Remarks by Commissioner Moscovici at the College readout: Commission supports normalisation in Greece through activation of post-programme framework

Dans 40 jours exactement, la Grèce va sortir de son programme d'assistance financière.

J'ai toujours dit que la fin du programme grec devait marquer un changement réel dans le statut de la Grèce au sein de l'Union Européenne et de la zone euro. Un changement dans le sens d'une plus grande autonomie, disons d'une plus grande liberté, dans l'élaboration des politiques économiques. Un changement vers la normalité.

La normalité signifie que la Grèce sera comme tout autre pays de la zone euro. Elle sera donc, pour la première fois, soumise aux mêmes mesures et procédures de coordination des politiques économiques, ce que nous appelons le Semestre Européen.

Cela signifie, par exemple, que la Commission préparera un avis cet automne sur le projet de budget de la Grèce pour 2019, qu'elle devra nous envoyer en octobre. Exactement comme nous le faisons pour la France, l'Allemagne ou l'Italie.

Tous les pays sortis dans le passé de l'aide financière sont soumis à un suivi des institutions européennes et du FMI. Ce n'est pas une invention, ce n'est pas quelque chose de discrétionnaire, c'est prévu par la législation européenne et ça fait partie des mécanismes ordinaires, là encore, la normalité parce que l'Europe continue d'accompagner ces pays.

Mais c'est vrai que la crise grecque a duré si longtemps, que ses réformes ont été si ambitieuses, si dures et profondes, et que sa dette reste encore aujourd'hui si élevée, et dans ces conditions il est normal que ce suivi post programme, cette surveillance post programme soit un peu plus étroite, du moins à court terme. Je note d'ailleurs que d'après un récent sondage, une majorité de Grecs souhaitent que l'Europe continue de soutenir la Grèce dans ses efforts et cette surveillance renforcée a été définie avec les autorités grecques.

C'est ça le sens de cette "surveillance renforcée" que nous adoptons aujourd'hui et qui entrera en vigueur le 21 août, au lendemain du terme juridique du programme. Ce processus a sa base légale dans le fameux "Two-Pack", paquet législatif adopté en 2013, dont cet élément est mis en œuvre pour la première fois. Il s'agit d'un cadre destiné à soutenir l'achèvement et la mise en œuvre des réformes en cours. Un cadre qui pourra aussi rassurer

les créanciers et les investisseurs — ainsi que les citoyens grecs eux-mêmes — sur le fait que la Grèce va continuer à mener des politiques budgétaires responsables.

Je le redis avec force, comme Valdis, la surveillance renforcée n'est pas un quatrième programme, le président Juncker y a insisté de manière très claire ce matin lors de la réunion de la Commission. Prétendre le contraire, c'est une contre-vérité. La surveillance renforcée n'implique aucune nouvelle réforme, aucune nouvelle mesure, aucun nouvel effort, en tout cas aucun effort supplémentaire, alors que pendant le troisième programme, celui qui vient de s'écouler, ce sont plus de 450 réformes qui ont été adoptées, la plupart votées par le parlement grec, et des ajustements budgétaires très importants, hors des normes prévues par le Semestre européen. Et donc si on ne voit pas la différence entre un programme et le post programme, c'est qu'il y a un problème de lunettes.

C'est de surcroit lutter contre son camp. C'est ne pas tenir compte des progrès réalisés par les Grecs depuis 8 ans et validés par tous les Etats de la zone euro, la Commission, la Banque centrale européenne, le Mécanisme européen de Stabilité et le Fonds monétaire international. Il y a un consensus international et européen pour considérer que la Grèce n'a pas besoin d'un nouveau programme, mais bel et bien d'achever les réformes entamées et de rester dans cette voie.

Je le redis donc très clairement : le programme actuel s'achèvera le 20 août prochain et ce sera le dernier programme d'assistance à la Grèce. Le mécanisme de suivi que nous mettons en place n'est pas un nouveau programme.

Il s'agit d'un cadre pour veiller à ce que la Grèce continue à respecter les engagements pris au cours du programme écoulé. C'est essentiel, car la reprise de la Grèce n'est pas un événement, c'est un processus qui nécessite un suivi dans le long terme.

La surveillance renforcée permettra aussi à l'Eurogroupe de respecter ses propres engagements, puisque — sur la base des rapports de la Commission tous les 6 mois, les Etats membres pourront décider la mise en œuvre des mesures d'allégement de la dette accordées à l'Eurogroupe du 21 juin. Nous parlons ici des revenus générés par l'Eurosystème sur les bonds grecs, soit environ 4Mds d'euros, donc tous les 6 mois nous aurons à décider des déboursements prévus.

Surveillance as Valdis said, will focus on the specific commitments made by Greece in the context of the 22 June Eurogroup agreement. These fall into six categories:

- fiscal and fiscal structural policies
- social welfare
- financial stability
- labour and product markets
- privatisation
- and public administration.

Again, we are talking only about existing reforms already legislated and being implemented.

Under enhanced surveillance, Greece will be monitored through more frequent review missions from the Commission and partner institutions, notably the European Central Bank and the European Stability Mechanism, in close coordination, I expect, also with the International Monetary Fund. This aspect is no different from what takes place in other Member States once they enter into post-programme surveillance.

Importantly, we want to avoid any duplication of processes. That's why we intend that the monitoring and reporting under enhanced surveillance, which will be quarterly, will to a large extent coincide with what takes place under the normal European Semester process. We will do all we can to maximise synergies between the two procedures.

A final thought before we take your questions:

Greece is now able to stand on its own two feet; that does not mean that it must stand alone. Europe will remain engaged and will continue to support Greece, and so will the European Commission.

Today's decision is about just that: no more, no less.

<u>Questions and Answers — EU External</u> Investment Plan

It aims to promote inclusive growth, job creation and sustainable development and in this way tackle some of the root causes of irregular migration.

What is the state of play on the External Investment Plan?

Less than a year after <u>the EIP's official launch</u>, the EU is on the right track towards achieving its commitment to leverage $\[mathbb{e}\]$ 44 billion of public and private investments in sustainable development, with an input of $\[mathbb{e}\]$ 4.1 billion from the EU for blending operations (mixing public grants and loans) as well as guarantee operations.

On 10 July, the EU took a milestone decision to mobilise ≤ 800 million in guarantee operations, which is expected to trigger investments of $\le 8-9$ billion.

This adds to the ≤ 1.6 billion that were mobilised for blending operations (i.e. the mixing of public grants and loans), which will mobilise up to ≤ 14.6 billion.

Overall, this will therefore translate into over €22 billion public and

private investments. This will support much needed investment in sustainable development and decent job creation particularly in Africa.

Each of the Investment Programmes presented on 10 July is accompanied by substantial technical assistance to support partners in developing good projects. Policy dialogue with partner countries at all levels is ongoing.

What is the target of the EIP and how much has already been achieved?

The Plan's financial arm, the €4.1 billion European Fund for Sustainable Development (EFSD), comprises two parts:

- Guarantee Fund (for a total of €1.5 billion by 2020): The decision of 10 July 2018 allocated €800 million from the Guarantee of the European Fund for Sustainable Development. This is expected to leverage €8-9 billion of public and private investments.
- Blending Facilities (for a total of €2.6 billion by 2020): Since 2017, the EU has made available a total of €1.6 billion for interventions mixing EU grants with loans (so-called blending). This will help to leverage up to €14.6 billion in potential investments.

Overall, this will translate into over €22 billion public and private investments. This will support much needed investment in sustainable development and decent job creation particularly in Africa.

What was decided on 10 July concerning the European External Investment Plan?

On 10 July, the Strategic Board of the European Fund for Sustainable Development (i.e. the financial fund underpinning the EU's External Investment Plan) gave its green light for twelve EU guarantees worth around €800 million. The Board comprises representatives of: EU Member States, the European Parliament (as observer), the European Commission (who chairs the meeting), the European External Action Service and the European Investment Bank. Partner countries and regional stakeholders can also join as observers.

The guarantees lower the risk of investing in projects in countries neighbouring the EU and in Africa. The guarantees will cover operations in several areas: financing for small businesses, including ones involved in agriculture; sustainable cities; sustainable energy and connectivity; and access to the internet and digital services.

The guarantees will help bring in private sector investment because they can:

- attract financing for some of the initial capital ('equity' or 'risk capital') which projects need to get off the ground. This could be for example solar parks or other projects related to sustainable development
- serve as a pledge (guarantee) to pay back parts of a loan if a borrower incurs losses and defaults on it.

What are the next steps?

The agreement on 10 July on first guarantee programmes paves the way for signing the first contracts for guarantee agreements already in the second

half of 2018. The European Commission is expected sign the first EIP guarantee agreements with eligible partner financial institutions later this year. These institutions will then use EU guarantees to finance new development projects and attract additional private investments.

Financial institutions should then start to roll out projects in early 2019.

What sectors are covered by these guarantees?

The EU had <u>in September 2017 identified five areas of intervention</u>, in which the External Investment Plan can have the highest impact for sustainable development. The first four are covered by the guarantee programmes approved on 10 July:

- financing for small businesses, including ones involved in agriculture
- sustainable cities
- sustainable energy and connectivity and
- access to the internet and digital services.

Furthermore, the Commission will review proposals in the field of agribusiness in autumn 2018.

Can you give some examples of the new guarantee programmes:

 NASIRA Risk-Sharing Facility: With €75 million EU input and managed by Dutch development bank, this new risk-sharing facility is expected to generate a total investment of €750 million to €1 billion. It will benefit people who currently have difficulty borrowing money at affordable rates, such as:

oPeople who have been forced to flee other parts of their countries (internally displaced people) or to leave their country all together (refugees)

oThose who had fled but have recently returned to rebuild their lives (returnees)

oWomen and young people aged 18-30

- InclusiFI will enable over 25,000 small businesses to access mobile accounts and long-term credit. The objective is to support financial inclusion driven by diasporas, migrants' families and migrants who have recently returned to their country of origin, in Sub-Saharan Africa and EU Neighbourhood. The lead financial institutions are AECID (Spain), COFIDES (Spain) and CDP (Italy).
- **DESCO financing programme**: This initiative will help bringing solar power kits to thousands of homes in Sub-Saharan Africa. With an input of €50 million from the EU and led by the African Development Bank, the guarantee tool will support access to clean electricity to an estimated **3.5 million people** in Sub-Saharan Africa (in particular in the Sahel region). The programme will help offset some of the risks that local banks perceive in financing solar power.
- A digital transformation platform and a broadband investment programme

will support rural access to broadband in the EU's southern and eastern neighbouring countries, with an EU input of €70 million and managed by the European Investment Bank (EIB) and the European Bank for Reconstruction and Development (EBRD). This programme is expected to bring fast broadband to 300 000 to 600 000 homes in rural areas which will allow people and businesses to take part more fully in the digital economy.

- The initiative **Boosting investment in renewable energy**, receives an EU input €100 million, and will be managed by the Association of European Development Finance Institutions (EDFI) and the European Bank for Reconstruction and Development (EBRD). By supporting investments in renewable energy in Sub-Saharan Africa and EU neighbouring countries, this programme is expected to:
- o Cut carbon emissions by an estimated 2-3 million tonnes per year
- o Create an additional 1.5 2 Gigawatts of renewable energy
- o Increase power production from renewable energy sources to 4,500-6000 GWh/year.

Can you give some examples of blending operations?

The EU has been supporting development and growth in partner countries through blending operations (mixing public grants and loans), for example:

- The <u>Electrification Financing Initiative or ElectriFI</u> helps to support investments in reliable, affordable and sustainable electricity and energy services that serve populations in rural areas in many partner countries. It does so by easing access to seed capital, as well as midand long-term capital. Funded by the European Commission, this initiative is managed by the Association of European Development Finance Institutions (EDFI).
- The <u>SANAD Fund</u> supports businesses, growth and job creation in in the Middle East and North Africa. It provides debt and equity finance to partner financial institutions, who then in turn support micro-, small and medium-sized enterprises. Such small companies account for 60 % of GDP and 70 % of employment in the region and are therefore crucial to a vibrant economy. However, surveys show that only 20 % of them have access to financing. Co-financed by the EU with €28 million and implemented by the development bank Kreditanstalt für Wiederaufbau (KfW), this initiative offers not only access to finance, but also support technical assistance.
- The <u>Boost Africa initiative</u> is a joint initiative between the African Development Bank (AfDB) and the European Investment Bank (EIB). It uses a combination of investment tools, technical assistance and entrepreneur training to attract investors and support to micro-, small and mediumsized enterprises at the earliest and riskiest stages of their development. A particular emphasis is put supporting young people and women. The focus is on sectors where innovations can improve quality of people's lives, in particular that of poorer households, providing access to affordable products and services. These sectors include, but

- are not limited to: ICT, agribusiness, financial services and financial inclusion, health, education, and renewable energy.
- <u>Women in Business programme</u>: Female entrepreneurship plays a key role in creating jobs and driving economic growth. However, female-run small and medium-sized enterprises often face reluctance from banks to lend to them as they are perceived as higher-risk customers. EU support through this programme provides partial risk cover to local banks to encourage the development of specific products that target eligible women-led companies as well as advisory services, training and support for women entrepreneurs and their businesses. The EU contribution to this project led by the European Bank for Reconstruction and Development (EBRD) is €4.8 million.

How did you estimate the EIP leverage?

In the EIP context, leveraging is the use of EU grants and guarantees to enable and increase the overall size of investment. Leverage allows going to scale and delivering enhanced development impact.

Based on experience with EU-supported financial instruments since 2007, the EFSD guarantee and blending (i.e. mixing of public grants and loans) are expected to reach an average leverage of around x11. The total EU contribution of $\{4.1\ \text{billion}\}$ is therefore expected to result in a total investment of $\{44\ \text{billion}\}$.

How can we monitor the progress of the EIP's implementation?

The European Commission will closely monitor the progress of the EIP. It will report annually to the European Parliament and the Council on the EIP financing and investment operations. The Commission will communicate the progress to citizens and stakeholders through its website and dedicated EIP web portal.

Reports will also be presented to the public and all relevant stakeholders, including civil society.

What are the conditions to qualify for support under the EIP?

Projects must have a clear sustainable development objective for Africa or the European Neighbourhood. They should contribute to economic and social development, with a focus on sustainability and job creation, particularly for youth and women.

Investment proposals have to provide adequate risk sharing, be economically and financially viable, socially and environmentally sustainable. They must not distort market competition or crowd out commercial funding and they should address market failures or sub-optimal investment situations. Operations should be additional — i.e. in areas where financing would otherwise not be available, due to high or perceived high risks.

If I want to take part and submit a project proposal or invest through a guarantee tool, how can I find out more?

Businesses that want to benefit from the EIP are encouraged to:

- contact one of the financing institutions managing the investment windows to obtain further information (see a list of all guarantee programmes and the respective lead financial institutions here)
- submit investment proposals through the <u>EIP online web portal that</u> <u>functions as a one-stop-shop</u>. The EIP Secretariat will then check them and forward them to the relevant financing institutions.

For more information

Press release - The EU's External Investment Plan: a strong step forward

<u>European Commission appoints new Head</u> of Representation in Spain

Mr Fonseca Morillo, a Spanish national, will take up office on 1 September 2018 as the new Head of the Commission's Representation in Madrid. Currently he is Deputy Director-General in the Directorate-General for Justice and Consumers. A highly experienced civil servant with over 30 years of working experience in the European Commission, including as acting Director-General and Head of a Commission Representation, Mr Fonseca Morillo brings excellent knowledge of the EU institutions and relevant management and communication skills to his new post.

Mr Fonseca Morillo joined the Commission in 1986 and since then he has occupied several different positions. Having started as an administrator in the Directorate-General for Budgets, he worked later as Assistant to the Director-General of the Forward Studies Unit becoming Adviser to the 1996 Intergovernmental Conference task force and Adviser to the Secretary-General in charge of the Amsterdam Treaty monitoring unit.

He has then served as Deputy and later as Head of Cabinet of Commissioner António Vitorino, following which he served as Director for Civil Justice, Fundamental Rights and Citizens and later as Director of Judicial Cooperation.

Between 2009 and 2015 he was the Head of the European Commission Representation in Spain, where he developed excellent relations with the national authorities and stakeholders. He successfully led the office to develop an effective communication policy with media and representatives of organised civil society in Spain notably by organising, in the city of Cádiz in September 2012, the first-ever Citizens' Dialogue.

Since 2015 he has been working in the Directorate-General for Justice and Consumers, first as Director and later as Deputy Director-General.

Before joining the European Commission, Mr Fonseca Morillo was a tenured professor of Public International Law. He obtained his PhD in Law at the University of Valladolid in 1984, after having graduated in Political Sciences in the Universidad Complutense de Madrid in 1979 and in Law at the University of Valladolid in 1977.

Background

The Commission has Representations in all EU Member States as well as Regional Offices in Barcelona, Belfast, Bonn, Cardiff, Edinburgh, Marseille, Milan, Munich and Wroclaw. The Representations are the Commission's eyes, ears and voice on the ground in all EU Member States. They interact with national authorities and stakeholders and inform the media and the public about EU policies. The Representations report to the Commission's headquarters on significant developments in the Member States. Since the beginning of the Juncker Commission, Heads of Representations are appointed by the President and are his political representatives in the Member State to which they are posted.

<u>Speech by Michel Barnier at the</u> <u>European American Chamber of Commerce</u>

Ladies and gentlemen,

Let me first thank the European American Chamber of Commerce, its President James Rosener, and Executive Director Yvonne Bendinger-Rothschild for inviting me.

It is a timely occasion to talk about Brexit.

I am happy to be in the United States to make the European voice on Brexit heard.

After Brexit, with 27 countries, 440 million consumers and 22 million businesses, we will remain a major partner for the US and a global player.

*

Let me now make a few introductory remarks.

1/ I deeply regret, as a politician and a citizen, the United Kingdom's decision to leave the European Union. It is my conviction that we are stronger together.

Brexit will necessarily have a cost.

The United Kingdom has decided to leave the European Union's Single Market

and the Customs Union.

This means that Brexit will create friction to trade that does not exist today.

For various economic sectors, this will have an impact on value chains, which are currently closely integrated across national borders of European countries.

This will impact in particular manufacturing and logistics, as well as the agricultural and food sectors.

The cost of Brexit will be substantially higher for the UK than for the EU. But Brexit is clearly a "lose-lose" situation for both.

On both sides of the Channel, businesses, including subsidiaries of US firms, should analyse their exposure to the other side and be ready, when necessary, to adapt their logistical channels, supply chains and existing contracts.

They should also prepare for the worst case scenario of a "no deal", which would result in the return of tariffs, under WTO rules.

The "no deal" is not our objective. By the way, you do not need a negotiator for no deal. We are negotiating to avoid the "no deal", but it still cannot be excluded.

Our objective is to reach an agreement by October on the UK's orderly withdrawal from the EU. This would allow proper time for the British and European Parliaments to vote on the Withdrawal Agreement before the UK actually leaves the EU on 29 March 2019.

*

2/ Over the last few months, we have made progress in the negotiations, as you can see in this draft Withdrawal Agreement which we have published — more or less 80%. In particular:

We reached a deal to protect 4.5 million European citizens in the UK and British nationals in the EU.

We agreed that all decisions taken at 28 will be financed at 28.

We agreed on a transition period of 21 months during which the economic status quo between the EU and the UK will be maintained. It will give business more time to adapt.

However, a number of major issues remain open.

In particular, we need to find solutions for the difficult issue of Ireland and Northern Ireland.

Historically, alongside other partners such as the US, the EU has played an important role in supporting the peace process in Ireland.

And a key feature of the peace process was to make the border between Ireland and Northern Ireland invisible.

This was facilitated obviously by the fact that both Ireland and Northern Ireland were part of the EU.

We need to avoid a hard border and the UK has committed to this.

As the same time we need to protect the EU's external border to preserve the integrity of our market.

3/ We want an ambitious future relationship with the UK - not only in trade, but also in police and judicial cooperation and foreign policy, security and defence.

However, the basis for such cooperation between the UK and the 27 EU countries will necessarily be different.

Therefore, the level of integration will have to be lower than it is today.

Because what the Single Market creates is the most developed form of free trade among sovereign countries. It is as close as it gets to a domestic market.

*

Since we are in New York, only a few miles away from Wall Street, let me take the example of financial services.

Within the EU Single Market, companies established in the UK can provide their services across the entire European Union — we call it "passporting".

Many US financial institutions decided to establish their European hub in London to have these passporting rights and to be able to service clients across Europe.

This is made possible by the EU Single Market, where EU countries are bound by a common framework, and in particular:

By a single rulebook, which we have reviewed following the financial crisis to increase the resilience of our financial institutions and markets. In doing so, we have implemented the G20 roadmap, just as the US did with the Dodd-Franck Act.

By coordinating or centralising supervision of this single rulebook for banks, insurance companies and financial markets.

By ensuring the uniform interpretation of the single rulebook by the European Court of Justice.

Outside of this common "ecosystem" of regulation, supervision and enforcement, there can be no passporting. The UK has recognised this point,

in Ms. May's Mansion House speech.

But the UK still wants continuity. It would want the EU to accept UK standards by means of a system of mutual recognition.

The UK needs to understand that the EU cannot accept such mutual market access without all the safeguards that underpin it.

This would go against all our objectives:

- First, ensuring financial stability,
- Second, protecting investors,
- Third, securing market integrity
- And fourth, maintaining a level playing field.

These objectives would not be reached if financial institutions could passport in the EU and serve clients based on a licence by the supervisors of a third country.

I do not know of any country in the world that would accept such a loss of sovereignty.

Ladies and gentlemen,

That being said, I think that we should have a close relationship with the UK, also in financial services.

This is our common interest.

I see a number of ways to achieve this.

First, the EU Single Market is open to third countries, in general, to the US. and also to the UK. And it will remain so.

In the EU, free movement of capital is open to third countries.

As regards market access to provide financial services, the European Council made clear that our future Free Trade Agreement with the UK should include the right of establishment, with EU rules applying.

Secondly, the EU has a long history of relying on the regulation and supervision of third countries.

This is what the G20 calls deference, what you call in the US substituted compliance, and what we call in the EU equivalence.

To date, the EU has adopted more than 200 so-called equivalence decisions covering more than 30 foreign jurisdictions, including of course the US. This integrates financial markets and facilitates the work of financial operators in the EU and the foreign jurisdiction.

Today, to be very clear, we are in the EU the most open jurisdiction in the

world for financial services.

Why would this equivalence system, which works well, including for the US industry, not work for the UK? Why?

Thirdly, in order to draw lessons from the financial crisis and limit the risks in the future, EU countries collectively developed more effective financial regulation and supervision.

And we were very happy to do this hand-in-hand with the UK.

I can personally testify it: for five years, I was in charge of financial services for the Commission and all these regulations, but two — short selling and banker bonuses — have been adopted in full agreement with the UK.

We need to keep this joint regulatory effort in mind, and be ready to exchange our ideas for future rules in the context of close and voluntary regulatory cooperation.

Here also, we have a regulatory dialogue with the US. We could build on this experience with the UK.

Fourthly, we will of course cooperate with the UK- as we do with the US- in international fora such as the Financial Stability Board and the Basel committee.

The world of finance is global and interdependent. We have a mutual interest in working together, not separately.

Ladies and gentlemen,

One thing is clear: we will not change who we are as the European Union because the UK is leaving.

The EU is and will remain the most open market in the world.

No other jurisdiction operates a framework that is more open, comprehensive and rules-based for foreign jurisdictions.

US companies are well aware of this. Many of them have been able to take a leading role in EU markets.

Open markets for financial services are an asset for the EU and will remain so in the future.

Thank you for your attention.

Explanatory note on the CSM Assessment Body referred to in Regulation (EU) N°402/2013 and in OTIF UTP GEN-G of 1.1.2016 on the Common Safety Method (CSM) for risk assessment

Explanatory note on the CSM Assessment Body referred to in Regulation (EU) N°402/2013 and in OTIF UTP GEN-G of 1.1.2016 on the Common Safety Method (CSM) for risk assessment Reference: ERA-GUI-01-2014-SAF Publication Date: 4/07/2018 Published by: Safety Document Types: Guide Keywords: Common safety method; independent safety

assessment; accreditation; recognition; cross-acceptance Description: This is an explanatory note on the main requirements to be fulfilled by the assessment body defined in Article 6 of the CSM for risk assessment. It does not contain any legally binding requirements. Related documents:

Related Documents

☐The main objectives of this note are to describe the roles and responsibilities of the assessment body and the way to acknowledge their compliance with the requirements defined in the CSM. In particular, the note is intended to help the Member States understanding the responsibilities set on them in Article 13 of the CSM and deciding on whether they opt for the accreditation or recognition of the assessment bodies or any combination of these two options.

The note contains only explanatory information of potential help for concerned users who directly or indirectly need to apply the CSM for risk assessment. It may serve as a clarification tool however without dictating in any manner mandatory procedures to be followed and without establishing any legally binding practice. The note provides explanations on the provisions contained in the CSM for risk assessment. It should be helpful for the understanding of the legal requirements described therein.

The note needs to be read and used together with the CSM for risk assessment in order to facilitate its understanding and application. It does not replace or otherwise amend the CSM.

Explanatory note on the assessment body referred to in the CSM for risk assessment — $EN\square$