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[1] Text with EEA relevance.

[1] Text with EEA relevance.

I

(Resolutions, recommendations and opinions)

RECOMMENDATIONS

COUNCIL

COUNCIL RECOMMENDATION

of 21 February 2017

concerning the discharge to be given to the Commission in respect of the implementation of the operations of the European Development Fund (eighth EDF) for the financial year 2015

(2017/C 58/01)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the fourth ACP-EEC Convention, signed at Lomé on 15 December 1989 ([1]) and amended by the Agreement signed in Mauritius on 4 November 1995 ([2]),

Having regard to the Internal Agreement between the Representatives of the Governments of the Member States, meeting within the Council, on the financing and administration of the Community aid under the Second Financial Protocol to the fourth ACP-EC Convention ([3]) (the 'Internal Agreement') setting up, amongst others, the eighth European Development Fund (eighth EDF), and in particular Article 33(3) thereof,

Having regard to the Financial Regulation of 16 June 1998 applicable to development finance cooperation under the fourth ACP-EC Convention ([4]), and in particular Articles 66 to 74 thereof,

Having examined the revenue and expenditure account and the balance sheet relating to the operations of the eighth EDF as at 31 December 2015 and the Annual Report of the Court of Auditors on the activities funded by the 8th, 9th, 10th and 11th European Development Funds (EDFs) concerning the financial year 2015, together with the Commission's replies ([5]) contained in that Annual Report,

Whereas:

(1) Pursuant to Article 33(3) of the Internal Agreement, the discharge for the financial management of the eighth EDF is to be given to the Commission by the European Parliament on the recommendation of the Council.

(2) The overall implementation by the Commission of the operations of the eighth EDF during the financial year 2015 has been satisfactory,

HEREBY RECOMMENDS that the European Parliament give the Commission a discharge in respect of the implementation of the operations of the eighth EDF for the financial year 2015.

Done at Brussels, 21 February 2017.

For the Council

The President

E. SCICLUNA

([1]) OJ L 229, 17.8.1991, p. 3.
([2]) OJ L 156, 29.5.1998, p. 3.
([3]) OJ L 156, 29.5.1998, p. 108.
([4]) OJ L 191, 7.7.1998, p. 53.
([5]) OJ C 375, 13.10.2016, p. 287.

COUNCIL RECOMMENDATION

of 21 February 2017

concerning the discharge to be given to the Commission in respect of the implementation of the operations of the European Development Fund (ninth EDF) for the financial year 2015

(2017/C 58/02)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000 ([1]) and amended by the Agreement signed in Luxembourg on 25 June 2005 ([2]),

Having regard to the Internal Agreement between Representatives of the Governments of the Member States, meeting within the Council, on the Financing and Administration of Community Aid under the Financial Protocol to the Partnership Agreement between the African, Caribbean and Pacific States and the European Community and its Member States signed in Cotonou (Benin) on 23 June 2000 and the allocation of financial assistance for the Overseas Countries and Territories to which Part Four of the EC Treaty applies ([3]) (the 'Internal Agreement') setting up, amongst others, the ninth European Development Fund (ninth EDF), and in particular Article 32(3) thereof,

Having regard to the Financial Regulation of 27 March 2003 applicable to the 9th European Development Fund ([4]), and in particular Articles 96 to 103 thereof,

Having examined the revenue and expenditure account and the balance sheet relating to the operations of the ninth EDF as at 31 December 2015 and the Annual Report of the Court of Auditors on the activities funded by the 8th, 9th, 10th and 11th European Development Funds (EDFs) concerning the financial year 2015, together with the Commission's replies ([5]) contained in that Annual Report,

Whereas:

(1) Pursuant to Article 32(3) of the Internal Agreement, the discharge for the financial management of the ninth EDF is to be given to the Commission by the European Parliament on the recommendation of the Council.

(2) The overall implementation by the Commission of the operations of the ninth EDF during the financial year 2015 has been satisfactory,

HEREBY RECOMMENDS that the European Parliament give the Commission a discharge in respect of the implementation of the operations of the ninth EDF for the financial year 2015.

Done at Brussels, 21 February 2017.

For the Council

The President

E. SCICLUNA

([1]) OJ L 317, 15.12.2000, p. 3.
([2]) OJ L 209, 11.8.2005, p. 27.
([3]) OJ L 317, 15.12.2000, p. 355.
([4]) OJ L 83, 1.4.2003, p. 1.
([5]) OJ C 375, 13.10.2016, p. 287.

COUNCIL RECOMMENDATION

of 21 February 2017

concerning the discharge to be given to the Commission in respect of the implementation of the operations of the European Development Fund (tenth EDF) for the financial year 2015

(2017/C 58/03)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000 ([1]) and amended by the Agreement signed in Luxembourg on 25 June 2005 ([2]),

Having regard to the Internal Agreement between the Representatives of the Governments of the Member States, meeting within the Council, on the financing of Community aid under the multiannual financial framework for the period 2008 to 2013 in accordance with the ACP-EC Partnership Agreement and on the allocation of financial assistance for the Overseas Countries and Territories to which Part Four of the EC Treaty applies ([3]) (the 'Internal Agreement') setting up, amongst others, the tenth European Development Fund (tenth EDF), and in particular Article 11(8) thereof,

Having regard to Council Regulation (EC) No 215/2008 of 18 February 2008 on the Financial Regulation applicable to the 10th European Development Fund ([4]), and in particular Articles 142 to 144 thereof,

Having examined the revenue and expenditure account and the balance sheet relating to the operations of the tenth EDF as at 31 December 2015 and the Annual Report of the Court of Auditors on the activities funded by the 8th, 9th, 10th and 11th European Development Funds (EDFs) concerning the financial year 2015, together with the Commission's replies ([5]) contained in that Annual Report,

Whereas:

(1) Pursuant to Article 11(8) of the Internal Agreement, the discharge for the financial management of the tenth EDF is to be given to the Commission by the European Parliament on the recommendation of the Council.

(2) The overall implementation by the Commission of the operations of the tenth EDF during the financial year 2015 has been satisfactory,

HEREBY RECOMMENDS that the European Parliament give the Commission a discharge in respect of the implementation of the operations of the tenth EDF for the financial year 2015.

Done at Brussels, 21 February 2017.

For the Council

The President

E. SCICLUNA

([1]) OJ L 317, 15.12.2000, p. 3.
([2]) OJ L 209, 11.8.2005, p. 27.
([3]) OJ L 247, 9.9.2006, p. 32.
([4]) OJ L 78, 19.3.2008, p. 1.
([5]) OJ C 375, 13.10.2016, p. 287.

COUNCIL RECOMMENDATION

of 21 February 2017

concerning the discharge to be given to the Commission in respect of the implementation of the operations of the European Development Fund (eleventh EDF) for the financial year 2015

(2017/C 58/04)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000 ([1]), as last amended,

Having regard to the Internal Agreement between the Representatives of the Governments of the Member States of the European Union, meeting within the Council, on the financing of European Union aid under the multiannual financial framework for the period 2014 to 2020, in accordance with the ACP-EU Partnership Agreement, and on the allocation of financial assistance for the Overseas Countries and Territories to which Part Four of the Treaty on the Functioning of the European Union applies ([2]) (the 'Internal Agreement') setting up, amongst others, the eleventh European Development Fund (eleventh EDF), and in particular Article 11(7) thereof,

Having regard to Council Regulation (EU) 2015/323 of 2 March 2015 on the Financial Regulation applicable to the 11th European Development Fund ([3]), and in particular Articles 43 to 45 thereof,

Having examined the revenue and expenditure account and the balance sheet relating to the operations of the eleventh EDF as at 31 December 2015 and the Annual Report of the Court of Auditors on the activities funded by the 8th, 9th, 10th and 11th European Development Funds (EDFs) concerning the financial year 2015, together with the Commission's replies ([4]) contained in that Annual Report,

Whereas:

(1) Pursuant to Article 11(7) of the Internal Agreement, the discharge for the financial management of the eleventh EDF is to be given to the Commission by the European Parliament on the recommendation of the Council.

(2) The overall implementation by the Commission of the operations of the eleventh EDF during the financial year 2015 has been satisfactory,

HEREBY RECOMMENDS that the European Parliament give the Commission a discharge in respect of the implementation of the operations of the eleventh EDF for the financial year 2015.

Done at Brussels, 21 February 2017.

For the Council

The President

E. SCICLUNA

([1]) OJ L 317, 15.12.2000, p. 3.
([2]) OJ L 210, 6.8.2013, p. 1.
([3]) OJ L 58, 3.3.2015, p. 17.
([4]) OJ C 375, 13.10.2016, p. 287.

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Euro exchange rates [1]

22 February 2017

(2017/C 58/05)

1 euro =

	Currency	Exchange rate		Currency	Exchange rate
USD	US dollar	1,0513	CAD	Canadian dollar	1,3844
JPY	Japanese yen	118,79	HKD	Hong Kong dollar	8,1585
DKK	Danish krone	7,4332	NZD	New Zealand dollar	1,4672
GBP	Pound sterling	0,84450	SGD	Singapore dollar	1,4905
SEK	Swedish krona	9,4700	KRW	South Korean won	1 201,28
CHF	Swiss franc	1,0642	ZAR	South African rand	13,7773
ISK	Iceland króna		CNY	Chinese yuan renminbi	7,2311
NOK	Norwegian krone	8,8153	HRK	Croatian kuna	7,4480
BGN	Bulgarian lev	1,9558	IDR	Indonesian rupiah	14 041,37
CZK	Czech koruna	27,021	MYR	Malaysian ringgit	4,6821
HUF	Hungarian forint	307,53	PHP	Philippine peso	52,868
PLN	Polish zloty	4,2987	RUB	Russian rouble	60,7803
RON	Romanian leu	4,5208	THB	Thai baht	36,806
TRY	Turkish lira	3,7871	BRL	Brazilian real	3,2422
AUD	Australian dollar	1,3689	MXN	Mexican peso	21,0585
			INR	Indian rupee	70,4230

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

COURT OF AUDITORS

Special Report No 1/2017

'More efforts needed to implement the Natura 2000 network to its full potential'

(2017/C 58/06)

The European Court of Auditors hereby informs you that Special Report No 1/2017 **'More efforts needed to implement the Natura 2000 network to its full potential'** has just been published.

The report can be accessed for consultation or downloading on the European Court of Auditors' website: http://eca.europa.eu or on EU Bookshop: https://bookshop.europa.eu

Commission communication concerning the procedure laid down by Article 1, paragraph 4 of Council Directive 96/67/EC

(2017/C 58/07)

According to the provisions of Article 1(4) of Council Directive 96/67/EC of 15 October 1996 on access to the groundhandling market at Community airports [1], the Commission is required to publish, for information, a list of the airports referred to in the Directive.

	Airports whose annual traffic is more than 2 million passenger movements or 50 000 tonnes of freight in 2015	Other airports open to commercial traffic in 2015
Austria	Vienna International Airport	Graz, Kärnten, Blue Danube Airport Linz, Salzburg/W.A. Mozart, Innsbruck
Belgium	Brussels National, Charleroi-Brussels South, Liège-Bierset	Antwerpen, Kortrijk-Wevelgem, Oostende-Brugge
Bulgaria	Sofia, Burgas	Varna, Plovdiv, Gorna Oriahovitza.
Croatia	Zagreb	Dubrovnik, Split, Pula, Zadar, Rijeka, Brač, Osijek, Mali Lošinj
Cyprus	Larnaka, Pafos	
Czech Republic	Praha/Ruzyně	Brno/Tuřany, Karlovy Vary, Mnichovo Hradiště, Ostrava/Mošnov, Pardubice, Olomouc, Benešov, Broumov, Břeclav, Bubovice, Česká Lípa, České Budějovice, Dvůr Králové, Frýdlant, Havlíčkův Brod, Hodkovice, Hořice, Hosín, Hradec Králové, Hranice, Cheb, Chomutov, Chotěboř, Chrudim, Jaroměř, Jičín, Jihlava, Jindřichův Hradec, Kladno, Klatovy, Kolín, Krnov, Křižanov, Kyjov, Letkov, Letňany, Mariánské Lázně, Medlánky, Mikulovice, Mladá Boleslav, Moravská Třebová, Most, Nové Město, Panenský Týnec, Plasy, Plzeň/Líně, Podhořany, Polička, Přerov, Příbram, Přibyslav, Rakovník, Raná, Roudnice, Sazená, Skuteč, Slaný, Soběslav, Staňkov, Strakonice, Strunkovice, Šumperk, Tábor, Toužim, Ústí nad Orlicí, Velké Poříčí, Vlašim, Vrchlabí, Vysoké Mýto, Vyškov, Zábřeh, Zbraslavice, Žamberk
Denmark	Copenhagen, Billund	Aalborg, Aarhus, Esbjerg, Karup, Bornholm, Soenderborg, Thisted, Roskilde
Estonia	Lennart Meri-Tallinn	Tartu, Pärnu, Kuressaare, Kärdla
Finland	Helsinki-Vantaa	Enontekiö, Helsinki-Malmi, Ivalo, Joensuu, Jyväskylä, Kajaani, Kemi-Tornio, Kittilä, Kokkola-Pietarsaari, Kuopio, Kuusamo, Lappeenranta, Maarianhamina, Mikkeli, Oulu, Pori, Rovaniemi, Savonlinna, Seinäjoki, Tampere-Pirkkala, Turku, Vaasa, Varkaus

[1] OJ L 272, 25.10.1996, p. 36.

	Airports whose annual traffic is more than 2 million passenger movements or 50 000 tonnes of freight in 2015	Other airports open to commercial traffic in 2015
France	Paris-Charles de Gaulle, Paris-Orly, Nice-Côte d'Azur, Lyon-Saint Exupéry, Marseille-Provence, Toulouse-Blagnac, Bâle-Mulhouse, Bordeaux-Mérignac, Nantes-Atlantique, Beauvais-Tille, Guadeloupe-Pôle Caraïbes, La Réunion-Roland Garros	Martinique Aimé Césaire, Lille Lesquin, Montpellier-Méditerranée, Ajaccio Napoléon Bonaparte, Bastia Poretta, Strasbourg Entzheim, Biarritz-Anglet-Bayonne, Brest-Bretagne, Pau Pyrénées, Figari Sud Corse, Rennes St Jacques, Toulon Hyères, Cayenne Rochambeau, Clermont-Ferrand-Auvergne, Carcassonne Salvaza, Tarbes-Lourdes-Pyrénées, Perpignan-Rivesaltes, Dzaoudzi Pamandzi, Calvi Ste Catherine, Grenoble Isère, Limoges Bellegarde, Bergerac Roumanière, Metz Nancy Lorraine, Béziers-Vias, La Rochelle Ile De Re, Chambéry/Aix Les Bains, Nîmes/Garons, St Martin Grand Case, Tours-Val De Loire, Deauville Normandie, St Etienne Bouthéon, Lorient-Lann-Bihoue, Dole Tavaux, Dinard-Pleurtuit-St-Malo, Caen Carpiquet, Poitiers-Biard, Paris Le Bourget, Rodez Marcillac, Quimper-Cornouaille, Châlons-Vatry, Saint-Pierre-Pierrefonds, Brive Souillac, Castres Mazamet, Agen La Garenne, Maripasoula, St Pierre-Pointe Blanche, Lannion, Aurillac, Saint-Nazaire-Montoir, Avignon Caumont [1]
Germany	Berlin-Tegel, Berlin-Schönefeld, Bremen, Düsseldorf, Frankfurt/Main, Hahn, Hamburg, Hannover, Köln/Bonn, Leipzig/Halle, München, Nürnberg, Stuttgart	Augsburg, Braunschweig, Dortmund, Dresden, Eggenfelden, Erfurt, Friedrichshafen, Harle, Helgoland, Heringsdorf, Ingolstadt/Manching, Jade Weser Airport, Juist, Karlsruhe/Baden-Baden, Kassel-Calden, Lübeck, Mannheim, Memmingen, Mönchengladbach, Münster-Osnabrück, Niederrhein, Norden-Norddeich, Paderborn-Lippstadt, Rostock-Laage, Saarbrücken, Sylt-Westerland, Wangerooge [2]
Greece	Athens, Irakleion, Thessaloniki, Rodos, Kerkyra, Kos, Chania	Araxos, Aktio, Alexandroupolis, Astypalaia, N. Anchialos, Zakynthos, Ikaria, Ioannina, Kavala, Kalamata, Kalymnos, Karpathos, Kasos, Kastelorizo, Kastoria, Kefallinia, Kozani, Kythira, Leros, Limnos, Milos, Mykonos, Mytilini, Naxos, Paros, Samos, Santorini, Siteia, Skiathos, Skyros, Syros, Chios
Hungary	Budapest Liszt Ferenc International Airport	Pécs-Pogány, Győr-Pér, Hévíz-Balaton, Debrecen, Szeged, Nyíregyháza
Ireland	Dublin, Cork	Shannon, Ireland West Knock Airport, Donegal, Kerry, Waterford
Italy	Roma-Fiumicino, Milano-Malpensa, Bergamo, Milano-Linate, Venezia, Catania, Bologna, Napoli, Roma-Ciampino, Palermo, Pisa, Bari, Cagliari, Torino, Verona, Firenze, Treviso, Lamezia Terme, Brindisi, Olbia	Taranto, Alghero, Trapani, Genova, Trieste, Pescara, Ancona, Reggio Calabria, Comiso, Crotone, Perugia, Parma, Lampedusa, Rimini, Pantelleria, Cuneo, Bolzano, Elba, Brescia, Grosseto, Salerno, Foggia, Albenga, Aosta, Biella
Latvia	Riga International Airport	
Lithuania	Vilnius International Airport	Kaunas International Airport, Palanga International Airport, Siauliai International Airport
Luxembourg	Luxembourg-Findel	
Malta	Luqa-Malta International Airport	
Netherlands	Amsterdam-Schiphol, Eindhoven, Maastricht	Eelde, Rotterdam-The Hague

	Airports whose annual traffic is more than 2 million passenger movements or 50 000 tonnes of freight in 2015	Other airports open to commercial traffic in 2015
Poland	Chopina w Warszawie, Kraków-Balice, Gdańsk im. Lecha Wałęsy, Katowice-Pyrzowice, Warszawa/Modlin, Wrocław — Strachowice	Poznań-Ławica, Rzeszów-Jasionka, Szczecin – Goleniów, Bydgoszcz – Szwederowo, Łódź-Lublinek, Lublin, Zielona Góra-Babimost, Radom-Sadków, Mielec, Kaniów, Olsztyn-Mazury
Portugal	Lisboa, Oporto, Faro, Madeira	Bragança, Cascais, Corvo, Flores, Graciosa, Horta, Lajes, Pico, Ponta Delgada, Portimão, Porto Santo, Santa Maria, São Jorge, Vila Real, Viseu
Romania	International Airport Bucuresti — Henri Coandă	Bucuresti Baneasa, Timisoara, Cluj, Constanta, Sibiu, Iasi, Bacau, Oradea, Suceava, Arad, Baia Mare, Craiova, Satu Mare, Targu Mures, Tulcea, Tuzla
Slovakia		Bratislava, Košice, Poprad, Sliač, Žilina, Piešťany
Slovenia		Ljubljana-Jože Pučnik, Maribor-Edvard Rusja, Portorož
Spain	Adolfo Suárez Madrid-Barajas, Barcelona-El Prat, Palma de Mallorca, Málaga-Costa del Sol, Gran Canaria, Alicante-Elche, Tenerife Sur, Ibiza, Lanzarote, Valencia, Fuerteventura, Sevilla, Bilbao, Tenerife Norte, Menorca, Santiago, Zaragoza	Girona, Asturias, Murcia-San Javier, A Coruña, La Palma, Seve Ballesteros-Santander, Jerez de la Frontera, Vigo, FGL Granada-Jaén, Reus, Almería, Melilla, San Sebastián, Valladolid, Pamplona, El Hierro, León, La Gomera, Salamanca, Badajoz, Logroño, Vitoria, Burgos, Córdoba, Sabadell, Son Bonet, Madrid-Cuatro Vientos, Albacete, Ceuta/Heliport, Huesca-Pirineos, Algeciras-Heliport, Castellón Costa-Azahar, Lleida Alguaire
Sweden	Stockholm-Arlanda, Göteborg-Landvetter, Stockholm-Bromma, Malmö	Arvidsjaur, Borlänge, Gällivare, Göteborg/Säve, Hagfors, Halmstad, Hemavan, Jönköping, Kalmar, Karlstad, Kiruna, Kramfors-Sollefteå, Kristianstad, Linköping/SAAB, Luleå/Kallax, Lycksele, Mora/Siljan, Norrköping/Kungsängen, Oskarshamn, Pajala-Ylläs, Ronneby, Skellefteå, Stockholm/Skavsta, Stockholm/Västerås, Sundsvall-Härnösand, Sveg, Torsby, Trollhättan/Vänersborg, Umeå, Vilhelmina, Visby, Växjö/Kronoberg, Åre-Östersund, Ängelholm, Örebro, Örnsköldsvik
United Kingdom	Heathrow, Gatwick, Manchester, Stansted, Luton, Edinburgh, Birmingham, Glasgow, Bristol, Newcastle, East Midlands, Belfast International, London City, Liverpool, Aberdeen, Leeds Bradford, Belfast City	Barra, Benbecula, Biggin Hill, Blackpool, Bournemouth, Cambridge, Campbeltown, Cardiff, City of Derry, Coventry, Doncaster Sheffield, Dundee, Durham Tees Valley, Exeter, Farnborough, Gloucestershire, Humberside, Inverness, Islay, Isles of Scilly (St Marys), Kirkwall, Lands End, Lerwick, Lydd, Newquay, Norwich, Oxford, Prestwick, Scatsta, Shoreham, Southampton, Southend, Stornoway, Sumburgh, Tiree, Wick John O'Groats

([1]) Airports whose annual traffic is under 10 000 passengers a year are not listed.
([2]) See table footnote 1.

NOTICES CONCERNING THE EUROPEAN ECONOMIC AREA

STANDING COMMITTEE OF THE EFTA STATES

Medicinal products — List of marketing authorisations granted by the EEA EFTA States for the first half of 2016

(2017/C 58/08)

Subcommittee I on the free movement of goods

To be noted by the EEA Joint Committee

With reference to EEA Joint Committee Decision No 74/1999 of 28 May 1999, the EEA Joint Committee is invited to note the following lists concerning marketing authorisations for medicinal products for the period 1 January-30 June 2016, at their meeting on 28 October 2016:

Annex I List of new marketing authorisations

Annex II List of renewed marketing authorisations

Annex III List of extended marketing authorisations

Annex IV List of withdrawn marketing authorisations

Annex V List of suspended marketing authorisations

ANNEX I

List of new marketing authorisations

The following marketing authorisations have been granted in the EEA EFTA States during the period 1 January-30 June 2016:

EU-Number	Product	Country	Date of authorisation
EU/1/15/1053	Neofordex	Liechtenstein	30.4.2016
EU/1/15/1053	Neofordex	Iceland	31.3.2016
EU/1/15/1053	Neofordex	Norway	1.4.2016
EU/1/15/1063	Pemetrexed Actavis	Liechtenstein	29.2.2016
EU/1/15/1063	Pemetrexed Actavis	Norway	25.1.2016
EU/1/15/1063	Pemetrexed Actavis	Iceland	25.1.2016
EU/1/15/1064	Imlygic	Liechtenstein	29.2.2016
EU/1/15/1064	Imlygic	Norway	20.1.2016
EU/1/15/1064	Imlygic	Iceland	14.1.2016
EU/1/15/1065	Eptifibatid Accord	Liechtenstein	29.2.2016
EU/1/15/1065	Eptifibatide Accord	Norway	18.1.2016
EU/1/15/1065	Eptifibatide Accord	Iceland	14.1.2016
EU/1/15/1066	Ongentys	Liechtenstein	30.6.2016
EU/1/15/1067	Lopinavir/Ritonavir Mylan	Liechtenstein	29.2.2016
EU/1/15/1067	Lopinavir/Ritonavir Mylan	Norway	21.1.2016
EU/1/15/1067	Lopinavir/Ritonavir Mylan	Iceland	20.1.2016
EU/1/15/1068	Wakix	Liechtenstein	30.4.2016
EU/1/15/1068	Wakix	Norway	19.4.2016
EU/1/15/1068	Wakix	Iceland	22.4.2016
EU/1/15/1069	Episalvan	Liechtenstein	29.2.2016
EU/1/15/1069	Episalvan	Norway	20.1.2016
EU/1/15/1069	Episalvan	Iceland	19.1.2016

EU-Number	Product	Country	Date of authorisation
EU/1/15/1070	Oncaspar	Liechtenstein	29.2.2016
EU/1/15/1070	Oncaspar	Norway	25.1.2016
EU/1/15/1070	Oncaspar	Iceland	25.1.2016
EU/1/15/1071	Pemetrexed Accord	Liechtenstein	29.2.2016
EU/1/15/1071	Pemetrexed Accord	Norway	25.1.2016
EU/1/15/1071	Pemetrexed Accord	Iceland	25.1.2016
EU/1/15/1072	Spectrila	Liechtenstein	29.2.2016
EU/1/15/1072	Spectrila	Norway	19.1.2016
EU/1/15/1072	Spectrila	Iceland	19.1.2016
EU/1/15/1073	Briviact	Liechtenstein	29.2.2016
EU/1/15/1073	Briviact	Norway	21.1.2016
EU/1/15/1073	Briviact	Iceland	25.1.2016
EU/1/15/1074	Benepali	Liechtenstein	29.2.2016
EU/1/15/1074	Benepali	Norway	19.1.2016
EU/1/15/1074	Benepali	Iceland	19.1.2016
EU/1/15/1075	Feraccru	Liechtenstein	29.2.2016
EU/1/15/1075	Feraccru	Norway	7.3.2016
EU/1/15/1075	Feraccru	Iceland	18.3.2016
EU/1/15/1076	Kovaltry	Liechtenstein	29.2.2016
EU/1/15/1076	Kovaltry	Norway	10.3.2016
EU/1/15/1076	Kovaltry	Iceland	16.3.2016
EU/1/15/1077	Iblias	Liechtenstein	29.2.2016
EU/1/15/1077	Iblias	Norway	10.3.2016
EU/1/15/1077	Iblias	Iceland	16.3.2016
EU/1/15/1079	Vaxelis	Liechtenstein	29.2.2016

EU-Number	Product	Country	Date of authorisation
EU/1/15/1079	Vaxelis	Norway	29.2.2016
EU/1/15/1079	Vaxelis	Iceland	1.3.2016
EU/1/15/1080	Zurampic	Liechtenstein	29.2.2016
EU/1/15/1080	Zurampic	Norway	3.3.2016
EU/1/15/1080	Zurampic	Iceland	16.3.2016
EU/1/15/1081	Caspofungin Accord	Liechtenstein	29.2.2016
EU/1/15/1081	Caspofungin Accord	Norway	29.2.2016
EU/1/15/1081	Caspofungin Accord	Iceland	25.2.2016
EU/1/15/1082	Galafold	Liechtenstein	30.6.2016
EU/1/15/1082	Galafold	Norway	14.6.2016
EU/1/15/1082	Galafold	Iceland	14.6.2016
EU/1/15/1083	Uptravi	Liechtenstein	30.6.2016
EU/1/15/1083	Uptravi	Iceland	26.5.2016
EU/1/15/1083	Uptravi	Norway	30.5.2016
EU/1/15/1084	Portrazza	Liechtenstein	29.2.2016
EU/1/15/1084	Portrazza	Norway	26.2.2016
EU/1/15/1084	Portrazza	Iceland	15.3.2016
EU/1/15/1085	Taltz	Liechtenstein	30.4.2016
EU/1/15/1085	Taltz	Norway	9.5.2016
EU/1/15/1085	Taltz	Iceland	20.5.2016
EU/1/16/1086	Tagrisso	Liechtenstein	29.2.2016
EU/1/16/1086	Tagrisso	Norway	19.2.2016
EU/1/16/1086	Tagrisso	Iceland	11.2.2016
EU/1/16/1087	Coagadex	Liechtenstein	30.4.2016
EU/1/16/1087	Coagadex	Norway	1.4.2016

EU-Number	Product	Country	Date of authorisation
EU/1/16/1087	Coagadex	Iceland	22.3.2016
EU/1/16/1088	Empliciti	Liechtenstein	30.6.2016
EU/1/16/1088	Empliciti	Norway	24.5.2016
EU/1/16/1088	Empliciti	Iceland	19.5.2016
EU/1/16/1089	Pandemic influenza vaccine H5N1 MedImmune	Liechtenstein	30.6.2016
EU/1/16/1089	Pandemic influenza vaccine H5N1 MedImmune	Norway	30.5.2016
EU/1/16/1089	Pandemic influenza vaccine H5N1 MedImmune	Iceland	30.5.2016
EU/1/16/1090	Rasagiline Mylan	Liechtenstein	30.4.2016
EU/1/16/1090	Rasagiline Mylan	Norway	19.4.2016
EU/1/16/1090	Rasagiline Mylan	Iceland	22.4.2016
EU/1/16/1092	Amlodipin/Valsartan Mylan	Liechtenstein	30.4.2016
EU/1/16/1092	Amlodipine/Valsartan Mylan	Norway	11.4.2016
EU/1/16/1092	Amlodipine/Valsartan Mylan	Iceland	31.3.2016
EU/1/16/1093	Zonisamide Mylan	Liechtenstein	30.4.2016
EU/1/16/1093	Zonisamide Mylan	Norway	19.4.2016
EU/1/16/1093	Zonisamide Mylan	Iceland	22.4.2016
EU/1/16/1095	Idelvion	Liechtenstein	30.6.2016
EU/1/16/1095	Idelvion	Norway	30.5.2016
EU/1/16/1095	Idelvion	Iceland	23.5.2016
EU/1/16/1096	Lonsurf	Liechtenstein	30.4.2016
EU/1/16/1096	Lonsurf	Norway	9.5.2016
EU/1/16/1096	Lonsurf	Iceland	20.5.2016
EU/1/16/1097	Strimvelis	Liechtenstein	30.6.2016
EU/1/16/1097	Strimvelis	Norway	9.6.2016

EU-Number	Product	Country	Date of authorisation
EU/1/16/1097	Strimvelis	Iceland	16.6.2016
EU/1/16/1098	Alprolix	Liechtenstein	30.6.2016
EU/1/16/1098	Alprolix	Norway	25.5.2016
EU/1/16/1098	Alprolix	Iceland	20.5.2016
EU/1/16/1099	Descovy	Liechtenstein	30.4.2016
EU/1/16/1099	Descovy	Norway	27.4.2016
EU/1/16/1099	Descovy	Iceland	18.5.2016
EU/1/16/1100	Palonosetron Hospira	Liechtenstein	30.4.2016
EU/1/16/1100	Palonosetron Hospira	Norway	19.4.2016
EU/1/16/1100	Palonosetron Hospira	Iceland	27.4.2016
EU/1/16/1101	Darzalex	Liechtenstein	30.6.2016
EU/1/16/1101	Darzalex	Norway	30.5.2016
EU/1/16/1101	Darzalex	Iceland	30.5.2016
EU/1/16/1103	Neparvis	Liechtenstein	30.6.2016
EU/1/16/1103	Neparvis	Norway	24.6.2016
EU/1/16/1104	Palonosetron Accord	Liechtenstein	30.6.2016
EU/1/16/1104	Palonosteron Accord	Norway	14.6.2016
EU/1/16/1104	Palonosetron Accord	Iceland	14.6.2016
EU/1/16/1106	Flixabi	Liechtenstein	30.6.2016
EU/1/16/1106	Flixabi	Norway	17.6.2016
EU/1/16/1106	Flixabi	Iceland	15.6.2016
EU/1/16/1109	Zavicefta	Liechtenstein	30.6.2016
EU/1/16/1112	Odefsey	Liechtenstein	30.6.2016
EU/1/16/1112	Odefsey	Norway	24.6.2016
EU/2/15/192	Velactis	Norway	4.1.2016

EU-Number	Product	Country	Date of authorisation
EU/2/15/193	Imrestor	Norway	5.1.2016
EU/2/15/193	Imrestor	Iceland	4.1.2016
EU/2/16/194	Evalon	Liechtenstein	30.4.2016
EU/2/16/194	Evalon	Norway	11.5.2016
EU/2/16/194	Evalon	Iceland	13.5.2016
EU/2/16/195	Letifend	Liechtenstein	30.4.2016
EU/2/16/195	Letifend	Norway	27.4.2016
EU/2/16/195	Letifend	Iceland	18.5.2016

ANNEX II

List of renewed marketing authorisations

The following marketing authorisations have been renewed in the EEA EFTA States during the period 1 January-30 June 2016:

EU-Number	Product	Country	Date of authorisation
EU/1/05/323	ProQuad	Iceland	4.1.2016
EU/1/05/323	ProQuad	Norway	11.1.2016
EU/1/05/330	Rotarix	Liechtenstein	29.2.2016
EU/1/05/330	Rotarix	Iceland	20.1.2016
EU/1/05/330	Rotarix	Norway	20.1.2016
EU/1/05/331	Neupro	Liechtenstein	29.2.2016
EU/1/05/331	Neupro	Iceland	28.1.2016
EU/1/05/331	Neupro	Norway	4.2.2016
EU/1/06/334	Evoltra	Liechtenstein	29.2.2016
EU/1/06/334	Evoltra	Norway	19.1.2016
EU/1/06/334	Evoltra	Iceland	20.1.2016
EU/1/06/336	Tygacil	Liechtenstein	29.2.2016
EU/1/06/336	Tygacil	Norway	18.3.2016
EU/1/06/336	Tygacil	Iceland	18.3.2016
EU/1/06/341	Zostavax	Liechtenstein	29.2.2016
EU/1/06/341	Zostavax	Norway	29.2.2016
EU/1/06/341	Zostavax	Iceland	18.2.2016
EU/1/06/346	Tysabri	Norway	29.4.2016
EU/1/06/346	Tysabri	Iceland	12.5.2016
EU/1/06/354	Competact	Liechtenstein	30.4.2016
EU/1/06/354	Competact	Norway	12.5.2016
EU/1/06/354	Competact	Iceland	18.5.2016

EU-Number	Product	Country	Date of authorisation
EU/1/06/356	Exjade	Liechtenstein	30.4.2016
EU/1/06/356	Exjade	Norway	2.5.2016
EU/1/06/356	Exjade	Iceland	12.5.2016
EU/1/09/543	Cayston	Liechtenstein	30.6.2016
EU/1/09/543	Cayston	Norway	14.6.2016
EU/1/09/543	Cayston	Iceland	13.6.2016
EU/1/10/652	TOBI Podhaler	Liechtenstein	29.2.2016
EU/1/10/652	TOBI Podhaler	Norway	1.3.2016
EU/1/10/652	TOBI Podhaler	Iceland	17.3.2016
EU/1/11/671	Xiapex	Liechtenstein	29.2.2016
EU/1/11/671	Xiapex	Norway	25.1.2016
EU/1/11/671	Xiapex	Iceland	27.1.2016
EU/1/11/672	Xeplion	Norway	11.1.2016
EU/1/11/672	Xeplion	Iceland	4.1.2016
EU/1/11/674	Repso	Liechtenstein	29.2.2016
EU/1/11/674	Repso	Norway	25.1.2016
EU/1/11/674	Repso	Iceland	20.1.2016
EU/1/11/679	Pravafenix	Liechtenstein	29.2.2016
EU/1/11/679	Pravafenix	Norway	2.2.2016
EU/1/11/679	Pravafenix	Iceland	26.1.2016
EU/1/11/681	Trobalt	Liechtenstein	29.2.2016
EU/1/11/681	Trobalt	Norway	25.1.2016
EU/1/11/681	Trobalt	Iceland	26.1.2016
EU/1/11/682	Methylthioninium chloride Proveblue	Norway	29.2.2016
EU/1/11/682	Methylthioninium chloride Proveblue	Iceland	16.2.2016

EU-Number	Product	Country	Date of authorisation
EU/1/11/682	Methylthioniniumchlorid Proveblue	Liechtenstein	29.2.2016
EU/1/11/685	Ibandronic acid Sandoz	Norway	11.5.2016
EU/1/11/685	Ibandronic acid Sandoz	Iceland	27.4.2016
EU/1/11/687	Hizentra	Liechtenstein	29.2.2016
EU/1/11/687	Hizentra	Norway	29.2.2016
EU/1/11/687	Hizentra	Iceland	17.3.2016
EU/1/11/688	Cinryze	Liechtenstein	30.6.2016
EU/1/11/688	Cinryze	Norway	22.6.2016
EU/1/11/688	Cinryze	Iceland	13.6.2016
EU/1/11/690	Zoely	Liechtenstein	30.4.2016
EU/1/11/690	Zoely	Norway	29.4.2016
EU/1/11/690	Zoely	Iceland	18.5.2016
EU/1/11/691	Eliquis	Liechtenstein	29.2.2016
EU/1/11/691	Eliquis	Norway	2.2.2016
EU/1/11/691	Eliquis	Iceland	26.1.2016
EU/1/11/692	Yellox	Liechtenstein	29.2.2016
EU/1/11/692	Yellox	Norway	2.2.2016
EU/1/11/692	Yellox	Iceland	19.1.2016
EU/1/11/693	Rivastigmin Actavis	Norway	3.3.2016
EU/1/11/693	Rivastigmine Actavis	Liechtenstein	29.2.2016
EU/1/11/693	Rivastigmine Actavis	Iceland	15.3.2016
EU/1/11/694	Nulojix	Liechtenstein	29.2.2016
EU/1/11/694	Nulojix	Norway	26.2.2016
EU/1/11/694	Nulojix	Iceland	17.3.2016
EU/1/11/695	Leganto	Liechtenstein	29.2.2016

EU-Number	Product	Country	Date of authorisation
EU/1/11/695	Leganto	Norway	1.2.2016
EU/1/11/695	Leganto	Iceland	26.1.2016
EU/1/11/696	Bydureon	Liechtenstein	29.2.2016
EU/1/11/696	Bydureon	Norway	10.3.2016
EU/1/11/696	Bydureon	Iceland	17.3.2016
EU/1/11/697	Temozolomide SUN	Liechtenstein	30.4.2016
EU/1/11/697	Temozolomide SUN	Norway	29.4.2016
EU/1/11/697	Temozolomide SUN	Iceland	18.5.2016
EU/1/11/698	Yervoy	Liechtenstein	30.4.2016
EU/1/11/698	Yervoy	Norway	29.4.2016
EU/1/11/698	Yervoy	Iceland	18.5.2016
EU/1/11/699	Fampyra	Liechtenstein	30.6.2016
EU/1/11/699	Fampyra	Iceland	15.6.2016
EU/1/11/700	Benlysta	Liechtenstein	29.2.2016
EU/1/11/700	Benlysta	Norway	26.2.2016
EU/1/11/700	Benlysta	Iceland	18.3.2016
EU/1/11/702	Levetiracetam ratiopharm	Liechtenstein	30.4.2016
EU/1/11/702	Levetiracetam ratiopharm	Norway	18.5.2016
EU/1/11/702	Levetiracetam ratiopharm	Iceland	19.5.2016
EU/1/11/703	Xgeva	Liechtenstein	30.6.2016
EU/1/11/703	Xgeva	Norway	18.5.2016
EU/1/11/703	Xgeva	Iceland	13.5.2016
EU/1/11/704	Victrelis	Liechtenstein	29.2.2016
EU/1/11/704	Victrelis	Iceland	17.3.2016
EU/1/11/704	Victrelis	Norway	3.3.2016

EU-Number	Product	Country	Date of authorisation
EU/1/11/705	Vibativ	Liechtenstein	30.6.2016
EU/1/11/705	Vibativ	Iceland	13.6.2016
EU/1/11/705	Vibativ	Norway	9.6.2016
EU/1/11/706	Levodopa/Carbidopa/Entacapone Orion	Liechtenstein	30.6.2016
EU/1/11/706	Levodopa/Carbidopa/Entacapone Orion	Iceland	15.6.2016
EU/1/11/707	Trajenta	Liechtenstein	30.4.2016
EU/1/11/707	Trajenta	Norway	19.4.2016
EU/1/11/707	Trajenta	Iceland	31.3.2016
EU/1/11/708	Entacapone Orion	Liechtenstein	30.4.2016
EU/1/11/708	Entacapone Orion	Norway	21.4.2016
EU/1/11/708	Entacapone Orion	Iceland	26.4.2016
EU/1/11/709	Buccolam	Liechtenstein	30.6.2016
EU/1/11/709	Buccolam	Norway	24.6.2016
EU/1/11/709	Buccolam	Iceland	13.6.2016
EU/1/11/714	Zytiga	Liechtenstein	30.6.2016
EU/1/11/714	Zytiga	Norway	14.6.2016
EU/1/11/714	Zytiga	Iceland	13.6.2016
EU/1/11/718	Dexdor	Liechtenstein	30.6.2016
EU/1/11/718	Dexdor	Norway	20.6.2016
EU/1/11/718	Dexdor	Iceland	13.6.2016
EU/1/11/719	Telmisartan Teva Pharma	Liechtenstein	30.6.2016
EU/1/11/719	Telmisartan Teva Pharma	Norway	23.6.2016
EU/1/11/749	Caprelsa	Norway	14.1.2016
EU/1/11/749	Caprelsa	Iceland	14.1.2016
EU/1/12/764	Pixuvri	Liechtenstein	30.4.2016

EU-Number	Product	Country	Date of authorisation
EU/1/12/764	Pixuvri	Norway	1.4.2016
EU/1/12/764	Pixuvri	Iceland	31.3.2016
EU/1/13/818	Bosulif	Norway	14.1.2016
EU/1/13/818	Bosulif	Iceland	13.1.2016
EU/1/13/848	Erivedge	Norway	16.6.2016
EU/1/13/848	Erivedge	Iceland	15.6.2016
EU/1/13/875	Deltyba	Norway	29.3.2016
EU/1/13/875	Deltyba	Iceland	22.3.2016
EU/1/13/890	Cometriq	Liechtenstein	29.2.2016
EU/1/13/890	Cometriq	Norway	20.1.2016
EU/1/13/890	Cometriq	Iceland	19.1.2016
EU/1/13/901	Sirturo	Liechtenstein	29.2.2016
EU/1/13/901	Sirturo	Norway	14.1.2016
EU/1/13/901	Sirturo	Iceland	13.1.2016
EU/1/14/987	Holoclar	Iceland	4.1.2016
EU/1/15/999	Zykadia	Liechtenstein	30.4.2016
EU/1/15/999	Zykadia	Norway	6.4.2016
EU/1/15/999	Zykadia	Iceland	31.3.2016
EU/2/06/061	Nobilis Influenza H5N2	Norway	28.6.2016
EU/2/10/107	Veraflox	Liechtenstein	29.2.2016
EU/2/10/107	Veraflox	Norway	13.1.2016
EU/2/10/107	Veraflox	Iceland	15.1.2016
EU/2/10/115	Comfortis	Liechtenstein	29.2.2016
EU/2/10/115	Comfortis	Norway	18.1.2016
EU/2/10/115	Comfortis	Iceland	15.1.2016

EU-Number	Product	Country	Date of authorisation
EU/2/10/116	Melosus	Liechtenstein	29.2.2016
EU/2/10/116	Melosus	Norway	22.1.2016
EU/2/10/116	Melosus	Iceland	22.1.2016
EU/2/10/118	Activyl	Liechtenstein	29.2.2016
EU/2/10/118	Activyl	Norway	29.1.2016
EU/2/10/118	Activyl	Iceland	15.1.2016
EU/2/10/119	Cimalgex	Liechtenstein	29.2.2016
EU/2/10/119	Cimalgex	Norway	19.1.2016
EU/2/10/119	Cimalgex	Iceland	15.1.2016
EU/2/11/120	Zulvac 1 + 8 Ovis	Liechtenstein	29.2.2016
EU/2/11/120	Zulvac 1 + 8 Ovis	Norway	19.1.2016
EU/2/11/120	Zulvac 1 + 8 Ovis	Iceland	15.1.2016
EU/2/11/121	CaniLeish	Liechtenstein	29.2.2016
EU/2/11/121	CaniLeish	Norway	18.1.2016
EU/2/11/121	CaniLeish	Iceland	15.1.2016
EU/2/11/122	Bluevac BTV8	Liechtenstein	30.4.2016
EU/2/11/122	Bluevac BTV8	Norway	29.3.2016
EU/2/11/122	Bluevac BTV8	Iceland	29.3.2016
EU/2/11/123	Procox	Liechtenstein	29.2.2016
EU/2/11/123	Procox	Norway	20.1.2016
EU/2/11/123	Procox	Iceland	20.1.2016
EU/2/11/124	Zuprevo	Liechtenstein	30.6.2016
EU/2/11/124	Zuprevo	Norway	1.6.2016
EU/2/11/124	Zuprevo	Iceland	26.5.2016
EU/2/11/125	Certifect	Liechtenstein	30.4.2016

EU-Number	Product	Country	Date of authorisation
EU/2/11/125	Certifect	Norway	4.5.2016
EU/2/11/125	Certifect	Iceland	12.5.2016
EU/2/11/126	MS-H Impfstoff	Liechtenstein	30.6.2016
EU/2/11/126	MS-H Vaccine	Iceland	23.5.2016
EU/2/11/126	MS-H-Vaksine	Norway	24.5.2016
EU/2/11/128	Emdocam	Liechtenstein	30.6.2016
EU/2/11/128	Emdocam	Norway	27.6.2016
EU/2/11/129	Proteq West Nile	Liechtenstein	30.6.2016
EU/2/11/129	Proteq West Nile	Norway	24.5.2016
EU/2/11/129	Proteq West Nile	Iceland	23.5.2016
EU/2/11/130	Zulvac 1 Bovis	Liechtenstein	30.4.2016
EU/2/11/130	Zulvac 1 Bovis	Norway	2.5.2016
EU/2/11/130	Zulvac 1 Bovis	Iceland	13.5.2016
EU/2/11/131	Zulvac 1 Ovis	Liechtenstein	30.4.2016
EU/2/11/131	Zulvac 1 Ovis	Norway	2.5.2016
EU/2/11/131	Zulvac 1 Ovis	Iceland	13.5.2016

ANNEX III

List of extended marketing authorisations

The following marketing authorisations have been extended in the EEA EFTA States during the period 1 January-30 June 2016:

EU-Number	Product	Country	Date of authorisation
EU/1/03/262/011	Emend	Norway	15.1.2016
EU/1/03/262/011	Emend	Iceland	14.1.2016
EU/1/06/356/011-019	Exjade	Norway	1.4.2016
EU/1/06/356/011-019	Exjade	Iceland	31.3.2016
EU/1/10/612/010-013	Revolade	Norway	14.4.2016
EU/1/10/612/010-013	Revolade	Iceland	26.4.2016
EU/1/10/655/007-011	Brilique	Norway	26.2.2016
EU/1/10/655/007-011	Brilique	Iceland	18.3.2016
EU/1/13/851/004-006	Lojuxta	Norway	1.3.2016
EU/1/13/851/004-006	Lojuxta	Iceland	18.3.2016
EU/1/14/971/007-010	Trevicta	Norway	7.6.2016
EU/1/14/971/007-010	Trevicta	Iceland	15.6.2016
EU/1/98/067/004	Mabthera	Iceland	15.6.2016
EU/1/98/067/004	Mabthera	Norway	26.5.2016
EU/2/13/158/016-031	Bravecto	Norway	7.6.2016
EU/2/13/158/016-031	Bravecto	Iceland	25.5.2016

ANNEX IV

List of withdrawn marketing authorisations

The following marketing authorisations have been withdrawn in the EEA EFTA States during the period 1 January-30 June 2016:

EU-Number	Product	Country	Date of withdrawal
EU/1/01/179	Osigraft	Norway	18.1.2016
EU/1/01/179	Osigraft	Iceland	4.1.2016
EU/1/05/314	Kepivance	Liechtenstein	30.4.2016
EU/1/05/314	Kepivance	Iceland	29.3.2016
EU/1/05/314	Kepivance	Norway	22.3.2016
EU/1/13/831	Capecitabin SUN	Liechtenstein	30.6.2016
EU/1/13/833	Nuedexta	Liechtenstein	30.4.2016
EU/1/13/833	Nuedexta	Norway	31.3.2016
EU/1/13/833	Nuedexta	Iceland	21.3.2016
EU/1/14/942	Clopidogrel/Acetylsalicylic acid Teva	Norway	15.6.2016
EU/2/12/138	RevitaCAM	Liechtenstein	30.6.2016
EU/2/12/138	RevitaCAM	Norway	15.6.2016
EU/2/12/138	RevitaCAM	Iceland	13.6.2016

ANNEX V

List of suspended marketing authorisations

The following marketing authorisations have been suspended in the EEA EFTA States during the period 1 January-30 June 2016:

EU-Number	Product	Country	Date of suspension

V

(Announcements)

PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION POLICY

EUROPEAN COMMISSION

Prior notification of a concentration

(Case M.8393 — Thyssenkrupp Technologies/Thyssenkrupp/Atlas Elektronik)

Candidate case for simplified procedure

(Text with EEA relevance)

(2017/C 58/09)

1. On 15 February 2017, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ([1]) by which Thyssenkrupp Technologies Beteiligungen GmbH, belonging to the Thyssenkrupp AG group, both of Germany, acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of Atlas Elektronik GmbH, of Germany, by way of a purchase of shares.

2. The business activities of the undertakings concerned are:

— for Thyssenkrupp: the production and trading of materials (including steel), industrial goods and capital goods and the provision of engineering solutions for industrial processes and services. Thyssenkrupp, through its subsidiary Thyssenkrupp Marine Systems GmbH, is active in the production of submarines and surface naval vessels,

— for Atlas Elektronik: the naval systems sector, in particular sonar systems and combat management system solutions for submarines, surface combatants and mine counter vessels, as well as naval weapons. In addition, Atlas Elektronik produces naval communication systems.

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

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

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by email to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference M.8393 — Thyssenkrupp Technologies/Thyssenkrupp/Atlas Elektronik, to the following address:

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

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

Prior notification of a concentration

(Case M.8367 — Bain Capital/Consolis)

Candidate case for simplified procedure

(Text with EEA relevance)

(2017/C 58/10)

1. On 14 February 2017, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ([1]) by which the undertaking Bain Capital Europe Fund IV, L.P. ('Bain Capital Europe Fund IV'), a fund managed by Bain Capital Investors, L.L.C. ('Bain Capital', United Kingdom), acquires within the meaning of Article 3(1)(b) of the Merger Regulation sole control of the whole of the undertakings Consolis Holding SAS and Consolis SAS and their subsidiaries ('Consolis Group', France) by way of a purchase of shares.

2. The business activities of the undertakings concerned are:

— Bain Capital: private equity investment firm that invests in companies across most industries, including information technology, healthcare, retail and consumer products, communications, financial and industrial/manufacturing,

— Consolis Group: design and manufacture of prefabricated concrete elements.

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

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

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by email to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference M.8367 — Bain Capital/Consolis, to the following address:

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

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

OTHER ACTS

EUROPEAN COMMISSION

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

(2017/C 58/11)

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

APPLICATION FOR APPROVAL OF NON-MINOR AMENDMENTS TO THE PRODUCT SPECIFICATION FOR A PROTECTED DESIGNATION OF ORIGIN OR PROTECTED GEOGRAPHICAL INDICATION

Application for approval of amendments in accordance with the first subparagraph of Article 53(2) of Regulation (EU) No 1151/2012

'TOMME DE SAVOIE'

EU No: PGI-FR-02097 — 23.11.2015

PDO ( ) PGI (X)

1. **Applicant group and legitimate interest**

Name: SAVOICIME
Address: Maison de l'Agriculture
52 avenue des Iles
74994 Annecy Cedex 9
FRANCE

Tel. +33 450881848
Fax +33 450881833
Email: savoicime@haute-savoie.chambagri.fr

The group is made up of milk producers, processors and ripeners and therefore has a legitimate right to request amendments to the product specification.

2. **Member State or Third Country**

France

3. **Heading in the product specification affected by the amendment(s)**

— ☐ Name of product

— ☒ Description of product

— ☒ Geographical area

— ☒ Proof of origin

— ☒ Method of production

— ☒ Link

— ☒ Labelling

— ☒ Other: reference to the applicant group, references to the inspection body

4. **Type of amendment(s)**

— ☐ Amendments to the product specification of a registered PDO or PGI not to be qualified as minor within the meaning of the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012

[1] OJ L 343, 14.12.2012, p. 1.

— ☒ Amendments to the product specification of a registered PDO or PGI for which a Single Document (or equivalent) has not been published and which cannot be qualified as minor within the meaning of the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012

5. **Amendment(s)**

Amendments concerning the description of the product

This heading has been reorganised and extended as follows:

— fat content: in line with changes to French law, this has been expressed in terms of the total weight of the cheese. The minimum fat content, set at 20 % of the dry matter in the current product specification, has therefore been replaced by a minimum fat content of 9 % of the final product. This clarification aids consumer information,

— in order to enhance the characteristics of the cheese and improve its definition, a dry matter content equal to or greater than 45 % and a salt content of between 1,2 and 2 % of the final product have been added to the amended product specification,

— the applicant group has replaced the diameter of the cheese of 18 cm defined in the current product specification with a range of 18 to 21 cm, to take into account the types of moulds used in production. The weight remains fixed at 1,2 to 2 kg,

— 'small format' cheeses have also been introduced, which weigh 400 to 900 g and have a maximum height of 8 cm.

These different formats reflect the domestic nature of the traditional production of this cheese, for which the quantity of milk available depended largely on the other uses of milk, in particular to supply fat, which was highly coveted.

The sensory characteristics of this small format are the same as those of the format described previously,

— a more precise and detailed description of the organoleptic properties has been added, in particular with regard to the properties of the rind (addition of 'smooth to slightly uneven'; addition of 'to grey-white' after the word 'grey'), to facilitate inspection and supplement the current product specification,

— the words 'naturally formed yellow or red patches' have been replaced with 'secondary mould' to make inspections more objective.

— a more precise and detailed description of the organoleptic properties has been added, in particular concerning the properties of the paste (addition of 'Its taste is clear and slightly salty, sometimes with a touch of acidity and a touch of sharpness'), to facilitate inspection and supplement the current product specification,

— new forms of presentation have been introduced into the amended specification to allow producers to adapt to new patterns of consumption, as follows:

  — the possibility of cutting the cheeses into portions or slices,

  — the possibility of selling the cheeses in pre-packed individual portions, in portions or slices,

— the arrangements concerning ripening and inoculation have been moved to the section on the production method.

Amendments concerning the geographical area

The geographical area currently registered for 'Tomme de Savoie' PGI distinguishes between a milk collection area and a processing/ripening area. The update of the PGI has been used to set a single geographical area for milk collection and processing/ripening. The objective of this first amendment is therefore to ensure that there is a single geographical area.

Some adjustments have been made to the list of municipalities that make up the geographical area. While preparing the amendment application for the product specification of 'Tomme de Savoie' PGI, it emerged that defining the area according to the administrative boundaries of the two departments of Savoie was not the most appropriate solution.

The current product specification refers to the 'historic area of the Province of Savoie', which corresponds to a geographical area that is larger than the defined administrative areas for milk production and processing/ripening.

The activity of the two groups that submitted the first request for PGI recognition in December 1993 was limited to the two departments of Savoie and Haute-Savoie. The demarcated areas for milk production and processing/ripening in the current product specification therefore only cover the two Savoie departments and, in the case of milk production, three municipalities located on the other side of the Rhône in the department of Ain, which delivered their milk to a cheese manufacturer that produced 'Tomme de Savoie'. However, identical environmental properties and common practice have led to a more appropriate demarcation including municipalities that border the Savoie departments.

With a view to defining a clear, uniform and coherent geographical area, 24 municipalities from the department of Ain and five municipalities from the department of Isère have been added. They belong to the same natural area, which is bordered by the first foothills of the Jura mountains to the west and characterised by fertile soil on mainly quaternary sediments and a semi-continental climate subject to an oceanic influence, resulting in an abundant production of high-quality fodder. The added municipalities also share common practices and a history of producing milk to be delivered to the processing/ripening area set out in the current product specification. The milk from these comparable municipalities, which has long been transported to cheese manufacturers in the production area, is currently separated from milk to be made into 'Tomme de Savoie'. Amending the product specification will make it possible to use this milk to produce 'Tomme de Savoie'.

In total, the geographical area now includes 632 municipalities, instead of the 603 initially included in the current product specification.

The link between 'Tomme de Savoie' and the geographical area is not affected.

Amendments concerning the proof of origin

The producers' obligations as regards declarations have been clarified in order to provide a better framework for recording data for inspection purposes. A traceability system has also been set up to facilitate product monitoring (record-keeping, clarifications on the identification of the product).

To facilitate inspection, a requirement has been added for each milk producer to submit an annual declaration, summarising all the points needed for the check. A requirement has also been introduced to declare the production of non-compliant feed intended for animals other than the dairy herd, to make it possible to check the feeding conditions of the dairy herd.

To ensure monitoring at industry level, it has been stipulated that processing and ripening facilities must submit their production declarations on a monthly basis.

In the interests of traceability, it has been specified that:

— batches intended for the PGI must be identified in the records so that the milk and cheese can be monitored,

— the origin and quantities of milk and the quantities of cheese must be recorded.

A table summarises all the points concerning traceability.

The bullet point '— by managing casein plates' has been replaced by a paragraph concerning the obligatory identification mark made up of the facility number and a serial number, made available by the group to all authorised producers. This wording allows the group to adapt the identification mark in line with technical developments. A procedure has been established for handing over identification marks if an authorisation is withdrawn or use of the designation is suspended. The procedure for 'downgrading' non-compliant cheeses has been specified: the downgrading is recorded in a register on the same day, along with the number of downgraded cheeses and their batch number or the serial number on the identification mark.

The list of required checks has been removed, because these checks come under the inspection plan. The 'accreditation' of ripening facilities has been removed, because it is redundant under the national rules for authorising every operator in the industry (ripening facilities, but also milk producers and manufacturing facilities).

Amendments concerning the production method

Breed composition of the herd:

The current product specification does not include any provisions on the breed composition of the herd. In order to increase the presence of dairy cows of the Abondance, Montbéliarde and Tarentaise breeds, which are those mainly used in the geographical area and whose milk has traditionally been used to produce 'Tomme de Savoie' and affects the quality of the final product, the amended product specification requires each cheese to be produced using at least 75 % milk from these breeds. This requirement is accompanied by a provision specifying that the proportion of local breeds in each herd may only increase, so as not to jeopardise the supply of milk for cheese manufacturers. Maintaining the tradition of farming the traditional Abondance, Montbéliarde and Tarentaise breeds is justified because these are local breeds, which have been bred in the Savoie region for a very long time and have demonstrated their ability to adapt to the physical and climatic constraints of the environment: body type adapted to grazing on sloping pastures, temperature tolerance, ability to thrive on grazing in the summer and dry fodder in the winter.

Four producers who lodged a statement of opposition during the national opposition period relating to the provision in question and fulfilling the conditions of Article 15(4) of Regulation (EU) No 1151/2012 have been granted a transitional period until 31 October 2025.

Animal feeding:

The current product specification in accordance with Regulation (EC) No 1106/96 does not include any specific requirements relating to the types of feed or characteristics of the animals' diet. The following points have been added:

— definition of the categories of feed used: addition of a list of feeds that can be used for the animals, taking into account the potential of the geographical area and with a view to controlling nutritional intake,

— a minimum proportion of coarse green fodder is defined: 'Feed based on course green fodder is obligatory for at least 150 days a year, which may or may not be consecutive, equivalent to at least 50 % of the basic ration.' This requirement is justified by the fact that it makes optimum use of the local pastures, which have typical Alpine flora. This requirement therefore improves the link between the product and its geographical origin.

  One producer who lodged a statement of opposition during the national opposition period relating to this provision and fulfilling the conditions of Article 15(4) of Regulation (EU) No 1151/2012 has been granted a transitional period ending on 31 December 2017,

— 100 % of the coarse fodder fed to lactating cows (grass, hay, second-cut hay, green maize, sorghum, straw, catch crops) comes from the geographical area. Complementary feed is not produced in sufficient quantities in the geographical area every year. Therefore, the use of dehydrated fodder, corn cob, moist grain maize and fodder beet that may come from outside the geographical area is limited to 4 kg of dry matter per lactating cow as a daily average throughout the year. These requirements are justified by the fact that the geographical area's soil composition and precipitation make it prime territory for high-quality grass. Both the hay meadows and pastures have a rich and diversified flora, typical of the Alpine mountain area, which encourages producers to make optimum use of these resources. Limiting the use of complementary feed from outside the area improves the link between the product and its geographical origin,

— feed of other herds on the holding: where holdings also farm other animals that are not intended for the production of 'Tomme de Savoie' and have to be fed a specific diet, specific provisions ensure that the feed and animals concerned are separated,

— genetically modified organisms: animals whose milk is intended for the production of 'Tomme de Savoie' may not be given this type of feed. This requirement has been introduced to keep as close as possible to the characteristics of the feed.

Milk collection:

— the references to health requirements concerning the animals have been removed from the product specification, because they are covered by the general legislation,

— the maximum storage temperature for milk on the holding is specified (8 °C) in order to guarantee the quality of the milk used to produce 'Tomme de Savoie',

— the collection frequency is specified: the milk must be delivered or collected at least once a day. This provision is linked to the need to work with raw milk,

— in order for the milk obtained to have as regular a composition as possible, the amended product specification introduces a requirement for the cows to be milked at least once a day.

Provisions concerning the processing facilities:

A requirement has been introduced for processing facilities to bring in only milk that meets all the production conditions in the amended product specification, in order to make the traceability checks more effective. However, when the facility is located within a factory, the requirements for separating milk on collection and separating circuits for carrying milk around the facility are described.

Processing aids and additives:

A positive list has been introduced to supplement the current product specification (animal rennet, salt, enzymes (including surface flora) and calcium chloride).

Milk storage at the cheese manufacturer:

A maximum time that milk may be stored at the cheese manufacturer before renneting has been introduced, to supplement the current product specification. This is set at 36 hours when the milk is kept at a temperature of + 8 °C and 48 hours when the milk is kept at + 4 °C. These time limits make it possible to use raw milk while preserving its natural flora.

Milk preparation:

A clearer and more complete description of the physical and heat treatments that may be carried out on the milk has been introduced in order to supplement the current product specification and facilitate inspection.

Processes that are not permitted to be carried out on the milk have been specified. In particular, these cover pasteurisation and sterilisation, which would destroy the alkaline phosphatase. Any other processes that could destroy the milk's natural flora and its influence on the properties of the final product are prohibited, as is the equipment required for such prohibited processes.

Processes for skimming and incorporating calcium chloride have been authorised. They were not prohibited by the current product specification.

Production:

Maturation, renneting, cutting of coagulum, stirring, optional heating and moulding: these various stages have been defined more precisely in order to facilitate inspection and make them easier for the producers to apply.

— Maturation: to take production practices into account, it is specified that 'two types of maturation may be used':

  — long maturation: minimum 4 hours, at a temperature of between 8 °C and 16 °C,

  — short maturation: the time bracket of 45 to 60 minutes has been widened to 30 to 90 minutes.

    The maximum temperature is set at 35 °C (instead of 34 °C as it was previously). It has been added that 'if both types are used, the long maturation must precede the short maturation. In this case, the short maturation must last at least 20 minutes.' These techniques, which were omitted from the current product specification, are sometimes needed to adapt to the properties of the milk, and its seasonal properties in particular.

— Renneting: it has been specified that this step must be carried out in the production vat.

— Cutting of coagulum: the duration of this stage has been deleted, because in practice it is too variable. It has been added that 'the curd is cut after hardening'.

— Stirring: the minimum stirring time has been reduced from 30 to 20 minutes, because this is sufficient to obtain the traditional properties of the cheese.

— Heating: it has been specified that, if carried out, heating should not exceed 40 °C, in order to encourage the development of the natural and inoculation flora.

— Moulding: this term has replaced 'lactoserum extraction'. The following sentence has been added: 'The curd is placed into moulds or strainers'. The sentence 'Moulding is preceded by lactoserum extraction' has been removed because it is unnecessary.

— Pressing and acidification: these two stages have been introduced in place of lactoserum extraction and draining. Their wording has been simplified and clarified. The pressing times have been deleted because they depend on the know-how of each cheese manufacturer, who has to adapt the times to the variable properties of the curd. The maximum acidification time has been deleted, because it has no technical relevance. The ambient temperature of 15 to 20 °C has been replaced by a minimum temperature of 20 °C, because the earlier set temperature could be insufficient to guarantee satisfactory acidification.

  The casein plates are to be added at this stage, as they are essential for traceability.

— Salting: the duration criterion has been replaced by a requirement to obtain a product with a final salt content of between 1,2 g/100 g and 2 g/100 g. This provision allows producers to manage the salting stage by adapting to the development of the cheeses during the early stages of production. In order to remain in control of fermentation, the group has proposed that salting should not be carried out in the vat during production. Only dry salting or brining is permitted (it is not permitted to carry out salting in the production vat).

Ripening:

The maximum temperature of the ripening cellars has been increased from 13 °C to 14 °C, because this temperature allows the ripening to begin more rapidly and therefore improves the organoleptic properties of the ripened cheese. The humidity restrictions have been simplified, because only the minimum humidity is important in order for the cheese to preserve its traditional characteristics. The minimum number of times the cheeses must be turned over during ripening has been reduced from twice to once per week, since this is sufficient to guarantee the cheese's characteristics. The amendment therefore preserves the product's characteristics, while also preserving the practice of turning the cheeses, which is not affected in principle.

The 'Product description' chapter of the current product specification imposes a 6-week ripening period before consumption. In the amended specification, this period has been set at 30 days between the renneting date and the date the cheeses leave the ripening cellars, in order to make the inspections more objective. After 30 days, under the conditions laid down in the amended product specification, the cheese has ripened sufficiently to display all the characteristics of the finished product, ready to be put on the market.

The group has specified that the cheese must be ripened on wooden boards. This material acts as a blotter for the water and the cheeses' surface flora.

Amendments concerning the evidence of the link with the geographical origin

The link with the geographical origin has been amended in line with the production method, particularly in terms of the breeds of dairy cows and the origin of their feed.

Amendments concerning the specific labelling details

The labelling requirements have been supplemented and clarified, in order to provide the consumer with clear information, in particular with regard to the 'small format', and to ensure the product's upstream traceability.

Other amendments:

Applicant:

Following changes made to the organisation of the local dairy industry, the SAVOICIME group has been set up by the producers as the applicant group.

References to the inspection body

In accordance with national guidelines aimed at harmonising specifications, the name and contact details of the certification body have been deleted. Under this heading, the contact details of the authorities responsible for national inspections are now indicated, i.e. the National Institute of Origin and Quality (INAO) and the Directorate-General for Competition, Consumer Affairs and Fraud Prevention (DGCCRF). The name and contact details of the certification body can be consulted via the website of the INAO and the European Commission's database.

SINGLE DOCUMENT

'TOMME DE SAVOIE'

EU No: PGI-FR-02097 — 23.11.2015

PDO ( ) PGI (X)

1. **Name(s)**

'Tomme de Savoie'

2. **Member State or Third Country**

France

3. **Description of the agricultural product or foodstuff**

3.1. *Type of product*

Class 1.3. Cheeses

3.2. *Description of the product to which the name in (1) applies*

'Tomme de Savoie' is a pressed, uncooked cheese, made from raw or thermised cow's milk. The minimum ripening period is 30 days between the renneting date and the date the cheeses leave the ripening cellars.

It comes in the form of a flat cylinder and measures 18 to 21 cm in diameter and 5 to 8 cm in height. It weighs between 1,2 and 2 kg. It can also come in a smaller format, but with the same organoleptic properties. In this case, its maximum height is 8 cm and its weight may be between 400 and 900 g.

The rind is smooth to slightly uneven, of a grey to grey-white colour. Secondary mould may develop on the rind.

The paste is semi-hard, of a white to yellow colour, with small openings. Its taste is clear and slightly salty, sometimes with a touch of acidity and a touch of sharpness.

The cheese's minimum fat content is 9 % of the total weight and 45 % of the dry matter.

The salt content is between 1,2 % and 2 %.

'Tomme de Savoie' is sold in the following formats: whole, cut into portions or slices, or in pre-packaged units for sale to the consumer (portions or slices).

3.3. *Feed (for products of animal origin only) and raw materials (for processed products only)*

The different types of authorised feed are:

— coarse fodder (grass, hay, second-cut hay, green maize, sorghum, straw, catch crops),

— corn cob and wet grain maize, permitted only between 15 October and 15 May,

— dehydrated fodder, dehydrated lucerne, dehydrated beetroot pulp, fodder beet, which must be fed clean and sound,

— the following complementary feed and additives:

  — cereal grains and products derived from them (bran, sharps, flour, dehydrated distilling dregs); the cereal grains may be preserved by inerting,

  — seeds, oilseed and protein cakes,

  — byproducts: lucerne protein concentrate, non-protein nitrogen (byproducts of starch or yeast production), urea < 3 % in complementary feed,

  — molasses and vegetable oil, minerals, vitamins, trace elements and natural plant extracts,

  — lactoserum produced on the holding may be used within 24 hours.

For lactating cows:

— 100 % of the coarse fodder comes from the geographical area;

— dehydrated fodder, corn cob, wet grain maize and fodder beet from outside the geographical area is limited to 4 kg of dry matter per lactating cow as a daily average throughout the year.

These restrictions guarantee that the majority of the dry material consumed by the dairy cows comes from the defined geographical area. They therefore improve the link between the product and its geographical origin.

In the case of farm-based production, the milk used to produce 'Tomme de Savoie' comes from a herd of dairy cows that consists of at least 75 % of cows from the Abondance, Montbéliarde or Tarentaise breeds.

At a processor's facility, the milk collected for producing 'Tomme de Savoie' comes from a herd of dairy cows at least 75 % of which consists of cows from the Abondance, Montbéliarde or Tarentaise breeds.

Maintaining the tradition of farming the traditional Abondance, Montbéliarde and Tarentaise breeds is justified because they have demonstrated their ability to adapt to the physical and climatic constraints of the environment: body type adapted to grazing on sloping pastures, temperature tolerance, ability to thrive on grazing in the summer and dry fodder in the winter.

3.4. *Specific steps in production that must take place in the defined geographical area*

The milk production, processing and ripening stages take place in the defined geographical area.

The production of milk intended for the production of 'Tomme de Savoie' in the geographical area is justified by the considerable sources of fodder in the area, which are used in the production of the cheese.

3.5. *Specific rules concerning slicing, grating, packaging, etc. of the product the registered name refers to*

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3.6. *Specific rules concerning labelling of the product the registered name refers to*

The labelling of cheeses with the protected geographical indication 'Tomme de Savoie' must meet the following requirements:

— the name 'Tomme de Savoie' must be specified on all the packaging,

— the manufacturer or ripener or packager must indicate their name and address,

— the name of the certifying body must be specified,

— any cheese marketed using the name of the geographical indication must include a reference to the geographical origin, in the format defined by the group, on one side or on the edge; this identification does not apply to cheeses marketed directly to the consumer by a farm producer or cheese manufacturer,

— in addition, for cheeses from small moulds, the word 'petite' (small) may be included on the labelling, invoices and commercial documents, but it may not be adjacent to or immediately above the name 'Tomme de Savoie'.

4. **Concise definition of the geographical area**

The geographical area covers the whole of the two departments of Savoie and Haute Savoie and the following municipalities in the Departments of Ain and Isère.

Department of Ain: Anglefort, Bellegarde-sur-Valserine, Béon, Billiat, Ceyzérieu, Chanay, Châtillon-en-Michaille, Corbonod, Cressin-Rochefort, Culoz, Flaxieu, Injoux-Génissiat, Lancrans, Lavours, Léaz, Lhôpital, Massignieu-de-Rives, Nattages, Parves, Pollieu, Saint-Martin-de-Bavel, Seyssel, Surjoux, Talissieu, Villes, Virignin, Vongnes.

Department of Isère: Entre-deux-Guiers, Miribel-les-Échelles, Saint-Christophe-sur-Guiers, Saint-Pierre-de-Chartreuse, Saint-Pierre d'Entremont.

5. **Link with the geographical area**

Specificity of the area

The natural surroundings of the 'Tomme de Savoie' area have a large variety of soil substrates and a homogeneous mountain climate.

In topographical and geological terms, the geographical area for 'Tomme de Savoie' is quite diverse. The area is mainly at an altitude of between 200 and 2 500 m, with characteristic soil types from both old crystalline and limestone massifs.

The climate is typical of mountain climates: the winters are long and sometimes harsh and the summers hot. With the exception of the valleys in the Maurienne and Tarentaise, which receive less precipitation on the whole, the annual precipitation is high, with an average of 1 000 mm and up to 1 500 mm at the base of the pre-Alpine mountain ranges. Precipitation is distributed over the whole year.

The combination of deep soils and considerable precipitation throughout the year makes the geographical area a distinctive and characteristic prime territory for high-quality grass (pasture and meadows with rich and diverse flora).

In the foreland, cereal and maize production is also well developed.

As regards human factors, 'Tomme de Savoie' is the oldest of the Savoie cheeses. 'Tomme de Savoie' has long been a cheese intended for domestic consumption. It was an essential source of protein in the peasants' diet.

The quantity of milk available depended largely on the other uses of milk, in particular to supply fat, which was highly coveted. The peasants of the Province of Savoie produced this cheese with the small amount of milk left over.

In the same way that 'Tomme de Savoie' cheeses had varying fat contents depending on the degree of skimming, there were also different sizes of 'Tomme de Savoie' depending on the farms where they were produced.

'Tomme de Savoie' was originally produced domestically, and production was then extended to certain cheese-making dairies.

The production of milk intended for producing 'Tomme de Savoie' still relies on the wide availability of grass in the geographical area and also on the continued tradition of farming traditional breeds: Abondance, Montbéliarde and Tarentaise. These breeds have demonstrated their ability to adjust to the physical and climate constraints of the environment: body type adapted to grazing on sloping pastures, temperature tolerance, ability to thrive on grazing in the summer and dry fodder in the winter. The dairy cows' feed is based on the use of fodder and cereals produced mainly in the geographical area.

In these mountain areas, specific cheese-making know-how has been developed that is well suited to the environment. The techniques used in the region are adapted to the properties of the milk, and the cheese producers take particular care to master certain points such as inoculation, management of the mesophilic and thermophilic flora and ripening.

These techniques are the result of shared know-how in a region where there has long been a culture of producing pressed cheeses.

Ripening the cheese on wooden boards in cellars allows the paste to develop properly and also enables the development of the surface flora, in particular the mucor. 'Tomme de Savoie' cheeses are turned over at least once a week during ripening, and the 'hairs' are removed during handling.

Specificity of the product

'Tomme de Savoie' is a pressed, uncooked cheese, made from raw or thermised cow's milk.

'Tomme de Savoie' is distinguished by its relatively small, flat, cylindrical format, its smooth to slightly uneven, white to white-grey rind, and its clear and slightly salty taste, sometimes with a touch of acidity and a touch of sharpness.

Causal link

The link between 'Tomme de Savoie' and its geographical origin is based on its specific quality.

The ability of the geographical area to produce sufficient quantities of coarse fodder and cereals to meet milk production needs, while maintaining extensive production systems, guarantees that the animals are fed a varied diet.

The systems for farming dairy herds prioritise the use of the great variety of local fodder resources available in the geographical area. Milk production in the geographical area makes optimum use of grazing resources in line with ancestral practices and uses milk obtained from traditional breeds. Local breeds are preferred, because they now account for over 90 % of the total livestock population. These breeds, which are well suited to the climate and mountain topography, are able to meet their full production potential despite sometimes difficult conditions, and through their milk, the diversity of the flora they consume is reflected in the cheese.

This milk, produced in large quantities thanks to a specific diet, is better suited to the production of 'Tomme de Savoie' than that of other breeds raised in the same conditions and displays the following particular features: the curd obtained after adding the rennet is firmer and the cheese yield greater.

Several studies have highlighted the effect of the feed and composition of the fodder on the quality of milk (e.g. Bugaud C., Buchin S., Hauwuy A., Coulon J.B., 2002. *Texture et flaveur du fromage selon la nature du pâturage: cas du fromage d'Abondance* (Texture and flavour of cheese according to the type of pasture: the case of cheese from the Abondance breed), INRA Prod. Anim., GIS AlpesJura; Dorioz J.M., Fleury P., Coulon J.B., Martin B., 2000. *La composante milieu physique dans l'effet terroir pour la production fromagère: quelques réflexions à partir du cas des fromages des Alpes du Nord* (The physical environment as a factor in the impact of '*terroir*' on cheese production: a discussion relating to cheese from the Northern Alps), Courrier de l'environnement, GIS AlpesJura; or Lucas A., Hulin S., Michel V., Agabriel C., Chamba J.F., Rock E., Coulon J.B., 2006. *Relations entre les conditions de production du lait et les teneurs en composés d'intérêt nutritionnel dans le fromage: étude en conditions réelles de production* (Relationship between milk production conditions and nutritional constituents in cheese: a study under actual production conditions), INRA Prod Anim, GIS AlpesJura). The last of these studies, which concerned 'Tomme de Savoie', highlights the significant effect of feed on the cheeses' liposoluble micronutrient content. It also demonstrates that the fatty acid profile of the milk, and by extension the cheese, is principally linked to the basic ration of the cows' feed.

The milk used for production is raw or thermised, which guarantees the presence of natural flora, protected by the production process being initiated quickly. It is partly this diverse flora that is responsible for the attributes of 'Tomme de Savoie'.

Using raw or thermised milk respects the milk's initial properties, in particular those that result from the animals' feed, the diversity of which is one of the features of the geographical area.

In the same way that 'Tomme de Savoie' cheeses had varying fat contents depending on the degree of skimming, there were also different sizes of 'Tomme de Savoie' depending on the farms where they were produced. The quantity of milk available depended largely on the other uses of milk, in particular to supply fat, which was highly coveted. The peasants produced this cheese with the small amount of milk left over.

To stay true to the product's traditional characteristics, the cheese manufacturers use a cheese pressing technique to produce cheeses that are of various sizes but all fairly small in comparison with other cheeses from the region, and which have varying fat contents.

Production practices have led to the selection of the appropriate flora for production. Its use enables current producers to develop the characteristic taste of the cheese. The ripening process develops this flavour further.

The surface flora, consisting mainly of mucor, gives 'Tomme de Savoie' its characteristic grey appearance. Its development is assisted by ripening the cheese on wood. The care taken when turning the cheese during ripening also helps to form the rind that is so characteristic of 'Tomme de Savoie', in particular by removing the mucor 'hairs'.

Reference to publication of the specification

(the second subparagraph of Article 6(1) of this Regulation)

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