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Notice for the attention of the persons subject to the restrictive measures provided for in Council Decision 2013/255/CFSP and in Council Regulation (EU) No 36/2012 concerning restrictive measures in view of the situation in Syria

(2015/C 80/01)

The following information is brought to the attention of the persons and entities designated in Annex I to Council Decision 2013/255/CFSP ([1]), as implemented by Council Implementing Decision (CFSP) 2015/383 ([2]), and in Annex II to Council Regulation (EU) No 36/2012 ([3]), as implemented by Council Implementing Regulation (EU) 2015/375 ([4]), concerning restrictive measures in view of the situation in Syria.

The Council of the European Union has decided that the persons and entities that appear in the abovementioned Annexes should be included in the list of persons and entities in Annex I to Decision 2013/255/CFSP and Annex II to Regulation (EU) No 36/2012. The grounds for designation of those persons and entities appear in the relevant entries in those Annexes.

The attention of the persons and entities concerned is drawn to the possibility of making an application to the competent authorities of the relevant Member State(s) as indicated on the websites in Annex IIa to Regulation (EU) No 36/2012, in order to obtain an authorisation to use frozen funds for basic needs or specific payments (cf. Article 16 of the Regulation).

The persons and entities concerned may submit a request to the Council before 31 March 2015, together with supporting documentation that the decision to include them on the abovementioned list should be reconsidered to the following address:

Council of the European Union
General Secretariat
DG C 1C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

E-mail: sanctions@consilium.europa.eu

The attention of the persons and entities concerned is also drawn to the possibility of challenging the Council's decision before the General Court of the European Union, in accordance with the conditions laid down in Article 275, second paragraph, and Article 263, fourth and sixth paragraphs, of the Treaty on the Functioning of the European Union.

([1]) OJ L 147, 1.6.2013, p. 14.
([2]) OJ L 64, 7.3.2015, p. 41.
([3]) OJ L 16, 19.1.2012, p. 1.
([4]) OJ L 64, 7.3.2015, p. 10.

Notice for the attention of the data subjects to whom the restrictive measures provided for in Council Regulation (EU) No 36/2012, as implemented by Council Implementing Regulation (EU) 2015/375 concerning restrictive measures in view of the situation in Syria apply

(2015/C 80/02)

The attention of data subjects is drawn to the following information in accordance with Article 12 of Regulation (EC) No 45/2001 of the European Parliament and of the Council [1]:

The legal basis for this processing operation is Council Regulation (EU) No 36/2012 [2], as implemented by Council Implementing Regulation (EU) 2015/375 [3].

The controller of this processing operation is the Council of the European Union represented by the Director-General of DG C (Foreign Affairs, Enlargement, Civil Protection) of the General Secretariat of the Council and the department entrusted with the processing operation is the Unit 1C of DG C that can be contacted at:

Council of the European Union
General Secretariat
DG C 1C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

E-mail: sanctions@consilium.europa.eu

The purpose of the processing operation is the establishment and updating of the list of persons subject to restrictive measures in accordance with Regulation (EU) No 36/2012, as implemented by Implementing Regulation (EU) 2015/375.

The data subjects are the natural persons who fulfil listing criteria as laid down in that Regulation.

The personal data collected includes data necessary for the correct identification of the person concerned, the Statement of Reasons and any other data related thereto.

The personal data collected may be shared as necessary with the European External Action Service and the Commission.

Without prejudice to restrictions provided for in Article 20(1)(a) and (d) of Regulation (EC) No 45/2001, requests for access, as well as requests for rectification or objection will be answered in accordance with Section 5 of Council Decision 2004/644/EC [4].

Personal data will be retained for 5 years from the moment the data subject has been removed from the list of persons subject to the asset freeze or the validity of the measure has expired, or for the duration of court proceedings in the event they had been started.

Data subjects may have recourse to the European Data Protection Supervisor in accordance with Regulation (EC) No 45/2001.

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[1] OJ L 8, 12.1.2001, p. 1.
[2] OJ L 16, 19.1.2012, p. 1.
[3] OJ L 64, 7.3.2015, p. 10.
[4] OJ L 296, 21.9.2004, p. 16.

EUROPEAN COMMISSION

Euro exchange rates [1]

6 March 2015

(2015/C 80/03)

1 euro =

	Currency	Exchange rate		Currency	Exchange rate
USD	US dollar	1,0963	CAD	Canadian dollar	1,3666
JPY	Japanese yen	131,48	HKD	Hong Kong dollar	8,5055
DKK	Danish krone	7,4514	NZD	New Zealand dollar	1,4627
GBP	Pound sterling	0,72200	SGD	Singapore dollar	1,5004
SEK	Swedish krona	9,1893	KRW	South Korean won	1 203,83
CHF	Swiss franc	1,0700	ZAR	South African rand	12,9134
ISK	Iceland króna		CNY	Chinese yuan renminbi	6,8651
NOK	Norwegian krone	8,5420	HRK	Croatian kuna	7,6205
BGN	Bulgarian lev	1,9558	IDR	Indonesian rupiah	14 182,39
CZK	Czech koruna	27,297	MYR	Malaysian ringgit	3,9923
HUF	Hungarian forint	303,78	PHP	Philippine peso	48,282
PLN	Polish zloty	4,1178	RUB	Russian rouble	65,2170
RON	Romanian leu	4,4410	THB	Thai baht	35,531
TRY	Turkish lira	2,8275	BRL	Brazilian real	3,2949
AUD	Australian dollar	1,3990	MXN	Mexican peso	16,6451
			INR	Indian rupee	68,4064

[1] *Source*: reference exchange rate published by the ECB.

Opinion of the Advisory Committee on restrictive agreements and dominant position given at its meeting of 5 June 2013 regarding a draft decision relating to Case C.39226 (1) — Lundbeck

Rapporteur: Czech Republic

(2015/C 80/04)

1. The Advisory Committee agrees with the European Commission that the respective parties concluded agreements within the meaning of Article 101 TFEU and Article 53 of the EEA Agreement that had the object of restricting competition.

2. The Advisory Committee agrees with the European Commission that the following agreements, and extensions to the agreements, constituted a single and continuous infringement for the relevant time-frame:

   — Merck's agreements with Lundbeck,

   — Arrow's agreements with Lundbeck,

   — Alpharma's agreement with Lundbeck, and

   — Ranbaxy's agreement with Lundbeck.

3. The Advisory Committee agrees with the European Commission's draft Decision as regards the conclusion that the agreements between the addressees were capable of having an appreciable effect upon trade between EU Member States and between Contracting Parties of the EEA-Agreement.

4. The Advisory Committee agrees with the European Commission that the conditions of Article 101 paragraph 3 TFEU are not met.

5. The Advisory Committee agrees with the European Commission's draft Decision as regards all addressees of the Decision, specifically regarding parental liability.

6. The Advisory Committee agrees with the Commission's assessment as regards the duration of the infringements.

7. The Advisory Committee recommends the publication of its opinion in the *Official Journal of the European Union*.

Opinion of the Advisory Committee on restrictive agreements and dominant position given at its meeting of 17 June 2013 regarding a draft decision relating to Case C.39226 (2) — Lundbeck

Rapporteur: Czech Republic

(2015/C 80/05)

1. The Advisory Committee agrees with the Commission that fines should be imposed on the addressees of the draft decision.

2. The Advisory Committee agrees with the Commission on the basic amounts of the fines for Lundbeck.

3. The Advisory Committee agrees with the Commission that Lundbeck should be given a 10 % reduction of the basic amount in view of the long duration of the investigation. A minority disagrees.

4. The Advisory Committee agrees with the Commission on the final amounts of the fines for Lundbeck. A minority abstains.

5. The Advisory Committee agrees with the Commission's approach to base the calculation of fines for the generic undertakings on the value transferred.

6. The Advisory Committee agrees with the Commission that the generic undertakings should be given a 10 % reduction in view of the long duration of the investigation. A minority disagrees.

7. The Advisory Committee agrees with the Commission on the final amounts of the fines for the generic undertakings. A minority abstains.

8. The Advisory Committee agrees with the Commission to reject the inability to pay request made in this case.

9. The Advisory Committee recommends the publication of its opinion in the *Official Journal of the European Union*.

Final Report of the Hearing Officer [1]

Lundbeck (AT.39226)

(2015/C 80/06)

I. BACKGROUND

1. This case concerns agreements entered into by the originator pharmaceutical company Lundbeck and four generic pharmaceutical companies in 2002 concerning the production and sale of the anti-depressant citalopram.

2. The Commission's investigation started on the basis of information received from the Danish Competition Authority in October 2003. The investigation was interrupted by the competition inquiry into the pharmaceutical sector lasting from January 2008 until July 2009 [2].

3. In January 2010 the Commission initiated proceedings against Lundbeck, and in July 2012 against four groups of generic undertakings involved in the infringement, when it sent out the Statement of Objections.

II. WRITTEN PROCEDURE

1. Statement of Objections

4. On 24 July 2012 the Commission issued a Statement of Objections ('SO') against Lundbeck, Alpharma, A.L. Industrier, Arrow, Resolution Chemicals, GUK, Merck and Ranbaxy [3]. It expressed the preliminary view that the settlement agreements concluded between the originator company and the generic companies represent so-called pay-for-delay agreements and amount therefore to a restriction of competition by object infringing Article 101 TFEU and Article 53 of the EEA agreement.

2. Access to file

5. All parties were granted access to the file in the form of a DVD in August 2012.

6. In September 2012 Alpharma, later followed by other parties, made a detailed request for disclosure of all redacted parts of the so-called Matrix documents on the Commission's file. In order to address these requests, DG Competition requested the provider of the Matrix documents, Lundbeck, to seek disclosure. The ensuing disclosure process lasted several months.

3. Time limit for reply to the SO

7. DG Competition initially set a deadline of 10 weeks for the parties' replies to the SO which was prolonged once by approximately 3 weeks. When Alpharma requested a further extension on the ground that it wished to see the Matrix documents before replying to the SO DG Competition granted a further limited extension but regarded it as final. It informed the parties that they would be afforded the opportunity to supplement their replies should Matrix documents only become accessible after the expiry of the deadline. Alpharma, Arrow, GUK and Merck subsequently insisted on an extension until they had seen the outstanding documents.

8. After this request was rejected by DG Competition, the four parties referred the matter of the extension of the deadline for their replies to the SO to me. They claimed that a violation of their rights of defence would ensue if they had to respond before being given full access to the file because the Matrix documents contained information critical to their defence.

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[1] Pursuant to Articles 16 and 17 of Decision of the President of the European Commission of 13 October 2011 on the function and terms of reference of the hearing officer in certain competition proceedings (OJ L 275, 20.10.2011, p. 29). ('Decision 2011/695/EU').

[2] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/

[3] H. Lundbeck A/S and Lundbeck Limited, Xellia Pharmaceuticals ApS and Alpharma LLC (now called Zoetis Products LLC) ('Alpharma'), A.L. Industrier AS, Arrow Generics Limited and Arrow Group ApS ('Arrow'), Resolution Chemicals Limited, Generics (UK) Limited, Merck KGaA, and Ranbaxy (UK) Limited and Ranbaxy Laboratories Limited ('Ranbaxy').

Suspension of time limit

9. Indeed, parties are in principle not expected to reply to the SO before they have been given full access to the file and before all requests for additional access have been settled. In order to determine the importance of the Matrix documents for the parties' defence and whether DG Competition's approach to impose a staggered process for the replies to the SO might in light of the significance of the Matrix documents for the parties' defence exceptionally be acceptable in the interest of the efficiency of the proceeding, I suspended the time limit set by DG Competition ([1]).

10. The additional access request concerned 29 documents (IDs) accounting for approximately 4 000 redacted pages. The documents had been part of the Lagap litigation in the UK and parallel litigation in other European countries. They related to manufacturing processes, collected during patent infringement inspections at the premises of a company with the name of Matrix. The redactions were made as a result of a UK consent order and non-disclosure orders by other national patent judges.

11. Upon my initiative DG Competition established a timetable together with Lundbeck and Matrix setting out when the other parties would receive access to the requested Matrix documents. All UK documents became subsequently available shortly before the end of 2012 and the documents originating from the parallel litigation proceedings followed until 31 January 2013.

Extension of time limit

12. On 18 December 2012, I decided to grant the parties a further extension of the time limit for their replies to the SO. Their responses were thus due after they had had the opportunity to see all Matrix documents related to the UK litigation but before the documents related to other parallel litigation had been made accessible, *i.e.*, in the period between 9 and 14 January 2013.

13. I took my decision considering both the right of parties to be properly heard and the public interest in efficient proceedings. In my opinion, the Matrix documents relating to the UK litigation were potentially useful for the parties' defence but not 'critical' as some claimed. In contrast, the Matrix documents relating to parallel litigation added little information to what the documents originating from the UK litigation already contained. I concluded therefore that the parties' rights of defence would be safeguarded, if they were given the opportunity to see the papers stemming from the UK litigation, before responding to the SO. I also took into account that DG Competition had offered the parties the opportunity to supplement their replies should they wish to do so after having been given full access to the Matrix documents. All four parties submitted their replies in time and none made use of the right to supplement them in the light of the Matrix documents that became accessible only after the expiry of the time limit.

14. Since none of the parties came back to me in relation to the Matrix documents, I regard this matter as settled.

4. **Procedural claims raised in the replies to the SO**

15. Alpharma, Arrow, GUK, Lundbeck and Merck raised certain procedural claims in their replies to the SO, but they did so only vis-à-vis DG Competition. In relation to the rights of defence, Alpharma, GUK and Merck submitted that the excessive length of the Commission's investigation breached their rights of defence ([2]). At any rate, they argued, the duration of the proceeding was too long and the Commission should draw appropriate consequences from this fact. I will analyse the two parts of the claim below.

16. Article 41 of the EU Charter of Fundamental Rights provides that the institutions of the European Union need to act within a reasonable time when conducting administrative procedures. The reasonableness of the length of administrative proceedings is to be assessed in light of the individual circumstances of each case. In particular, the context, the various procedural stages followed by the Commission, the conduct of the parties during the procedure, and its complexity need to be examined ([3]).

([1]) The situation in this case was in my view similar to the situation described in recital 15 of Decision 2011/695/EU and justified a similar suspension decision.

([2]) Alpharma raised this point again with me in a letter submitted on 3 June 2013.

([3]) Case T-228/97 *Irish Sugar v Commission* [1999] ECR II-02969, paragraph 278.

17. On the basis of the information available to me, neither the context of the case, its complexity, the various procedural steps as described in the SO nor certainly the conduct of the parties would appear to justify the considerable duration of the proceedings of 8 years and 9 months counted from the date when the Commission started the investigation until the date when the SO was sent.

18. Assuming that it were established that the administrative procedure was unreasonably long, the Commission would only be barred from imposing fines, if the parties could show that the Commission's failure to conduct the administrative procedure within a reasonable time was capable of actually compromising or adversely affecting their rights of defence ([1]). The burden of proof lies with the parties who must submit convincing evidence.

19. After considering the evidence submitted, I concluded that the parties did not demonstrate to the requisite legal standard that the extraordinary length of the investigation infringed their rights of defence. In response in particular to Alpharma's detailed claim, I note that it is the party's responsibility in the first place to ensure that neither the passage of time nor the sale of the business involved in the putative infringement cause the alleged difficulty or inability to produce all possible existing exculpatory evidence. Undertakings have a duty of care, pursuant to case-law, which obliges them to ensure the proper maintenance of records in their books or files enabling details of their activities to be retrieved, in order to make the necessary evidence available in the event of legal or administrative proceedings. Such duty applies even when the business at stake was sold some considerable time before the investigation began ([2]). A similar obligation exists in respect of access to former employees. It would furthermore seem that Alpharma did not indicate with the precision required by case-law ([3]), the nature and the scope of the exculpatory information which has allegedly been lost because of the passage of time.

20. My conclusion that the parties' rights of defence have not been violated does not mean that the considerable length of the investigation stage has no consequences at all. In light of the right to good administration and in accordance with case-law ([4]), I consider that the first stage of the administrative procedure was unreasonably long. This should be taken into account when determining the fine.

5. **Access to other parties' replies**

21. DG Competition granted all parties access to copies of the non-confidential version of the other parties' replies to the SO. The parties were given the opportunity to submit comments in writing prior to the Oral Hearing. Alpharma, Lundbeck and Ranbaxy made supplemental submissions before the Oral Hearing, while A.L. Industrier did so thereafter.

III. **ORAL PROCEDURE**

22. All parties to the proceedings, with the exception of Resolution Chemicals, exercised their right to be heard in an Oral Hearing, which took place on 14 and 15 March 2013.

IV. **PROCEDURE AFTER THE ORAL HEARING**

1. **Letter of Facts**

23. On 12 April 2013 the Commission sent a Letter of Facts ('LF') to Alpharma, Arrow, GUK, Lundbeck and Ranbaxy. Another LF was sent to GUK's former parent company Merck and Alpharma's former parent company A.L. Industrier on 6 May 2013. All parties were given 10 calendar days to respond.

2. **Extension of time limit**

24. Following the receipt of the LF, Alpharma, Arrow, GUK and Lundbeck made a request first to DG Competition and, after their request had been rejected, to me to extend the time limit for their reply to the LF.

([1]) Case T-99/04 *AC-Treuhand AG v Commission*, [2008] ECR II-1501, paragraph 58.
([2]) Case T-587/08 *Fresh del Monte Produce Inc.* v *Commission* [2013] not yet reported, paragraphs 683 and 684.
([3]) Case C-105/04 P *Nederlandse Federatieve Vereniging voor de Groothandel op Elektrotechnisch Gebied* v *Commission (FEG)* [2006] ECR I-08725, paragraphs 56 to 60.
([4]) Case T-240/07 *Heineken Nederland BV and Heineken NV* v *Commission* [2011] ECR II-03355, paragraphs 290 and 291.

25. GUK requested that I suspend the deadline for its reply to the LF until I had taken a decision on their claims that the Commission should have issued a Supplementary Statement of Objections ('SSO') in relation to some of the evidence put forward in the LF and a new LF clarifying the intended use of some of the evidence (see Section IV.4. below).

26. I note that while under the Terms of Reference I can review the claims submitted by GUK and indeed the other parties there is no basis for me to issue a decision on either matter. This also implies that I cannot suspend the time limit.

27. All four parties obtained extensions of different duration considering their individual circumstances. All parties submitted responses within the respective deadlines.

3. **Access to other parties' replies**

28. DG Competition granted all parties access to copies of the non-confidential version of the other parties' replies to the LF and afforded them the opportunity to comment upon them. Only Lundbeck submitted comments.

4. **Procedural claims regarding the Letter of Facts**

29. Arrow, GUK and Lundbeck raised two procedural claims in relation to the LF. Following DG Competition's rejection of these complaints the parties referred the issues to me for review.

Supplementary Statement of Objections necessary?

30. First of all, in relation to a total of 10 points out of 62 of the LF, the three parties argued that the new evidence and the intended use, as indicated by the Commission, went beyond merely corroborating objections of the SO. Rather, they submitted that with those points the Commission was substantially reformulating the objections, introducing additional objections or modifying the intrinsic nature of the infringement. The parties thus questioned whether such evidence could be communicated in a LF and did not necessitate the issuance of an SSO, if the Commission intended to rely on it.

31. An SSO is required when the Commission raises additional objections or alters the intrinsic nature of the objections ([1]), while a LF suffices where it only introduces new evidence considered useful to support the objections already contained in the SO ([2]). The latter format is fully compatible with the rights of defence, in particular where it is applied in order to refute the arguments put forward by the parties during the administrative procedure ([3]).

32. Having analysed the 10 points of the LF for which the parties argued that an SSO was required, I cannot find that any of these points raise additional objections or alter the nature of existing objections. These points, like the other points of the LF, are to a large extent introduced in response to the parties' observations to the SO. Conceivably, some of the claims may have been provoked by a poor indication of the intended use of the new evidence (see further below). At any rate, the introduction of new incriminating evidence, even if partially of a different kind as the already adduced evidence, does not necessitate an SSO. Therefore, I conclude that the rights of defence of the parties have not been violated by introducing the 10 points complained of by means of a LF.

Letter of Facts unclear?

33. Secondly, in relation to a total of 23 points out of 62 of the LF, the three parties alleged that the LF is unclear, ambiguous or too succinct with regard to the use the Commission intends to make of some of the new evidence. Such points partially overlap with the 10 points for which the parties ask for the issuance of an SSO.

([1]) See Case T-111/08 *MasterCard Inc. and others* v *Commission* [2012] not yet reported, paragraph 268.

([2]) See Case T-23/99, *LR AF 1998 A/S, formerly Løgstør Rør A/S* v *Commission* [2002] ECR II-1705, paragraphs 190 and 193; See also Joined Cases T-236/01, T-239/01, T-244/01 to T-246/01, T-251/01 and T-252/01, *Tokai Carbon and Others* v *Commission* [2004] ECR II-1181, paragraph 45; and Case T-340/03 *France Télécom SA* v *Commission* [2007] ECR II-107, paragraph 30.

([3]) *MasterCard Inc. and others* v *Commission*, cited above, paragraph 273.

34. In particular, the parties argued that the link between the evidence and the objections set out in the SO is not clear. They maintained that the alleged lack of clarity would hamper their ability to defend themselves.

35. In order to enable its addressees to express their views effectively on new evidence, a LF has to cite the paragraph of the SO to which it relates and to explain the relevance of the new evidence to the objections already communicated ([1]).

36. Whilst I agree that in a few instances the Commission could have better explained the use it intends to make of the new evidence, I do not consider that the parties' rights of defence have been impinged.

37. Firstly, except for one instance, for each new piece of evidence the LF refers to a paragraph or a section of the SO and indicates how the Commission intends to use it.

38. Secondly, in the one instance where the LF does not refer to a paragraph of the SO as well as in those instances in which the intended use of the new evidence has been alleged to be unclear, it is possible to reasonably deduce from the content of both the LF and the SO the relevance of the new evidence for a specific objection ([2]).

39. This conclusion is confirmed by the parties' replies to the LF. They show that the parties were able to understand or, at least, to reasonably deduce for each of the 23 points the significance of the new evidence for the objections against them. In this regards, I note that where one party does not reply to an allegedly unclear point, the same point has been addressed by at least one other party and that party has correctly identified the link between the new evidence and the objection referred to.

40. Where in one instance one party responds by referring to a different objection than the other party reacts to, this most probably has other reasons than the alleged lack of clarity of the LF.

41. Therefore, I conclude that the criticised points in the LF have not affected the parties' ability to effectively exercise their rights of defence and that the asserted deficiency has not influenced the outcome of the procedure.

5. **Other procedural claims regarding the Letter of Facts**

Lundbeck

42. On 22 May 2013, approximately one month after its reply to the LF, Lundbeck addressed to me a further submission claiming that the LF had undermined Lundbeck's due process and defence rights. While the submission reiterated most of the arguments already addressed above, Lundbeck also raised two new claims ([3]).

43. First, Lundbeck contended that the Commission breached its obligation to conduct the proceedings in an impartial and objective manner. The Commission would ignore evidence that confirms Lundbeck's and the generic's views and take at face value evidence that seems to help its case tangentially. Allegedly, the LF would make again obvious that the Commission failed to assess the evidence in the file in an accurate, objective and undistorted manner, that it omitted to take into account the full body of relevant evidence, including Lundbeck's observations, and that it did not exclude disputed or otherwise insufficient evidence.

([1]) *LR AF 1998 A/S*, cited above, paragraph 191; See also Case T-353/06 *Vermeer Infrastructuur BV* v *Commission* [2012] not yet reported, paragraph 182.

([2]) The situation here, where the link between the LF and the SO is not easily understood, is in my view similar to the situation which the GC was confronted with in Case T-11/89 *Shell* v *Commission* [1992] ECR 11-757, paragraphs 56 and 62; See also Joined Cases T-191/98 and T-212/98 to T-214/98, *Atlantic Container Line AB and others* v *Commission*, [2003] ECR II-03275, paragraph 162; and Case T-13/89 *ICI* v *Commission* [1992] ECR II-1021, paragraph 35. Hence, the test applied to the latter situation should also be appropriate here.

([3]) Given that Lundbeck submitted to me a detailed complaint at a very late stage of the proceeding, I can only deal with it in a summary fashion.

44. After a thorough review of the arguments without pre-judging the merits of the substantive points put forward by Lundbeck, I find the party's contention unfounded. The right to good administration includes the duty to examine carefully and impartially all the relevant aspects of the individual case ([1]). However, it is not an indication of bias when the Commission does not follow the arguments put forward by a party. Neither does the persistently different interpretation of pertinent evidence amount as such to bias. Moreover, the LF merely adduces new facts. It does not discuss the arguments or evaluate the evidence advanced by the parties in response to the SO. This has to be done in the fully reasoned final decision. It would thus seem to be inappropriate to assess the objectivity and impartiality of the Commission's proceedings on this basis. However, even if the SO and the Commission statements at the Oral Hearing were taken into account, I do not find Lundbeck's contention justified.

45. Second, Lundbeck purported that Article 6(3)(d) of the European Convention of Human Rights has been infringed because the LF relies on information from one third party in particular, which has not been part of the proceedings, without giving Lundbeck the opportunity to cross-examine this third party and the veracity of its statements.

46. I also regard this contention to be groundless. In the administrative procedure, the Commission is not obliged to afford the parties the opportunity to cross-examine third parties on their statements vis-à-vis the Commission. The parties' rights of defence are respected if the statements used by the Commission are recorded in the file, made accessible to them and can, after a final decision be challenged before the judicature of the European Union ([2]). This was the case here. Lundbeck was given access to the statement in question before the Oral Hearing and was able to comment on it.

47. It should also be noted that Lundbeck has raised this issue very late in the proceedings. If Lundbeck believed it relevant for its defence to hear the third person during the administrative proceeding it could have suggested the Commission to invite the third party to the Oral Hearing or to organise a triangular meeting as indicated in the Best Practices ([3]). According to the information available to me Lundbeck did not make such suggestions.

48. On this basis, I conclude that Lundbeck's rights of defence have not been infringed.

Alpharma

49. On 3 June 2013, five weeks after its reply to the LF, I received a letter from Alpharma raising three main issues ([4]).

50. First, the party claimed that it is likely that the Commission will significantly amend in its final decision the findings concerning Alpharma in at least three regards, i.e., potential competition, the value transferred and the legal and economic context. Alpharma asked the Commission to grant it the opportunity to comment on the revised findings before the final decision is adopted.

51. I have carefully analysed the draft Decision in view of Alpharma's claim and the three examples provided. I could not find that the draft Decision alters the objections or introduces new evidence on which the party has not been given the possibility to make observations either after the communication of the SO or, subsequently, the LF. DG Competition's rejection of Alpharma's request does therefore not violate the party's right to be heard.

52. Second, Alpharma contends that the SO is no longer correct in respect of five preliminary findings concerning Alpharma: the legal and economic context, the link between payment and the restrictions on entry, the amount of the value transfer, potential competition and the scope of the settlement agreement. The SO is allegedly based on factual assumptions in regard of these five findings which have subsequently been proven incorrect. According to Alpharma, these deficiencies have not been cured by the LF. The document rather introduces new facts which conflict with those set out in the SO. Faced with such a confusing and contradictory array of facts and allegations,

([1]) Case T-31/99 *ABB Asea Brown Boveri* v *Commission* [2002] ECR II-1881, paragraph 99.
([2]) Case T-439/07 *Coats Holdings Ltd* v *Commission* [2012] not yet reported, paragraphs 174 and 175.
([3]) See Commission Notice on Best Practices for the conduct of proceedings concerning Articles 101 and 102 TFEU (OJ C 308, 20.10.2011, p. 6), paragraphs 68 and 69.
([4]) Taking into consideration that Alpharma referred a number of issues to me and submitted a comprehensive and very detailed complaint at a very late stage of the proceeding, I can only deal with it in a summary fashion.

Alpharma claims that the Commission has failed to explain which of the facts it believes are correct, making it difficult to understand which evidence the Commission intends to rely on and what allegations it is making against Alpharma. In such circumstance, it purports that it is impossible for Alpharma to defend itself properly. On this basis, Alpharma asked me to recommend the Commission to issue a SSO or provide a clarification clearly setting out the objections against it and the facts supporting these objections prior to adopting the final decision.

53. I have also thoroughly reviewed this procedural issue, leaving aside the substantive contentions made by Alpharma. However, I cannot find that its request is founded.

54. The party has already received a reply on the question about which facts the Commission considers to be correct. After it had raised the same issue with DG Competition, Alpharma received the response that the Commission believes that the new facts in the LF are correct. It should also be noted in this regard that the large majority of the new facts introduced in the LF concerning Alpharma were provided by the party itself after the issuance of the SO, although DG Competition had already sent a request to provide the information in March 2011.

55. Furthermore, the LF received by the party indicates for each new fact to which part of the SO it relates to and its relevance for the objection. Alpharma has thus been put in a position to comment on the new evidence and its significance for the objections. Contrary to what Alpharma appears to suggest, there is no obligation for the Commission to indicate in a LF or SSO which of the facts, initially adduced in the SO, it believes are no longer correct in light of the evidence subsequently discovered. Neither has the Commission an obligation to provide a legal assessment of the new facts. As already indicated above, the Commission is only obliged to issue an SSO when it wants to alter existing objections. Therefore, I find that the rights of defence of Alpharma have not been breached.

56. Finally, the Terms of Reference do not empower the hearing officer to formally recommend to the Commission the clarification of certain objections, or its interpretation of certain facts supporting such objections, for the benefit of a party as Alpharma seems to assume.

57. Third, albeit only with regard to one point, Alpharma also claimed that the LF does not properly explain the use the Commission intends to make of the new facts. I cannot find that the party's rights of defence have been breached and refer to my analysis of similar claims made by other parties to this proceeding in Section IV.4. above. At any rate, Alpharma's reply to the LF demonstrates that the party was able to understand the LF.

58. Alpharma finally pointed to the excessive length of the administrative procedure. In this matter, I also refer to my analysis of similar claims in Section II.4. above.

V. **THE DRAFT DECISION**

59. In my opinion the draft Decision relates only to objections in respect of which the parties have been afforded the opportunity to make known their views.

60. Overall, I conclude that all participants have been able to effectively exercise their procedural rights in this case.

Brussels, 17 June 2013.

Michael ALBERS

Summary of Commission Decision

of 19 June 2013

relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement

(Case AT.39226 — Lundbeck)

(notified under document number C(2013) 3803)

(Only the English text is authentic)

(2015/C 80/07)

On 19 June 2013, the Commission adopted a decision relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA agreement. In accordance with the provisions of Article 30 of Council Regulation (EC) No 1/2003 [1], the Commission herewith publishes the names of the parties and the main content of the decision, including any penalties imposed, having regard to the legitimate interest of undertakings in the protection of their business secrets

1. INTRODUCTION

(1) This decision concerned six agreements which operated in the years 2002 and 2003 between the Danish originator pharmaceutical undertaking Lundbeck on the one hand and each of four generic pharmaceutical undertakings on the other hand. The generic pharmaceutical undertakings concerned by this Decision were:

— Merck KGaA (Generics (UK)): two agreements with Lundbeck, one regarding the United Kingdom (from 24 January 2002 until 1 November 2003), one regarding the EEA excluding the United Kingdom (from 22 October 2002 until 22 October 2003),

— Arrow: two agreements with Lundbeck, one regarding the United Kingdom (from 24 January 2002 until 20 October 2003), one regarding Denmark (from 3 June 2002 until 1 April 2003),

— Alpharma: one agreement with Lundbeck regarding the EEA (from 22 February 2002 until 30 June 2003), and

— Ranbaxy: one agreement with Lundbeck regarding the EEA (from 16 June 2002 until 31 December 2003).

In its decision, the Commission found that the agreements between Lundbeck and each of the generic undertakings concerned constituted four infringements.

(2) The product concerned by the infringements was the anti-depressant citalopram, whether in the form of an active pharmaceutical ingredient (API) or in the form of a medicinal product.

(3) At the time the agreements were concluded, Lundbeck's patents and data protection on the citalopram compound and the two original production processes had expired. Lundbeck did still have a number of process patents, which gave Lundbeck exclusivity rights on certain, but not all, new ways of producing citalopram to the extent such patents would be found to be valid and infringed. But any undertaking using either the original production processes or any production process not covered by valid Lundbeck process patents could in principle freely enter EEA markets with generic citalopram, provided the product and its production process met regulatory requirements applicable in the EEA at that time.

(4) The agreements were concluded in the context of at least a potential patent dispute [2] between Lundbeck and the generic undertaking concerned regarding the (intended) marketing by the generic undertaking of citalopram API or medicine in the geographic area concerned by the agreement. Prior to the agreements concerned, Lundbeck had usually claimed infringement of one or more of its process patents and the generic undertaking concerned had usually claimed non-infringement of the patent(s) concerned or invalidity of the patent(s) Lundbeck invoked. Each of the agreements was concluded before a court ruling on these issues was given between the parties concerned, even by way of interim measures, and all except one (Lundbeck's agreement with Alpharma regarding the EEA) were concluded before any litigation had started.

[1] OJ L 1, 4.1.2003, p. 1.

[2] The term 'patent dispute' as used in the decision refers to a disagreement between two or more parties over a patent and includes the notion of patent litigation as one possible stage of such a dispute.

(5) Patent dispute settlements are, in principle, a generally accepted, legitimate way of ending private disagreements. They can also save courts or competent administrative bodies, such as patent offices, time and effort and can therefore be in the public interest.

(6) What is important from the perspective of Union competition law is that the agreements were characterised by the fact that they contained a transfer of value from Lundbeck to a potential or actual generic competitor, which was related to the latter's agreement not to market generic citalopram in the geographic area concerned for the duration of the agreement. The value which Lundbeck transferred took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market. The agreements in question did not resolve any patent dispute; they rather postponed the issues raised by potential generic market entry. It was also established that the agreements contained no commitment from Lundbeck to refrain from infringement proceedings if the generic undertaking entered the market with generic citalopram after expiry of the agreement. Finally, the agreements concerned obtained results for Lundbeck that Lundbeck could not have achieved by enforcing its process patents before the national courts: The agreements in question prevented the generic company concerned from selling generic citalopram, irrespective of whether such citalopram would be produced in infringement of Lundbeck's process patents.

2. **PROCEDURE**

(7) The Commission first became aware of the agreements in question in October 2003 through information from the Danish Competition Authority. Between December 2003 and October 2005, the Commission collected further information. In October 2005, the Commission conducted inspections pursuant to Article 20(4) of Regulation (EC) No 1/2003 at the premises of, inter alia, H. Lundbeck A/S. In 2006, requests for information were sent to a number of parties. The replies to these requests for information were examined in 2007.

(8) In January 2008, the Commission decided to launch a broad inquiry into the pharmaceutical sector pursuant to Article 17 of Regulation (EC) No 1/2003. The final report of the sector inquiry was released on 8 July 2009.

(9) In December 2009, the Commission conducted further inspections. On 7 January 2010, the Commission opened formal proceedings against Lundbeck. In 2010 and the first half of 2011, while preparing the current decision, the Commission sent out a considerable number of requests for information to Lundbeck, the generic companies with which the agreements concerned were concluded, their parent companies and third parties. On 24 July 2012, the Commission opened proceedings against the generic companies that concluded the agreements concerned with Lundbeck and issued a Statement of Objections to Lundbeck and to those generic companies.

(10) The Advisory Committee on Restrictive Practices and Dominant Positions issued favourable opinions on the draft decision on 5 June 2013 and on 17 June 2013. The Hearing Officer issued his final report on 17 June 2013.

3. **SUMMARY OF THE COMMISSION'S LEGAL ASSESSMENT**

(11) Based on the jurisprudence of the Court of Justice of the European Union, the Commission found in its decision that patent settlements agreements, like any other agreements, are subject to Union competition law.

(12) Even if the limitations included in a patent settlement agreement remain within the scope of the patent, that agreement may, under certain circumstances, have to be considered as contrary to competition law.

(13) In order to identify whether each agreement covered by the decision had the potential to restrict competition by its very nature, the Commission analysed the specific facts of the case relating to each agreement to determine whether:

— the generic undertaking and the originator undertaking were at least potential competitors,

— the generic undertaking committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter one or more EEA markets with generic product, and

— the agreement was related to a transfer of value from the originator undertaking which substantially reduced the incentives of the generic undertaking to independently pursue its efforts to enter one or more EEA markets with generic product.

The Commission's assessment took into account the economic and legal context leading up to the agreement's conclusion, the actual content and objectives of the agreement, and each party's subjective intentions, as evidenced by the facts of the case.

(14) In the present case other important factors were also taken into consideration, namely: the fact that the value which Lundbeck transferred took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market; the fact that Lundbeck could not have obtained the limitations on entry through enforcement of its process patents, the obligations on the generic undertaking in the agreement going beyond the rights granted to holders of process patents; and the fact that the agreement contained no commitment from Lundbeck to refrain from infringement proceedings if the generic undertaking entered the market with generic citalopram after expiry of the agreement.

(15) The Commission also analysed the parties' arguments on the existence of justifications for the agreements under Article 101(3) of the Treaty and found that the conditions of this provision were not met. Parties' claimed efficiencies pertained, for instance, to avoided litigations costs and to improved distribution of Lundbeck's own products through distribution agreements with two of the generic undertakings. Parties failed, however, to sufficiently substantiate the alleged efficiency gains and, in particular, to show that the restrictions on the generic undertakings imposed by the agreements were necessary to the attainment of any such efficiency gains. Nor did the parties show that any such efficiency gains outweighed the disadvantages for consumers of the restrictions in the agreements.

(16) Based on the above analysis, the Commission found that the six agreements covered by the decision constituted restrictions of competition by object, amounting to four separate infringements of Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA agreement.

4. **ADDRESSEES**

(17) The following companies were addressees of the Commission's decision:

— Lundbeck Limited

— H. Lundbeck A/S

— Generics (UK) Limited

— Merck KGaA

— Arrow Generics Limited

— Arrow Group ApS

— Resolution Chemicals Limited

— Xellia Pharmaceuticals ApS

— Zoetis Products LLC

— A.L. Industrier AS

— Ranbaxy (U.K) Limited

— Ranbaxy Laboratories Limited.

5. **FINES**

(18) The Commission imposed on Lundbeck a total of fines of EUR 93 766 000 for the four infringements in question. These fines were calculated in accordance with the general methodology of the Commission's Guidelines on fines ([1]). In view of the fact that Lundbeck's four infringements related to the same product, citalopram, and largely to the same geographic areas and periods of time, and to avoid a potentially disproportionate outcome resulting from the imposition of multiple fines in parallel, the Commission in its discretion decided to apply a correction factor that was appropriate to achieve deterrence in the specific circumstances of this case.

(19) The Commission imposed a total of fines of EUR 52 239 000 on the four generic undertakings (or their legal successors) in question. As these undertakings had agreed not to sell generic citalopram in the geographic area concerned by each agreement and therefore did not have any, or only very limited, sales in the geographic area concerned, the Commission applied point 37 of the Guidelines on fines. In particular, the Commission took the value transferred to each generic undertaking in the agreement(s) into account for the basic amounts of that generic undertaking's fine.

([1]) Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation (EC) No 1/2003 (OJ C 210, 1.9.2006, p. 2).

(20) The amounts of the fines took into account the long duration of the Commission's investigation. All the parties received a reduction on that account.

(21) The specific fines imposed for the four infringements were as follows:

— For the infringement between Lundbeck and Merck:

H. Lundbeck A/S: EUR 19 893 000

of which jointly and severally with Lundbeck Limited: EUR 5 306 000;

Merck KGaA: EUR 21 411 000

of which jointly and severally with Generics (UK) Limited: EUR 7 766 843.

— For the infringement between Lundbeck and Arrow:

H. Lundbeck A/S: EUR 12 951 000;

Arrow Group ApS: EUR 9 975 000

of which jointly and severally with Arrow Generics Limited: EUR 9 360 000

of the latter amount of which jointly and severally with Resolution Chemicals Limited: EUR 823 735.

— For the infringement between Lundbeck and Alpharma:

H. Lundbeck A/S: EUR 31 968 000;

Zoetis Products LLC and Xellia Pharmaceuticals ApS jointly and severally: EUR 10 530 000

of which jointly and severally with A.L. Industrier AS: EUR 43 216.

— For the infringement between Lundbeck and Ranbaxy:

H. Lundbeck A/S: EUR 28 954 000;

Ranbaxy Laboratories Limited and Ranbaxy (UK) Limited, jointly and severally: EUR 10 323 000.

(22) The Commission ordered the undertakings concerned to refrain from repeating any act or conduct have the same or similar object or effect.

WITHDRAWAL OF COMMISSION PROPOSALS

(2015/C 80/08)

List of withdrawn proposals

Document	Inter-institutional procedure	Title
		Agriculture and Rural Development
COM(2010) 537	2010/0266/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)
COM(2010) 539	2010/0267/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 73/2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers
COM(2010) 745	2010/0365/COD	Proposal for a Regulation (Eu) No …/… of the European Parliament and of the Council of … amending Council Regulation (EC) No 1290/2005 on the financing of the common agricultural policy and repealing Council Regulation (EC) No 165/94 and Council Regulation (EC) No 78/2008
COM(2010) 738	2010/0354/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1234/2007 as regards marketing standards
COM(2010) 759	2010/0364/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 834/2007 on organic production and labelling of organic products
COM(2010) 761	2010/0366/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 485/2008 on scrutiny by Member States of transactions forming part of the system of financing by the European Agricultural Guarantee Fund
COM(2010) 799	2010/0385/COD	Proposal for a Regulation of the European Parliament and of the Council establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)
COM(2011) 193	2011/0075/NLE	Proposal for a Council Regulation determining measures on fixing certain aids, refunds and prices related to the single common organisation of agricultural markets
COM(2011) 663	2011/0290/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 3/2008 on information provision and promotion measures for agricultural products on the internal market and in third countries.
COM(2013) 159	2013/0087/COD	Proposal for a Regulation of the European Parliament and of the Council on fixing an adjustment rate to direct payments provided for in Regulation (EC) No 73/2009 in respect of calendar year 2013
COM(2013) 521	2013/0247/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)

Document	Inter-institutional procedure	Title
COM(2014) 175	2014/0097/COD	Proposal for a Regulation of the European Parliament and of the Council on fixing an adjustment rate for direct payments provided for in Council Regulation (EC) No 73/2009 in respect of calendar year 2014
		Budget and Human Resources
COM(2004) 509	2004/0172/COD	Proposal for a Regulation of the European Parliament and of the Council on mutual administrative assistance for the protection of the financial interests of the Community against fraud and any other illegal activities
COM(2010) 71	2010/0047/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities
COM(2010) 72	2010/0048/APP	Proposal for a Council Regulation laying down the multiannual financial framework for the years 2007-2013
COM(2012) 754	2012/0350/NLE	Proposal for a Council Regulation adjusting with the effect from 1 July 2012 the remuneration and pension of the officials and other servants of the European Union and the correction coefficients applied thereto
COM(2011) 518	2011/0225/NLE	Proposal for a Council Regulation establishing a Community system for registration of carriers of radioactive materials
		Economic and Financial Affairs, Taxation and Customs
COM(1998) 30	1998/0025/CNS	Proposal for a Council Directive governing the tax treatment of private motor vehicles moved permanently to another Member State in connection with a transfer of residence or used temporarily in a Member State other than that in which they are registered
COM(2002) 456	2002/0246/CNS	Proposal for a Council Decision amending Decision 77/270/Euratom empowering the Commission to issue Euratom loans for the purpose of contributing to the financing of nuclear power stations
COM(2002) 457	2002/0246/NLE	Proposal for a Council Decision amending Decision 77/271/Euratom on the implementation of Decision 77/270/Euratom empowering the Commission to issue Euratom loans for the purpose of contributing to the financing of nuclear power stations
COM(2005) 261	2005/0130/CNS	Proposal for a Council Directive on passenger car related taxes
COM(2006) 486	2006/0165/CNS	Proposal for a Council Directive amending Directive 92/84/EEC on the approximation of the rates of excise duty on alcohol and alcoholic beverages
COM(2010) 32	2010/0018/NLE	Proposal for a Council Decision on the position to be taken by the Union within the Joint Committee established under the Agreement between the European Coal and Steel Community and the Republic of Turkey on trade in products covered by the Treaty establishing the European Coal and Steel Community, with regard to the amendment of Annex II of Protocol 1 to that Agreement, pursuant to the entry into force of the Harmonised System 2007

Document	Inter-institutional procedure	Title
COM(2010) 34	2010/0019/NLE	Proposal for a Council Decision on the position to be taken by the Union within the Association Council with regard to the amendment of Annex II of Protocol 3 to Decision No 1/98 of the EC-Turkey Association Council of 25 February 1998 on trade regime for agricultural products, concerning the list of working or processing required to be carried out on non-originating materials in order that the product manufactured can obtain originating status, pursuant to the entry into force of the Harmonised System 2007
COM(2010) 778	2010/0378/NLE	Proposal for a Council Decision on the position to be taken by the European Union within the Stabilisation and Association Council created by the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Croatia, of the other part, on the amendments to Protocol 4 to that Agreement concerning the definition of the concept of 'originating products' and methods of administrative cooperation
COM(2011) 169	2011/0092/CNS	Proposal for a Council Directive amending Directive 2003/96/EC restructuring the Community framework for the taxation of energy products and electricity
Employment, Social Affairs, Skills and Labour Mobility		
COM(2014) 239	2014/0131/NLE	Proposal for a Council Decision on the position to be adopted on behalf of the European Union at the 103rd session of the International Labour Conference concerning a Recommendation to supplement the Forced Labour Convention no 29, 1930, of the International Labour Organisation
Environment, Maritime Affairs and Fisheries		
COM(2009) 189	2009/0057/COD	Proposal for a Council Regulation establishing a multi-annual plan for the western stock of Atlantic horse mackerel and the fisheries exploiting that stock.
COM(2009) 399	2009/0112/COD	Proposal for a Council Regulation establishing a long-term plan for the anchovy stock in the Bay of Biscay and the fisheries exploiting that stock
COM(2010) 572	2010/0290/NLE	Proposal for a Council Decision on the conclusion of the Protocol to the Fisheries Partnership Agreement between the European Community and Federated States of Micronesia
COM(2012) 155	2012/0077/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1098/2007 of 18 September 2007 establishing a multi-annual plan for the cod stocks in the Baltic Sea and the fisheries exploiting those stocks
COM(2012) 471	2012/0232/COD	Proposal for a Regulation of the European Parliament and of the Council on certain technical and control measures in the Skagerrak and amending Regulation (EC) No 850/98 and Regulation (EC) No 1342/2008
COM(2012) 591	2012/0285/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 2187/2005 for the conservation of fishery through technical measures in the Baltic Sea, the Belts and the Sound
COM(2013) 300	2013/0153/NLE	Proposal for a Council Decision establishing the position to be taken in HELCOM and IMO concerning the designation on the Baltic Sea as Nitrogen Oxyde Emissions Control Area (NECA)

Document	Inter-institutional procedure	Title
COM(2014) 397	2014/0201/COD	Proposal for a Directive of the European Parliament and of the Council amending Directives 2008/98/EC on waste, 94/62/EC on packaging and packaging waste, 1999/31/EC on the landfill of waste, 2000/53/EC on end-of-life vehicles, 2006/66/EC on batteries and accumulators and waste batteries and accumulators, and 2012/19/EU on waste electrical and electronic equipment
European Neighbourhood Policy and Enlargement Negotiations		
COM(2008) 308	2008/0095/COD	Proposal for a Regulation of the European Parliament and of The Council amending Regulation (EC) No 1638/2006 laying down general provisions establishing a European Neighbourhood and Partnership Instrument
COM(2012) 92	2012/0041/NLE	Proposal for a Council Decision on the position to be adopted on behalf of the European Union in the EU-Turkey Association Council
COM(2012) 133	2012/0063/NLE	Proposal for a Council Decision on the position to be taken by the European Union in the EEA Joint Committee concerning the amendment of Protocol 4 (Rules of origin) to the EEA Agreement
COM(2012) 329	2012/0159/COD	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1085/2006 establishing an Instrument for Pre-Accession Assistance (IPA)
Foreign Affairs and Security Policy		
COM(2005) 281	2005/0121/CNS	Proposal for a Council Decision on the signature of a Protocol to the Framework Agreement for Trade and Cooperation between the European Community and its Member States, on the one part, and the Republic of Korea, of the other part, to take account of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Hungary, the Republic of Latvia, the Republic of Lithuania, the Republic of Malta, the Republic of Poland, the Republic of Slovenia, and the Slovak Republic to the European Union
COM(2013) 289	2013/0155/NLE	Proposal for a Council Decision on the signing, on behalf of the European Union, and provisional application of the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part
COM(2013) 653		Recommendation for a Council Decision approving the conclusion by the Commission, on behalf of the European Atomic Energy Community, of the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part
Health and food safety		
COM(2007) 90	2007/0037/COD	Proposal for a Regulation of the European Parliament and of the Council amending Regulation No 11 concerning the abolition of discrimination in transport rates and conditions, in implementation of Article 79(3) of the Treaty establishing the European Economic Community and Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs
COM(2013) 262	2013/0137/COD	Proposal for a Regulation of the European Parliament and of the Council On the production and making available on the market of plant reproductive material (plant reproductive material law)

Document	Inter-institutional procedure	Title
		Internal Market, Industry, Entrepreneurship and SMEs
COM(2010) 371	2010/0199/COD	Proposal for a Directive of the European Parliament and of the Council amending Directive 97/9/EC of the European Parliament and of the Council on investor compensation schemes
COM(2012) 84	2012/0035/COD	Proposal for a Directive relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems
COM(2012) 241	2012/0124/NLE	Proposal for a Council Decision authorising the Member States to negotiate in the United Nations Conference on the Arms Trade Treaty (New York, 2-27 July 2012) on those matters coming under the exclusive competence of the Union
COM(2014) 85	2014/0043/NLE	Proposal for a Council Recommendation on European Tourism Quality Principles
		International Cooperation and Development
COM(2008) 244	2008/0270/NLE	Proposal for a Council Decision amending the proposal for a Council Decision on the signing and conclusion by the European Community of the International Coffee Agreement 2007
		Inter-institutional relations
COM(2013) 451	2013/0218/COD	Proposal for a Regulation of the European Parliament and of the Council adapting to Article 290 of the Treaty on the Functioning of the European Union a number of legal acts providing for the use of the regulatory procedure with scrutiny
COM(2013) 452	2013/0220/COD	Proposal for a Regulation of the European Parliament and of the Council adapting to Article 290 of the Treaty on the Functioning of the European Union a number of legal acts in the area of Justice providing for the use of the regulatory procedure with scrutiny
COM(2013) 751	2013/0365/COD	Proposal for a Regulation of the European Parliament and of the Council adapting to Article 290 and 291 of the Treaty on the Functioning of the European Union a number of legal acts providing for the use of the regulatory procedure with scrutiny
		Justice, Consumers and Gender Equality
COM(2010) 82	2010/0050/COD	Proposal for a Directive of the European Parliament and of the Council on the right to interpretation and translation in criminal proceedings
COM(2012) 35	2012/0022/APP	Proposal for a Council Regulation on the Statute for a European Foundation
		Migration, Home Affairs and Citizenship
COM(2009) 102	2009/0033/CNS	Proposal for a Council Regulation on the establishment of an evaluation mechanism to verify the application of the Schengen *acquis*

Document	Inter-institutional procedure	Title
		Research, Science and Innovation
COM(2011) 931	2011/0460/NLE	Proposal for a Council Decision on the adoption of a Supplementary Research Programme for the ITER project (2014-2018)
		Trade
COM(2011) 380	2011/0167/NLE	Proposal for a Council Decision on the conclusion of the Anti-Counterfeiting Trade Agreement between the European Union and its Member States, Australia, Canada, Japan, the Republic of Korea, the United Mexican States, the Kingdom of Morocco, New Zealand, the Republic of Singapore, the Swiss Confederation and the United States of America
		Transport
COM(2000) 802	2000/0326/COD	Proposal for a Regulation of the European Parliament and of the Council on the establishment of a fund for the compensation of oil pollution damage in European waters and related measures
COM(2005) 353	2005/0141/APP	Proposal for a Council Decision on the signature and provisional application of the Agreement between the European Community and Serbia and Montenegro on certain aspects of air services
COM(2008) 700		Proposal for a Council Decision on the signing of the Amending Protocol to the Convention regarding the Regime of Navigation on the Danube of 18 August 1948 (Belgrade Convention)
COM(2009) 217	2009/0063/COD	Proposal for a Directive of the European Parliament and of the Council on aviation security charges
COM(2009) 229	2009/0066/APP	Proposal for a Decision of the Council and the representatives of the Governments of the Member States of the European Union, meeting within the Council On the conclusion of the of the Air Transport Agreement between the United States of America, for the one part, the European Community and its Member States, for the second part, Iceland, for the third part, and the Kingdom of Norway, for the fourth part; and On the conclusion of the Ancillary Agreement between the European Community and its Member States, of the first part, Iceland, on the second part, and the Kingdom of Norway, of the third part, regarding the application of the Air Transport Agreement between the United States of America, of the first part; the European Community and its Member States, of the second part; Iceland, of the third part; and the Kingdom of Norway, of the fourth part
COM(2010) 653	2010/0320/NLE	Proposal for a Council Decision on the fulfilment by the Republic of Croatia of the conditions for completing the first transitional period under the Multilateral Agreement between the European Community and its Member States, the Republic of Albania, Bosnia and Herzegovina, the Republic of Bulgaria, the Republic of Croatia, the Former Yugoslav Republic of Macedonia, the Republic of Iceland, the Republic of Montenegro, the Kingdom of Norway, Romania, the Republic of Serbia and the United Nations Interim Administration Mission in Kosovo on the establishment of a European Common Aviation Area
COM(2011) 824	2011/0397/COD	Proposal for a Regulation Of The European Parliament And Of The Council On Groundhandling Services At Union Airports And Repealing Council Directive 96/67/EC

Document	Inter-institutional procedure	Title
		Codifications
COM(2008) 761	2008/0225/COD	Proposal for a Council Regulation listing the third countries whose nationals must be in possession of visas when crossing the external borders and those whose nationals are exempt from that requirement
COM(2009) 446	2009/0123/COD	Proposal for a Directive …/…/EC of the European Parliament and of the Council of […] on uniform procedures for checks on the transport of dangerous goods by road (codified version)
COM(2009) 535	2009/0151/COD	Proposal for a Regulation (Ec) No …/… of the European Parliament and of the Council of […] on waste statistics (Codified version)
COM(2009) 634	2009/0176/COD	Proposal for a Regulation of the European Parliament and of the Council on common rules for the allocation of slots at Community airports (Codified version)
COM(2010) 179	2010/0095/COD	Proposal for a Directive of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (Codification)
COM(2010) 184	2010/0098/CNS	Proposal for a Council Regulation (Euratom) laying down maximum permitted levels of radioactive contamination of foodstuffs and of feeding stuffs following a nuclear accident or any other case of radiological emergency (Recast)
COM(2010) 507	2010/0260/COD	Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to units of measurement (Codification)
COM(2010) 691	2010/0338/NLE	Proposal for a Council Regulation on denominations and technical specifications of euro coins intended for circulation (Codification)
COM(2012) 8	2012/0007/COD	Proposal for a Directive of the European Parliament and of the Council on the classification, packaging and labelling of dangerous preparations (Recast)

V

(Announcements)

PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION POLICY

EUROPEAN COMMISSION

Prior notification of a concentration

(Case M.7545 — Blackstone/Koala/Acenden/AMS)

Candidate case for simplified procedure

(Text with EEA relevance)

(2015/C 80/09)

1. On 26 February 2015, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ([1]) by which the Blackstone Group L.P. ('Blackstone', USA) and Koala HoldCo, LLC (affiliated with TPG Global, LLC and TPG Special Situations Partners, LLC (collectively referred to as 'TPG', USA)) will acquire joint control of Acenden Ltd ('Acenden', UK) and AMS Decisions Advisers LLP ('AMS', UK) by way of purchase of shares.

2. The business activities of the undertakings concerned are:

— Blackstone: a global alternative asset manager and provider of financial advisory services,

— TPG: a global private investment firm. The private investment funds of TPG invest in a variety of companies through acquisitions and corporate restructuring,

— Acenden: a provider of mortgage management and administration services for mortgage lenders in the UK and Ireland,

— AMS: a provider of mortgage management services for mortgage lenders in the UK.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved. Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under Council Regulation (EC) No 139/2004 ([2]) it should be noted that this case is a candidate for treatment under the procedure set out in this Notice.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by email to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference number M.7545 — Blackstone/Koala/Acenden/AMS, to the following address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

([1]) OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').
([2]) OJ C 366, 14.12.2013, p. 5.

Prior notification of a concentration

(Case M.7529 — Mohawk/International Flooring Systems)

(Text with EEA relevance)

(2015/C 80/10)

1. On 2 March 2015, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 [1] by which the undertaking Mohawk Industries, Inc ('Mohawk', the USA) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of the undertaking International Flooring Systems S.A. ('IFS', Luxembourg) by way of purchase of shares.

2. The business activities of the undertakings concerned are:

— for Mohawk Industries: Mohawk is a US-headquartered global producer and supplier of wood-based panels, insulation materials and a broad range of flooring products, including carpets, rugs, hardwood, laminate, ceramic tiles, stones and vinyl flooring. Within the EEA, Mohawk is mainly active through its wholly-owned subsidiary Unilin,

— for IFS: IFS is a Luxembourg-based group of companies active in the production and supply of vinyl flooring, laminate flooring and wood-based panels, in particular raw and coated MDF.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by email to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference number M.7529 — Mohawk/International Flooring Systems, to the following address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

[1] OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

Prior notification of a concentration

(Case M.7553 — PAI/Lion Adventure)

Candidate case for simplified procedure

(Text with EEA relevance)

(2015/C 80/11)

1. On 2 March 2015, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 [1] by which the undertaking PAI Partners SAS ('PAI', France) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of the undertaking Lion Adventure Coöperatief U.A. ('Lion Adventure', Netherlands) by way of other means.

2. The business activities of the undertakings concerned are:

— PAI is a privately held private equity company and manages and advises a number of funds that own companies active in a variety of business sectors,

— Lion Adventure is active in the retailing of outdoor sporting equipment, clothing, and footwear, and fashion through its 'AS Adventure', 'Bever', 'Cotswold Outdoor', and 'North Face' stores in Belgium, France, Luxembourg, the Netherlands, and the UK.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved. Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under Council Regulation (EC) No 139/2004 [2] it should be noted that this case is a candidate for treatment under the procedure set out in this Notice.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by email to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference number Case M.7553 — PAI/Lion Adventure, to the following address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

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[1] OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').
[2] OJ C 366, 14.12.2013, p. 5.

OTHER ACTS

EUROPEAN COMMISSION

Publication of an application pursuant to Article 50(2) point (b) of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs

(2015/C 80/12)

This publication confers the right to oppose the application pursuant to Article 51 of Regulation (EU) No 1151/2012 of the European Parliament and of the Council [1].

APPLICATION FOR REGISTRATION OF A TSG

COUNCIL REGULATION (EC) No 509/2006

on agricultural products and foodstuffs as traditional specialities guaranteed [2]

'TRADITIONAL BRAMLEY APPLE PIE FILLING'

EC No: UK-TSG-007-0057-5.11.2008

1. **Name and address of the applicant group**

Name: UK Apples & Pears Ltd

Address: Forest Lodge
Bulls Hill
Walford
Ross-on-Wye
Herefordshire HR9 5RH
UNITED KINGDOM

Tel. +44 1732529781

Fax +44 1732529781

E-mail: info@englishapplesandpears.co.uk

UK Apples & Pears Ltd is a grower owned organisation formed in 1987. It now represents 73 % of United Kingdom commercial apple and pear producers and has actively participated in EU funded programmes to promote the increased consumption of fresh and processed apples in the fresh market, manufacturing, catering and food service industries.

2. **Member State or Third Country**

United Kingdom

3. **Product specification**

3.1. *Name(s) to be registered (Article 2 of Commission Regulation (EC) No 1216/2007) of 18 October 2007 laying down detailed rules for the implementation of Council Regulation (EC) No 509/2006 on agricultural products and foodstuffs as traditional specialities guaranteed* [3]

'Traditional Bramley Apple Pie Filling'

3.2. *Whether the name*

☐ is specific in itself

☒ expresses the specific character of the agricultural product or foodstuff

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ L 93, 31.3.2006, p. 1. Replaced by Regulation (EU) No 1151/2012.
[3] OJ L 275, 19.10.2007, p. 3.

The name expresses the traditional composition of the product: only Bramley apples with water and sugar, possibly with a squeeze of lemon and some cornflour thickening.

The single purpose culinary variety Bramley, with its unique blend of low dry matter, high malic acid and low sugar levels, and the noted absence of any additives confer to the Traditional Bramley Apple Pie Filling its characteristic tangy flavour.

3.3. *Whether reservation of the name is sought under Article 13(2) of Regulation (EC) No 509/2006*

☒ Registration with reservation of the name

☐ Registration, without reservation of the name

3.4. *Type of product*

Group 1.6: Fruit, vegetables and cereals, fresh or processed

3.5. *Description of the agricultural product or foodstuff to which the name under point 3.1 applies (Article 3(1) of Regulation (EC) No 1216/2007)*

Traditional Bramley Apple Pie Filling is a homogeneous blend of Bramley apple pieces, sugar and water. The apples used in the making of Traditional Bramley Apple Pie Filling must be between 65 mm-115 mm in size, whole apples which are ripe and must be free from severe skin blemishes, cuts and bruises. The Bramley apples must be cut to the minimum 15 mm required size, the shapes of the apple pieces may vary. This ingredient mix must contain well defined pieces of fruit with good firm texture. The apple pieces range in colour and are found in various shades of green which is typical of the Bramley's Seedling variety.

The addition of Bramley apple purée and cornflour is optional and where it is used it should contain a minimum of 97 % Bramley apple with the remaining % being moisture added during the cooking process. The purée is processed by taking peel, core and flesh of the Bramley apple and applying heat and steam to the product. The purée is then sieved to remove any fibrous matter and should be a thick, smooth green/pale brown liquid typical of Bramley apple.

Lemon juice may also be added.

The end product contains the characteristic Bramley tangy taste. Traditional Bramley Apple Pie Filling is distributed to wholesalers, food service providers, bakeries, food manufacturers and retailers in a range of containers.

The ingredients for Traditional Bramley Apple Pie Filling consist of:

Bramley apple pieces — minimum size 15 mm

Sugar

Water

Bramley apple purée — optional

Cornflour — optional

Lemon juice — optional

The quantities of the ingredients used vary according to each manufacturer however the following technical characteristics must be adhered to:

Bramley apple pieces — minimum 40 %

Sugar — maximum 20 %

Water content — Maximum water activity should be 0,97 aw.

pH — less than 4

solids — minimum 2º Bx –

Viscosity — maximum flow 8 when using a Ford cup.

3.6. *Description of the production method of the agricultural product or foodstuff to which the name under point 3.1 applies (Article 3(2) of Regulation (EC) No 1216/2007)*

Bramley apples are sourced as the raw material for Traditional Bramley Apple Pie Filling. The apples are grown in accordance with the following protocol:

Complete records of the growing, harvesting and storage of fruit are maintained for each consignment delivered to the manufacturing plant. Following initial inspection to ensure that the consignment is suitable for the Traditional Bramley Apple Pie Filling, apples go through a water floatation process followed by machine grading and manual line inspection prior to the manufacturing process.

The size of the apples that are used in making Traditional Bramley Apple Pie Filling vary between a minimum 65 mm to a maximum 115 mm. Due to the unique shape of the Bramley, adequate specialist sizing and handling procedures must be used to ensure accurate preparation of the raw materials.

The apples must be sound, clean, free from severe skin blemish, whole and ripe, and free from cuts and bruises > 0,5 mm in depth, bitter pit, rot or disfiguring scab. Due to the soft nature of the fruit, floatation and mechanical lines must be adapted to minimise low energy impact during the preparation and processing procedures.

The flavour of the Bramley Seedling apple is tangy and sharp. The colour is typical of Bramley Seedling Apple; ranging from very dark green to a lighter shade of green colour covering the whole skin of the apple. The texture of the apple should be of good firm crispy texture and in general fall into the categories of crunchy, juicy and firm.

Machine peeling and coring: the Bramley shape is irregular and specialist sizing, peeling coring and handling equipment is required to meet the demanding specification for the commercial manufacture of Traditional Bramley Apple Pie Filling, and hand trimming is required.

Preparation: diced Bramley has unique oxidisation characteristics and requires specialist techniques listed below:

The Bramley apples are cut to the required size. The pieces are generally irregular in size, varying between a 15 mm diced 'cube' to 70 mm long 'strips', the cross-section of should not be less than 15 mm across. The irregularity of the pieces is part of the character of Traditional Bramley Apple Pie Filling and is a result of the size and shape of the apples themselves, the cutting method and the preference of the customer or consumer.

These Bramley apple pieces may then be immersed in an antioxidant dip, to prevent browning of the apples' flesh. The use of lemon juice, citric acid or ascorbic acid as an antioxidant dip is optional and a specific phase of the processing. It is neither an ingredient nor an additive and therefore has no impact on the composition of the final product.

The apple is then transferred straight to the apple pie filling area or to chill storage, after which it is processed into Traditional Bramley Apple Pie Filling, either hot or in a cold mix.

A mixture of water and sugar is added to the apple pieces until it is all evenly dispersed, at this point, if desired, cornflour and/or Bramley apple purée and/or lemon juice may be added. The apple purée must be processed from 100 % Bramley apples and be free from any preserving agent.

3.7. *Specific character of the agricultural product or foodstuff (Article 3(3) of Regulation (EC) No 1216/2007)*

Traditional Bramley Apple Pie Filling is a homogeneous blend of fresh Bramley apple pieces, sugar and water, with the option of Bramley apple purée, cornflour and lemon juice.

The unique flavour characteristics of the Bramley apple and the noted absence of any additives are responsible for the Traditional Bramley Apple Pie Filling's particular tangy taste. The flavour of the apples are characterised by the balance between sugar and malic acid. Most other varieties of apples have lower levels of acid and higher sugar content, giving them the sweet flavour that makes them good to eat — but this flavour is lost when the apple is cooked. Bramley apples, however, contain a higher malic acid content and lower sugar levels, producing a stronger, tangier flavour that is retained when cooked.

The firm texture of Bramley apples is a vital quality which contributes to producing a 'melt in the mouth' moist texture when cooked. Dessert apples can produce a chewy, dissatisfying texture because they contain up to 20 % more dry matter than Bramley apples.

The United Kingdom's Good Housekeeping Institute has conducted research that confirms Bramley apples' superiority over dessert apple varieties when cooked in popular recipes. The Bramley was tested against Granny Smith, Braeburn and Golden Delicious apples. All the apples where treated identically using recipes taken from the Good Housekeeping recipe book, including traditional apple pie, and were tested for flavour, texture and overall quality when cooked. The research showed that Bramley performs better than all the dessert apple varieties in traditional British apple pies.

The table below shows the average scores (out of 9) recorded by the Good Housekeeping Institute consumer taste4 panel, comprised of 12 adults, male and female, of all age groups, including members of the cookery team:

	Golden Delicious	Braeburn	Bramley	Granny Smith
Appearance	5,2	5,8	6,9	6,2
Flavour	6,0	5,2	7,0	5,0
Texture	5,5	4,9	6,5	5,5
Overall Quality	5,2	5,4	6,7	5,0

A list of the unique characteristics of the Traditional Bramley Apple Pie Filling:

— Made using only the 'traditional' ingredients of Bramley apple, water and sugar with Bramley apple purée — made from 100 % Bramley apples, cornflour and lemon juice if desired. No additives used

— Unique taste a result of the Bramley's high malic acid to sugar ratio

— Apples from 65 mm-115 mm in size

3.8. *Traditional character of the agricultural product or foodstuff (Article 3(4) of Regulation (EC) No 1216/2007)*

Bramley's Seedling was discovered in around 1809 by Miss Mary Anne Brailsford (a seedling grown by nature in response to a unique temperate island climate). It was planted in a garden in Southwell, Nottinghamshire.

The fruits of the grafted Bramley apple were first exhibited before the Royal Horticultural Society's Fruit Committee on 6 December 1876. They were highly commended.

During the Victorian Age, there was a quest to develop single purpose culinary apple varieties for the ultimate apple pie recipe. At the 1883 National Apple Congress the Bramley was acclaimed as the best suited variety for apple pies. It has therefore become a popular tradition.

In October 1887, Bramley Seedlings received a First Class Certificate by the Committee of the Royal Jubilee Exhibition of Apples held in Manchester.

Bramley's seedling is a unique single purpose culinary apple (it is not usually eaten raw as most people would find it too acidic). It produces both a distinctive flavour and individual texture and it is these qualities which have created and perpetuated the tradition of the apple pie.

The British did not favour the American notion of an apple to spike with a fork, nor the French style with its decorative topping of apple slices, both of which require that an apple keeps its shape when cooked and are therefore less acidic than a proper 'cooker'. Whether the preferences or the apples came first is an open question but 'Bramley's Seedlings', with the highest acidity levels of any 'cooker' passed the English tests with honours. Plentiful acidity and the resulting characteristic sharp fruity taste also ensured its continuing use.

The early tradition of covering pieces of sliced Bramley in lemon juice (or some other acidic juice) to prevent them turning brown has remained unchanged and is the same as the Traditional Bramley Apple Pie Filling recipe used commercially today.

A number of the United Kingdom's leading chefs have provided testimonials directly to UK Apples & Pears, to the effect that the recipe for Traditional Bramley Apple Pie Filling has remained unchanged since it was popularised following the National Apple Congress of 1883:

'I have worked in the food world for fifty years and to the best of my knowledge the traditional English apple pie filling is nothing but Bramley apples and sugar, possibly with a squeeze of lemon and some cornflour thickening.' — Prue Leith, OBE

'The Bramley apple celebrated its bicentenary in 2009 and has been used for apple pie fillings since it began to be cultivated commercially in the mid 19th century. In all of that time, the recipe for Bramley apple pie filling has remained unchanged, being just Bramley apples, sugar, starch such as cornflour, a preservative such as lemon juice and water.' — Phil Vickery

'To the best of my knowledge the recipe for traditional Bramley Apple Pie filling has not changed; Bramley apples, sugar, cornflour and a preservative such as lemon juice and water. The Bramley is rightly recognised as being the best apple for cooking. Indigenous to Britain, the apple's unique qualities such as higher acid and lower sugar levels produce a strong apple flavour even when cooked and a superb texture once cooked.' — Antony Worrall Thompson, MOBG

Some apple pie fillings including other Bramley apple pie fillings may contain a mix of apple varieties and these do not adhere to our definition of 'Traditional Bramley Apple Pie Filling', which is made using Bramley apples exclusively. Similarly, the use of artificial preservatives would not adhere to our definition of 'Traditional Bramley Apple Pie Filling'.

3.9. *Minimum requirements and procedures to check the specific character (Article 4 of Regulation (EC) No 1216/2007)*

These are set out below and refer specifically to the commercial manufacture of Traditional Bramley Apple Pie Filling:

Raw Product Description

Bramley's Seedling Apple. No other apple varieties are permissible.

Fruit Quality

Upon delivery to the processor, the fruit must be sound, clean, whole and ripe. Apple must be free from severe skin blemish and free from cuts and bruises > 0,5 mm in depth.

Colour should be green and typical of the Bramley variety, ranging from very dark green to a lighter shade of green colour covering the whole skin of the apple; not yellow/green, yellow.

Faults

Specific faults that must be minimised are: severe bruising (> 0,5 mm in depth); king fruit; core rot; bitter pit; badly misshapen fruit; low temperature breakdown; excessive skin damage; corky core; rotten apples. Mussel scale shall not be present on the bulk of the peel.

Fruit Size

A range of fruit size is acceptable, between 65 mm-115 mm.

Texture

Texture should be of a good, firm, crispy texture.

Processing

Due to the soft nature of the fruit, processing conditions must be such to minimise mechanical impact during preparation and processing.

The Bramley shape is irregular and specialist sizing, peeling coring and handling equipment is required to meet the specification.

Once peeled and cored, apples must be inspected and hand trimmed.

Apple may be dipped in an antioxidant dip, which is then shaken off, then drained to remove any excess.

Apple to be stored in chilled conditions < 5 °C prior to use.

Manufacturing

Other than the above ingredients, Traditional Bramley Apple Filling should contain only water and sugar, with the option of Bramley apple purée and cornflour. Variations on the recipe are permissible, but not the ingredients.

The blending and pumping process must be such that it produces a homogenous blend with good fruit definition.

Pie filling to be tested, every batch, for pH, total soluble solids, viscosity, colour, flavour to verify specification parameters are met. Levels may vary between manufacturers, depending on the end customer's specification. Products must be labelled to ensure full traceability and maintained in chilled storage/distribution.

4. **Authorities or bodies verifying compliance with the product specification**

4.1. *Name and address*

Name: The National Britannia Group

Address: Caerphilly Business Park
Caerphilly CF83 3GG
UNITED KINGDOM

Tel. +44 2920852852

Fax +44 2920867738

E-mail address: client_support@natbrit.com

Name: LawLabs Limited

Address: Law Labs House
121 Shady Lane
Great Barr
Birmingham B44 9ET
UNITED KINGDOM

Tel. +44 1212514000

Fax +44 1212514040

E-mail address: market.lawlabs@bodycote.com

These Inspection Bodies are both EN45011 accredited. Auditing to the requirements of the BRC Global Standards — Food (current Issue 4, January 2005)

http://www.brc.org.uk/standards/default.asp

☒ Public ☐ Private

4.2. *Specific tasks of the authority or body*

The Inspection Body is responsible for the verification of the entirety of the specification.

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