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⁽¹⁾ Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1615

of 22 October 2018

entering a name in the register of protected designations of origin and protected geographical indications ('Lucanica di Picerno') (PGI)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Italy's application to register the name 'Lucanica di Picerno' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Lucanica di Picerno' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Lucanica di Picerno' (PGI) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.2. — Meat products (cooked, salted, smoked, etc.), as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 153, 2.5.2018, p. 15.

⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 October 2018.

*For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission*

DECISIONS

COMMISSION DECISION (EU) 2018/1616

of 18 May 2018

on the measure SA.12594 (C13a/2003) (ex NN/2002) implemented by France for Orange (France Télécom)

(notified under document C(2018) 2882)

(Only the French text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 108(2) thereof,

Having regard to the Agreement on the European Economic Area, and in particular Article 62(1)(a) thereof,

Having called on interested parties to submit their comments pursuant to the provisions cited above ⁽¹⁾ and having regard to those comments,

Whereas:

1. PROCEDURE

1.1. The administrative procedure

- (1) By letter dated 31 January 2003, the Commission informed France of its decision to open the formal investigation procedure provided for in Article 88(2) of the Treaty establishing the European Economic Community ⁽²⁾ ('the opening decision') in respect of financial measures introduced by the French authorities for France Télécom ('France Télécom' or 'FT').
- (2) The opening decision was notified to France on 31 January 2003. After a number of substantive errors had been corrected, a corrigendum was notified to France on 7 March 2003.
- (3) France communicated additional information to the Commission by letters dated 4 April 2003, 15 May 2003 and 29 January 2004.
- (4) The Commission decision to initiate the procedure was published in the *Official Journal of the European Union* ⁽³⁾. The Commission invited interested third parties to submit their comments on the aid measures in question.
- (5) The Commission received comments from interested third parties. The Commission forwarded the comments to France on 16 May 2003. It received France's comments by letters dated 30 June and 29 July 2003.
- (6) On 30 May 2003, the Commission published an invitation to tender for a contract 'for the provision of services to assist in assessing the compliance of the financial assistance granted to France Télécom with the principle of the private investor in a market economy and if necessary to analyse France Télécom's recovery plan' ⁽⁴⁾. On 24 September 2003, the contract for the provision of services was awarded to the firm NERA ('NERA', or 'the consultant').
- (7) The Commission sent the French authorities the NERA report of 28 April 2004 ('the NERA report'), which consists of a legal part and an economic part. On 9 and 21 June 2004, the French authorities submitted comments on the NERA report.

⁽¹⁾ OJ C 57, 12.3.2003, p. 5.

⁽²⁾ With effect from 1 December 2009, Articles 87 and 88 of the EC Treaty have become Articles 107 and 108, respectively, of the Treaty on the Functioning of the European Union ('TFEU'). The two sets of provisions are, in substance, identical. For the purposes of this Decision, references to Articles 107 and 108 TFEU should be understood as references to Articles 87 and 88, respectively, of the EC Treaty, where appropriate.

⁽³⁾ See footnote 1.

⁽⁴⁾ 2003/S 103-091487.

- (8) On 3 August 2004, the Commission notified the French authorities of its decision of 2 August 2004, declaring that the shareholder loan granted by France to France Télécom in December 2002 in the form of a EUR 9 billion credit line constituted State aid incompatible with the internal market ⁽⁵⁾.

1.2. Judicial proceedings following the decision of 2 August 2004

- (9) The French Republic, France Télécom and the Bouygues companies each brought an action for annulment of the Commission's decision. By judgment of 21 May 2010, the General Court annulled the Commission's decision ⁽⁶⁾. The Court found that the Commission had failed to demonstrate that the announcement on 4 December 2002 involved a transfer of State resources.
- (10) The Commission and the Bouygues companies brought an appeal against the judgment of 21 May 2010. By judgment of 19 March 2013 ('the Bouygues judgment'), the Court of Justice set aside the judgment of 21 May 2010 and referred Cases T-425/04, T-444/04 and T-450/04 back to the General Court for a ruling on the pleas in law raised and the applications submitted to it which it had not previously ruled on ⁽⁷⁾.
- (11) In that regard, the Court found that, in the contested decision, the Commission had not expressed a view on the argument raised by the Bouygues companies in their complaint of 22 January 2003, according to which the declarations from July 2002 constituted, in themselves, State aid.
- (12) Next, the Court held that, as State interventions take various forms and have to be assessed in relation to their effects, it cannot be excluded that several consecutive measures of State intervention must, for the purposes of Article 107(1) TFEU, be regarded as a single intervention.
- (13) The Court of Justice went on to conclude that, having found that it was necessary to identify a reduction of the State budget or a sufficiently concrete economic risk of burdens on that budget, closely linked and corresponding to, or having as a counterpart, a specific advantage deriving either from the announcement of 4 December 2002 or from the shareholder loan offer of 20 December 2002, the General Court had erred in law by applying a test that immediately excluded those State interventions, depending on their links with one another and their effects, from being regarded as a single intervention. However, the Commission was right in its decision to examine the two measures together, since the first measure was clearly inseparable from the second measure.
- (14) In the judgment of 2 July 2015, the General Court found that the Commission's decision was vitiated by errors of law and manifest errors of assessment as regards the application of the prudent private investor test ⁽⁸⁾. The Court therefore annulled the Commission's decision.
- (15) The Commission appealed against that judgment. That appeal was dismissed by the Court of Justice in its judgment of 30 November 2016 ⁽⁹⁾.
- (16) The Commission must therefore adopt a new decision concluding the formal investigation procedure provided for in Article 108(2) TFEU, which it opened on 31 January 2003.

2. DESCRIPTION OF FACTS

- (17) France Télécom, an operator and supplier of telecommunications networks and services, was formed in 1991 as a legal person governed by public law, and since 31 December 1996 has had the status of a public limited company. Since October 1997, France Télécom has been listed on the stock exchange. In 2002 the French State's participation in France Télécom's capital was 56,45 %, the remainder of the shares being divided between the public (32,25 %), FT itself (8,26 %) and employees of the company (3,04 %). On 1 July 2013, France Télécom changed its name to Orange.
- (18) A detailed description of FT's financial situation is set out in recitals 16 to 61 of the annulled decision of 2 August 2004.

⁽⁵⁾ Commission Decision 2006/621/EC of 2 August 2004 on the State Aid implemented by France for France Télécom (OJ L 257, 30.9.2006, p. 11).

⁽⁶⁾ Judgment of the General Court of 2 July 2015, *France v Commission*, T-425/04, T-444/04, T-450/04 and T-456/04, ECLI:EU:T:2010:216.

⁽⁷⁾ Judgment of the Court of Justice of 19 March 2013, *Bouygues SA and Bouygues Télécom SA v European Commission and Others and European Commission v French Republic and Others*, C-399/10 P and C-401/10 P, ECLI:EU:C:2013:175.

⁽⁸⁾ Judgment of the General Court of 2 July 2015, *French Republic (T-425/04 RENV) and Orange (T-444/04 RENV) v European Commission*, ECLI:EU:T:2015:450.

⁽⁹⁾ Judgment of the Court of Justice of 30 November 2016, *European Commission v French Republic and Orange*, C-486/15 P, ECLI:EU:C:2016:912.

2.1. France Télécom's financial situation in the first half of 2002 and the events of that period

- (19) The analysis under the State aid rules of a State's conduct must be carried out using the data and information available at the time of each state intervention. Given that the present case concerns events that occurred in 2002, it is essential to set out chronologically the evidence available from the time of publication of the results for the 2001 financial year.
- (20) France Télécom was, from June 2002 onwards, a company with serious structural problems and an unbalanced balance sheet. The 2001 accounts showed improved operating results and substantial cash flow generation.
- (21) France Télécom was forced to announce, on 21 March 2002, not only a *major clean-up* of its balance sheet through balance sheet provisions and asset disposals totalling EUR 27,2 billion, but also a substantial increase in the available cash flow to the tune of EUR 14 billion for the period 2002-2005.

2.1.1. France Télécom's credit rating

- (22) During the first half of 2002, France Télécom's situation worsened rapidly, as reflected in a series of downgrades in the Company's credit rating. Thus, on 27 March 2002, the Moody's credit rating agency announced a downgrading of France Télécom's rating for long-term debt. On 28 March 2002, Standard & Poor's ('S&P') maintained France Télécom's rating but downgraded its prospects to negative following news concerning Mobilcom⁽¹⁰⁾.
- (23) On 13 May 2002, Moody's, doubting the Company's capacity to implement its debt-reduction strategy, announced a possible downgrade of France Télécom's short-term debt rating. On 14 May 2002, Standard & Poor's maintained France Télécom's existing rating.
- (24) On 24 June 2002, Moody's downgraded France Télécom's rating. The Company's prospective rating was maintained at a negative level. Moody's decision at that time was based on the fact that the agency did not expect France Télécom to be in a position to generate sufficient cash flow to reduce the group's consolidated debt. The rating agency pointed out that France Télécom was confronted with debts of about EUR 15 billion falling due in 2003.
- (25) On 25 June 2002, Standard & Poor's downgraded France Télécom's short- and long-term debt rating, basing its decision on the difficulties concerning Mobilcom and France Télécom's inability to reduce its debt far and fast enough. S&P also refers to the EUR 15 billion of debt falling due in 2003.
- (26) On 12 July 2002, Standard & Poor's even drew attention to a potential problem involving the refinancing of the debt falling due in 2003.
- (27) The table summarises the various positions of S&P, Moody's and Fitch regarding France Télécom's rating:

Events connected with credit ratings

	S&P		Moody's		Fitch	
	Short-term	Long-term	Short-term	Long-term	Short-term	Long-term
Situation in May 2002	A2	BBB+	P2	Baa1	F2	BBB+
24 June 2002			P3	Baa3		
25 June 2002	A3	BBB				
5 July 2002					F3	BBB-
12 July 2002		BBB-				

Source: NERA.

⁽¹⁰⁾ A stake in Mobilcom was acquired in difficult circumstances by investing a very large amount of EUR 3,7 billion in a 28,5 % shareholding, valuing the operator at 80 times its EBITDA (compared with a stock-exchange valuation before rumours of the deal emerged of the order of 65 times EBITDA). In the summer of 2002, an audit of Mobilcom's prospects revealed the company's extreme fragility and the manifest impossibility of obtaining a return on the investment (report drawn up on behalf of the commission of enquiry into the management of public undertakings with a view to improving the decision-making system, registered at the office of the President of the National Assembly on 3 July 2003).

2.1.2. France Télécom's share price

- (28) At the same time, France Télécom's share price fell significantly during the first half of 2002, reaching its lowest level first on 27 June 2002 (EUR 7,79), and then on 30 September 2002 (EUR 6,01).

2.2. The events of July 2002

- (29) In an interview published in *Les Echos* on 12 July 2002, the French Minister for Economic Affairs, Finance and Industry (the Minister for Economic Affairs and Finance) confirmed more than once that if France Télécom were to face any financing problems, the State would take whatever measures were necessary to overcome them. The precise wording of the published interview is as follows:

'You mention market excesses. France Télécom's share price is highly volatile. You are the majority shareholder in the company, do you have a message to convey?

We are the majority shareholder, with 55 % of the capital; there is clearly no question of our "renationalising" the company, as I have sometimes heard it said. I feel responsible for the State's financial interests. The State shareholder will behave like a prudent investor and would take appropriate steps if France Télécom were to face any difficulties.

Was the State behaving like a prudent investor when it let France Télécom get deeper into debt, by moving, for example, into Germany?

It is not for me to criticise my predecessors. I would point out that the entire industry was pursuing the same strategy at the same time. Having said that, the ideologically motivated retention of a majority holding has not made it any easier to internationalise France Télécom, as it has not been able to pay for its acquisitions with shares. Hence the indebtedness. I repeat, if France Télécom were to face any financing problems, which is not the case today, the State would take whatever decisions were necessary to overcome them.

You are reviving the rumour of a capital increase ...

No, certainly not! I am simply saying that we shall take appropriate measures when the time comes. If it is necessary.' ⁽¹¹⁾

- (30) On that same day, S&P downgraded France Télécom's rating to BBB-. That downgrade was nevertheless limited to a rating still qualifying as investment grade: any further downgrade would have led to the Company's debt being accorded junk-bond status, as being no longer of investment grade.
- (31) In its press release of 12 July 2002, S&P states that the reason why it had decided to maintain France Télécom at investment grade was to do with the State's indications as to its intentions towards the Company: 'FT could face certain difficulties refinancing its debt obligations coming due in 2003. Nevertheless, the State's indication underpins France Télécom's investment-grade credit quality.' That assurance had been provided, firstly, directly by the French Government to S&P: 'the French State — which owns 55 % of France Télécom — has clearly indicated to Standard & Poor's that it will behave as an aware investor and would take appropriate steps if France Télécom were to face any difficulties. *France Télécom LT rating cut to BBB-*' ⁽¹²⁾, and, secondly, publicly in the interview referred to in paragraph 29.
- (32) In the light of the above, it appears that in July 2002, France Télécom was facing a crisis of confidence. Rating agencies and analysts alike were convinced that France Télécom risked not being able to implement the refinancing plan presented by its management in order to meet its maturities. France Télécom was therefore faced with an acute financing problem linked to its indebtedness. Nevertheless, the agencies had maintained the Company's rating at investment grade on the strength of the State's indications. A downgrading of the rating would have worsened the crisis and lessened the Company's ability to cope.

⁽¹¹⁾ *Les Echos* No 18695, France, 12 July 2002, p. 2.

⁽¹²⁾ *Off Watch; Outlook Stable; Teleconf 3:30PM BST Today*, Standard & Poor's Ratings Direct, 12 July 2002.

2.3. The data published on 13 September 2002 and events at that time

2.3.1. The data published on 13 September 2002

- (33) In September 2002, France Télécom's half-yearly accounts showed an improvement in France Télécom's figures in the first half of 2002 compared with the previous year: an increase of 10 % in turnover, 13,2 % in EBITDA and 17,3 % in the operating result. The sustained growth in mobile telephony and the improved performance of the internet business were also noted. However, the operating result of the fixed telephony segment in France, which accounted for 31 % of turnover for the same period, was down by 12,2 %. Earnings after interest (EUR 1,75 billion) but before taxes, shareholdings and minority interests, exclusive of extraordinary items, were EUR 718 million against EUR 271 million as at 30 June 2001. The operating free cash flow amounted to EUR 3,6 billion, up 15 % on the first six months of 2001.
- (34) Alongside the good operating results described above, France Télécom confirmed the imbalance in its financial situation. The negative result of EUR 12,2 billion as at 30 June 2002 was primarily due to the substantial provisions made for investments. As a result of that half-year loss, France Télécom's consolidated own funds became negative as at 30 June 2002 to the tune of EUR 440 million.
- (35) An analysis of cash flow as at 30 June 2002 shows that net debt increased during the first half of 2002 by EUR 6,3 billion, inasmuch as EBITDA, at EUR 6,870 billion, did not cover expenditure represented by:
- debt interest (EUR 3 099 million),
 - investments (EUR 3 820 million),
 - the repurchase of France Télécom shares from Vodafone (EUR 4 973 million),
 - the repurchase of Orange shares from E.On (EUR 950 million),
 - the payment of taxes (EUR 608 million).
- (36) Of a net indebtedness of EUR 69,69 billion as at 30 June 2002, the bulk, or EUR 50,6 billion worth, is made up of bonds.
- (37) The maturity schedule of that debt is characterised by its short duration, EUR 12,9 billion maturing in 2003. During the first half of 2004, EUR 11,9 billion worth of bonds came due, followed by EUR 5,4 billion in the second half of 2004. In all of 2005, a total of EUR 18,6 billion came due.
- (38) Therefore, in September 2002, FT faced the prospect of a total repayable debt of EUR 48,9 billion during the period 2003-2005.

2.3.2. The events of September and October 2002

- (39) On 12 September 2002, the French authorities announced that they had accepted the resignation of France Télécom's CEO.
- (40) On 13 September, the Government reiterated in a press release its support for France Télécom and expressly indicated that it had decided to take part in a forthcoming operation aimed at increasing France Télécom's own funds: '... After the exceptional losses of the first six months, France Télécom is faced with a serious shortage of capital. ... The Government is therefore determined to exercise its responsibilities to the full ... The new chairman will propose to the board a plan for improving the company's accounts, enabling its debts to be reduced and its financial structure to be restored while maintaining its strategic advantages. The State will help France Télécom implement this plan and will contribute to a very substantial strengthening of the company's capital base, according to a timetable and in a manner to be determined in the light of market conditions. In the meantime, the State will, if necessary, take steps to prevent the company from being faced with any financing difficulties ...' ⁽¹³⁾.
- (41) That same day, Moody's changed the outlook of France Télécom's debt from negative to stable owing to the restated commitment to support the Company ⁽¹⁴⁾.

⁽¹³⁾ Press release of the Minister for Economic Affairs and Finance of 13 September 2002, *Financial situation of France Télécom*.

⁽¹⁴⁾ Moody's Investors Service, 13 September 2002. The relevant part of the press release states: 'Moody's have taken increased comfort from the Government's statement, which once again confirmed their strong support for FT. Whilst Moody's concerns regarding the overall level of financial risk and particularly FT's weak liquidity position remain, Moody's has grown more comfortable with expectation that the French Government will act in a supportive manner, if FT started to encounter difficulties with its debt repayment schedule.'

- (42) On 2 October 2002, in a press release, the Government repeated its commitments: 'the new chairman will immediately carry out an inventory of the company, the findings of which will be communicated to the board ... and which will form the basis for a financial recovery and strategic development plan enabling the company's debt to be reduced while building on its strengths. Within this framework, Thierry Breton will enjoy the support of the State in its capacity as shareholder, determined as it is to exercise its responsibilities to the full. The State will assist in implementing the recovery measures and will contribute, for its part, to the strengthening of the company's own capital base in a manner to be determined in close collaboration with the company's chairman and board. As has already been indicated, the State will, if necessary, take steps in the meantime to prevent the company from being faced with any financing difficulties' ⁽¹⁵⁾.
- (43) France Télécom's share price rebounded on 2 October 2002 (up more than 10,4 % on the previous week) following the announcement of the appointment of the new CEO.

2.4. The events of December 2002 and January 2003 and the 'Ambition FT 2005' plan

- (44) On 4 December 2002, an action plan entitled 'Ambition FT 2005' ⁽¹⁶⁾ (the 'Ambition 2005 plan') was presented by France Télécom's new management, being aimed at bringing about a noticeable improvement in the Company's operational performance and offering the prospect of a satisfactory return on capital invested. Thus, the medium-term objectives were to meet France Télécom's financing requirements and to achieve a net reduction in debt and a reconstitution of capital.
- (45) The action plan is based on the following components: (i) the Total Operational Performance Plan ('the TOP plan'), whereby France Télécom will have to generate an additional EUR 15 billion of cash flow from its own resources; (ii) EUR 15 billion to be raised from the shareholders to strengthen the Company's capital base; and (iii) EUR 15 billion to be raised from the bond and banking markets.
- (46) In terms of own resources, the TOP plan includes internal savings designed to improve the Company's operating performance and increase free cash flow with a EUR 15 billion reduction in debt by 2005. These measures are accompanied by asset disposals. The TOP plan is the main pillar of France Télécom's overall recovery plan. It needs to show that the Company is prepared to make a swift and significant contribution to the efforts required to bring its debt back down to normal levels for this sector by the end of 2005. Regarding the increase in cash flow over three years, the TOP plan consists of the reduction and optimisation of investments (with savings of 40 % to 45 %); a reduction in operating costs (savings of 35 % to 40 %); and an optimisation of the working capital requirement (savings of 20 % to 25 %).
- (47) The TOP plan has considerable implications for the Company's management and organisation, particularly in terms of operating expenses, jobs and above all investment. It predicts annual growth in turnover, EBITDA and operational cash flow during the period 2003-2005.
- (48) The asset disposal plan is in line with the disposals already undertaken by France Télécom to restructure its operations in 2001. Its aim is to minimise the level of indebtedness without jeopardising the Company's ability to generate increasing free cash flow. Achieving this goal requires the Company to refocus on its core business, without undermining France Télécom's ambition to be a telecommunications operator integrating all telecommunications services.
- (49) Strengthening France Télécom's capital base would entail a significant capital increase. The contribution from the State and other private shareholders would be proportional to their shareholding and would be EUR 9 billion and EUR 6 billion, respectively.
- (50) To that end, the French Government and France Télécom gathered together a banking syndicate, which agreed to underwrite, when the time came, the portion of the capital increase intended for private investors. Like the Government's decision to invest, the banks' commitment was contingent on the announcement to the market of a credible plan with management measures and strategic changes able to convince the market, as well as cash flow forecasts showing the prospect of satisfactory free cash flow.
- (51) The State and private investors participating in the operation to strengthen the Company's capital base, in line with the TOP plan, could expect a rate of return on investment of 16,7 % in 2004 and 21,5 % in 2005, based on France Télécom's operating results of EUR 11,1 billion and EUR 13,9 billion in 2004 and 2005 respectively.

⁽¹⁵⁾ Press release of the Minister for Economic Affairs and Finance of 2 October 2002.

⁽¹⁶⁾ France Télécom press release of 5 December 2002, p. 1.

- (52) According to the French authorities, the strengthening of the Company's capital base could not take place immediately given the situation on the financial markets, especially as far as telecoms stocks were concerned. There were also other factors to consider, such as the length of time it would take to launch such an operation and the need to call an extraordinary general meeting and prepare financial statements.
- (53) The French authorities also stressed that it would be better both for France Télécom and its shareholders that such an operation take place after the market had fully integrated the prospects of operational improvement and had been able to assess its initial results or tangible signs.
- (54) In these circumstances, and in order to give France Télécom the necessary room for manoeuvre to enter the market under the best possible conditions, the French State declared that as majority shareholder, it was prepared to make an upfront prepayment towards the capital increase. To that end, it would ensure that a temporary shareholder loan in the form of a credit line was made available to France Télécom, any amount drawn by France Télécom being consolidated when new share capital was issued. The maximum loan that could be made available to France Télécom was EUR 9 billion, which corresponded to the State's future contribution to strengthening the Company's capital base. The conversion of the loan into securities was obligatory upon completion of the operation to strengthen the capital base.
- (55) The action plan stipulated that the loan would only be drawn upon to the extent that France Télécom required, considering its cash flow plan. It would also be remunerated at the prevailing market rates and the interest would be capitalised. It would thus appear that the granting and making available of the shareholder loan would not be remunerated as such, and that interest would be charged only on the amount drawn against the loan, at a rate equal to Euribor plus a margin established by reference to the average spread recorded at that time on the four main France Télécom bond lines compared with the corresponding swap rate, plus 1 %. It was also stipulated that, whatever the date on which these drawings were made, the margins applicable to the drawings would be increased automatically by 0,35 % from the sixth month following the date of the first drawing and by 0,7 % from the 12th month following the date of the first drawing. The French authorities pointed out that the terms for launching the December bond issues were more favourable for France Télécom than those granted by the State, as the main shareholder, for making funds available for a potential loan. The French authorities explained that, on comparable terms (floating rate swap), the euro tranche of the bond issue corresponded to Euribor + 290 bp, or around 100 bp below that of the shareholder loan, whereas the bond was due to mature long after the loan.
- (56) In order to proceed with the shareholder loan, the French authorities planned to use a vehicle, the Entreprise de Recherches et d'Activités Pétrolières (ERAP), a French public industrial and commercial entity, which would be responsible for holding the State participation in France Télécom and reflected the State's intention to identify clearly the financial outlay being granted by isolating it in a dedicated structure.
- (57) The French authorities said that ERAP would initially borrow from the State to subscribe to the capital increase, before turning to the bond markets.
- (58) The presentation of the Ambition 2005 plan was accompanied by a press release of the Minister for Economic Affairs and Finance, dated 5 December 2002, in which the Government confirmed its support for the plan, its commitment to take part in the operation to strengthen the Company's capital base and the making available of a shareholder loan in the form of a EUR 9 billion credit line. The relevant paragraphs of the press release are as follows: 'Francis Mer, Minister for Economic Affairs, Finance and Industry, confirms the State's support for the action plan approved by France Télécom's board of directors on 4 December. (1) The France Télécom group is a coherent industrial entity with a remarkable track record. However, the company is now faced with an unbalanced financial structure and a need for capital and refinancing in the medium term. This state of affairs is due to the failure of past investments, which were carried out badly at the height of the financial "bubble" and, more generally, to the market downturn. The impossibility for France Télécom to finance its growth otherwise than through debt has made the situation worse. (2) The State, as majority shareholder, has asked the new management to restore the company's financial equilibrium while maintaining the group's integrity ... (3) In the light of the action plan drawn up by management and the investment return prospects, the State will participate in the EUR 15 billion strengthening of the company's capital base in proportion to its share in the capital, giving an investment of EUR 9 billion. The State shareholder thus intends to act like a prudent investor. It will be for France Télécom to work out the detailed arrangements and precise timetable for the strengthening of its capital base. ... To enable the company to launch a market operation at the most opportune moment, the State is prepared to make an upfront prepayment towards the strengthening of the capital base in the form of

a temporary shareholder loan, remunerated at market rates, placed at France Télécom's disposal. (4) The State's entire shareholding in France Télécom will be transferred to a public industrial and commercial entity, ERAP. The latter will borrow on the financial markets in order to finance the State's share in the strengthening of the company's capital base.'

- (59) France Télécom's share price continued its upward progress with the announcement of the TOP plan and of the new executive board on 5 December 2002, which led to a rise of more than 25 % in two days.
- (60) A few days after the presentation of the Ambition 2005 plan, France Télécom launched two successive bond issues on 11 and 12 December 2002 for a total amount of EUR 2,9 billion. The first bond issue was for a total amount of EUR 2,5 billion over seven years, at a fixed rate of 7 %, or Euribor + 290 bp. The second bond issue was placed on the pound sterling (GBP) market for an amount of GBP 250 million at a fixed rate of 8 % over 15 years, or LIBOR + 330 bp. Other issues were made on 15 January 2003 for a total amount of EUR 5,5 billion. On 10 February 2003, that part of the EUR 15 billion syndicated loan which had matured, namely approximately EUR 5 billion over three years at the rate Euribor + 125 bp, was renewed.
- (61) On 17 December 2002, S&P indicated that, since July 2002, the Government's support had been a key factor in maintaining France Télécom's investment-grade status ⁽¹⁷⁾ and that its announcement concerning the shareholder loan and the commitment to subscribe, in proportion to its shareholding, to a EUR 15 billion recapitalisation operation had confirmed that support ⁽¹⁸⁾.
- (62) On 20 December, the French authorities sent the loan contract initialled and signed by ERAP to France Télécom. France Télécom never signed this contract.
- (63) France Télécom ended the 2002 financial year with a loss of approximately EUR 21 billion and a net financial debt of almost EUR 68 billion.
- (64) On 4 March 2003, the operation to strengthen the Company's capital base by EUR 15 billion as envisaged by the Ambition 2005 plan was launched. The operation was broadly successful and was terminated on 11 April.
- (65) The capital increase largely met the structural needs of France Télécom's financing. Thus, following the operation, France Télécom's credit rating began to improve: on 14 May 2003 S&P raised its rating to BBB, outlook stable (from A-3 to A-2 for its short-term rating) and on 8 August 2003 Fitch raised its rating from BBB- to BBB.

3. COMMENTS FROM THIRD PARTIES

- (66) The Commission has received comments from Cable and Wireless, Cégétel, AFORS Télécom, LDCOM, Tiscali, WorldCom France, Bouygues SA and Bouygues Télécom, and Telecom Italia. Several interested parties (A, B and C) wished to keep their identity confidential.

3.1. Comments from Telecom Italia and WorldCom

- (67) Telecom Italia and WorldCom stress that any aid granted to France Télécom is likely to affect competition in the telecommunications markets, and in the French market in particular. It is therefore essential that the aid granted by the French authorities should be accompanied by compensatory measures aimed at reducing its impact on competition.

⁽¹⁷⁾ Research France Télécom, Standard & Poor's Ratings Direct, 17 December 2002: 'Since July 2002, support from the French state has been a key rating factor, underpinning the group's investment-grade status.' This statement follows that of 5 December 2002: 'Standard & Poor's rating services said today that it has affirmed its BBB- long-term and A-3 short-term corporate credit ratings [on FT] ... Since July 2002 Standard & Poor's has indicated that expected support from FT's 56 % shareholder, the French State, is a likely factor underpinning the group's investment-grade status. The French State's announcement today that it will immediately grant a EUR 9 billion shareholder loan to help FT face its 2003 debt obligations is viewed by Standard & Poor's as strong evidence of this support'.

⁽¹⁸⁾ Research France Télécom, Standard & Poor's Ratings Direct, 17 December 2002: 'The state's December 2002 announcement that it will grant a EUR 9 billion shareholder loan, coupled with its commitment to subscribe to a EUR 15 billion capital increase, underscores this support and provides significant credit protection for FT's debtholders. ..., FT and the state's targets in this respect meet Standard & Poor's expectations for the ratings. While market conditions may challenge the operation, the state's commitment to subscribe to the equity injection — so as to at least maintain its stake — strongly mitigates execution risks'.

3.2. Comments from A, B and C

- (68) According to A, B and C, the measures at issue constitute State aid. C argues that, in accordance with the Guidelines on State aid for rescuing and restructuring firms in difficulty ⁽¹⁹⁾ ('the Guidelines'), where public funding is provided to a firm which is in financial difficulties there is a presumption that State aid is involved. A, B and C state that the announcement of and terms governing the making available by the French State to France Télécom of the EUR 9 billion credit line and the participation by the French State in the recapitalisation of France Télécom involve aid elements. The prudent investor test is not satisfied as regards the arrangements for providing the credit line, inter alia, because of the interest rate proposed and the amount of the commitment fee. B and C also point out that the principle of concomitance has not been complied with insofar as the French authorities granted the credit line and announced their participation in the recapitalisation prior to the announcement of the Ambition 2005 plan and prior to the firm commitment of the investors.

3.3. Comments from Bouygues and Bouygues Télécom

- (69) Bouygues Telecom points out that the support of the State is the cornerstone of France Télécom's recapitalisation plan, which led to the Company's recovery. Thus, according to Bouygues Telecom, only the French State could restore the markets' confidence and create a virtuous circle enabling it to meet its short-term commitments and launch a huge recapitalisation operation under favourable economic conditions. According to Bouygues Telecom, the statements made by the Minister for Economic Affairs and Finance during the period from 12 July to 4 December 2002 constitute a state guarantee committing the State's resources; likewise, the shareholder loan and the operation to strengthen the Company's capital base commit state resources. These measures constitute State aid. They confer advantages on France Télécom which it would not have obtained under normal market conditions and do not satisfy the test of a prudent private investor operating under normal market conditions.
- (70) As regards the statements by the Minister for Economic Affairs and Finance, the repeated support of the State, expressed in a series of announcements from 12 July 2002 to 4 December 2002 and supplemented by a series of measures including the opening of the EUR 9 billion credit line and the irrevocable commitment by the State to participate in a capital increase in proportion to its shareholding in France Télécom, amounts to a commitment on its part, from which it cannot withdraw, to make good by all available means any failure by the Company to meet its financial commitments. Bouygues Telecom stresses here that this commitment constitutes a veritable state guarantee producing legal effects committing the State's resources.
- (71) In preparing its comments, Bouygues Telecom called on the services of an expert ⁽²⁰⁾ who stated that it followed from a long line of judgments by the French administrative courts that the existence of a commitment entered into by an administrative authority must be assessed in the light, not of the commitment's form, but of its intrinsic characteristics. The expert remarked that that case law was expressly applied in the specific case of declarations: the administrative courts thus considered that, even where they were not accompanied by any specific legal act, the promises constituted commitments as they were the embodiment of the administrative authority's will. For there to be a commitment on the part of the State, it was sufficient for the authority to have behaved in such a way as to convince others that it would act in a certain manner. The declarations by the Minister for Economic Affairs and Finance satisfied all the criteria for being characterised as a commitment by the State. Those declarations were firm and precise and made without reservations, and could thus be construed as constituting commitments by the State vis-à-vis France Télécom, its creditors or its employees.
- (72) With regard to the shareholder loan and the operation to strengthen the Company's capital base, Bouygues Telecom maintains that, firstly, the opening of a EUR 9 billion credit line for the benefit of France Télécom and, secondly, the irrevocable commitment by the State to participate in any future capital increase in proportion to its shareholding in the Company followed by the recapitalisation operation as such, are the implementation of the state guarantee and are financed by state resources. As a result, the measures at issue are financed by state resources, even if the credit line has ultimately not been used.
- (73) As regards the condition relating to the advantage, Bouygues Telecom points out that the occurrence giving rise to the guarantee took place subsequently to the reduction in France Télécom's credit rating by the rating agencies with a view to restoring the market's confidence. The guarantee had the effect of enabling France Télécom to gain renewed access to the financial markets.
- (74) As to the prudent private investor test, Bouygues Telecom argues that the support measures do not satisfy that test. Bouygues Telecom takes the view that the State's declarations constitute a firm and unconditional legal commitment which an investor would never have undertaken without entering the slightest reservation. It is therefore an unlimited guarantee granted to a company which is extraordinarily leveraged and fragile in the short term.

⁽¹⁹⁾ Information from the Commission — Community Guidelines on State aid for rescuing and restructuring firms in difficulty (Notice to Member States including proposals for appropriate measures) (OJ C 288, 9.10.1999, p. 2).

⁽²⁰⁾ Memo from Mr Sureau dated 14 January 2004.

- (75) Bouygues Telecom argues that, in view of the prolonged crisis in the world economy and more particularly in a telecommunications sector undergoing transition, and bearing in mind the size of the sum in question, no private investor could have envisaged a capital increase of that amount without conditions and only a State of the creditworthiness of France could have coped with such uncertainty. It thus points out that the financing of the strengthening of the Company's capital base, covered entirely by debt without any own funds, would have affected the credit rating of any private investor who behaved in a similar way, whereas a State, on the other hand, can be punished only by its electors, who do not have the same objectives. The creditors and shareholders of the private investor would have asked for the investment to be backed by a business plan containing precise commitments, including the disposal of assets. Bouygues Telecom concludes that, at all events, a prudent investor whose financial capacity was comparable to that of the French State and who issued such a guarantee would not have inspired much confidence in the markets and that it is clear that it was due to the qualification of 'sovereign debt' enjoyed by the State's commitments that confidence was restored.
- (76) Bouygues Telecom argues that the concomitance principle has not been complied with. Bouygues Telecom points out that the participation of private investors was neither certain nor significant at the time of the announcement by the Government of its participation in the capital increase, even if the date of taking the decision to invest is brought forward to 5 December. Where private investors are prepared to intervene only after the authorities have decided to grant aid, the fact that those investors are then prepared to intervene at the same time is no longer relevant. Such an intervention is the consequence of the support given by the State and not the result of a decision of a private investor. Hence, in the present case, the fact that a banking syndicate undertook to underwrite the transaction cannot be taken as a basis for concluding that the concomitance principle is complied with. The French authorities' decision to invest is firm and unconditional whereas that of the private investors is not, and the private investors made their contribution only after having received, on a number of occasions and with certainty, the assurance that the State would also participate in the transaction and especially that it would take every step to ensure that France Télécom did not have any financing problems.

3.4. Comments from Cable & Wireless

- (77) Cable & Wireless expresses the view that the measures at issue constitute State aid. The market's confidence as a result of the announcement of the granting by the French authorities of the shareholder loan sufficed to confer an advantage on France Télécom. Insofar as a prudent private investor would not have taken the decision to recapitalise a company such as France Télécom, which was clearly inefficient prior to the adoption of the Ambition 2005 plan, the Company enjoyed an advantage which it would not have secured under normal market conditions.

3.5. Comments from AFORS Télécom

- (78) AFORS Télécom (Association française des Opérateurs de Réseaux et Services de Télécommunications) observes that the measures at issue constitute State aid. Through a series of step-by-step decisions taken in the course of 2002 until the opening of a EUR 9 billion credit line made available to France Télécom, the French authorities restored investors' confidence by giving formal status to their support. Moreover, even if the credit line opened by ERAP were never used by France Télécom, it symbolises the guarantee of state support and hence mobilises state resources within the meaning of Article 107(1) TFEU.
- (79) The terms on which the credit line was granted and the terms governing its remuneration do not satisfy the tests of the prudent private investor principle. AFORS Télécom argues that France Télécom's financial failings since 2000 could not have happened in the presence of a prudent investor. The State's support has had the effect of preventing any further downgrading of France Télécom's credit rating by the rating agencies, which has made it possible to speed up France Télécom's return to the market and the refinancing of its debt under less onerous financial conditions. Hence, it is the credibility of the French State that determined the conditions of France Télécom's return to the financial markets.

3.6. Comments from Cégétel

- (80) Cégétel maintains that there are two separate measures: the announcement by the French authorities of the granting of a shareholder loan to France Télécom, and the participation by the State in the recapitalisation of France Télécom.
- (81) As regards the first measure, Cégétel remarks that the situation of a company with a private reference shareholder and that of a company with a public majority shareholder are not comparable. Cégétel explained that a similar announcement made by a private shareholder would have been received with the greatest circumspection by the rating agencies. Cégétel concludes from this that the mere fact of being backed by the State confers a considerable

advantage vis-à-vis investors and prevented any further downgrading of France Télécom's credit rating by the rating agencies despite the fact that the operator appeared to be in an insoluble situation. Cégétel maintains that the French State granted aid to France Télécom even before an agreement for the granting of a EUR 9 billion credit line was signed as the announcement of support was sufficient to render this emergency financing unnecessary. Lenders were thus certain that France Télécom could never default on its payments inasmuch as the State would always be ready to grant it the funds it needed to honour its commitments, and this enabled France Télécom to obtain financing directly on the market. France Télécom has therefore received advantages which it would not have secured under normal market conditions. The recourse to the bond market enabled it to avoid having to resort exclusively to financial institutions in order to cope with its liquidity crisis and suffering all the constraints linked to that type of financing. Cégétel maintains that the terms of grant of the credit line by the French authorities are not in keeping with those that a prudent investor holding such investments would require.

3.7. Comments from LDCOM ⁽²¹⁾

- (82) LDCOM identifies a dual mechanism of aid in support of France Télécom, backed by support for staff mobility, the provision of an unlimited guarantee and the granting of a EUR 9 billion credit line.
- (83) Concerning the provision of the unlimited guarantee, LDCOM bases its considerations on the content of the declarations by the French authorities which have appeared since July 2002, which seek to reassure the financial markets about France Télécom's situation. These declarations contributed directly to the improvement in France Télécom's credit rating in the markets and helped the Company to face up to the liquidity wall with which it was confronted. According to LDCOM, under French law, an oral declaration may, under certain conditions, constitute a legal act giving rise to a right on the part of its addressee.
- (84) LDCOM states that the announcement of the making available of a EUR 9 billion credit line constitutes aid; both from the point of view of its amount and of that of its modalities or its very objective, the State's support is not covered by the prudent investor criterion. Thus, no prudent investor would, in September 2002 (when the State announced that it would be supporting France Télécom financially), have advanced EUR 9 billion under such economic circumstances without basing itself on a restructuring plan.
- (85) In LDCOM's opinion, the State's position that a prudent majority investor would not have called into question France Télécom's functional integrity does not stand up to an analysis of the conduct of such an investor under the market conditions prevailing in June-July 2002. Thus, investors who invest an extremely large proportion of their assets in a company threatened with collapse will be the first to demand a radical and immediate review of its strategy, involving, if necessary, a huge sell-off of strategic assets.
- (86) LDCOM also stresses that the State cannot go back on its declarations without harming its own financial credibility. In its intervention on the market, the State plays a role of borrower and a role of majority shareholder in a number of companies. This dual role leads to a dual credit rating by the rating agencies, in its capacity as borrower and in its capacity as shareholder through the ratings given to public undertakings. This twofold intervention possibility calls for particular vigilance as any deficiency established in either of these two roles is likely to have consequences for its other role and for its rating. LDCOM further stresses the fact that the credibility of the State is fundamentally different from that of other enterprises in a similar situation which cannot reassure the market. The taking into account of the support given by the State following its entering into direct contact with the rating agencies highlights the credibility of the State's support for France Télécom.

3.8. Comments from Tiscalinet

- (87) Tiscalinet adds that the declarations made by the State as from 2 July 2002 signal to the market that any compulsory administration of France Télécom is ruled out. At the same time, the State's option for its 2002 dividends to be paid in shares and not in cash is another signal by the State to the market that it supports France Télécom even though a prudent investor would have opted for payment of the dividends in cash.

⁽²¹⁾ Now known as Neuf Télécom.

- (88) Tiscalinet also stresses that the set of legislative measures aimed at extending ERAP's company objects so as to enable it to hold France Télécom shares ⁽²²⁾, the provision of a state guarantee to ERAP to enable it to invest in France Télécom ⁽²³⁾ and the instrument dealing with the method by which the State would hold France Télécom's capital strengthen the analysis of the irrevocable character of the state guarantee on which market operators, and in particular bond holders, relied when subscribing to the successive calls made by France Télécom. These factors bear out that the State is acting as a 'last resort' vis-à-vis France Télécom, which a prudent investor would not have done.

3.9. Comments from ECTA

- (89) The European Telecoms Association (ECTA) is of the opinion that the ministerial declarations of July and October 2002, the granting of a EUR 9 billion credit line and the advance commitment by the State to take part in the future capital increase constitute State aid. The aid granted to France Télécom enabled it to continue as an integrated operator while increasing its stake in Orange. ECTA is of the opinion that a company in France Télécom's situation ought to have acted altogether differently, as did France Télécom's competitors in the global telecommunications services market, such as British Telecom and KPN, which had to dispose of strategic assets to reduce their debt.

3.10. Comments from France Télécom

- (90) France Télécom has presented its comments in the form of three reports: (i) a report drawn up by Mr Ehlermann dated 12 January 2004 entitled 'Opinion for the attention of France Télécom'; (ii) a report drawn up by Mr Galmot dated 6 January 2004 entitled 'Does the case law of the Court of Justice of the Communities allow the conclusion to be drawn that the "financial measures introduced by the State in support of France Télécom", regarding which the Commission has initiated the procedure provided for in Article 88(2) of the Treaty, have effected a "transfer of state resources" for the benefit of that company?'; and (iii) a report by HSBC entitled: 'HSBC Opinion of 6 January 2004'.
- (91) The first report analyses the French authorities' conduct in the light of the rules applicable to State aid in general and of the prudent investor test in particular. The report also seeks to show that France Télécom was not a company in financial difficulties within the meaning of the Guidelines at the time the State decided to take part in the recapitalisation and announced its readiness to provide a shareholder loan. It stresses that it is normal and usual for the majority shareholder to grant a loan upfront of its participation in the recapitalisation.
- (92) The second report focuses on whether the mere announcement of the making available of a shareholder loan in the form of a credit line can as such constitute a commitment of state resources. According to the report, there is no transfer of state resources because, in the end, there was no opening of a credit line or provision of a guarantee, which would have required authorisation by a finance act. There is likewise no transfer of state resources because, under French law, no oral declaration by a public authority is capable of having any effect whatever on the public finances and of carrying out the slightest transfer of state resources. And in the present case, all that is involved is mere ministerial declarations having no negative impact on the public finances.
- (93) The third report focuses on the economic rationale behind the State's conduct between 4 September 2002 (the announcement of the first six months' results) and 15 April 2003 (the carrying out of the capital increase). The report is based on an analysis of France Télécom's situation in September 2002 and draws a distinction between, on the one hand, France Télécom's operational performance (healthy activities with a potential for improving the operational cash flow) and, on the other, the amount of the operator's debt. The report concludes on this point that the time lag between the generation of the group's cash flow and the heavy short-term financial commitments (2003-2005) poses a problem of refinancing but not of solvency.
- (94) HSBC also describes the background to the short-term liquidity crisis, worsened as it was by a crisis of confidence on the part of the market vis-à-vis the group. It states that, in a situation such as that, reason demanded that urgent steps be taken and required the introduction of a plan to improve the operational results, an increase in capital, a rescheduling of debt and a targeted policy of disposing of assets. It argues that, in the present case, the Ambition 2005 plan is a complete and rational coherent plan as it permits among other things the generation of a EUR 15 billion cash flow via an operational improvement and a disposal of assets that does not involve any amputation of core businesses. It stresses that a capital increase in support of a company introducing an operational recovery plan is a natural way of rebalancing the accounts. It points out that the oral

⁽²²⁾ Decree No 2002-1409 of 2 December 2002 amending Decree No 65-1117 of 17 December 1967 organising ERAP administratively and financially.

⁽²³⁾ Article 80 of Law No 2002-1576 of 30 December 2002 rectifying the 2002 Finance Act.

support of a majority shareholder is also usual and rational and that it is normal practice for reference shareholders to announce their decision before other shareholders do. It also points out that in this case the shareholder loan was a low-risk, profitable and normal transaction — pending a capital increase — aimed at safeguarding the majority shareholder's financial interests at a time (the month of December) when it was not possible to recapitalise the company for reasons of scheduling. It adds that the loan was to be made on market conditions.

- (95) The HSBC report mentions also the trend in the price of France Télécom shares on the stock exchange, pointing out that the shares had risen in July 2002 as a result of rumours of nationalisation, only to fall again in September because, although the market had got wind of a possible EUR 15 billion capital increase, the practical arrangements were not as yet clear. It points out that France Télécom's financial projections presage, for the State, a highly satisfactory return: according to the DCF — discounted cash flow — method, the recapitalisation involves an annual rate of return of 25 %, whereas the average rate on the telecommunications market is 9,9 %.
- (96) In response to the dispatch of the NERA report, France Télécom notes that the conditions required for the State's responsibility to be incurred for non-compliance with its promise are not met in the present case. In no way does the mere act of making a promise, even to pay certain sums of money, suffice in itself to commit public finances, to 'immobilise state resources', without a legal instrument. It concludes on this point that there is nothing in French case law to show that there has been a 'transfer of state resources' in the present case due to the conditional promise of a shareholder loan.
- (97) According to France Télécom, the State has not placed any credit line at France Télécom's disposal through ERAP. Declarations are not legally binding on the State, either vis-à-vis France Télécom or vis-à-vis third parties. The State, however, cannot commit itself without an act giving rise to a right, carried out in compliance with the rules on competence and on budgetary procedure.
- (98) France Télécom emphasises more particularly the context in which the declarations were made, pointing out that this is necessary in order to measure their true scope. An analysis of the declarations in the light of events between late June and December 2002 thus shows that the declarations could not constitute a promise, and does not show that the appropriate measures planned by the State were financial measures. There were differences of opinion within the Government at the time and the Minister for Economic Affairs and Finance did not represent the Government standpoint. A study of the facts reveals that there was no such intention on the part of those responsible, who were at a loss how to solve the problem, and that operators had never said they believed the State had committed itself to one or other solution.
- (99) France Télécom concludes by saying that the consultant's conclusions are wrong because:
- 'Analysis of the France Télécom group's situation at the time of the announcement of the results for the first half of 2002 shows that the group has an unbalanced balance sheet and a short-term liquidity problem, but the business's operating results are very good.
 - Analysis of the range of measures a prudent shareholder must envisage in a situation of heavy indebtedness indicates that it was rational to introduce a recovery plan, including a recapitalisation, for a group with healthy assets whose intrinsic worth is greater than the sum of its market capitalisation and its net debt.
 - Analysis of value creation and profitability prospects suggest that the State is making a very good investment by participating in a capital increase and that it is taking little risk in providing a shareholder loan'.

4. COMMENTS BY FRANCE

- (100) The French authorities state by way of introduction that they have behaved in accordance with the prudent private investor principle from the outset. Since the announcement of France Télécom's results for the first half of 2002, which highlighted an unbalanced financial structure and significant capital needs despite good operating results, the State has drawn the necessary conclusions, placing a new CEO at the head of the Company and gathering together a banking syndicate which undertook from September 2002 to underwrite a capital increase when the time came. At the same time, the State asked the new management to carry out an in-depth audit of the Company. On the basis of the Ambition 2005 plan, about which the majority shareholder was kept regularly informed, and of the banking syndicate's commitment, the State announced, on 4 December 2002, its decision to

participate in the strengthening of the Company's capital base to the tune of EUR 9 billion and the fact that it was prepared to place at France Télécom's disposal, through ERAP, an advance on this subscription remunerated at market rates. However, in view of the financial terms of grant of this advance by the French authorities and of the Commission's misgivings about the presence of aid elements in the measure, France Télécom preferred to resort directly to the bond market.

4.1. France Télécom's financial situation

- (101) The French authorities maintain that, when the decision to invest was taken, France Télécom was not a firm in difficulty within the meaning of the Guidelines ⁽²⁴⁾. The Company's turnover was increasing steadily (by 10 % between the first half of 2001 and the first half of 2002), and its gross cash flow was high and growing faster than its turnover. The French authorities refer to the Company's unbalanced financial structure as at 30 June 2002 and point out that the losses were mainly due to the exceptional provisions and write-downs linked to the depreciation of assets acquired prior to the entirely unforeseeable reversal of the markets. France Télécom's operating costs were increasing more slowly than its turnover, which meant that its profitability was improving. Moreover, operating results and cash flow were increasing (with cash flow up 15 % on the first half of 2001). France Télécom's very good performance prospects were further improved by the TOP plan. This performance was confirmed when the 2002 accounts were published, showing as they did the virtuous dynamic triggered within the Company by the new management.
- (102) On the criterion concerning the movement in company capital referred to in point 5(a) of the Guidelines, the French authorities point out that the relevant indicator is, pursuant to Article L225-248 of the Commercial Code, the company capital of France Télécom SA, which has always remained positive and has never fallen by half. France Télécom was therefore not in the situation referred to in the Guidelines in which shareholders' funds fall below the company capital.
- (103) France Télécom was not in a cessation of payments situation; there were merely signs of a possible liquidity requirement by the first half of 2003 should the expected market recovery not occur. The French authorities add that France Télécom had anticipated reserves of EUR 6,9 billion as at 31 December 2002 and could have crossed the threshold of the year 2003 without resorting to the financial market. The French authorities indicated that France Télécom had had recourse to the syndicated loan, which was less expensive than the bond market and out of which EUR 4 billion had been made available to the Company.
- (104) The French authorities observe, inter alia, that France Télécom had access to the financial markets during the course of 2002 and describe all of the financing instruments at the Company's disposal between 11 July 2002 and 15 January 2003 ⁽²⁵⁾. They mention the fact that, on 14 February 2002, France Télécom negotiated the provision of a syndicated credit line of EUR 15 billion and that during the course of 2002 the Company issued bonds ⁽²⁶⁾, EUR 442,2 million worth of which was repayable in shares.
- (105) The French authorities also state that France Télécom was not open to any financial risk owing to the downgrading of its credit rating by the rating agencies as there was no early repayment clause in the covenants.
- (106) Moreover, according to the concordant opinion of several banks consulted between June and November 2002, France Télécom was, prior to the announcement of the Ambition 2005 plan and of the majority shareholder's support, able to refinance itself on the bond markets. The French authorities thus indicate that, in July and September 2002 respectively, Barclays and Dresdner Kleinwort Wasserstein offered to refinance, through swap programmes starting in October or November, France Télécom's bond debts maturing between 2003 and 2005.

4.2. Rationality of the TOP plan

- (107) The French authorities stress that, in the light of the above, the increase in the cash flow and the strengthening of the capital base provided for in the Ambition 2005 plan are components of a strategy that would have been followed by any prudent majority shareholder.

⁽²⁴⁾ Community guidelines on State aid for rescuing and restructuring firms in difficulty (OJ C 244, 1.10.2004, p. 2).

⁽²⁵⁾ The French authorities mention, among other things, bond issues, credit lines, treasury bills, short-term loans and securitisation and derivatives operations.

⁽²⁶⁾ From 26 July 2002 until the presentation of the Ambition 2005 plan on 4 December 2002, France Télécom made a EUR 70 million bond issue on 26 July 2002 and issued a fungible tranche of EUR 150 million with the EUR 3,5 billion debenture loan issued in March 2001.

- (108) As to the rationality of the TOP plan, the French authorities state that the plan in question represents a considerable effort on France Télécom's part. It is an overall plan for a change of management direction based on specific actions which has already produced its first positive results. The French authorities stress in this connection that the plan is an extremely precise one which makes possible an increase in the Company's profitability with a rate of return on investment (RRI) of 43 % in 2005 for those investors who participated in the April 2003 capital increase, that is, a much higher return than the reference RRI (11 %) expected by a private investor in the telecommunications sector. The TOP plan also includes a staff management optimisation chapter. As to the disposal plan, the French authorities state that the disposal of assets at the end of 2002 made it possible to carry forward any liquidity constraint to the end of 2003 without even having to resort to the financial markets.
- (109) The French authorities stress, lastly, that the strategies followed by competing operators are no more prudent and that a plan must be assessed, not in the light of the scope or strategic character of the assets whose disposal is being contemplated, but in that of the rationality of the plan as a whole. Moreover, the success of the December 2002 and January 2003 bond issues confirmed *a posteriori* the confidence private investors place in France Télécom's operational potential.

4.3. Application of the prudent investor principle to the participation in the strengthening of the Company's capital base

- (110) With regard to the application of the prudent private investor principle to the announcement by the State of its anticipated participation in the strengthening of the Company's capital base, the French authorities observe that they made their agreement conditional on the presentation, by the new management, of a new, credible rebalancing plan and on participation by the banks.
- (111) On compliance with the concomitance principle, the French authorities point out that, from the outset, the State shareholder took every step to ensure the concomitant participation of public and private shareholders and that it took no risk before private investors did. Thus, the announcement of the State's intention to participate in the strengthening of the Company's capital base dates from 12 September 2002, and on that date a banking syndicate had already undertaken to underwrite, when the time came, that part of a capital increase which was intended for private investors alongside the public shareholder, on condition that a credible rebalancing plan was announced to the market. The French authorities stress that this condition was normal in view of France Télécom's unbalanced financial situation, the State's participation also being conditional on the announcement of a plan considered by the market to be credible. If the private investors had not stood as guarantors, the State would not have made such an announcement.
- (112) The French authorities also state that the private financing predated the public financing inasmuch as the financial contributions by private investors — in the form of debenture loans and the rescheduling of bank loans between December 2002 and February 2003 — took place in significant proportions. The analysis of any making available of state funds must, in the French authorities' view, be carried out in the light of such private financing.
- (113) The French authorities stress that, in accordance with the judgment in *Alitalia* ⁽²⁷⁾, the State did not commit itself formally prior to the banks' formal undertaking. The private shareholder participation is significant at 40 %.
- (114) As regards the expected return, the French authorities state that, as has already been indicated, compliance with the prudent private investor principle is also demonstrated by the high profitability prospects of the TOP plan, as confirmed by the plan's favourable reception by the market.
- (115) The French authorities stress that the capital increase was effected as soon as it was technically possible to present to the State and to investors updated data on the Company's operational prospects, which demonstrates the State's choice of high-quality investors motivated by long-term return prospects.

4.4. The shareholder loan

- (116) The French authorities maintain that the loan proposal was never signed by France Télécom owing to the excessive cost of the financial terms proposed to it and the fact that the Commission was raising doubts about the measure's lawfulness under the Treaty. Consequently, no state resources were placed at the Company's disposal via the shareholder loan proposal. The French authorities argue that the entry into force of the loan

⁽²⁷⁾ Judgment of the Court of First Instance of 12 December 2000, *Alitalia v Commission*, T-296/97, ECLI:EU:T:2000:289.

cannot be deduced from the announcement made by the State on 4 December 2002, which concerns only the commitment by the State shareholder to participate in the operation to strengthen the Company's capital base, mention being made only of the 'possible' provision of a shareholder loan.

- (117) The French authorities observe that, at all events, the loan proposal conferred no advantage on France Télécom.
- (118) The French authorities thus make clear that, insofar as it has not entered into force, the loan has not been used by France Télécom and therefore has not been able to postpone the Company's liquidity needs. They maintain that the loan announcement does not constitute a guarantee. French law does not recognise an implicit guarantee: any guarantee provided by the State must be enshrined in a law. It is wrong to treat the announcement of a possible state loan as a guarantee. The French authorities insist that the guarantee which the State provided to ERAP to enable it to finance its participation in the strengthening of France Télécom's capital base must not be equated with a guarantee given to France Télécom. As far as ERAP is concerned, the French authorities state categorically that its role was entirely neutral and that it intervened only for budgetary reasons.
- (119) Likewise, the announcement by the State of a loan proposal did not facilitate France Télécom's access to the bond market. First of all, the debenture loans are not covered by any sort of guarantee, their duration being longer than that of the shareholder loan. Moreover, bondholders have no recourse in the event of non-payment upon maturity. Secondly, it is not possible to compare the announcement, by the State, of the possibility of its making an upfront prepayment towards the strengthening of the Company's capital base with the guarantee given in Commission Decision 2001/89/EC ⁽²⁸⁾ (Crédit Foncier de France) because, inasmuch as the loan envisaged in the present case was hypothetical and strictly limited in duration and amount, it could not by itself resolve the Company's financial problems having regard to its debt repayment schedule. Thirdly, the bond issues were determined solely by the market's perception of France Télécom's capacity to honour its commitments unaided by any state guarantee. The confidence shown by the market at the time of the said bond issues is thus due essentially to the change in the management team and the favourable reception accorded to the new strategy revealed when the Ambition 2005 plan was presented.
- (120) As to compliance with the prudent investor principle in relation to any shareholder loan, the French authorities stress that, when the decision to take part in a capital increase was taken and the conditions therefor were met, it was logical that the State should make an upfront prepayment. The first discussions about the loan proposal date back to November 2002. The French authorities also stress that the legitimacy of such a measure could not be challenged because, as is mentioned above, it was based on a credible, detailed plan the content of which was mostly known at the time of the announcement of the loan proposal on 4 December 2002. Moreover, the State had already received the undertaking, conditional on the presentation to the market of a credible plan, from the banking syndicate and it knew full well at the end of November that that condition would be met given the market's positive reaction to the appointment of the new management. The French authorities stress in this connection that it is not pertinent to assess the amount involved in the present case but that, in accordance with the Alitalia judgment, it is necessary to examine the conformity of the conditions of financing the operation for a company of comparable size.
- (121) As to the remuneration of the potential loan, the French authorities stress that it was granted on normal market terms and that it was increased by a premium to reflect its subordinate nature. The proposal provided for a non-utilisation commission and the absence of security was in keeping with the practice of a prudent investor in the case of a short-term loan granted by a shareholder upfront of his subscription to a capital increase. The repayment of the sum in shares was customary and was based on the cash value.

4.5. The announcements made by the State

- (122) The French authorities stress the context which must be taken into account when analysing the declarations made by the State in its capacity as a prudent shareholder. Thus, between the months of September and December 2002, the State engineered a change in management, the key feature of which was the change in France Télécom's CEO, and closely monitored the drafting of a rebalancing plan while at the same time ensuring the support of private investors with an eye to the launch of a possible capital increase. According to the French authorities, these operational measures had a decisive financial impact, were very well received by the financial markets and led to the recovery in France Télécom's share price.

⁽²⁸⁾ Commission Decision 2001/89/EC of 23 June 1999 conditionally approving aid granted by France to Crédit Foncier de France (OJ L 34, 3.2.2001, p. 36).

- (123) The French authorities stress that the State never indicated or suggested that it would give France Télécom its unconditional and unlimited support. They add that ‘the State ... emphasised in the summer that it would act like a prudent private shareholder and not as a public authority and that it intended to intervene as a shareholder in a way (still to be defined) which would be no different from that which a private investor would choose, which necessarily ruled out the possibility that the State had already decided to intervene in an unconditional and irrevocable manner’ ⁽²⁹⁾. This declaration that the conditions would not differ from those of a private investor, excludes de facto any unconditional and irrevocable support. The French authorities also argue that the declarations made by the French authorities between July and October 2002 constituted ‘vague prior declarations’ without any ‘corresponding practical measures’ ⁽³⁰⁾. The French authorities state in this connection that the subsequent declarations were to be assessed in the light of the first declaration and that it is wrong to assert that as of 12 July 2002 the State had ‘committed itself irrevocably to supporting France Télécom’ and had, on that occasion, entered into ‘an irrevocable commitment to participate in the strengthening of the capital base’. The French authorities point out that the State shareholder announced its intention to participate in the strengthening of the Company’s capital base for the first time in September 2002 and that ‘this would take the form of a transaction followed by the market (reference to a timetable to be defined in the light of market conditions)’ ⁽³¹⁾.
- (124) Concerning the declaration of 2 October 2002, the French authorities argue that this confirmed that the presentation of a credible plan was a precondition for the State’s participation.
- (125) The French authorities maintain that ‘the only specific measures envisaged by the State in its capacity as majority shareholder in France Télécom are those set out in the information/notification dossier forwarded to the Commission and announced publicly on 5 December 2002, namely the participation alongside private shareholders in a EUR 15 billion capital increase in proportion to the share held by the State in France Télécom’s capital and a possible shareholder loan remunerated at market rates upfront of the capital increase. The indication by the State that it would play its role of prudent shareholder in no way constitutes a state guarantee. If the declarations made by the State between July and October 2002 had really been legally equivalent to, or even simply perceived by the market and the rating agencies as being, a promise to provide France Télécom with an “unlimited guarantee”, then there would not have been any downgrading of France Télécom’s rating in July and the company’s spreads and rating during that period would have reflected the state risk (AAA rating and very low spread). Lastly, any factoring in by the rating agencies of the State’s presence as majority shareholder irrespective of any implicit or explicit guarantee or of any specific measure and irrespective of the company’s specific financial situation at any given moment cannot in itself be considered State aid. Such an approach would be contrary to the principle of neutrality of Community law as recognised by Article 295 of the EC Treaty.’ ⁽³²⁾

4.6. Movements in France Télécom’s share price

- (126) The French authorities argue that only the operational measures had an impact on France Télécom’s share price. Thus, the Company’s share price rebounded on 2 October 2002 (up more than 10,4 % on the previous week) following the announcement of the appointment of the new CEO, and the share price’s progress continued upwards with the announcement of the TOP plan and of the new executive board on 5 December 2002, which led to a rise of more than 25 % in two days. The declarations of principle made by the State between July and October 2002 were not the determining factor in this increase and as long as there were no operational measures the share price fluctuated, reflecting the market’s uncertainty about the Company’s situation. This perception led to a fall in the share price, which reached its lowest point on 30 September 2002 following a period of relative stability during the summer in the absence of any specific announcements or rumours. During that period, the State’s declarations as to its intention to play fully its role of shareholder did not stop the downward trend in France Télécom’s share price.

4.7. Comments on the NERA report

- (127) The French authorities have presented the following comments on the legal part of the NERA report:

— ‘the legal report is based on an erroneous (not to say tendentious) interpretation of the facts. In particular, ... the report manifestly twists — albeit clear — remarks made by the Minister for Economic Affairs in the course of an interview with a journalist published in July 2002. The French authorities strongly contest that it is possible to propose interpretations as unfounded as these in order to draw legal conclusions and in

⁽²⁹⁾ French authorities’ comments of 29 July 2003, p. 8.

⁽³⁰⁾ French authorities’ comments of 29 July 2003, p. 9.

⁽³¹⁾ French authorities’ comments of 29 July 2003, p. 8.

⁽³²⁾ French authorities’ comments of 29 July 2003, p. 9.

particular to assert that there exists any guarantee granted by the State to France Télécom'. 'What is involved here is not even an official communiqué from the Government or from France Télécom, but merely a press article reproducing the text of an interview with the Minister for Economic Affairs in the wider context of the Government's priorities and therefore lacking any probative force'.

- 'The State as shareholder in France Télécom has not only always intended to behave like a prudent investor with regard to France Télécom but has also chosen to express clearly and publicly that this position would be the point of departure for all of its potential actions in this area ...'. The Minister's July 2002 interview makes no mention of any decision being taken. '... [W]hile remaining confident in the company's viability, the State was merely taking note of the market's doubts about France Télécom's situation and, in its capacity as majority shareholder, was trying to refine its analysis without being able, at that stage, to make an accurate diagnosis or take any decision'. 'Moreover, there was no reason to suppose *a priori* that the phrase "appropriate steps" referred specifically to financial measures'.
- 'The French authorities have also noted numerous inaccuracies in the reasoning set out in the legal report. The report is thus manifestly short on objectivity, adopting highly contestable legal analyses (for example regarding the characterisation of letters of intent and the scope of a unilateral commitment in civil and commercial law) and making an unjustified application to the facts at issue of certain irrelevant legal precepts (this is the case, for example, with the application of the theory of business management or of the rules of public international law in relations between a company and its majority shareholder)'.
- 'The legal report's finding of the existence of an "unlimited guarantee", granted by the State to France Télécom, is in any event totally baseless in Community law'. In accordance with the *Compagnie nationale Air France* judgment ⁽³³⁾, the remarks in question cannot give rise to any firm and unconditional commitment on the part of the State.
- With regard to the comparison between the Minister's July declarations and a letter of intent, the French authorities stress that '(i) firstly, it is of the essence of the letter of intent that it is addressed to a beneficiary; (ii) secondly, and as an extension of the preceding observation, the effectiveness of the method is dependent on acceptance by the said beneficiary; and (iii), lastly, the scope of the commitment given (both as regards its object and as regards the force which its author wishes to give to it) depends exclusively on the terms employed'. 'Thus ... the general — to say the least — character of the Minister's remarks ... rules out without doubt any commitment in favour of France Télécom or its creditors, and *a fortiori* any obligation as to the result to be achieved (and hence any idea of guarantee) as well as any obligation as to the means'. 'The Minister's reply ... only confirms that no decision — other than to act like a "prudent investor" — had as yet been taken by the State shareholder, which, while trusting in the operational quality of the company, was not at that time able to make a sufficiently accurate diagnosis or to take any decision'. 'The courts have ... never held that a guarantee commitment without a specific beneficiary or beneficiaries may thus be relied upon by any person who might have an interest therein. This is not surprising as it is in the nature of a guarantee or of a letter of intent that it is addressed to one or more beneficiaries. Nor is it surprising, since it was not intended for any specific beneficiary, that the alleged commitment was not accepted'. As for the business management hypothesis, this concept is entirely inapplicable to the present case.
- As far as administrative law is concerned, '[f]irst of all, mere remarks made to a journalist — such as those made by the Minister for Economic Affairs on 12 July 2002 — do not constitute a "tortious act" capable of giving rise to rights and obligations, and even less a guarantee granted to France Télécom by the State'.
- 'The legal consultant's conclusions clearly fly in the face of the Commission's decision-making practice and of Community case law in the field of State aid, which make the existence of aid conditional on proof of a firm, precise and unconditional commitment on the part of the State concerned — something which the Minister's remarks of 12 July 2002 could in no way be construed as being'. 'A state measure, in whatever form, must be sufficiently precise and concrete for the Commission to be able to determine the very existence of an advantage'.

- (128) As regards the economic report, the French authorities argue that France Télécom was not a firm in difficulty at the time of the events in question (as it had access to the capital markets and no long-term viability problem) and that the participation by the State shareholder in the plan to rebalance the company's balance sheet was in keeping with the private investor criterion.

⁽³³⁾ Judgment of the Court of First Instance of 12 December 1996, *Compagnie nationale Air France v Commission*, T-358/94, ECLI:EU:T:1996:194; see also Commission Decision 94/662/EC of 27 July 1994 concerning the subscription by CDC participations to bonds issued by Air France (OJ L 258, 6.10.1994, p. 26).

5. ASSESSMENT OF THE MEASURE IN THE LIGHT OF ARTICLE 107(1) OF THE TREATY

- (129) Article 107(1) TFEU defines as being incompatible with the internal market, in so far as it affects trade between Member States, aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods. According to well established case law, the concept of aid embraces not only subsidies themselves, but also interventions which, in various forms, mitigate the charges which are normally included in the budget of an undertaking and which, without therefore being subsidies in the strict meaning of the word, are similar in character and have the same effect ⁽³⁴⁾. It follows from the above that the concept of aid is based on the economic concept of advantage, the formal criterion being therefore immaterial ⁽³⁵⁾.
- (130) It is settled case law that classification as State aid for the purposes of Article 107(1) TFEU requires that all the conditions set out are fulfilled ⁽³⁶⁾. Thus, for a national measure to be classified as 'State aid' for the purposes of Article 107(1) TFEU, first, there must be an intervention by the State or through State resources; second, that intervention must be liable to affect trade between Member States; third, it must confer a selective advantage on the recipient; and fourth, it must distort or threaten to distort competition ⁽³⁷⁾.
- (131) It is also settled case law that investment by the public authorities in the capital of undertakings, in whatever form, may constitute State aid within the meaning of Article 107 TFEU where the conditions set out in that Article are fulfilled ⁽³⁸⁾.
- (132) As regards the condition according to which the measure in question must be analysed as conferring an advantage on the recipient within the meaning of Article 107(1) TFEU, measures which, whatever their form, are likely directly or indirectly to favour certain undertakings or are to be regarded as an economic advantage which the recipient undertaking would not have obtained under normal market conditions are regarded as State aid ⁽³⁹⁾.
- (133) In the present case, it seems appropriate to examine, first, whether France Télécom obtained an advantage financed using state resources. If the Commission cannot conclude that such an advantage exists, or if it was not financed by state resources, it must conclude that the measure scrutinised does not constitute State aid, the conditions for the existence of State aid being cumulative.
- (134) First, it is worth recalling the principles that apply to this analysis, as laid down in the *Bouygues* judgment. The Court considered that:

'103. ... it cannot be excluded ... that several consecutive measures of State intervention must, for the purposes of Article 107(1) TFEU, be regarded as a single intervention.

104. That could be the case in particular where consecutive interventions, especially having regard to their chronology, their purpose and the circumstances of the undertaking at the time of those interventions, are so closely linked to each other that they are inseparable from one another ...

⁽³⁴⁾ Judgment of the Court of 15 March 1994, *Banco Exterior de España SA*, C-387/92, ECLI:EU:C:1994:100, paragraph 13; judgment of the Court of 19 September 2000, *Federal Republic of Germany v Commission*, C-156/98, ECLI:EU:C:2000:467, paragraph 25; judgment of the Court of First Instance of 13 June 2000, *EPAC v Commission*, T-204/97 and T-270/97, ECLI:EU:T:2000:148.

⁽³⁵⁾ Judgment of the Court of 14 November 1984, *SA Intermills v Commission*, C-323/82, ECLI:EU:C:1984:345, paragraph 31; Judgment of the Court of First Instance of 27 January 1998, *Ladbroke Racing Ltd v Commission*, T-67/94, ECLI:EU:T:1998:7, paragraph 52.

⁽³⁶⁾ Judgment of the Court of 2 September 2010, *European Commission v Deutsche Post AG*, C-399/08 P, ECLI:EU:C:2010:481, paragraph 38 and case law cited; judgment of the Court of 21 December 2016, *European Commission v Hansestadt Lübeck*, C-524/14 P, ECLI:EU:C:2016:971, paragraph 40; judgment of the Court of 21 December 2016, *European Commission v World Duty Free Group SA and Others*, C-20/15 P and C-21/15 P, ECLI:EU:C:2016:981, paragraph 53; judgment of the Court of 20 September 2017, *European Commission v Frucona Košice a.s.*, C-300/16 P, ECLI:EU:C:2017:706, paragraph 19.

⁽³⁷⁾ Judgment of the Court of 2 September 2010, *European Commission v Deutsche Post AG*, C-399/08 P, ECLI:EU:C:2010:481, paragraph 39 and case law cited; judgment of the Court of 21 December 2016, *European Commission v Hansestadt Lübeck*, C-524/14 P, ECLI:EU:C:2016:971, paragraph 40; judgment of the Court of 21 December 2016, *European Commission v World Duty Free Group SA and Others*, C-20/15 P and C-21/15 P, ECLI:EU:C:2016:981, paragraph 53; judgment of the Court of 20 September 2017, *European Commission v Frucona Košice a.s.*, C-300/16 P, ECLI:EU:C:2017:706, paragraph 19.

⁽³⁸⁾ Judgment of the Court of 14 September 1994, *Spain v Commission*, C-278/92 to C-280/92, ECLI:EU:C:1994:325, paragraph 20 and case law cited, and Judgment of the Court of 8 May 2003, *Italy and SIM 2 Multimedia v Commission*, C-399/00 and C-328/99, EU:C:2003:252, paragraph 36 and case law cited.

⁽³⁹⁾ Judgment of the Court of 2 September 2010, *European Commission v Deutsche Post AG*, C-399/08 P, ECLI:EU:C:2010:481, paragraph 40 and case law cited.

105. It follows that, having found that it was necessary to identify a reduction of the State budget or a sufficiently concrete economic risk of burdens on that budget, closely linked and corresponding to, or having as a counterpart, a specific advantage deriving either from the announcement of 4 December 2002 or from the shareholder loan offer, the General Court erred in law by applying a test that immediately excludes those State interventions, depending on their links with one another and their effects, from being regarded as a single intervention.
 106. Next, according to the case law of the Court, State intervention capable of both placing the undertakings which it applies to in a more favourable position than others and creating a sufficiently concrete risk of imposing an additional burden on the State in the future, may place a burden on the resources of the State ...
 107. In particular, the Court of Justice has had occasion to state that advantages given in the form of a State guarantee can entail an additional burden on the State ...
 108. Furthermore, the Court has already held that, where, in economic terms, the alteration of the market conditions which gives rise to an advantage given indirectly to certain undertakings is the consequence of the public authorities' loss of revenue, even the fact that investors then take independent decisions does not mean that the connection between the loss of revenue and the advantage given to the undertakings in question has been eliminated ...
 109. Consequently, for the purposes of establishing the existence of State aid, the Commission must establish a sufficiently direct link between, on the one hand, the advantage given to the beneficiary and, on the other, a reduction of the State budget or a sufficiently concrete economic risk of burdens on that budget ...
 110. However ... it is not necessary that such a reduction, or even such a risk, should correspond or be equivalent to that advantage, or that the advantage has as its counterpoint such a reduction or such a risk, or that it is of the same nature as the commitment of State resources from which it derives.'
- (135) As regards the interpretation and scope of the decision to open the formal investigation procedure relating to the measure at issue, the *Bouygues* judgment notes that this opening decision solely concerns the measures notified and not 'whether the declarations from July 2002 constituted, in themselves, State aid' ⁽⁴⁰⁾. This final decision, whose subject matter is defined by the opening decision, does not therefore extend to that question.
- (136) As a further preliminary point, the Commission notes that the assessments of fact or of law adopted by the General Court in its judgment of 2 July 2015 ⁽⁴¹⁾, in the light of the judgment on appeal of 30 November 2016 issued by the Court of Justice ⁽⁴²⁾, have the force of *res judicata*, particularly as they form the grounds supporting its operative part.

5.1. The measures taken by France between July and October 2002 had a significant effect on the market

- (137) The declarations from July 2002 allowed FT's rating to be maintained at investment grade and enabled the financial markets to regain confidence. They made it possible, easier and cheaper for FT to gain access to new loans necessary to refinance its short-term debts for the amount of EUR 15 billion, and ultimately helped to stabilise its fragile financial situation which, in June and July 2002, was on the point of deteriorating substantially.
- (138) During the first half of 2002, France Télécom saw its credit rating downgraded following the publication of its 2001 annual accounts. On 24 June 2002, Moody's downgraded the Company's rating to the lowest investment grade, just above that of junk bond, thereby making it very difficult for it to refinance its debt ⁽⁴³⁾.

⁽⁴⁰⁾ See paragraphs 70 to 72 of the *Bouygues* judgment.

⁽⁴¹⁾ Judgment of the General Court of 2 July 2015, *French Republic* (T-425/04 RENV) and *Orange* (T-444/04 RENV) v *European Commission*, ECLI:EU:T:2015:450.

⁽⁴²⁾ Judgment of the Court of 30 November 2016, *European Commission v French Republic*, C-486/15 P, ECLI:EU:C:2016:912.

⁽⁴³⁾ See statements by France Télécom's previous CEO, Michel Bon, appearing in the press: article in *La Tribune* dated 16 September 2002, '... the downgrading is preventing the planned refinancing'; article in *Le Monde* dated 16 September 2002, 'the downgrading at the end of June of the rating attributed to FT's debt by the Moody's rating agency ... has denied us access to the market'; article in the *Financial Times* dated 16 September 2002, 'FT cannot continue to survive when no one wants to lend us money and, on the contrary, when everyone wants to be paid on the nail. In the current markets, the refinancing of our debt is simply out of the question'.

This downgrading caused considerable concern on the financial markets about France Télécom's financial situation (and in particular about its capacity to refinance its EUR 15 billion debt falling due at the end of 2003), and the markets expected a reaction from the State designed to reassure them. These circumstances show that the State had to act urgently to reassure the market and to prevent any further downgrading of France Télécom's credit rating to that of junk bond status, as this would have had a highly negative impact ⁽⁴⁴⁾ on the Company's financial situation.

- (139) The State thus retained this trust through successive declarations. In fact, the State's intervention had the effect of preventing any downgrading of France Télécom's credit rating to that of junk bond status, as is, moreover, clearly stated in S&P's press release of 12 July 2002, where the assurances provided by the State are hailed as being a key factor in France Télécom's not being reduced to junk bond status.
- (140) As to the market's reaction, the announcement of 12 July 2002 led to an abnormal and not negligible increase in the value of France Télécom's shares and bonds. Thus, compared with a set of telecom indexes representative of the market, France Télécom's share price rose by between 37,8 % and 43,8 %. The abnormal increase in bond prices amounted, for its part, to between 3,2 % and 9,7 %. This reaction implies that the market believed that, by the announcement, the State was committing itself to offering France Télécom greater support ⁽⁴⁵⁾. As to the comments by financial analysts, Deutsche Bank, for example, mentioned in a report published on 22 July 2002 that the market was convinced, in the light of the Government's declarations, of the state support that would be provided by the Government to France Télécom, even if the market did query the scope and modalities of that support ⁽⁴⁶⁾. Similarly, S&P considered the Government's declarations to be credible to the point of influencing the Company's credit rating. On 12 July, S&P thus downgraded France Télécom's rating to BBB- but maintained its investment-grade rating with a stable outlook ⁽⁴⁷⁾. The fact that the State's support was credible to the point of enabling France Télécom's credit rating to remain at investment-grade quality is also corroborated by France Télécom itself ⁽⁴⁸⁾.
- (141) The declarations had a major impact on the market. A study of the comments and documents submitted by the French authorities and of the available parliamentary debates shows that the State's declarations helped to restore the financial markets' confidence ⁽⁴⁹⁾. In fact, ever since S&P's press release of 12 July 2002, the rating agencies were all agreed that the support shown by the State since July 2002 was decisive in maintaining France Télécom's investment-grade credit quality. The maintenance of France Télécom's investment-grade credit quality thus enabled France Télécom to avoid additional financial costs ⁽⁵⁰⁾ on the funds it had already borrowed owing to the existence of step-up clauses ⁽⁵¹⁾ in some bond issues and on future borrowings. The maintenance of the investment-grade rating enabled France Télécom, moreover, to put its finances back on to a sound footing through a recapitalisation operation. Back in September 2002, one of the conditions imposed by the banks for their participation in a recapitalisation operation was 'the maintenance of at least the current ratings investment-grade quality of the company's long-term debt by the Moody's and Standard & Poor's rating agencies; this condition will be included in the guarantee and investment contract.' ⁽⁵²⁾

⁽⁴⁴⁾ Some even take the view that the Company would not have been able to find the necessary liquidity on the market in the event of a downgrading of its credit rating. See, for example, page 9 of the abovementioned report by Goldman Sachs of 22 July 2002: 'If these bonds moved from the investment grade segment of the fixed income market, to "junk", i.e. high yield, they would swamp the current European high yield market ... [and] we believe it would be difficult for the existing European investor base alone to absorb all France Telecom bonds.'

⁽⁴⁵⁾ NERA report: 'The results of an event study analysing the effect on share and bond prices of the announcement on 12 July 2002. The study shows that there is a strong positive effect: as a result of the statement, market participants believed the cash flows that France Télécom would generate were going to be higher than they would have been otherwise. Moreover the effect is strongly statistically significant: it is not the result of random fluctuations in prices ... The market believed that, as a result of the statement, the French Authorities would offer more support to France Télécom than they would do in the absence of any costs of non-performance'.

⁽⁴⁶⁾ Deutsche Bank report of 22 July 2002 entitled *France Télécom/Deutsche Telekom Debt Liquidity and possible solution*, pp. 19-33.

⁽⁴⁷⁾ *France Télécom LT Rating cut to 'BBB-'; Off Watch; Outlook Stable; Teleconf 3:30PM BST Today*, Standard & Poor's Ratings Direct, 12 July 2002.

⁽⁴⁸⁾ *Board meeting presentation*, France Télécom stock-taking exercise, December 2002, p. 36.

⁽⁴⁹⁾ In a covering letter accompanying the financial protocol signed by the bank Morgan Stanley on 12 September 2002 concerning the bank's commitment in relation to the Company's planned capital increase, the bank's representative is unambiguous on this point: 'We feel that the planned transaction would be difficult under present conditions and that a favourable reaction by the markets to the declarations and official statements to be published at the end of the week will be a key factor in creating the necessary conditions for carrying out the transaction.'

⁽⁵⁰⁾ See FT form 20-F, March 2003, P15-16 'a decrease of one notch in its long-term debt rating by S&P's and Moody's would automatically increase its annual interest expense by approximately EUR 75 million'.

⁽⁵¹⁾ A step-up clause determines an increase in a bond's coupon rate and in the interest rates on credit lines as the credit rating declines.

⁽⁵²⁾ Memoranda of understanding signed on 11 and 12 September 2002 between the State and the banks (condition h).

5.2. Nevertheless, they are not inextricably linked to the December 2002 measures

- (142) Following a sovereign assessment of the facts, the General Court held that the shareholder loan offer granted by the State to France Telecom came only in December 2002, that the French Government had made no firm commitment in July 2002, and that the decision to provide France Télécom with financial support through the shareholder loan offer had been taken not in July 2002 but in early December 2002 ⁽⁵³⁾.
- (143) The General Court also concluded that, between the months of July and December 2002, a private investor might have displayed behaviour similar to that displayed by the French State ⁽⁵⁴⁾.
- (144) It further emerges from the General Court's findings and assessments, in paragraphs 249 to 254 of the judgment of 2 July 2015 ⁽⁵⁵⁾, that there was a significant break in the series of State measures taken by France for France Télécom between the months of July 2002 and December 2002.
- (145) In addition, at paragraph 230 of that judgment, the General Court noted 'a number of relevant factors which effectively determined the French State's decision in December 2002, that is, in addition to restoring the confidence of the financial markets and preserving FT's credit rating, primarily the restructuring and rebalancing measures taken within FT, including the Ambition 2005 plan drawn up by its new management between October and December 2002, which provided in particular for the implementation of a plan, "the TOP plan".' It also considered as 'key factors' in the case 'the commitment given in September 2002 by a banking syndicate to underwrite that part of an increase in the capital of FT which was intended for private investors, the sale by FT of some EUR 2,5 billion in non-strategic assets between July and December 2002, the appointment of a new management team for the company in October 2002, and the resolution in November 2002 of the dispute between FT and the German operator Mobilcom. Taken as a whole, those factors brought about a marked improvement in FT's operational prospects and performance during the second half of 2002.'
- (146) In paragraph 143 of the judgment on the appeal of 30 November 2016 ⁽⁵⁶⁾, the Court found that 'as rightly held by the General Court in paragraph 230 of the judgment under appeal, deciding in advance in July 2002 the time when the prudent private investor criterion fell to be assessed would have necessarily excluded from that assessment relevant factors that occurred between July 2002 and December 2002.'
- (147) Consequently, in view of the particular circumstances of the case, there is no inextricable link between the measures that the French authorities took prior to December 2002 and the measures that they took in December 2002. It is necessary therefore to examine whether, between 4 December 2002 (when the State announced its shareholder loan to France Télécom) and 20 December 2002 (when the State sent France Télécom a signed and initialled draft shareholder loan agreement), the conditions for State aid were met, and in particular, whether the State acted in the same way as a prudent private investor in a market economy.

5.3. The measures taken by France in December 2002 fulfilled the private investor criterion

- (148) The December 2002 shareholder loan appears to confer an advantage on France Télécom, since it enables it to increase its means of financing and to reassure the market as to its ability to meet its maturities. Even if the loan agreement has never been signed, the appearance given to the market of the existence of such a loan is, *a priori*, likely to confer an advantage on France Télécom as the market has considered the Company's financial situation to be more secure ⁽⁵⁷⁾. This may have influenced France Télécom's borrowing terms. The advantageous effect of the measures taken by the State in December 2002 in favour of France Télécom is thus apparent.

⁽⁵³⁾ Judgment of the Court of 30 November 2016, *European Commission v French Republic and Orange*, C-486/15 P, ECLI:EU:C:2016:912, paragraph 142 and paragraphs of the judgment of the General Court of 2 July 2015, *French Republic and Orange v European Commission*, T-425/04 RENV and T-444/04 RENV, ECLI:EU:T:2015:450, to which it refers.

⁽⁵⁴⁾ Judgment of the Court of 30 November 2016, *European Commission v French Republic and Orange*, C-486/15 P, ECLI:EU:C:2016:912, paragraph 137 and paragraphs of the judgment of the General Court of 2 July 2015, *French Republic and Orange v European Commission*, T-425/04 RENV and T-444/04 RENV, ECLI:EU:T:2015:450, paragraph 247.

⁽⁵⁵⁾ Judgment of the General Court of 2 July 2015, *French Republic (T-425/04 RENV) and Orange (T-444/04 RENV) v European Commission*, ECLI:EU:T:2015:450.

⁽⁵⁶⁾ Judgment of the Court of 30 November 2016, *European Commission v French Republic*, C-486/15 P, ECLI:EU:C:2016:912.

⁽⁵⁷⁾ See, for example, 'Moody's now expects that a combination of this facility headroom under the existing EUR 15 billion syndicated facility and the free cash flow will enable debt maturities of EUR 15 billion to be repaid during the next 12 months', Moody's, 9 December 2002.

- (149) However, a measure is not deemed to constitute an advantage and so does not qualify as State aid if the recipient undertaking could, in circumstances which correspond to normal market conditions, obtain the same advantage as that which is made available to it through State resources. In the case of public undertakings, that assessment is made by applying, in principle, the prudent private operator test.
- (150) In the present case, it is necessary to determine whether, in similar circumstances, in December 2002, a private investor of a comparable dimension could have been prevailed upon to make capital contributions of the same size, having regard in particular to the information available and foreseeable developments at the date of those contributions ⁽⁵⁸⁾. The prudent private investor criterion must therefore be applied when the State financial support measure that may be characterised as State aid is adopted, ⁽⁵⁹⁾ that is between 4 December 2002 and 20 December 2002.
- (151) The announcement of 4 December 2002 and the shareholder loan offer of 20 December 2002 must be jointly examined ⁽⁶⁰⁾.
- (152) In December 2002, it appeared that the confidence of the financial markets in France Télécom's future had been largely restored and that France Télécom's credit rating had been preserved, mainly as a result of the restructuring and rebalancing measures taken within FT, including the appointment of new management and their development of the Ambition 2005 plan between October and December 2002, which included the implementation of a plan, the 'TOP plan', to improve the Company's operational performance.
- (153) In assessing the shareholder loan, it is important to determine whether the participation in the strengthening of the Company's capital base satisfies normal market conditions.

5.3.1. *Participation in the strengthening of the Company's capital base*

- (154) France's participation in the strengthening of the Company's capital base was conditional on the presentation to the market of a credible plan for the restructuring of France Télécom. The Ambition 2005 plan and the TOP plan together form a complete and rational coherent plan. It permits among other things the generation of a EUR 15 billion cash flow via an operational improvement and a disposal of assets that does not involve any amputation of core businesses.
- (155) The TOP plan represents a considerable effort on France Télécom's part. It is an overall plan for a change of management direction based on specific actions. The French authorities stress that the plan makes possible an increase in the Company's profitability with a rate of return on investment (RRI) of 43 % in 2005 for those investors who participated in the April 2003 capital increase, that is, a much higher return than the reference RRI (11 %) expected by a private investor in the telecommunications sector. The TOP plan also includes a staff management optimisation chapter.
- (156) As regards the expected return, the French authorities state that compliance with the prudent private investor principle is also demonstrated by the high profitability prospects of the TOP plan, as confirmed by the plan's favourable reception by the market. France Télécom's share price rebounded on 2 October 2002 (up more than 10,4 % on the previous week) following the announcement of the appointment of the new CEO, and the share price's progress continued upwards with the announcement of the TOP plan and of the new executive board on 5 December 2002, which led to a rise of more than 25 % in two days.
- (157) The capital increase was initiated as soon as it was technically possible to present to investors updated data on France Télécom's operational prospects.
- (158) The State had already received the undertaking, conditional on the presentation to the market of a credible plan, from the banking syndicate and it knew full well at the end of November that that condition would be met given the market's positive reaction to the appointment of the new management. In addition to the commitment given in September 2002 by the banking syndicate to underwrite that part of an increase in the capital of FT which was intended for private investors, consideration must be given to other key factors, namely the sale by FT of some EUR 2,5 billion in non-strategic assets between July and December 2002, the appointment of a new

⁽⁵⁸⁾ Judgment of the General Court of 2 July 2015, *French Republic* (T-425/04 RENV) and *Orange* (T-444/04 RENV) v *European Commission*, ECLI:EU:T:2015:450, paragraph 220; Judgment of the Court of 8 May 2003, *Italian Republic and SIM 2 Multimedia SpA v Commission of the European Communities*, C-399/00 and C-328/99, ECLI:EU:C:2003:252, paragraph 38 and case law cited.

⁽⁵⁹⁾ Judgment of the General Court of 2 July 2015, *French Republic* (T-425/04 RENV) and *Orange* (T-444/04 RENV) v *European Commission*, ECLI:EU:T:2015:450, paragraph 251.

⁽⁶⁰⁾ Judgment of the Court of Justice of 19 March 2013, *Bouygues SA and Bouygues Télécom SA v European Commission and Others* and *European Commission v French Republic and Others*, C-399/10 P and C-401/10 P, ECLI:EU:C:2013:175, paragraphs 127 to 131.

management team for the company in October 2002, and the resolution in November 2002 of the dispute between FT and the German operator Mobilcom ⁽⁶¹⁾. Taken as a whole, those factors brought about a marked improvement in FT's operational prospects and performance during the second half of 2002.

- (159) When the decision to invest was taken, France Télécom was not a firm in difficulty within the meaning of the Guidelines. The Company's turnover was increasing steadily (by 10 % between the first half of 2001 and the first half of 2002), and its gross cash flow was high and growing faster than its turnover. The French authorities point out that the losses were mainly due to the exceptional provisions and write-downs linked to the depreciation of assets acquired prior to the entirely unforeseeable reversal of the markets. France Télécom's operating costs were increasing more slowly than its turnover, which meant that its profitability was improving. Moreover, operating results and cash flow were increasing (with cash flow up 15 % on the first half of 2001). This performance was confirmed when the 2002 accounts were published. Furthermore, France Télécom was not in a cessation of payments situation.
- (160) France Télécom had access to the financial markets during the course of 2002, and all of the financing instruments were at the Company's disposal between 11 July 2002 and 15 January 2003 ⁽⁶²⁾. The French authorities mention the fact that, on 14 February 2002, France Télécom negotiated the provision of a syndicated credit line of EUR 15 billion and that during the course of 2002 the Company issued bonds ⁽⁶³⁾, EUR 442,2 million worth of which was repayable in shares.
- (161) Market confidence in a recovery of France Télécom's financial situation may also be based on the fact that the losses were mainly due to the exceptional provisions and write-downs linked to the depreciation of assets acquired prior to the entirely unforeseeable reversal of the markets and that France Télécom's operating costs were increasing more slowly than its turnover. Moreover, operating results and cash flow were increasing.
- (162) The State shareholder took every step to ensure the participation of public and private shareholders in the strengthening of France Télécom's capital base. Thus, the announcement of the State's intention to participate in the strengthening of the Company's capital base dates from 12 September 2002 ⁽⁶⁴⁾, and on that date the banking syndicate had already undertaken to underwrite, when the time came, that part of a capital increase which was intended for private investors alongside the public shareholder, on condition that a credible rebalancing plan was announced to the market. According to the French authorities, the State's participation was also conditional on the announcement of a plan considered by the market to be credible, and the State did not commit itself formally prior to the banks' formal undertaking. The terms of the operation were the same for the public bodies and all the private operators participating in the strengthening of the Company's capital base.
- (163) In addition, the EUR 15 billion from the shareholders only represents a third of the funds mobilised in support of France Télécom's financial restructuring.

5.3.2. *The shareholder loan offer and its announcement on 4 December 2002*

- (164) On 4 December 2002, once the condition for the banking syndicate's commitment had been fulfilled — namely, the announcement to the market of a credible rebalancing plan — the State announced the shareholder loan to France Télécom.
- (165) In this situation, it would have been rational for a prudent private operator in similar circumstances to the State (France Télécom's majority shareholder) to express its oral support for France Télécom. The loan granted by the State, as majority shareholder, in view of the planned investment, was in this case a low-risk, profitable and normal transaction — pending a capital increase (on equal terms) — aimed at safeguarding the majority shareholder's financial interests at a time (the month of December) when it was not possible to recapitalise France Télécom for reasons of scheduling.

⁽⁶¹⁾ These factors are relevant according to the judgment of the General Court of 2 July 2015, *French Republic* (T-425/04 RENV) and *Orange* (T-444/04 RENV) v *European Commission*, ECLI:EU:T:2015:450, paragraph 230.

⁽⁶²⁾ The French authorities mention, among other things, bond issues, credit lines, treasury bills, short-term loans and securitisation and derivatives operations.

⁽⁶³⁾ From 26 July 2002 until the presentation of the *Ambition 2005* plan on 4 December 2002, France Télécom made a EUR 70 million bond issue on 26 July 2002 and issued a fungible tranche of EUR 150 million with the EUR 3,5 billion debenture loan issued in March 2001.

⁽⁶⁴⁾ French authorities' comments of 29 July 2003, p. 8.

- (166) Indeed, as France Télécom explains, the market window virtually closes at the end of November, since investors have to take into account their financial year-end on 31 December and major deals can be difficult to arrange. In addition, a minimum of 15 days' notice must be given before holding an extraordinary general meeting to approve a capital increase, which takes a further 30 days to complete.
- (167) The loan is temporary and provides bridging finance for the capital increase, which by many accounts is expected to be a success. France Télécom has cited several examples of shareholder loans dating from the time of the events as evidence that a loan from a majority shareholder to be converted into equity during a capital increase is standard practice.
- (168) For example, the EUR 1 billion shareholder loan from Italenergia Bis to Edison was converted into equity during Edison's capital increase in 2003.
- (169) In preparation for the restructuring and IPO of Thus on the London Stock Exchange, Scottish Power granted a loan of GBP 320 million, of which GBP 260 million was converted into equity; the undrawn balance was cancelled.
- (170) In 2002, America Movil and Bell Canada International participated in the financial restructuring of their South American joint venture Telecom Americas, alongside another investor. In this case, USD 120 million was paid in the form of a shareholder loan which had to be refinanced two years later in Telecom Americas shares.
- (171) During the Ericsson capital increase, the commitment of the main shareholder (*Industrivärden* and *Investor*) was announced by the company in April 2002, even though the deal was not approved until June 2002 and was not launched until August of that year.
- (172) In the case of Fiat's capital increase in July 2003, the intention of the reference shareholders to subscribe to new shares in proportion to their shareholding was published in March 2003.
- (173) In the light of these examples, and given France Télécom's position in December 2002, the Commission cannot rule out the possibility that in December 2002, the State acted towards France Télécom as a prudent private operator in a market economy would have done in similar circumstances, as France Télécom's majority shareholder.

5.3.3. Conclusion

- (174) The measure being scrutinised — namely, the announcement of the shareholder loan of 4 December 2002, coupled with the shareholder loan offer of 20 December 2002 — thus meets the criterion of the prudent private investor in a market economy. Therefore, this measure should not be considered as an advantage for France Télécom.

5.4. The further conditions laid down by Article 107(1) TFEU

- (175) It is settled case law that classification as State aid requires all the conditions set out in Article 107(1) TFEU to be fulfilled ⁽⁶⁵⁾. In the absence of an advantage for France Télécom from state resources within the meaning of Article 107(1) TFEU, it is no longer necessary to analyse whether the other conditions required for determining the presence of aid are fulfilled.

6. CONCLUSION

- (176) The Commission finds that the shareholder loan granted by France to France Télécom in December 2002 in the form of a EUR 9 billion credit line does not constitute State aid within the meaning of Article 107(1) TFEU,

HAS ADOPTED THIS DECISION:

Article 1

The shareholder loan granted by France to France Télécom in December 2002 in the form of a EUR 9 billion credit line does not constitute aid within the meaning of Article 107(1) of the Treaty on the Functioning of the European Union.

⁽⁶⁵⁾ Judgment of the Court, *European Commission v Deutsche Post AG*, C-399/08 P, ECLI:EU:C:2010:481, paragraph 38 and case law cited.

Article 2

This decision is addressed to the French Republic.

Done at Brussels, 18 May 2018.

For the Commission
Margrethe VESTAGER
Member of the Commission

COMMISSION DECISION (EU) 2018/1617**of 25 October 2018****concerning a measure adopted by France pursuant to Council Directive 93/42/EEC with regard to the Terrafor and Defiligne medical devices***(notified under document C(2018) 6943)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽¹⁾, and in particular Article 8(2) thereof,

Whereas:

1. PROCEDURE

- (1) On 16 August 2016, the French authorities adopted a decision based on the national provisions transposing Directive 93/42/EEC (hereinafter 'Directive 93/42/EEC' or 'the Directive') with regard to two medical devices with the same composition, the same route of administration and the same purposes, marketed under the names 'Terrafor' or 'Defiligne' (hereinafter 'the device'), and manufactured by the Claytone-Terrafor Laboratory (hereinafter 'the manufacturer').
- (2) The device in question takes the form of capsules administered orally, which, according to the instructions for use, 'prevent digestive problems, reduce digestive discomfort, restore digestive comfort and reduce abdominal circumference'. The substance used in manufacturing the device is Octalite, a mineral complex of natural origin (clay).
- (3) According to the decision taken by the French authorities, in view of the essential requirements of the Directive and given the presence of lead in the device, it may pose a risk to the health of users. As a consequence, the decision provides that 'the manufacture, placing on the market, distribution, export and use of the Terrafor and Defiligne medical devices [...] shall be suspended until the products have been brought into line with the legislative and regulatory provisions which apply to them'. Moreover, 'the Claytone-Terrafor laboratory is required to withdraw the Terrafor and Defiligne medical devices from all the distributors concerned'.
- (4) By letter of 4 October 2016, the French authorities notified the Commission of their decision of 16 August 2016 in the context of Directive 93/42/EEC.
- (5) As part of the consultations referred to in Article 8(2) of Directive 93/42/EEC, the Commission sent the manufacturer an email on 26 October 2016 asking it to state its position on the decision taken by the French authorities.
- (6) By letter of 30 November 2016, the manufacturer sent the Commission a memorandum setting out its reasons for contesting the decision taken by the French authorities.
- (7) On 19 December 2016, at the manufacturer's request, a meeting was held between the manufacturer and the Commission.
- (8) In the course of 2017, numerous e-mails were exchanged between the manufacturer and the Commission. In particular, the Commission asked the manufacturer several times to contact the French authorities in order to identify the information which would be necessary to allow the decision of those authorities to be lifted.
- (9) By email of 20 March 2017, the manufacturer sent the Commission a report from the NAMSA laboratory ⁽²⁾ which, according to the manufacturer, showed that the device was safe. The Commission asked the manufacturer several times to send that document to the French authorities. The manufacturer did so several months later, in August 2017. At the same time, the Commission exchanged e-mails with the French authorities in order to obtain further information.

⁽¹⁾ OJ L 169, 12.7.1993, p. 1.

⁽²⁾ This report is entitled 'Addendum to risk assessment No 164726 of 17 February 2017'.

- (10) In July 2017, the manufacturer submitted a complaint to the European Ombudsman concerning the Commission's delay in adopting a decision. On 5 April 2018, the Ombudsman decided to close the case, concluding that there had been no maladministration on the Commission's part in its handling of the case.
- (11) By email of 20 November 2017, the Belgian authorities notified the Commission of their decision of 28 October 2016 to prohibit the placing on the market, putting into service, distribution and importation of the Terrafor medical device, and to order the withdrawal of the device from the market.
- (12) On 7 February 2018, at the manufacturer's request, a meeting was held between the manufacturer, the French authorities, the Belgian authorities, the NAMSA laboratory and the Commission.
- (13) In March 2018, the Commission submitted additional written questions to the manufacturer, to its notified body (TÜV Rheinland LGA Products GmbH) and to the Belgian and French authorities. They replied to these questions during March and April 2018.

2. EXAMINATION OF THE JUSTIFICATION FOR THE MEASURE

- (14) Directive 93/42/EEC establishes a system under which medical devices must meet the essential requirements set out in Annex I to the Directive which apply to them (Article 3, first paragraph). In order to prove compliance with these essential requirements, the manufacturer must follow one of the conformity assessment procedures provided for in the Directive, which allows the CE marking to be affixed to the devices (Article 11 and Article 17(1)). Devices bearing the CE marking indicating that they have undergone a conformity assessment may move freely within the Union (Article 4(1)).
- (15) However, in accordance with Article 8 (safeguard clause) of Directive 93/42/EEC, 'where a Member State ascertains that the devices [...], when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision [...]' (Article 8(1)). The Commission must then determine whether the measures are justified or not (Article 8(2)). It is therefore for the Member States to determine whether a product is liable to compromise the health and safety of persons and, if so, to take the requisite measures. Such an exercise may entail complex technical and scientific assessments on the part of the national authorities. It is for the Commission to verify whether or not these measures are justified, and in particular to make sure that the legal and factual reasons for their adoption are valid. The Commission enjoys wide discretion in this context ⁽¹⁾.
- (16) In the present case, in the decision and note notified on 4 October 2016, the French authorities take the view that the devices in question 'may pose a risk to health' and 'do not comply with the essential requirements'. However, where there is a risk to the health and/or safety of persons, resulting in particular from failure to comply with the essential requirements referred to in Annex I to Directive 93/42/EEC, a safeguard clause procedure may be initiated under Article 8(1) of that Directive ⁽²⁾. It follows that, in the present case, the safeguard clause procedure applies, with the result that it is for the Commission to determine whether the measure taken by the French authorities is justified or not.
- (17) The decision taken by the French authorities makes provision for suspension of the 'manufacture, placing on the market, distribution, exportation and use' of the device and its withdrawal from the distributors concerned. As Directive 93/42/EEC essentially provides that medical devices may be placed on the market and/or put into service only if they meet the requirements of the Directive (Article 2) and that the Member States must not create any obstacle to the placing on the market and/or the putting into service of devices which, in order to prove compliance with the requirements, have been the subject of an assessment of their conformity in accordance with the Directive (Article 4) and as Article 8 of the Directive requires the Member State concerned, where there is

⁽¹⁾ See in particular, regarding the safeguard clause of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24), the judgment of the General Court of 15 July 2015, *CSF v Commission*, T-337/13, ECLI:EU:T:2015:502, paragraphs 46, 79 and 80.

⁽²⁾ See the judgment of the Court of 22 April 2015, *Klein v Commission*, C-120/14 P, ECLI:EU:C:2015:252, paragraph 71.

a risk to health or safety, to take measures 'to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service' and requires the Commission to verify whether such measures are justified, this Commission Decision relates to the measure taken by the French authorities to restrict the presence on the market of the device in question.

- (18) It is clear from the decision notified by the French authorities and from the consultations conducted with the interested parties that compliance with the essential requirements of the Directive concerning the risk/benefit ratio and minimising risk and the proper application of standards are being called into question.

2.1. Failure to comply with essential requirements

2.1.1. Essential requirements concerning the risk/benefit ratio

- (19) Section 1 of Annex I to Directive 93/42/EEC provides: 'The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety [...]'. Section 6 of Annex I to the Directive provides: 'Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended'.
- (20) As regards the risks, it should be pointed out at the outset that the risk caused by the ingestion of lead is widely documented, in particular in the publications cited by the 'Guideline for elemental impurities – Q3D' drawn up by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) ⁽¹⁾, in the 'Report on Carcinogens, fourteenth edition' of the U.S. Department of Health and Human Services, in the 'Scientific opinion on lead in food' of the European Food Safety Authority (EFSA) and in the publications cited by Commission Regulation (EC) No 1881/2006 ⁽²⁾. In the present case, the device contains lead and is intended to be ingested.
- (21) It should also be noted that the public is exposed to lead by many routes (air, water, food), with the result that any additional exposure, such as that caused by use of the device, increases the risk associated with exposure to lead.
- (22) Moreover, the French authorities refer to the 'Guideline for elemental impurities – Q3D' (hereinafter 'Guideline ICH Q3D'), drawn up by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), adopted by the European Medicines Agency (EMA) in December 2014 and applied by it to new applications for authorisation to place medicinal products on the market as of June 2016 and to existing authorisations for placing medicinal products on the market as of December 2017. This Guideline concerns elemental impurities in medicinal products, namely elements which do not provide any therapeutic benefit to the patient, with the result that their levels must remain within acceptable limits. It establishes a permitted daily exposure for elements of toxicological concern. For lead, the Guideline indicates that exposure to this element may cause neurological, reproductive, immune, cardiovascular and renal health effects; it establishes permitted daily exposure at 5 µg per day, irrespective of the route of administration.
- (23) The tests to which the French authorities refer show that the device contains levels of lead between 16 and 22,9 µg/g. A course of treatment involving six capsules of 335 mg per day (i.e. 2 g per day), as provided for in the instructions for use of the device, corresponds to an ingested amount of lead of between 32 and 46 µg per day, which is several times higher than the reference threshold of 5 µg per day.
- (24) With regard to use of Guideline ICH Q3D, it should be pointed out that this Guideline, while it applies formally to medicinal products, concerns the presence of elements (including lead) which do not provide any therapeutic benefit (elemental impurities) and which raise toxicological concerns in products administered orally, amongst other routes. It may therefore be considered relevant in assessing the risk associated with using a medical device which contains lead as an impurity and which is administered orally.

⁽¹⁾ Agency for Toxic Substances and Disease Registry, Public Health Service, U.S. Department of Health and Human Services, 'Toxicological profile for lead', 2007; National Toxicology Program, U.S. Department of Health and Human Services, 'Monograph on health effects of low-level lead', 2012.

⁽²⁾ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

- (25) Finally, it should be pointed out that the manufacturer does not contest the fact that the device contains lead. Nor does the manufacturer contest the fact that lead is released by the device, albeit to a minor extent. Moreover, the manufacturer indicates that the risks identified by the reports cited by the French authorities — namely cardiovascular, neurological and nephrotoxic effects of lead in humans — were taken into account through the indications in the instructions for use of the device, in such a way that the essential requirement of Section 1 of Annex I to the Directive has been met; the manufacturer therefore acknowledges that use of the device poses risks, albeit at an acceptable level. In addition, a report from the NAMSA laboratory cited by the manufacturer acknowledges that there is a risk associated with the presence of lead in the device, while describing this risk as low.
- (26) It follows from the above that use of the device poses a risk to the health or safety of patients which the manufacturer is responsible for keeping within acceptable limits in relation to the benefits provided by the device.
- (27) As regards the benefits, according to the instructions for use, the device is intended to 'prevent digestive problems, reduce digestive discomfort, restore digestive comfort and reduce abdominal circumference'. It should be pointed out that, in accordance with Article 1(2) of the Directive, a medical device is assumed to have a medical purpose. In the present case, it would seem that among the four claims made in the instructions for use, only the one relating to 'preventing digestive problems' could possibly be described as being medical in nature. In the absence of details in the instructions for use or technical documentation and in view of the other claims and the advertising for the device focusing on obtaining a 'flat stomach', it is fair to assume that the digestive problems in question are nothing out of the ordinary. All in all, the device appears to be of little benefit in medical terms.
- (28) In view of this, the French authorities were able to conclude that the device does not comply with the essential requirements of the Directive with regard to the risk/benefit ratio.
- (29) This conclusion is confirmed by the failure to comply with the essential requirement concerning clinical evaluation. Section 6a of Annex I to Directive 93/42/EEC provides: 'Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X'. Section 1.1 of Annex X (clinical evaluation) to the Directive provides: 'As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data'.
- (30) In the present case, as regards the benefits, the device is intended to 'prevent digestive problems, reduce digestive discomfort, restore digestive comfort and reduce abdominal circumference', as indicated above. However, the conclusions of the clinical evaluation report prepared by the NAMSA laboratory at the manufacturer's request ⁽¹⁾, and based on all the data available, state that three clinical claims were examined ('reduces digestive discomfort, helps to reduce the circumference of the waist, allows digestive comfort to be rapidly improved') and that only the two claims associated with reducing digestive discomfort and reducing the circumference of the waist are considered to be backed up by clinical data. The fourth claim associated with preventing digestive problems is not mentioned in the conclusions of this clinical assessment report. The manufacturer therefore did not provide clinical data to support the existence of all the beneficial effects claimed and in particular the existence of a beneficial effect in terms of preventing digestive problems. The assessment of the clinical data therefore does not confirm that the device complies with the essential requirement relating to the risk/benefit ratio.
- (31) In view of this, it was possible to conclude that the device does not comply with the essential requirement relating to the clinical evaluation, in connection with the essential requirement relating to the risk/benefit ratio.

2.1.2. *Essential requirements relating to minimising risk*

- (32) Section 7.2 of Annex I to Directive 93/42/EEC provides: 'The devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure'. Section 7.5 of Annex I to the Directive provides: 'The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council

⁽¹⁾ This report is entitled 'Project 1 647 26 — Clinical evaluation report — Ventre plat devices — Version: V2 final May 24, 2016'.

Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [...]. Annex I to Council Directive 67/548/EEC ⁽¹⁾ has become Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽²⁾.

- (33) It follows from the above that use of the device poses a risk to the health or safety of patients (points 20-26), which it is the manufacturer's responsibility to reduce to a minimum. Moreover, lead is described as a substance toxic to reproduction in Part 3 of Annex VI to Regulation (EC) No 1272/2008; it is also considered to be a 'substance of very high concern' by the European Chemicals Agency (ECHA) ⁽³⁾, which justifies special attention being paid to it.
- (34) For the manufacturer of a medical device, the above-mentioned essential requirements may involve choosing batches of raw materials posing the least risk in terms of the toxic substances which they contain, i.e. verifying the concentration of a harmful substance in the batches of the raw material and selecting the batches showing a concentration which is compatible with the state of the art. In the present case, the raw material which forms part of the composition of the device, namely clay, contains harmful substances, in particular lead, in concentrations which may vary as it is a raw material of natural origin. The French authorities, like the Belgian authorities, have shown that there is a high degree of variation in the lead levels of different batches of capsules of the device. The manufacturer had the option of checking the lead content of the different batches of clay prior to manufacture and of selecting only those batches whose low lead content would have guaranteed that the capsules manufactured from this raw material contained a concentration lower than the threshold in Guideline ICH Q3D. However, under the contract between the manufacturer and its supplier, the batches of raw material were tested to determine their lead concentration and the manufacturer accepted batches whose lead concentration did not exceed 15 ppm, which equates to 15 µg/g. Given that a daily treatment of six capsules corresponds to 2 g, the quantity of lead ingested by patients could reach 30 µg per day, i.e. much more than the threshold of 5 µg per day. The manufacturer has therefore not reduced as far as possible the risk associated with the presence of lead in the device by selecting batches of raw material which would have made it possible to manufacture a device containing a level of lead below the threshold set by Guideline ICH Q3D.
- (35) The above-mentioned essential requirements may also lead the manufacturer of a device to select, from different raw materials, the one which poses the fewest risks as regards the toxic substances which it contains. Indeed, Section 7.1 of Annex I to the Directive provides that 'particular attention must be paid to the choice of materials used, particularly as regards toxicity [...]'. In the present case, other raw materials — such as, for example, activated charcoal, simeticone or dimeticone — have properties similar to clay and are likely to achieve the medical purpose claimed by the manufacturer for its device, namely 'to prevent digestive problems'. These other raw materials are not known to contain lead and are therefore unlikely to pose the risks associated with the device in question. The manufacturer did not, however, try to find an alternative raw material uncontaminated with toxic substances (see its email of 30 March 2018). It has therefore not reduced as far as possible the risk associated with the presence of lead in the device in this way.
- (36) In view of this, the French authorities were able to conclude that the device did not comply with the essential requirements of the Directive with regard to minimising risk.

2.1.3. Objections raised by the manufacturer concerning failure to comply with essential requirements

- (37) The manufacturer calls into question the use of Guideline ICH Q3D. It argues in particular that the Guideline is not applicable *ratione materiae* — it applies to medicinal products — and *ratione temporis* — it applies to new applications for authorisation to place medicinal products on the market as of June 2016 and to existing authorisations to place medicinal products on the market as of December 2017 — and that its application runs counter to the principles of legality and legal certainty.
- (38) However, use of Guideline ICH Q3D is in keeping with Article 8(1) of the Directive, which requires a Member State to take certain interim measures if it notices that a medical device poses a risk to safety and/or health, and which does not limit the information which the Member State may draw on to show that such a risk exists. Moreover, for the reasons mentioned above (point (24), while being formally applicable to medicinal products, the Guideline is relevant in identifying the risk associated with the presence of lead in a medical device whose situation is similar to that of a medicinal product. It follows that use of the Guideline appears to have a legal basis and be predictable.

⁽¹⁾ OJ 196, 16.8.1967, p. 1.

⁽²⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1).

⁽³⁾ <https://echa.europa.eu/substance-information/-/substanceinfo/100.028.273>

- (39) The manufacturer calls into question the method used to evaluate the risk. It argues, in particular, that this method, based on the quantity of lead contained in the device, is not relevant in assessing compliance with the essential requirements which refer to substances released by a device and that it is not suitable for a device based on clay, which does not release its elements.
- (40) However, in the circumstances surrounding the present case, in the absence of an *in vivo* study making it possible to assess the quantity of lead actually released by the device, the method based on the quantity of the toxic substance contained in the device makes it possible to determine the quantity likely to be released into the body and thus to assess the risk posed by substances released by the device. It should also be pointed out, first, that the fact that the device releases a certain amount of lead is not disputed (as shown by tests carried out by the manufacturer itself) and, second, that while the manufacturer considers the amount of lead released to be small, the method used by the manufacturer to reach this conclusion is disputable (see points 47 et seq. below).
- (41) The manufacturer argues that even if Guideline ICH Q3D were used, the amount of lead released (which it assesses at 3,126 µg per day in its communication of 30 November 2016, and which is estimated at 3,96 µg per day in the report of February 2017 by the NAMS laboratory) would be below the threshold mentioned in Guideline ICH Q3D (which is 5 µg per day).
- (42) However, the method used by the manufacturer to determine the quantity of lead released by the device is disputable (see points 47 et seq. below) and therefore does not make it possible to tell whether the quantity determined using this method is so low that it does not pose a risk, taking into consideration Guideline ICH Q3D and other reference documents.
- (43) The manufacturer argues that the (cardiovascular, neurological and nephrotoxic) risks identified by the French authorities were taken into account through the indications the instructions for use of the device, with the result that the device complies with the essential requirement of Section 1 of Annex I to the Directive. It also argues that excessive exposure to lead may be avoided through measures taken by the manufacturer such as indications in the instructions for use, with the result that a measure taken by the authorities which, among other things, prohibits the device from being placed on the market and requires it to be withdrawn from the market, runs counter to the principle of proportionality.
- (44) However, the indications added to the instructions for use by the manufacturer restricting use of the device with regard to certain patients (children, pregnant women and individuals with kidney disease) do not eliminate the risk of lead poisoning for the population as a whole. An *in vivo* study showing that the quantity of lead actually released by the device is lower than the threshold indicated in the Guideline would help to eliminate the risk of excessive exposure to lead.
- (45) Article 8(1) of Directive 93/42/EEC takes the proportionality principle into account by providing that where a risk to the health and/or safety of persons is ascertained, appropriate interim measures must be taken to withdraw the devices in question from the market or prohibit or restrict their being placed on the market. It follows in the present case that where the French authorities show that a risk of this kind exists, a measure consisting in suspending the placing on the market of the device and withdrawing the device from the distributors until it is brought into line with the regulations is in keeping with Article 8(1) of the Directive and with the principle of proportionality.
- (46) In view of this, the objections raised by the manufacturer are not such as to call into question the French authorities' observation that the device does not comply with certain essential requirements of the Directive.

2.2. Incorrect application of standards

- (47) It follows from Article 8(1) of Directive 93/42/EEC that the risk requiring the Member States to take measures may result from the incorrect application of the standards referred to in Article 5 of the Directive which the manufacturer claims to have applied.
- (48) The manufacturer argues that the device was assessed and deemed compliant with certain harmonised standards concerning the biological evaluation of medical devices (in particular standards EN ISO 10993-1 2009/AC: 2010, EN ISO 10993-12 2012, EN ISO 10993-17 2009 and EN ISO 10993-18 2009), which correspond to certain essential requirements laid down in the Directive and a reference to which has been published in the *Official Journal of the European Union*, with the result that the device must be presumed to comply with the essential requirements in question.

- (49) These standards concerning the biological evaluation of medical devices provide in particular that the method used must reproduce the actual conditions of use of the medical device and that it may be necessary to conduct tests in addition to those described in the standards, as indicated by the provisions below.

- Standard EN ISO 10993-1 2010: biological evaluation of medical devices – evaluation and testing within a risk management process

The introduction to the standard states that ‘this approach combines the review and evaluation of existing data from all sources with, where necessary, the selection and application of additional tests, thus enabling a full evaluation to be made of the biological responses to each medical device, relevant to its safety in use’; that ‘biological testing is based upon, among other things, *in vitro* and *ex vivo* test methods and upon animal models’; that ‘it is not intended that ISO 10993 provide a rigid set of test methods, including pass/fail criteria’; that it must be used ‘taking into consideration all the factors relevant to the device, its intended use and the current knowledge of the medical device provided by review of the scientific literature and previous clinical experience’.

Point 4.4 of the standard states in particular that ‘the choice of tests and the data required in a biological evaluation, and their interpretation, shall take into account the chemical composition of the materials, including the conditions of exposure as well as the nature, degree, frequency and duration of exposure of the medical device or its constituents to the body, enabling the categorisation of devices to facilitate the selection of appropriate tests (...). The rigour necessary in the biological evaluation is principally determined by the nature, degree, duration and frequency of the exposure and the hazards identified for the material’.

Point 6.1 of the standard states in particular that ‘the results of the risk assessment can lead to the conclusion that additional material characterization is necessary, for example, where the margin of safety is not considered adequate if the entire amount of a particular chemical were to leach out. In such cases, appropriate extraction testing, simulating clinical exposure, can be used to estimate the degree of clinical exposure to the chemical constituent’.

Point 6.2.2 of the standard, concerning test descriptions, states in particular that ‘it is indispensable for testing that each device be considered on its own merits. Additional tests not indicated in the table [in Annex A] may be necessary’ (point 6.2.2.1), that ‘*in vivo* tests may be required to assess biodegradation of a material’ (point 6.2.2.13) and that ‘toxicokinetic studies shall be considered if (...) substantial quantities of potentially toxic or reactive degradation products and leachables are likely or known to be released from a medical device into the body during clinical use’ (6.2.2.14).

Annex A (informative) of the standard, which includes a table describing the biological evaluation tests to be taken into consideration with regard to the nature and duration of contact with the human body, does not explicitly cover ingestible medical devices. It states that ‘Table A.1 is a framework for the development of an assessment programme and is not a checklist’ and that ‘In addition to the framework set out in Table A.1, the following [i.e. the tests to be carried out] should be considered based on a risk assessment (...)’.

- Standard EN ISO 10993-12 2012: Biological evaluation of medical devices – Sample preparation and reference materials

Point 10.3.2 of the standard, which deals with extraction conditions and methods, indicates that it is necessary to ‘perform extraction using the appropriate extraction vehicle and time/temperature conditions to simulate exaggerated exposure wherever possible. Complete dissolution may be appropriate’.

Annex C (informative) of the standard, concerning the principles of test sample extraction, point C.1, indicates that ‘extraction conditions and application of the extract to test systems should therefore ideally reflect not only actual conditions of use of the products but also the purpose and predictability of the tests’ and that ‘biological tests are carried out to identify hazards and estimate the risks of the hazards occurring in exaggerated use and/or in actual conditions of use [...] exaggerated and exhaustive extraction is appropriate for hazard identification’.

- Standard EN ISO 10993-18 2009: Biological evaluation of medical devices – Chemical characterisation of materials

Point 5 of the standard states ‘However it is necessary to obtain information demonstrating the extent to which the constituents will be available under the actual conditions of use of the finished product to estimate the risk arising from them’.

- (50) In the present case it would appear that the manufacturer has used a testing method which does not reflect the actual conditions of use of the device. In particular, the method used to determine the quantity of lead released, which involves using an extraction volume of only 12 ml of water and using only acidified water without a bolus or an adequate (dynamic) environment, is not representative of the actual conditions of use of the device, namely ingestion with a greater quantity of liquid, the presence of a bolus and the progress of it all through the digestive tract. Moreover, it would appear that the manufacturer did not use another testing method, in particular tests in humans (*in vivo*), making it possible to determine the level of lead actually found in the bloodstream. It follows that the manufacturer does not show that the quantity of lead released is low and/or less than the reference threshold in Guideline ICH Q3D.
- (51) In view of this, it was possible to conclude that the standards referred to in Article 5 of the Directive, which the manufacturer claims to have applied, were incorrectly applied, with the result that the risk associated with the presence of lead in the device has not been ruled out.

2.3. Conclusion

- (52) Based on the information obtained from the decision notified by the French authorities, from the consultations conducted with the interested parties and in view of all the considerations above, the French authorities were able to conclude that the device may compromise the health and/or safety of persons and were thus able to adopt a provisional measure to ensure that the device is no longer placed on the market and is withdrawn from the market via the distributors,

HAS ADOPTED THIS DECISION:

Article 1

The measure adopted by the French authorities on 16 August 2016 regarding the Terrafor and Defiligne medical devices, in order to suspend their placing on the market and provide for the withdrawal of these devices from the market, is justified.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 25 October 2018.

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission

CORRIGENDA**Corrigendum to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007**

(Official Journal of the European Union L 150 of 14 June 2018)

On page 54, Article 54(2), first sentence:

- for:* 'The power to adopt delegated acts referred to in Article 2(6), Article 9(11), Article 10(5), Article 12(2), Article 13(3), Article 14(2), Article 15(2), Article 16(2), Article 17(2), Article 18(2), Article 19(2), Article 21(1), Article 22(1), Article 23(2), Article 24(6), Article 30(7), Article 32(4), Article 33(6), Article 34(8), Article 35(9), Article 36(3), Article 38(8), Article 40(11), Article 44(2), Article 46(7), Article 48(4), Article 53(2), (3) and (4), Article 57(3) and Article 58(2) shall be conferred on the Commission for a period of five years from 1 January 2021.'
- read:* 'The power to adopt delegated acts referred to in Article 2(6), Article 9(11), Article 10(5), Article 12(2), Article 13(3), Article 14(2), Article 15(2), Article 16(2), Article 17(2), Article 18(2), Article 19(2), Article 21(1), Article 22(1), Article 23(2), Article 24(6), Article 30(7), Article 32(4), Article 33(6), Article 34(8), Article 35(9), Article 36(3), Article 38(8), Article 40(11), Article 44(2), Article 46(7), Article 48(4), Article 53(2), (3) and (4), Article 57(3) and Article 58(2) shall be conferred on the Commission for a period of five years from 17 June 2018.'
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