#### Re:

APPLICATION for the suspension of operation of the decision of the Delegation of the European Union to Montenegro of 21 March 2011 rejecting the tender submitted by the applicant in the public procurement procedure EuropeAid/129435/C/SUP/ME-NP and containing the information that that contract had been awarded to another tenderer.

### Operative part of the order

- 1. The application for interim measures is dismissed.
- 2. The costs are reserved.

Order of the judge of the General Court hearing applications for interim measures of 3 October 2011 — Qualitest FZE v Council

(Case T-421/11 R)

(Application for interim measures — Common foreign and security policy — Restrictive measures adopted against Iran with the aim of preventing nuclear proliferation — Freezing of funds and economic resources — Application for suspension of operation of a measure — Lack of urgency)

(2011/C 347/63)

Language of the case: English

#### **Parties**

Applicant: Qualitest FZE (Dubai, United Arab Emirates) (represented by: M. Catrain González, lawyer, E. Wright and H. Zhu, Barristers)

Defendant: Council of the European Union (represented by: G. Marhic and R. Liudvinaviciute-Cordeiro, acting as Agents)

# Re:

Application for suspension of operation of Council Implementing Regulation (EU) No 503/2011 of 23 May 2011 implementing Regulation (EU) No 961/2010 on restrictive measures against Iran (OJ 2011 L 136, p. 26) and of Council Decision 2011/299/CFSP of 23 May 2011 amending Decision 2010/413/CFSP concerning restrictive measures against Iran (OJ 2011 L 136, p. 65), in so far as they concern the applicant.

#### Operative part of the order

- 1. The application for interim measures is dismissed.
- 2. The costs are reserved.

Order of the President of the General Court of 5 October 2011 — Computer Resources International (Luxembourg) v Commission

(Case T-422/11 R)

(Interim measures — Public procurement — Tendering procedure — Rejection of a tender — Application for suspension of operation of a measure — Loss of opportunity — Lack of serious and irreparable damage — Lack of urgency)

(2011/C 347/64)

Language of the case: English

#### **Parties**

Applicant: Computer Resources International (Luxembourg) SA (Dommeldange, Luxembourg) (represented by: S. Pappas, lawyer)

Defendant: European Commission (represented by: S. Delaude and D. Calciu, Agents, and by E. Petritsi, lawyer)

#### Re:

Application for suspension of operation of the decision of the Publications Office of the European Union of 22 July 2011 which, on the one hand, rejects the tenders submitted by the applicant in tendering procedure AO 10340 concerning the supply of computing services for software development, maintenance, consultancy and assistance for different types of IT applications (OJ 2011/S 66-106099) and, on the other, informs the applicant that the relevant framework contract has been awarded to other tenderers.

# Operative part of the order

- 1. The application for interim measures is dismissed.
- 2. Costs are reserved.

Action brought on 15 September 2011 — Klein v Commission

(Case T-309/10)

(2011/C 347/65)

Language of the case: German

#### **Parties**

Applicant: Christoph Klein (Großgmain, Austria) (represented by: D. Schneider-Addae-Mensah)

Defendant: European Commission

#### Form of order sought

- Declare that, by failing to take a decision in the safeguard clause procedure in progress since 1997 concerning the inhaler Broncho Air® and the effecto® and by not initiating a safeguard procedure pursuant to Article 8 of Directive 93/42/EEC following an order by Germany prohibiting distribution of the effecto®, the European Union, represented by the Commission, has failed to comply with its obligations under Directive 93/42/EEC and under general Community law and has thereby caused the applicant direct damage;
- Order the applicant to pay damages of an amount still to be calculated in respect of the damage caused to it by the European Union, represented by the Commission;
- Order the European Union, represented by the Commission, to pay the costs of the proceedings and the applicant's expenses.

#### Pleas in law and main arguments

The applicant claims compensation for the damage suffered by him as a result of the alleged failure by the Commission to take action in the safeguard clause procedure pursuant to Article 8 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. (1) The applicant developed an inhalation aid for asthma sufferers and persons suffering from COPD [chronic obstructive pulmonary disease], which in the view of the German authorities did not fulfil the basic requirements of Directive 93/42/EEC, because the applicant had in particular omitted to provide sufficient clinical data concerning the lack of danger presented by the inhaler. The applicant claims that the safeguard clause procedure opened by the Commission in 1997 pursuant to Article 8 of Council Directive 93/42/EEC in order to resolve that issue, following the first banning of the inhaler, was never concluded. Following the second ban in 2005 the Commission did not initiate another safeguard clause procedure, considering that the matter fell under Article 18 of Directive 93/42/EEC.

In support of the action, the applicant relies on three pleas in law

 First plea in law, alleging that the Commission failed to act insofar as it did not conclude the safeguard clause procedure initiated in 1997 and failed to initiate the stated safeguard clause procedure following the banning of the effecto® in 2005.

Owing to the lack of clarity of the legal situation in the absence of a decision by the Commission, the applicant and/or atmed AG, of whose board the applicant is the chairman, have been burdened with unnecessary costs in relation to legal proceedings and patents.

2. Second plea in law, complaining that the Commission failed to reach a positive conclusion in the safeguard clause procedure, having decided that the banning orders of the German authorities were unjustified.

The inhaler Broncho Air® and the effecto® are not dangerous; the burden of proof with regard to the dangerousness of the product rests however with the Member State, given the presumption of conformity of the medical device in question which bears the EC marking. The usefulness of the inhaler Broncho Air® and the effecto® have moreover been clearly established on the basis of the submission of sufficient clinical data. In the absence of a positive decision by the Commission, atmed AG — and therefore the applicant — have suffered substantial loss of revenue, leading to insolvency, and to a lapse of the patents and the exclusive marketing right.

Third plea in law, alleging that the applicant lacks sufficient information concerning the required documentation supposed to be forwarded, because the clinical data to be submitted were never clearly described.

(¹) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), in the version as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ 1993 L 284, p. 1).

# Action brought on 20 September 2011 — Rousse Industry v Commission

(Case T-489/11)

(2011/C 347/66)

Language of the case: Bulgarian

#### **Parties**

Applicant: Rousse Industry (Rousse, Bulgaria) (represented by: A. Angelov and S. Panov, lawyers)

Defendant: European Commission

# Re

Application for annulment of Articles 2, 3, 4 and 5 of the Commission decision of 13 July 2011 concerning State aid C 12/2010 and N 389/2009 granted by Bulgaria to Rousse Industry

# Form of order sought

- Annul Articles 2, 3, 4 and 5 of the Commission decision of
  13 July 2011 concerning State aid C 12/2010 and
  N 389/2009 granted by Bulgaria to Rousse Industry;
- Order the defendant to pay the costs.