because (pre 15 May 1997) sales receipts can amount to "very good" or "good" evidence, before rejecting this category of evidence in the present case by reason of the sales receipts being "*dated after May 1997*".

113. In paragraph (8) of the Decision, the Agencies then conclude that the "limited evidence presented", which is a reference back to the post-dated sales receipts in paragraph (7), had not been clearly demonstrated as being exclusively for food uses. There is no reference whatsoever to all of the other categories of evidence adduced by the claimant in its dossier which show the consumption of monk fruit *as a food*, in particular its qualitative and quantitative surveys and personal testimonies (which the Claimant maintains demonstrates consumption pre-May 1997). That is, no doubt, because the Agencies have already rejected that evidence as insufficient, by reason of their erroneous application of the relevant test.

114. It follows that *even if* what the Agencies intended to emphasise, as their witnesses state by way of clarification, was that only food use was relevant to the novel status determination, the reasoning in paragraphs (7) and (8) of the Decision is in any event fatally flawed as a result of their misapplication of the relevant test.

115. In the circumstances, Ground 3 does not provide a separate successful ground of challenge to the Decision. Rather, the same erroneous reasoning can be found in paragraphs (7) and (8) of the Decision as can be found in the earlier paragraphs: the Agencies misapplied the relevant test and for that reason the Decision must be quashed.

Remedy

116. Mr. McGurk submitted that the Decision should not be quashed because even if the Agencies had not adopted its legally flawed approach to the application of the statutory test, the outcome would have been the same, namely that the evidence adduced by the Claimant was insufficient to demonstrate a significant HoC pre-May 1997. But that submission is misconceived: had the Agencies applied the correct approach, and assessed all of the evidence on its merits, they might well have reached a different decision[19]. This court is not in a position to say. But the point is that they have never done so and so the outcome of the *correct* application of the test is unknown.

117. At one stage in the argument Mr. McGurk also submitted that the Claimant had an alternative remedy whereby it could have obtained authorisation as a traditional food which, if granted, would have meant that the Claimant could have placed its product on the market over a year ago. However, he accepted that this would not correct any unlawfulness in the Decision which the court has found. This would not therefore be an alternative remedy (to judicial review) available to the Claimant to challenge the decision in question. On this approach, the unlawful Decision remains unchallenged, and instead the Claimant is compelled to pursue an entirely different application for an entirely different decision (one relating to traditional foods). That is plainly an impermissible approach for the Agencies to adopt. In any event, Mr. Scannell maintained that it is "legally wrong" to assert that authorisation as a traditional food could have been obtained. But since I was told nothing about the regulatory regime for traditional foods nor how an authorisation to put a product on the market as a traditional food compared to an authorisation to put a product on the market as a non-novel food, I cannot form any judgment as to whether this was a viable alternative course to adopt in any event.

118. In all the circumstances the claim for judicial review succeeds. The Decision is quashed and the Agencies are ordered to re-consider the Claimant's application in the light of this judgment. I am grateful to both advocates for the skilful and succinct way in which this claim was argued by them.

[19] In his second witness statement, Mr. Thorrold answers all of the queries raised by the Agencies' Social Sciences and Statistics experts which the Agencies will no doubt now need to consider.

APPENDIX 1

Type of Evidence*	Type of evidence	Possible Weighting
Comprehensive Sales Informa- tion	Invoices etc detailing sale of food, including evidence of large quantities of sale in the EU	Very Good Evidence, if purpose (food use) is indicated
Sales Information	Invoices etc detailing sale of food	Good Evidence, if purpose (food use) is indicated
Government Import/Export In- formation	Official documents	Supporting Evidence, if purpose (food use) is indicated
Sales Information	Catalogues, Sales Brochures	Supporting Evidence, if purpose (food use) is indicated
Listed in recognised catalo- gues/documents		Supporting Evidence
Expert knowledge	Personal Testimonies	Supporting Evidence
Supporting Information	Magazine articles, Recipe Books etc.	Supporting Evidence
Other	Please Specify	