DECISIONS

COMMISSION IMPLEMENTING DECISION

of 27 June 2012

concerning a financial contribution by the Union to Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom for studies on Schmallenberg virus

(notified under document C(2012) 4203)

(Only the Dutch, English, French, German, Italian and Spanish texts are authentic)

(2012/349/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field [1], and in particular Article 23 thereof,

Whereas:

(1) In accordance with Article 75 of the Financial Regulation and Article 90(1) of the Implementing Rules, the commitment of expenditure from the budget of the European Union shall be preceded by a financing decision setting out the essential elements of the action involving expenditure and adopted by the institution or the authorities to which powers have been delegated by the institution.

(2) Schmallenberg virus is an emerging contagious pathogen of ruminants putatively included in the Simbu serogroup of the *Bunyaviridae* family, genus *Orthobunyavirus*. Very little information is known on this emerging pathogen, most assumptions are extrapolated from scientific information available on other viruses of the Simbu serogroup.

(3) Only some *Orthobunyavirus* had been isolated in the Union (Tahyna virus from the California serogroup) but never from the Simbu serogroup. Schmallenberg virus was first detected in November 2011 in Germany in samples collected in the summer and autumn 2011 from diseased animals. In December 2011, congenital malformations were reported in newborn lambs in the Netherlands, linked to the presence of the virus. Subsequently up to March 2012, Belgium, Germany, United Kingdom, France, Luxembourg, Italy and Spain have reported stillbirth and congenital malformations. Schmallenberg virus presence was confirmed through the Polymerase Chain Reaction (PCR) tests.

(4) As this is the first time that this virus is isolated in the Union, there are no harmonised rules as regards control or notification of Schmallenberg virus.

(5) No efficient diagnostic tools are available to assess the actual spread of Schmallenberg virus and its impact on animal health.

(6) Several trading partners have taken temporary protective measures including trade restrictions and requested for additional guarantees for certain commodities awaiting for further scientific knowledge before resuming trade.

(7) On 23 January 2012, the Agriculture Council requested the Commission to take actions with respect to this emerging disease.

(8) In a meeting organised on 14 February 2012, the Commission in close collaboration with the Member States identified the priorities and areas for which additional information should be gathered prior to considering the development of veterinary legislation addressing this new infection. These are in particular, the mechanism by which the disease is caused (pathogenesis), the epidemiology, notably focusing on transmission pathways, the host range, the role of vectors and reservoirs; and the confirmation of the non-zoonotic potential of this virus and the methods to diagnose the disease in animal samples and their validation.

(9) Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom have drawn up scientific studies intended to gain knowledge on Schmallenberg virus in the areas identified above and submitted them to the Commission on 5 March 2012, requesting EU financial support.

[1] OJ L 155, 18.6.2009, p. 30.

(10) Some of the scientific studies have been presented by several Member States in the form of a consortium, in these cases and for the purpose of clarity, one of the partners has been identified as coordinator of the consortium and responsible for communication with the Commission and transmission of technical reports.

(11) Pursuant to Article 22 of Decision 2009/470/EC, the Union may undertake, or assist the Member States or international organisations in undertaking, the technical and scientific measures necessary for the development of EU veterinary legislation and for the development of veterinary education or training.

(12) A financial contribution should be granted to the studies on Schmallenberg virus implemented by Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom as the outcomes may lead to new insights on the subject mentioned above.

(13) The Commission has evaluated all the proposals and selected those that matched with the agreed priorities. Considering the resources needed to develop the studies and the need to start as soon as possible the activities in order to get the results, it is appropriate to start financing them as from 1 April 2012.

(14) Under Council Regulation (EC) No 1290/2005 of 21 June 2005 on the financing of the common agricultural policy [1], veterinary measures are to be financed under the European Agricultural Guarantee Fund. For financial control purposes, Articles 9, 36 and 37 of that Regulation are to apply.

(15) The payment of the financial contribution shall be subject to the condition that the studies planned have actually been carried out and that the authorities supply all the necessary information to the Commission.

(16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

1. The Union shall grant Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom financial assistance for their scientific studies on Schmallenberg virus, as summarised in Annex I. The present decision constitutes a financing decision in the meaning of Article 75 of the Financial Regulation.

2. The financial contribution by the Union

(a) shall be at the rate of 50 % of the eligible costs to be incurred by each Member State referred to in paragraph 1 for the studies listed in Annex I and in accordance with the budgets listed in Annex II, for the period 1 April 2012 to 31 December 2013;

(b) shall not exceed the following:

(i) EUR 438 615 for Belgium;

(ii) EUR 595 883 for Germany;

(iii) EUR 146 590 for Spain;

(iv) EUR 589 380 for France;

(v) EUR 124 120 for Italy;

(vi) EUR 639 342 for the Netherlands;

(vii) EUR 371 811 for the United Kingdom;

(c) Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom, or in cases when the scientific studies are carried out by more than one Member State in a consortium, the coordinator Member State as listed in Annex I, shall submit to the Commission:

— no later than 31 March 2013 an intermediate technical report per project,

— no later than 31 March 2014 a final technical report per project;

(d) Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom shall submit to the Commission:

— no later than 31 March 2014 a paper version and an electronic version of their financial report drawn up in accordance with Annex IV. The supporting documents, evidencing all the expenditure referred to in the application for reimbursement, shall be sent to the Commission on request;

(e) the outcome of the studies must be made available to the Commission, all Member States and EFSA and presented at the Standing Committee on the Food Chain and Animal Health.

Article 2

1. The maximum overall contribution authorised by this Decision for the costs incurred for the work referred to in Article 1(1) is set at EUR 2 905 741 to be financed from the following budgetary line of the general budget of the European Union for 2012:

— budgetary line No 17 04 02 01.

2. Expenditure relating to staff dedicated to the projects, consumables, animal studies, travel costs linked to meetings and overheads shall be eligible within the limits set out in Article 1 and in accordance with the eligibility rules set out in Annex III.

3. The Union's financial assistance shall be paid following presentation and approval of the reports and supporting documents referred to Article 1(2)(c) and (d).

[1] OJ L 209, 11.8.2005, p. 1.

Article 3

This Decision is addressed to the Kingdom of Belgium, the Federal Republic of Germany, the Kingdom of Spain, the French Republic, the Italian Republic, the Kingdom of the Netherlands and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 27 June 2012.

For the Commission
John DALLI
Member of the Commission

ANNEX I

Description of the technical and scientific studies on Schmallenberg virus (SBV), referred to in Article 1(1)

Area 1 — Pathogenesis

Project 1.1

To determine the pathogenicity and dynamics of the virus in foetuses at different gestation stages by experimental infection in pregnant ewes, goats and cattle.

— Member States involved: Belgium, Germany, France, the Netherlands and the United Kingdom.

Coordinator: Germany

Project 1.2

To identify the primary (and possibly secondary) replication sites and virus virulence in non-pregnant animals by experimental infection studies in young animals of cattle, sheep and goats.

— Member States involved: Belgium, Germany, France, the Netherlands and the United Kingdom.

Coordinators: Sheep — the Netherlands, Goats — France

Project 1.3

To study the development of immunity to SBV by experimental infection studies in sero-positive as well as sero-negative animals of the different species.

— Member States involved: Belgium, Germany, France, the Netherlands and the United Kingdom.

Coordinator: United Kingdom

Outcome for projects 1.1, 1.2 and 1.3:

Data on pathogenesis, viremia duration, incubation time, virus distribution, virus shedding and possible persistence of Schmallenberg virus to be used for tests on live animals, generation of vaccines as well as collection of reference materials for tests' validation.

Project 1.4

To test available serological samples (cattle and sheep) for SBV. A case-control study will be undertaken to investigate the clinical impact of the disease and the risk factors for introduction, transmission and clinical symptoms at the herd level.

Outcome:

Description of the current spread of SBV disease in the bovine and ovine population, the clinical consequences of SBV infection and the risk factors for introduction, transmission and morbidity in holdings and animals.

— Member States involved: Belgium

Project 1.5

Collection of SBV case data, baseline data on abortion, stillbirth and malformations and results of epidemiological studies (case/control study in cattle, sheep and goats; source identification study, seroprevalence study, sentinel study) to be provided to for meta-analyses of study results.

Outcome:

Joint epidemiological analysis with EFSA of data on SBV in Germany and other affected EU Member States including assessment of the impact of SBV on population dynamics, breeding management, and economy. Determination of the within-herd prevalence and between-herd prevalence as well as the spatial distribution of SBV infections in different susceptible species. Analysis of the route of entry, transmission pathways, the source of the epidemic and its temporal development in Germany. Analysis of potential coincidence with animal density, herd/flock density, climate, and weather conditions, geography and ecological parameters.

— Member State involved: Germany

Project 1.6

To identify clinical symptoms following SBV infection as well as potential risk factors for introduction and spread of SBV in dairy cattle herds and sheep.

Outcome:

1. Analysis of the impact of the SBV infection on health and productivity of dairy cattle and their offspring, the possibility of vertical transmission. Determination of how long infected calves stay viraemic. Guidance for potential control measures (e.g. grazing management).

2. Description and quantification of clinical signs in adult infected sheep after a primary infection with SBV. Determination of mortality rates in newborn lambs, relation between seroprevalence and clinical manifestations in herds. Identification of potential risk factors for introduction and spread of SBV in sheep flocks. The study will obtain baseline information on impact of SBV on sheep health and production, and risk factors associated with introduction, spread and impact of SBV.

— Member State involved: the Netherlands

Area 2 — Epidemiology

Project 2.1

To clarify or exclude horizontal transmission by trying to provoke infection with most virulent virus (preferably not cell cultured).

Outcome:

Determine if there are transmission routes without vector.

— Member States involved: Belgium, Germany, the Netherlands and the United Kingdom.

Coordinator: United Kingdom

Project 2.2a

To investigate which species are potential vectors for SBV by prospective and retrospective investigations.

Outcome:

To confirm status of a series of suspected SBV vectors from affected countries and their ability to effectively transmit the virus.

— Member States involved: Belgium, Germany, the Netherlands.

Coordinator: the Netherlands

Project 2.2b

To perform an experimental assessment of the rates of infection, dissemination and probable transmission in each vector group.

Outcome:

Epidemiological role played by the most common midge and mosquito species in transmitting SBV and assessment of the rates of infection, dissemination and probable transmission in each vector group.

— Member States involved: Spain, France, Italy and the United Kingdom.

Coordinator: Spain

Project 2.3

To investigate if bulls may excrete SBV in semen and to investigate risk of transmission via embryos by using frozen semen and *in vitro* fertilisation procedures with non-infected ovaries.

Outcome:

Reliable information on the risk of transmission of SBV via semen and embryos.

— Member States involved: Belgium, Germany, France, the Netherlands and the United Kingdom.

Coordinator: the Netherlands

Project 2.4

Determination of the role of other species (pigs, rabbits, mice or birds (chicken)) in the epidemiology of SBV.

Outcome:

Identification of other species susceptible to SBV.

— Member States involved: Belgium, Germany, the Netherlands and the United Kingdom.

Coordinator: Belgium

Project 2.5

Determination of the role of wildlife (deer, wild boar, etc.) in the epidemiology of SBV.

Outcome:

Clarify if the virus infects wildlife and if wildlife could play a role in the epidemiology of the virus.

— Member States involved: Germany, the Netherlands and the United Kingdom.

Coordinator: United Kingdom

Area 3 — Diagnostics

Project 3.1

To develop SBV specific monoclonal antibodies for the development and evaluation of a competitive or blocking enzyme-linked immunosorbent assay (ELISA) to detect SBV specific antibodies in sera.

Outcome:

Development of diagnostic assays to detect SBV specific antibodies.

— Member States involved: France and the United Kingdom.

Coordinator: United Kingdom

Project 3.2

To harmonise the validation of the different RT-PCR methods for the detection of SBV

Outcome:

Common protocol and minimum criteria for the validation of molecular and serological diagnostic tools with the involvement of the private sector.

— Member States involved: Belgium, Germany, France, the Netherlands and the United Kingdom.

Coordinator: Germany

ANNEX II

Budget per project (in EUR)

Area 1 — Pathogenesis

Projects 1.1, 1.2 and 1.3

Item	Heading	Belgium	Germany	France	Netherlands	United Kingdom	Total
1	Staff	70 000	235 200	119 012	111 010	105 356	640 578
2	Consumables	40 000	78 800	104 300	19 000	50 007	292 107
3	Animal studies	140 000	98 000	112 000	127 147	86 708	563 855
4	Travel costs linked to meetings	0	3 000	8 200	0	7 076	18 276
5	Overheads (7 %)	17 500	29 050	24 046	18 001	17 440	106 037
	Total	267 500	444 050	367 558	275 158	266 587	1 620 853

Project 1.4

Item	Heading	Belgium
1	Staff	125 347
2	Consumables	90 000
3	Animal studies	0
4	Travel cost linked to meetings	0
5	Overheads (7 %)	15 074
	Total	230 421

Project 1.5

Item	Heading	Germany
1	Staff	121 950
2	Consumables	100 850
3	Animal studies	
4	Travel costs linked to meetings	6 000
5	Overheads (7 %)	16 016
	Total	244 816

Project 1.6

Item	Heading	Netherlands
1	Staff	279 005
2	Consumables	77 500
3	Animal studies	180 212
4	Travel costs linked to meetings	28 500
5	Overheads (7 %)	39 565
	Total	604 782

Area 2 — Epidemiology

Project 2.1, 2.2a, 2.3, 2.4 and 2.5

Item	Heading	Belgium (excl. 2.5)	Germany	France (excl. 2.2a, 2.4 and 2.5)	Netherlands	United Kingdom (excl. 2.2a)	Total
1	Staff	139 937	255 150	30 000	250 865	127 807	803 759
2	Consumables	173 200	160 850	120 000	33 108	41 653	528 811
3	Animal studies	14 576	18 000	0	49 520	6 746	88 843
4	Travel costs linked to meetings	0	6 000	0	8 900	9 435	24 335
5	Overheads (7 %)	22 940	30 800	10 500	23 968	12 955	101 202
	Total	350 653	470 800	160 500	366 361	198 636	1 546 950

Project 2.2b

Item	Heading	Spain	France	Italy	United Kingdom	Total
1	Staff	175 000	373 220	170 000	72 305	790 525
2	Consumables	93 000	115 000	56 000	36 000	300 000
3	Animal studies	0	0	0	0	0
4	Travel costs linked to meetings	6 000	16 500	6 000	4 800	33 300
5	Overheads (7 %)	19 180	35 330	16 240	7 917	78 667
	Total	293 180	540 050	248 240	121 022	1 202 492

Area 3 — Diagnostics

Project 3.1 and 3.2

Item	Heading	Belgium (excl. 3.1)	Germany (excl. 3.1)	France	Netherlands (excl. 3.1)	United Kingdom	Total
1	Staff	17 281	12 800	68 413	8 575	114 398	221 467
2	Consumables	9 000	16 200	30 000	6 150	28 224	89 574
3	Animal studies				3 040		3 040
4	Travel costs linked to meetings	500	1 000	5 000		4 459	10 959
5	Overheads (7 %)	1 875	2 100	7 239	1 244	10 296	22 754
	Total	28 656	32 100	110 652	19 009	157 377	347 794

Coordination

Item	Heading	Netherlands
1	Staff	10 000
2	Travel costs linked to meetings	2 500
5	Overheads (7 %)	875
	Total	13 375

ANNEX III

Eligibility rules

1. **Staff**

   Staff costs shall be limited to actual attributable labour costs (remuneration, wages, social charges and retirement costs) accrued in implementation of the study. To this end monthly time sheets have to be maintained.

   Daily rate will be calculated on a 220 working days/year.

2. **Consumables**

   Reimbursement is to be based on actual costs incurred for laboratory tests:

   — the purchase of test kits, reagents and all consumables identifiable and especially used to carry out the laboratory test.

3. **Animal studies**

   Reimbursement is to be based on actual costs incurred for the

   — purchase of animals at market value,

   — transport to facilities and housing and feeding,

   — rendering of animals used in the experiments.

   All other expenditure on administration and secretarial services is considered to be covered by 'overheads'.

4. **Meetings (travel costs)**

   Travel and hotel costs incurred by the staff for the participation to meetings related to the studies are eligible in accordance with the rules laid down in Annex IV to Commission Implementing Regulation (EU) No 926/2011 ([1]).

5. **Overheads**

   A flat rate contribution of 7 % of actual eligible costs, calculated on the basis of all direct costs listed in items 1 to 4, may be claimed.

6. The expenditure submitted by the Member States for a financial contribution by the Union shall be expressed in euro and shall exclude value added tax (VAT) and all other taxes.

7. Member States may adjust the estimated budgets listed in Annex II by transfer between headings of eligible costs, provided that this adjustment of expenditure does not affect the implementation of the study, and without exceeding the total eligible cost per project. The Member States shall submit a written request to the Commission for its prior approval to increase the budget for one of the headings by more than 20 %.

([1]) OJ L 241, 17.9.2011, p. 2.

ANNEX IV

Financial report

Member State:

Project number and title:

Total expenditure for the project (real costs, VAT excl.)

Item		Staff category	No of days	Daily rate	Total
1	Staff				

2	Consumables	
3	Animal studies	
4	Travel costs linked to meetings	
5	Overheads (max. 7 % of total costs)	
	TOTAL	

Certification by the beneficiary

We certify that:

— the expenditure listed above was incurred in connection with the tasks defined,

— the expenditure was actually incurred, accurately accounted for and eligible under the provisions of Commission Implementing Decision 2012/349/EU [1],

— all supporting documents relating to the expenditure are available for inspection,

— no other Union contribution was requested for the projects listed in this Decision.

Date:

Name and signature of the financial officer responsible:

[1] OJ L 173, 3.7.2012, p. 12.