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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Horizontal Working Party on Drugs
Subject:	Proposal for a Regulation of the European Parliament and of the Council on the European Union Drugs Agency - Outcome of technical meetings

Delegations are informed that since the last HDG meeting the Presidency continued the negotiations with the European Parliament and the Commission on the draft Regulation on the EU Drugs Agency.

The first technical meeting took place on 12 January 2023, where five topics and the respective positions of the institutions were discussed: cooperation with the civil society, National Focal Points, fees to be charged by the Agency and other budgetary aspects, organisation of the Agency, and New Psychoactive Substances.

This was followed by informal technical meetings on 24, 25 and 26 January 2023 and on 1 February 2023, where Articles 1-12 and Articles 36-41 were discussed together with two recitals relating to budgetary provisions. Delegations will find the outcome of these meetings in the enclosed table in columns 4 and 5, containing compromise proposals and comments. The lines highlighted in green are considered provisionally agreed.

Delegations are invited to examine the lines highlighted in yellow and inform the Presidency by 13 February 2023 in case they have any substantial objections to the compromise proposals in those lines together with arguments in favour or against, which would help the Presidency in the upcoming negotiations.

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Union Drugs Agency

2022/0009(COD)

Outcome of informal meetings of 24-26/1/2023 and 1/2/2023

02-02-2023 at 09h16

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Comments
Recital 29					
39	*(29)* The Agency should be properly resourced to carry out its tasks and granted an autonomous budget. It should be mainly financed by a contribution from the general budget of the Union. The Union budgetary procedure should be applicable as far as the Union contribution and any other subsidies chargeable to the general budget of the Union are concerned. The auditing of accounts should be undertaken by the Court of Auditors of the European Union.	(29) The Agency should be ~~*properly*~~***adequately*** resourced to carry out ~~*its*~~***the*** tasks***, objectives and responsibilities assigned to it under this Regulation. That should be properly reflected in the multiannual financial framework by means of a dedicated and ambitious*** ~~*and granted an autonomous*~~ budget. ~~*It*~~***The Agency*** should be mainly financed by a contribution from the general budget of the Union ***with the necessary appropriations drawn exclusively from unallocated margins under the relevant heading of the multiannual financial framework or through the mobilisation of the relevant special instruments***. The Union budgetary procedure should be applicable as far as the Union contribution	(29) The Agency should be properly resourced to carry out its tasks and granted an autonomous budget. It should be mainly financed by a contribution from the general budget of the Union. The Union budgetary procedure should be applicable as far as the Union contribution and any other subsidies chargeable to the general budget of the Union are concerned. The auditing of accounts should be undertaken by the Court of Auditors of the European Union.		(29) COM to propose a text of a declaration on the single budget line in the next MFF.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Comments
		and any other subsidies chargeable to the general budget of the Union are concerned. The auditing of accounts should be undertaken by the Court of Auditors of the European Union.			
Recital 30					
40	(30) Fees improve the funding of an agency and may be considered for specific issues that can be clearly separated from the core tasks of the agency. Any fees levied by the Agency should cover its costs for providing the respective services.	(30) Fees ***could*** improve the funding of ~~an~~***the*** Agency and may***, to the extent that such fees are duly justified and necessary,*** be considered for specific ~~issues~~***activities*** that can be clearly separated from the core tasks of the agency. ~~Any~~***The method by which*** fees levied by the Agency ***are calculated should be transparent, and such fees*** should cover ~~its~~***only the Agency's human and financial*** costs for providing ***those non-core services. An annual independent external audit, separate from the annual audit undertaken by the Court of Auditors, which specifically focuses on such fees should be undertaken and transmitted to the European Parliament***~~the respective~~	(30) Fees improve the funding of an agency and may be considered for specific issues that can be clearly separated from the core tasks of the Agency. ~~Any fees levied by the Agency should~~**The Agency should thus be empowered to levy fees, which should be set out in a transparent manner and** cover its costs for providing the respective services.		Informal COM suggestion: (30) ~~*Fees improve the funding of an agency and may be considered for specific issues that can be clearly separated from the core tasks of the agency.*~~ ***The possibility for the Agency to deliver additional services, beyond its core tasks laid down in the Regulation, against payment of fees should be introduced in order to support Member States and other stakeholders in understanding and addressing the drugs phenomenon. The method by which fees levied by the Agency are calculated should be transparent, and the*** ~~*Any*~~ *fees levied by the Agency should cover* ~~*its*~~ ***the full*** *costs for providing*

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Comments
		~~*services*~~.			~~*respective*~~ ***the activities related to the*** *services* ***delivered, including staff and operational costs. When fees have been levied in a financial year, the Agency's provisional accounts should be accompanied by a report on those fees, which would also be subject to the audit of the Court of Auditors of the European Union. Fees should be set at a level that avoids a deficit or a significant accumulation of surplus, and should be revised when this is not the case***. *** Alternative suggestions by the Presidency, following the consultation with the Legal Service: (30) ~~*Fees improve the funding of an agency and may be considered for specific issues that can be clearly separated from the core tasks of the agency.*~~ ~~***The possibility for the Agency to deliver additional services, beyond its core tasks laid down in the***~~

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Comments
					~~Regulation, against payment of fees should be introduced~~ In order to promote a coherent, Union-wide approach and to enhance the effectiveness of the Agency's work as well as in order to support Member States and other stakeholders in understanding and addressing the drugs phenomenon, it should be possible for the Agency to deliver, upon request, additional services, beyond its core tasks laid down in the Regulation, against payment of fees. The method by which fees levied by the Agency are calculated should be transparent, and the ***~~Any~~*** *fees levied by the Agency should cover* ***~~its~~*** ***the full*** *costs for providing* ***~~respective~~*** ***the activities related to the*** *services* ***delivered, including staff and operational costs. When fees have been levied in a financial year, the Agency's provisional accounts should be accompanied by a report on those fees, which would also be subject to the audit of the***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	Comments
					Court of Auditors of the European Union. Fees should be set at a level that avoids a deficit or a significant accumulation of surplus, and should be revised when this is not the case.
Formula					
48	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:		

Articles 1-12

	CHAPTER I					
G	49	CHAPTER I OBJECTIVES AND GENERAL TASKS OF THE AGENCY	CHAPTER I OBJECTIVES AND GENERAL TASKS OF THE AGENCY	CHAPTER I OBJECTIVES AND GENERAL TASKS OF THE AGENCY	CHAPTER I OBJECTIVES AND GENERAL TASKS OF THE AGENCY Text Origin: Commission Proposal	G
	Article 1					
G	50	Article 1 Establishment of the Agency	Article 1 Establishment of the Agency	Article 1 Establishment of the Agency	Article 1 Establishment of the Agency Text Origin: Commission Proposal	G
	Article 1(1)					
G	51	1. This Regulation establishes the European Union Drugs Agency ('the Agency').	1. This Regulation establishes the European Union Drugs Agency ('the Agency').	1. This Regulation establishes the European Union Drugs Agency ('the Agency').	1. This Regulation establishes the European Union Drugs Agency ('the Agency'). Text Origin: Commission Proposal	G
	Article 1(2)					
G	52	2. The Agency shall replace and succeed the European Monitoring Centre for Drugs and Drug Addiction	2. The Agency shall replace and succeed the European Monitoring Centre for Drugs and Drug Addiction	2. The Agency shall replace and succeed the European Monitoring Centre for Drugs and Drug Addiction	2. The Agency shall replace and succeed the European Monitoring Centre for Drugs and Drug Addiction	G

		established by Regulation (EC) No 1920/2006.	established by Regulation (EC) No 1920/2006.	established by Regulation (EC) No 1920/2006.	established by Regulation (EC) No 1920/2006. Text Origin: Commission Proposal	
	Article 2					
G	53	Article 2 Legal status and seat	Article 2 Legal status and seat	Article 2 Legal status and seat	Article 2 Legal status and seat Text Origin: Commission Proposal	G
	Article 2(1)					
G	54	1. The Agency shall be a body of the Union with legal personality.	1. The Agency shall be a body of the Union with legal personality.	1. The Agency shall be a body of the Union with legal personality.	1. The Agency shall be a body of the Union with legal personality. Text Origin: Commission Proposal	G
	Article 2(2)					
G	55	2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under national law. It shall, in particular, be able to acquire or dispose of movable and immovable property and be a party to legal proceedings.	2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under national law. It shall, in particular, be able to acquire or dispose of movable and immovable property and be a party to legal proceedings.	2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under national law. It shall, in particular, be able to acquire or dispose of movable and immovable property and be a party to legal proceedings.	2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under national law. It shall, in particular, be able to acquire or dispose of movable and immovable property and be a party to legal proceedings. Text Origin: Commission Proposal	G

Article 2(3)						
56	3. The seat of the Agency shall be in Lisbon, Portugal.	3. The seat of the Agency shall be in Lisbon, Portugal.	3. The seat of the Agency shall be in Lisbon, Portugal.	3. The seat of the Agency shall be in Lisbon, Portugal. Text Origin: Commission Proposal		
Article 3						
57	Article 3 Definitions	Article 3 Definitions	Article 3 Definitions	Article 3 Definitions Text Origin: Commission Proposal		
Article 3, first paragraph, introductory part						
58	For the purpose of this Regulation:	For the purpose of this Regulation:	For the purpose of this Regulation:	For the purpose of this Regulation: Text Origin: Commission Proposal		
Article 3, first paragraph, point (1)						
59	(1) 'drugs' means drugs as defined in Article 1, point 1, of Council Framework Decision 2004/757/JHA[1]; _____ 1. Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ	(1) 'drugs' means drugs as defined in Article 1, point 1, of Council Framework Decision 2004/757/JHA[1]; _____ 1. Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ	(1) '~~drugs~~**drug** ' means ~~drugs as defined in Article 1, point 1, of Council Framework Decision 2004/757/JHA[1];~~**any of the following:** _____ ~~1. Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions~~	(1) '~~*drugs*~~***drug*** ' means ~~*drugs as defined in Article 1, point 1, of Council Framework Decision 2004/757/JHA[1];*~~***any of the following:*** _____ ~~*1. Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions*~~	

		L 335 11.11.2004, p. 8).	L 335 11.11.2004, p. 8).	~~on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335 11.11.2004, p. 8).~~	~~*on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335 11.11.2004, p. 8).*~~ Text Origin: Council Mandate	
Article 3, first paragraph, point (1a)						
G	59a			**(1a) a substance covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances;**	***(1a) a substance covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances;*** Text Origin: Council Mandate	G
Article 3, first paragraph, point (1b)						
G	59b			**(1b) any of the substances listed in the Annex of Council Framework Decision 2004/757/JHA[1];** **1. Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335 11.11.2004, p. 8).**	***(1b) any of the substances listed in the Annex of Council Framework Decision 2004/757/JHA[1];*** ***1. Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335 11.11.2004, p. 8).*** Text Origin: Council Mandate	G

	Article 3, first paragraph, point (2)					
G	60	(2) ‘new psychoactive substances’ means substances as defined in Article 1, point 4, of Framework Decision 2004/757/JHA;	(2) ‘new psychoactive substances’ means substances as defined in Article 1, point 4, of Framework Decision 2004/757/JHA;	(2) ‘new psychoactive substances’ means substances as defined in Article 1, point 4, of Framework Decision 2004/757/JHA;	(2) ‘new psychoactive substances’ means substances as defined in Article 1, point 4, of Framework Decision 2004/757/JHA; Text Origin: Commission Proposal	G
	Article 3, first paragraph, point (3)					
G	61	(3) ‘poly-substance use’ means the concomitant use of one or more psychoactive substance or type of substance, whether licit or illicit, when those substances are taken together with drugs;	(3) ‘poly-substance use’ means the ~~*concomitant use*~~***consumption*** of one or more psychoactive substance or type of substance, whether ***illicit or*** licit***, in particular medicinal products, alcohol or tobacco, at the same time as the consumption of drugs, or the sequential consumption of one or more such substance or type of substance, within a short period of time,*** ~~*or illicit, when those substances are taken*~~ together with drugs;	(3) ‘poly-substance use’ means the ~~concomitant~~ use of one or more psychoactive substance or type of substance, whether ~~licit or illicit, when those substances are taken together~~**illicit or licit (in particular medicinal products, alcohol, tobacco), when consumed at the same time or sequentially within a short period of time** with drugs;	(3) ‘poly-substance use’ means the ~~*concomitant*~~ use of one or more psychoactive substance or type of substance, whether ~~*licit or illicit, when those substances are taken together*~~***illicit or licit (in particular medicinal products, alcohol, tobacco), when consumed at the same time or sequentially within a short period of time*** with drugs; Text Origin: Council Mandate	G
	Article 3, first paragraph, point (4)					
G	62	(4) ‘drug precursors’ means substances that are controlled and monitored in	(4) ‘drug precursors’ means substances that are controlled and monitored in	(4) ‘drug precursors’ means substances that are controlled and monitored in	(4) ‘drug precursors’ means substances that are controlled and monitored in	G

	accordance with Regulation (EC) No 273/2004 of the European Parliament and of the Council[1] and with Council Regulation (EC) No 111/2005[2]; 1. Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1). 2. Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).	accordance with Regulation (EC) No 273/2004 of the European Parliament and of the Council[1] and with Council Regulation (EC) No 111/2005[2]; 1. Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1). 2. Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).	accordance with Regulation (EC) No 273/2004 of the European Parliament and of the Council[1] and with Council Regulation (EC) No 111/2005[2]; 1. Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1). 2. Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).	accordance with Regulation (EC) No 273/2004 of the European Parliament and of the Council[1] and with Council Regulation (EC) No 111/2005[2]; 1. Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1). 2. Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1). Text Origin: Commission Proposal	
Article 3, first paragraph, point (5)					
63	(5) ‘participating countries’ means the Member States and third countries which have concluded an agreement with the Union in accordance with Article 54;	(5) ‘participating countries’ means the Member States and third countries which have concluded an agreement with the Union in accordance with Article 54;	(5) ‘participating countries’ means the Member States and third countries which have concluded an agreement with the Union in accordance with Article 54 **of this Regulation**;	(5) ‘participating countries’ means the Member States and third countries which have concluded an agreement with the Union in accordance with Article 54 ***of this Regulation***; Text Origin: Council Mandate	
Article 3, first paragraph, point (6)					
64	(6) ‘international organisation’ means an	(6) ‘international organisation’ means an	(6) ‘international organisation’ means an	(6) ‘international organisation’ means an	

	organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries;	organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries;	organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries;	organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries; Text Origin: Commission Proposal	
Article 3, first paragraph, point (7)					
65	(7) 'United Nations Drug Conventions' means the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol[1], the United Nations Convention on Psychotropic Substances of 1971[2] and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988[3]; _________ 1. United Nations Treaty Series, vol. 976, No. 14152. 2. United Nations Treaty Series, vol. 1019, No. 14956. 3. United Nations, Treaty Series, vol. 1582, No. 27627.	(7) 'United Nations Drug Conventions' means the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol[1], the United Nations Convention on Psychotropic Substances of 1971[2] and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988[3]; _________ 1. United Nations Treaty Series, vol. 976, No. 14152. 2. United Nations Treaty Series, vol. 1019, No. 14956. 3. United Nations, Treaty Series, vol. 1582, No. 27627.	(7) 'United Nations Drug Conventions' means the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol[1], the United Nations Convention on Psychotropic Substances of 1971[2] and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988[3]; _________ 1. United Nations Treaty Series, vol. 976, No. 14152. 2. United Nations Treaty Series, vol. 1019, No. 14956. 3. United Nations, Treaty Series, vol. 1582, No. 27627.	(7) 'United Nations Drug Conventions' means the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol[1], the United Nations Convention on Psychotropic Substances of 1971[2] and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988[3]; _________ 1. United Nations Treaty Series, vol. 976, No. 14152. 2. United Nations Treaty Series, vol. 1019, No. 14956. 3. United Nations, Treaty Series, vol. 1582, No. 27627. Text Origin: Commission Proposal	
Article 3, first paragraph, point (8)					
66					

		(8) ‘United Nations system’ means the control mechanism system established by the United Nations Drug Conventions.	(8) ‘United Nations system’ means the control mechanism system established by the United Nations Drug Conventions.	(8) ‘United Nations system’ means the control mechanism system established by the United Nations Drug Conventions.	(8) ‘United Nations system’ means the control mechanism system established by the United Nations Drug Conventions. Text Origin: Commission Proposal	
	Article 4					
G	67	Article 4 General task of the Agency	Article 4 General task of the Agency	Article 4 General task of the Agency	Article 4 General task of the Agency Text Origin: Commission Proposal	G
	Article 4, first paragraph					
Y	68	The Agency shall provide the Union and its Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs, drug addiction, drug markets and their consequences, and to recommend appropriate and concrete, evidence-based actions on how to address the related challenges in a timely manner.	The Agency shall ~~*provide the Union and its Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs, drug addiction, drug markets and their consequences, and to recommend appropriate and concrete, evidence-based actions on how to address the related challenges in a timely manner.*~~ :	The Agency shall provide the Union and its Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs, drug ~~addiction, drug markets~~**use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery, drug supply, including illicit production and trafficking, and other relevant drug related**	The Agency shall ~~*provide the Union and its Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs, drug addiction, drug markets and their consequences, and to recommend appropriate and concrete, evidence-based actions on how to address the related challenges in a timely manner.*~~ : Text Origin: EP Mandate	Y

				issues and their consequences, and ~~to~~ recommend appropriate and concrete, evidence-based actions on how to address the related challenges in ~~a~~**an efficient and** timely manner. **In carrying out its tasks, the Agency shall take an evidence-based, integrated, balanced and multidisciplinary approach to the drugs phenomenon, incorporating a human rights, gender equality, public health and health equity perspective.**		
Article 4, first paragraph, point (a)						
Y	68a		***(a) provide the Union and its Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs, drug markets, drug use, drug use disorders, drug addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration, recovery, drug supply and other relevant drug related issues and their consequences; and***		***(a) provide the Union and its Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration, recovery, drug markets and supply, including illicit production and trafficking, and other relevant drug related issues and their consequences;***	Y

					and Text Origin: EP Mandate		
Article 4, first paragraph, point (b)							
Y	68b		***(b) recommend appropriate and concrete evidence-based actions on how to address the challenges set out in point (a) in an efficient and timely manner.***		***(b) recommend appropriate and concrete evidence-based actions on how to address the challenges set out in point (a) in an efficient and timely manner.*** Text Origin: EP Mandate		Y
Article 4, first paragraph a							
Y	68c		***In carrying out its tasks, the Agency shall ensure full compliance with fundamental rights and data protection rules, act in a transparent, objective, impartial and scientifically rigorous manner, and take an evidence-based, integrated, balanced and multidisciplinary approach to the drugs phenomenon. That approach shall incorporate human rights, gender, age, public health, health equity and social perspectives.***		***In carrying out its tasks, the Agency shall ensure full compliance with fundamental rights and data protection rules, and take an evidence-based, integrated, balanced and multidisciplinary approach to the drugs phenomenon. That approach shall incorporate human rights, gender [and gender equality], age, public health, health equity and social perspectives [or: aspects] .*** Text Origin: EP Mandate	Parts in square brackets to be confirmed. Council's lawyer-linguists suggest "perspectives"	Y
Article 5							

G	69	Article 5 Specific tasks	Article 5 Specific tasks	Article 5 Specific tasks	Article 5 Specific tasks Text Origin: Commission Proposal		G
	Article 5(1), introductory part						
G	70	1. In order to implement the general task set out in Article 4, the Agency shall perform the following tasks:	1. In order to implement the general task set out in Article 4, the Agency shall perform the following tasks:	1. In order to implement the general task set out in Article 4, the Agency shall perform the following tasks:	1. In order to implement the general task set out in Article 4, the Agency shall perform the following tasks: Text Origin: Commission Proposal		G
	Article 5(1), point (a), introductory part						
G	71	(a) monitoring tasks that shall include:	(a) monitoring tasks that shall include:	(a) monitoring tasks that shall include:	(a) monitoring tasks that shall include: Text Origin: Commission Proposal		G
	Article 5(1), point (a)(1)						
G	72	(1) the collection of information and data pursuant to Article 6(1);	(1) the collection ***and analysis*** of information and data pursuant to Article 6(1);	(1) the collection **and analysis** of information and data pursuant to Article 6(1);	(1) the collection ***and analysis*** of information and data pursuant to Article 6(1); Text Origin: Council Mandate		G
	Article 5(1), point (a)(2)						
G	73	(2) the dissemination of	(2) the dissemination of	(2) the dissemination of	(2) the dissemination of		G

		information and data pursuant to Article 6(5); and	information***, data and results of analyses*** ~~*and data*~~ pursuant to Article 6(5)~~;~~ and	information**, data and results of analysis** ~~and data~~ pursuant to Article 6(5); and	information***, data and results of analyses*** ~~*and data*~~ pursuant to Article 6(5)~~;~~ and Text Origin: EP Mandate		
	Article 5(1), point (a)(3)						
Y	74	(3) the monitoring of the drug phenomenon, encompassing the public health, safety and security dimension, pursuant to Article 7.	(3) the monitoring of the drug phenomenon, encompassing the public health, ***social and human rights,*** safety and security dimension, pursuant to Article 7.	(3) the monitoring of the drug phenomenon, encompassing ~~the public health~~**health, social**, safety and security dimension, pursuant to Article 7.	(3) the monitoring of the drug phenomenon, encompassing the ~~*public health*~~***health, human rights, social***, safety and security dimension, pursuant to Article 7. Text Origin: Council Mandate		Y
	Article 5(1), point (b), introductory part						
G	75	(b) preparedness tasks that shall include:	(b) preparedness tasks that shall include:	(b) preparedness tasks that shall include:	(b) preparedness tasks that shall include: Text Origin: Commission Proposal		G
	Article 5(1), point (b)(1)						
G	76	(1) the information exchange on and early warning system for new psychoactive substances, including the preparation of an initial report and risk assessment, pursuant to Articles 8 to 11;	(1) the information exchange on and early warning system for new psychoactive substances, including the preparation of an initial report and risk assessment, pursuant to Articles 8 to 11;	(1) the information exchange on and early warning system for new psychoactive substances, including the preparation of an initial report and risk assessment, pursuant to Articles 8 to 11;	(1) the information exchange on and early warning system for new psychoactive substances, including the preparation of an initial report and risk assessment, pursuant to Articles 8 to 11;		G

					Text Origin: Commission Proposal	
Article 5(1), point (b)(2)						
G	77	(2) threat assessment and preparedness pursuant to Article 12;	(2) ***health and security*** threat assessment and preparedness pursuant to Article 12;	(2) **health and security** threat assessment and preparedness pursuant to Article 12;	(2) ***health and security*** threat assessment and preparedness pursuant to Article 12; Text Origin: EP Mandate	G
Article 5(1), point (b)(3)						
G	78	(3) the establishment and operation of a European drug alert system pursuant to Article 13;	(3) the establishment and operation of a European drug alert system pursuant to Article 13;	(3) the establishment and operation of a European drug alert system pursuant to Article 13;	(3) the establishment and operation of a European drug alert system pursuant to Article 13; Text Origin: Commission Proposal	G
Article 5(1), point (b)(4)						
G	79	(4) monitoring the developments related to trafficking and diversion of drug precursors and contributing to the implementation of drug precursors legislation pursuant to Article 14;	(4) monitoring the developments related to trafficking and diversion of drug precursors and contributing to the implementation of drug precursors legislation pursuant to Article 14;	(4) monitoring the developments related to trafficking and diversion of drug precursors and contributing to the implementation of drug precursors legislation pursuant to Article 14;	(4) monitoring the developments related to trafficking and diversion of drug precursors and contributing to the implementation of drug precursors legislation pursuant to Article 14; Text Origin: Commission Proposal	G
Article 5(1), point (b)(5)						

G	80	(5) the establishment and operation of a network of forensic and toxicological laboratories pursuant to Article 15;	(5) the establishment and operation of a network of forensic and toxicological laboratories pursuant to Article 15;	(5) the establishment and operation of a network of forensic and toxicological laboratories pursuant to Article 15;	(5) the establishment and operation of a network of forensic and toxicological laboratories pursuant to Article 15; Text Origin: Commission Proposal		G
Article 5(1), point (c), introductory part							
G	81	(c) competence development tasks that shall include:	(c) competence development tasks that shall include:	(c) competence development tasks that shall include:	(c) competence development tasks that shall include: Text Origin: Commission Proposal		G
Article 5(1), point (c)(1)							
G	82	(1) the development, expansion and promotion of Union-wide prevention programmes and campaigns pursuant to Article 16;	(1) the development~~,~~ ~~*expansion*~~ and promotion of ~~*Union-wide prevention programmes and campaigns*~~***evidence-based interventions, best practices and awareness raising*** pursuant to Article 16;	(1) the development~~,~~ ~~expansion~~ and promotion of ~~Union-wide prevention programmes and campaigns~~**evidence-based interventions, best practices and awareness raising activities** pursuant to Article 16;	(1) the development~~,~~ ~~*expansion*~~ and promotion of ~~*Union-wide prevention programmes and campaigns*~~***evidence-based interventions, best practices and awareness raising activities*** pursuant to Article 16; Text Origin: Council Mandate		G
Article 5(1), point (c)(2)							
	83	(2) the accreditation and certification of national	(2) the accreditation and certification of national	(2) the ~~accreditation and certification~~**assessment** of		To be addressed after discussions on Article 17	

	measures pursuant to Article 17;	measures pursuant to Article 17;	national measures pursuant to Article 17;		
Article 5(1), point (c)(3)					
84	(3) support to Member States pursuant to Article 18;	(3) support to Member States pursuant to Article 18;	(3) support to Member States pursuant to Article 18;	(3) support to Member States pursuant to Article 18; Text Origin: Commission Proposal	
Article 5(1), point (c)(4)					
85	(4) training pursuant to Article 19;	(4) training pursuant to Article 19;	(4) training pursuant to Article 19;	(4) training pursuant to Article 19; Text Origin: Commission Proposal	
Article 5(1), point (c)(5)					
86	(5) international cooperation and technical assistance pursuant to Article 20;	(5) international cooperation and technical assistance pursuant to Article 20;	(5) international cooperation and technical assistance pursuant to Article 20;	(5) international cooperation and technical assistance pursuant to Article 20; Text Origin: Commission Proposal	
Article 5(1), point (c)(6)					
87	(6) research and innovation activities pursuant to Article 21.	(6) research and innovation activities pursuant to Article 21.	(6) research and innovation activities pursuant to Article 21.	(6) research and innovation activities pursuant to Article 21. Text Origin: Commission Proposal	

	Article 5(2)					
G	88	2. The Agency shall establish and coordinate, in consultation and in cooperation with the competent authorities and organisations in the participating countries, the network referred to in Article 31.	2. The Agency shall establish and coordinate, in consultation and in cooperation with the competent authorities and organisations in the participating countries, the network referred to in Article 31.	2. The Agency shall establish and coordinate, in consultation and in cooperation with the competent authorities and organisations in the participating countries, the network referred to in Article 31.	2. The Agency shall establish and coordinate, in consultation and in cooperation with the competent authorities and organisations in the participating countries, the network referred to in Article 31. Text Origin: Commission Proposal		G
	Article 5(3)					
Y	89	3. The Agency shall act in an objective, impartial and scientifically rigorous manner when carrying out and implementing the tasks referred to in paragraph 1.	*deleted*	*3.* The Agency shall act in an objective, impartial and scientifically rigorous manner when carrying out and implementing the tasks referred to in paragraph 1.	3. The Agency shall act in ~~an~~ ***a transparent,*** objective, impartial and scientifically rigorous manner when carrying out and implementing the tasks referred to in paragraph 1. Text Origin: Council Mandate	Based on EP amendment in Art. 4 / line 68	Y
	Article 5(4)					
G	90	4. The Agency shall improve coordination between national and Union action in its areas of activity and facilitate exchanges of information between decision-makers, researchers, specialists and	4. The Agency shall ***support and*** improve coordination between national and Union action in its areas of activity and facilitate exchanges of information between decision-makers, researchers, specialists and	4. The Agency shall **support and** improve coordination between national and Union action in its areas of activity and facilitate exchanges of information between decision-makers,	4. The Agency shall ***support and*** improve coordination between national and Union action in its areas of activity and facilitate exchanges of information between decision-makers, researchers, specialists and		G

		those involved in drug-related issues in governmental and non-governmental organisations.	those involved in drug-related issues in governmental and non-governmental organisations.	researchers, specialists and those involved in drug-related issues in governmental and non-governmental organisations.	those involved in drug-related issues in governmental and non-governmental organisations. Text Origin: EP Mandate	
Article 5(4a)						
	90a		***4a. In cooperation with civil society organisations, the Agency shall develop a communication strategy in order to raise public awareness and actively disseminate information about its work.***			*[see how to address these elements in line 94]*
Article 5(5)						
Y	91	5. The Agency shall support the Commission, Member States and other relevant stakeholders, identified in the applicable Union strategies on drugs, in the implementation of those strategies, as appropriate.	5. The Agency shall support the Commission, Member States and other relevant stakeholders, identified in the applicable Union strategies on drugs, in the implementation of those strategies, as appropriate.	5. The Agency shall support the Commission, Member States and other relevant stakeholders, identified in the applicable Union ~~strategies on drugs~~**drugs related strategic documents**, in the implementation of those ~~strategies~~**strategic documents**, as appropriate.	5. The Agency shall support the Commission, Member States and other relevant stakeholders, identified in the applicable Union ~~*strategies on drugs*~~***drugs related strategic documents***, in the implementation of those ~~*strategies*~~***strategic documents***, as appropriate. Text Origin: Council Mandate	Exact wording on "strategic documents" to be checked by lawyer-linguists
Article 5(6)						
Y	92	6. In carrying out and	6. In carrying out and	6. In carrying out and	6. In carrying out and	Reference to Reitox related

		implementing the tasks referred to in paragraph 1, the Agency may organise meetings of experts, set up ad hoc working groups and finance projects, as necessary.	implementing the tasks referred to in paragraph 1, the Agency may organise meetings of experts, set up ad hoc working groups and finance projects, as necessary.	implementing the tasks referred to in paragraph 1, the Agency may organise meetings of experts, set up ad hoc working groups and finance projects, as necessary**, keeping the Reitox network as referred to in Article 31 informed in a timely manner. When organising those meetings, the possibility of online meetings shall be considered**.	implementing the tasks referred to in paragraph 1, the Agency may organise meetings of experts, set up ad hoc working groups and finance projects, as necessary***[, keeping the Reitox network as referred to in Article 31 informed in a timely manner.]*** Text Origin: Council Mandate	to other provisions on Reitox / NFPs. Holding meetings online to be addressed in the recitals.
Article 5(7)						
Y	93	7. In carrying out and implementing the tasks referred to in paragraph 1, the Agency shall cooperate actively with other Union decentralised agencies and bodies, in particular Europol, Eurojust, the European Medicines Agency, the European Centre for Disease Prevention and Control, civil society organisations and other relevant stakeholders, to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon.	7. In ~~*carrying out and implementing the tasks referred to in paragraph 1, the Agency shall cooperate actively with other Union decentralised agencies and bodies, in particular Europol, Eurojust, the European Medicines Agency, the European Centre for Disease Prevention and Control, civil society organisations and other relevant stakeholders, to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon.*~~***order to attain maximum efficiency in monitoring, assessing and***	7. In carrying out and implementing the tasks referred to in paragraph 1, the Agency shall cooperate actively with other Union ~~decentralised agencies and bodies~~**bodies, offices and agencies within their mandates**, in particular Europol, Eurojust, **European Union Agency for Fundamental Rights, European Union Agency for Law Enforcement Training (CEPOL),** the European Medicines Agency, the European Centre for Disease Prevention and Control**, the European Foundation for the Improvement in Living**	7. In ~~*carrying out and implementing the tasks referred to in paragraph 1, the Agency shall cooperate actively with other Union decentralised agencies and bodies, in particular Europol, Eurojust, the European Medicines Agency, the European Centre for Disease Prevention and Control, civil society organisations and other*~~***order to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon, the Agency shall, in carrying out and implementing its tasks, cooperate actively with***	Y

			responding to the drugs phenomenon, the Agency shall, in carrying out and implementing its tasks, cooperate actively with all of the following:	**and Working Conditions (Eurofound), scientific community**, civil society organisations and other relevant stakeholders, to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon.	relevant stakeholders, ~~*to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon.*~~***including:*** Text Origin: EP Mandate		
	Article 5(7), point (a)						
Y	93a		***(a) other relevant Union bodies, offices and agencies, within the limits of their mandates, in particular Europol, Eurojust, the European Union Agency for Fundamental Rights, the European Union Agency for Law Enforcement Training (CEPOL), the European Medicines Agency, the European Centre for Disease Prevention and Control and the European Foundation for the Improvement in Living and Working Conditions (Eurofound);***		***(a) other relevant Union bodies, offices and agencies, within the limits of their mandates, in particular Europol, Eurojust, the European Union Agency for Fundamental Rights, the European Union Agency for Law Enforcement Training (CEPOL), the European Medicines Agency, the European Centre for Disease Prevention and Control and the European Foundation for the Improvement in Living and Working Conditions (Eurofound);*** Text Origin: EP Mandate		Y
	Article 5(7), point (b)						
Y	93b		***(b) other international***		***(b) other international***		Y

			bodies, offices and agencies, in particular the UN Economic and Social Council and the UN Narcotics Board; and		***bodies, offices and agencies, in particular the UNODC, UN Economic and Social Council and the International Narcotics Control Board; and*** Text Origin: EP Mandate	
Article 5(7), point (c)						
Y	93c		***(c) the scientific community, academia, civil society organisations, in particular the Civil Society Forum on Drugs, and affected communities, including people who use drugs;***		***(c) the scientific community, civil society organisations [, in particular the Civil Society Forum on Drugs, and affected communities, including people who use drugs];*** Text Origin: EP Mandate	Clarify "academia" in recitals if needed. According to Council's lawyer-linguists, "scientific community" is sufficient, as it is a broad notion encompassing all scientists, whether from the private sector (industry) , academia or the public sector. Reference to CSFD and affected communities is linked to other provisions relating to civil society
Article 5(8)						
Y	94	8. The Agency may engage in communication activities on its own initiative within its mandate. The allocation of resources to communication activities shall not be detrimental to the effective exercise of the	8. The Agency may engage in communication activities on its own initiative within its mandate. The allocation of resources to communication activities shall not be detrimental to the effective exercise of the	8. The Agency may engage in communication activities on its own initiative within its mandate. The allocation of resources to communication activities shall not be detrimental to the effective exercise of the	8. The Agency ~~*may*~~***shall*** engage in communication activities on its own initiative within its mandate. The allocation of resources to communication activities shall not be detrimental to the effective exercise of the	Reference to civil society is linked to other provisions on civil society

		tasks referred to in paragraph 1. Communication activities shall be carried out in accordance with relevant communication and dissemination plans adopted by the Management Board.	tasks referred to in paragraph 1. Communication activities shall be carried out in accordance with relevant communication and dissemination plans adopted by the Management Board.	tasks referred to in paragraph 1. Communication activities shall be carried out in accordance with relevant communication and dissemination plans adopted by the Management Board.	tasks referred to in paragraph 1. Communication activities shall be carried out in accordance with relevant communication ***strategy*** and dissemination plans adopted by the Management Board. ***Relevant stakeholders[, including scientific community and civil society organisations], may be involved in the development of those documents.*** Text Origin: Commission Proposal		
	CHAPTER II						
G	95	CHAPTER II MONITORING	CHAPTER II MONITORING	CHAPTER II MONITORING	CHAPTER II MONITORING Text Origin: Commission Proposal		G
	Article 6						
G	96	Article 6 Collection and dissemination of information and data	Article 6 Collection and dissemination of information and data	Article 6 Collection and dissemination of information and data	Article 6 Collection and dissemination of information and data Text Origin: Commission Proposal		G
	Article 6(1), introductory part						
G	97	1. The Agency shall:	1. The Agency shall:	1. The Agency shall:	1. The Agency shall:		G

					Text Origin: Commission Proposal	
Article 6(1), point (a)						
G	98	(a) collect all relevant information and data, including information and data communicated by the national focal points, resulting from research, available from open sources, and data emanating from Union, non-governmental sources and competent international organisations;	(a) collect ~~*all*~~ relevant information and data, including information and data communicated by the national focal points, resulting from research, available from open sources, and data emanating from Union, non-governmental sources and competent international organisations ***and bodies***;	(a) collect ~~all~~ relevant information and data, including information and data communicated by the national focal points, resulting from research, available from open sources, and data emanating from Union, non-governmental sources and competent international organisations **and bodies**;	(a) collect ~~*all*~~ relevant information and data, including information and data communicated by the national focal points, resulting from research, available from open sources, and data emanating from Union, non-governmental sources and competent international organisations ***and bodies***; Text Origin: Council Mandate	G
Article 6(1), point (b)						
G	99	(b) collect information and data needed for the monitoring of poly-substance use as referred to in Article 7(1), point (c);	(b) collect information and data needed for the monitoring of poly-substance use ***and its consequences*** as referred to in Article 7(1), point ~~*(c)*~~***(ac)***;	(b) collect information and data needed for the monitoring of poly-substance use **and its consequences** as referred to in Article 7(1), point ~~(c)~~**(ac)**;	(b) collect information and data needed for the monitoring of poly-substance use ***and its consequences*** as referred to in Article 7(1), point ~~*(c)*~~***(ac)***; Text Origin: EP Mandate	G
Article 6(1), point (c)						
Y	100	(c) collect the available information and data from the national focal points and	(c) collect the available information and data from the national focal points and	(c) collect the available information and data from the national focal points ~~and~~	(c) collect the available information and data from the national focal points ~~*and*~~	Y

		the Europol national units on new psychoactive substances and communicate that information to the national focal points and the Europol national units as well as to the Commission without undue delay;	the Europol national units on new psychoactive substances and communicate that information to the national focal points and the Europol national units as well as to the Commission without undue delay;	~~the Europol national units~~**, in cooperation with Europol,** on new psychoactive substances and communicate that information to the national focal points and the Europol national units as well as to the Commission without undue delay;	~~*the Europol national units*~~***, in cooperation with Europol,*** on new psychoactive substances and communicate that information to the national focal points and the Europol national units as well as to the Commission without undue delay; Text Origin: Council Mandate		
	Article 6(1), point (d)						
G	101	(d) collect and analyse information and data on drug precursors, their diversion and trafficking;	(d) collect and analyse information and data on drug precursors, their diversion and trafficking;	(d) collect and analyse information and data on drug precursors, their diversion and trafficking;	(d) collect and analyse information and data on drug precursors, their diversion and trafficking; Text Origin: Commission Proposal		G
	Article 6(1), point (e)						
G	102	(e) conduct and commission research and monitoring studies, surveys, feasibility studies, and pilot projects necessary to accomplish its tasks;	(e) conduct and commission research and monitoring studies, surveys, feasibility studies, and pilot projects necessary to accomplish its tasks;	(e) conduct and commission research and monitoring studies, surveys, feasibility studies, and pilot projects necessary to accomplish its tasks;	(e) conduct and commission research and monitoring studies, surveys, feasibility studies, and pilot projects necessary to accomplish its tasks; Text Origin: Commission Proposal		G
	Article 6(1), point (f)						
Y	103						Y

		(f) ensure improved comparability, objectivity and reliability of information and data at Union level by establishing indicators and common standards of a non-binding nature, compliance with which may be recommended by the Agency, with a view to ensuring greater uniformity of the measurement methods used by the Member States and the Union; in particular, the Agency shall develop tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate Union policies.	(f) ensure improved comparability, objectivity and reliability of information and data at Union level by establishing indicators and common standards of a non-binding nature, compliance with which may be recommended by the Agency, with a view to ensuring greater uniformity of the measurement methods used by the Member States and the Union; in particular, the Agency shall develop tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate Union policies.	(f) ensure improved comparability, objectivity and reliability of information and data at Union level by establishing**, in cooperation with the national focal points, indicators and** ~~indicators and common standards of a~~ non-binding ~~nature~~**common standards**, compliance with which may be recommended by the Agency, with a view to ensuring greater uniformity of the measurement methods used by the Member States and the Union;~~ in particular, the Agency shall develop tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate Union policies.~~	(f) ensure improved comparability, objectivity and reliability of information and data at Union level by establishing***, [in cooperation with the national focal points], indicators and*** ~~*indicators and common standards of a*~~ non-binding ~~*nature*~~***common standards***, compliance with which may be recommended by the Agency, with a view to ensuring greater uniformity of the measurement methods used by the Member States and the Union;~~ *in particular, the Agency shall develop tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate Union policies.*~~ Text Origin: Council Mandate	Reference to NFPs related to other provisions on NFPs	
Article 6(1), point (fa)						
Y	103a			**(g) cooperate closely with relevant Union bodies, offices and agencies and international organisations and bodies, in particular Europol, UNODC and INCB, in order to facilitate the notification and avoid**	***(g) cooperate closely with relevant Union bodies, offices and agencies and international organisations and bodies, in particular UNODC and INCB, in order to facilitate the notification and avoid***		Y

				unnecessary burden for Member States.	***unnecessary burden for Member States.*** Text Origin: Council Mandate	
Article 6(2)						
104	2. The Agency shall collect relevant national data through the national focal points. It shall also cooperate closely with other national, European and international organisations and bodies that already have information of this kind.	2. The Agency shall collect relevant national data through the national focal points. It shall also cooperate closely with other national, European and international organisations and bodies that already have information of this kind. ***The Agency may use additional national sources of information.***	2. The Agency shall collect relevant national data through the national focal points. ~~It~~**The national reporting package** shall ~~also cooperate closely with other~~**be previously discussed and agreed among the** national~~,~~ ~~European and international organisations and bodies that already have~~ **focal points. The Agency may have recourse to additional national sources of** information ~~of this kind~~**while keeping the national focal point informed in a timely manner**.	2. The Agency shall collect relevant national data through the national focal points. ~~It~~***The national reporting package*** shall ~~*also cooperate closely with other*~~***be previously discussed and agreed with the*** national~~*, European and international organisations and bodies that already have*~~ ***focal points. The Agency may have recourse to additional sources of*** information ~~*of this kind*~~***for national data while keeping the national focal point informed [in a timely manner]***. Text Origin: Council Mandate	Last part in square brackets related to other provisions on NFPs Informal COM suggestion: 2. The Agency shall collect relevant national data through the national focal points. ~~*It*~~***The national reporting package*** shall ~~*also cooperate closely with other*~~***be previously discussed and agreed with the*** national~~*, European and international organisations and bodies that already have*~~ ***focal points. The Agency may have recourse to additional sources of*** information ~~*of this kind*~~***for national data while keeping the national focal point informed [in a timely manner]***. ***The data collected and transmitted by the national focal points in line with applicable national legislation shall not make it possible to identify***

						individuals or small groups of individuals and shall be in compliance with the relevant Union and national law. *** The Presidency would suggest to further examine this suggestion in particular as regards the burden on the National Focal Points.
Article 6(3)						
G	105	3. The Agency shall develop, within its mandate, data collection methods and approaches, including through projects with external partners.	3. The Agency shall develop, within its mandate, data collection methods and approaches, including through projects with external partners.	3. The Agency shall develop, within its mandate, data collection methods and approaches, including through projects with external partners.	3. The Agency shall develop, within its mandate, data collection methods and approaches, including through projects with external partners. Text Origin: Commission Proposal	G
Article 6(4), first subparagraph						
G	106	4. The Agency may develop the necessary digital solutions through which information and data are managed and automatically exchanged.	4. The Agency ~~may~~ ***shall*** develop the necessary digital solutions through which information and data are ***collected, validated, analysed, reported,*** managed and ~~automatically exchanged~~***exchanged, including in an automated***	4. The Agency ~~may~~ **shall** develop the necessary digital solutions through which information and data are **collected, validated, analysed, reported,** managed and ~~automatically exchanged~~**exchanged, including in an automated**	4. The Agency ~~may~~ ***shall*** develop the necessary digital solutions through which information and data are ***collected, validated, analysed, reported,*** managed and ~~automatically exchanged~~***exchanged, including in an automated***	G

			manner.	**manner**.	***manner***. Text Origin: EP Mandate	
Article 6(4), second subparagraph, introductory part						
G	107	If such digital solutions are developed, they shall:	*deleted*	*deleted*	*deleted*	G
Article 6(4), second subparagraph, point (a)						
G	*108*	*(a)* enable the automated collection of data, including open source information, while keeping the possibility of manual data provision available;	*deleted*	*deleted*	*deleted*	G
Article 6(4), second subparagraph, point (b)						
G	*109*	*(b)* apply artificial intelligence for data validation, analysis and automated reporting;	*deleted*	*deleted*	*deleted*	G
Article 6(4), second subparagraph, point (c)						
G	*110*	*(c)* allow for the computerised handling and exchange of information, data and documents.	*deleted*	*deleted*	*deleted*	G
Article 6(5), introductory part						
G	*111*					G

		5. The Agency shall disseminate information and data by:	5. The Agency shall disseminate information and data by:	5. The Agency shall disseminate information and data by:	5. The Agency shall disseminate information and data by: Text Origin: Commission Proposal	
	Article 6(5), point (a)					
G	112	(a) making the information it produces available to the Union, the Member States and other interested parties, including as regards new developments and changing trends;	(a) making the information it produces available to the Union, the Member States and other interested parties, including as regards new developments and changing trends;	(a) making the information it produces available to the Union, the Member States and other interested parties, including as regards new developments and changing trends;	(a) making the information it produces available to the Union, the Member States and other interested parties, including as regards new developments and changing trends; Text Origin: Commission Proposal	G
	Article 6(5), point (b)					
G	113	(b) ensuring wide dissemination of its analysis, conclusions and reports;	(b) ensuring wide dissemination of its analysis, conclusions and reports, ***including to the scientific community, civil society organisations and affected communities, including people who use drugs, with the exception of classified and sensitive non-classified data***;	(b) ensuring wide dissemination of its analysis, conclusions and reports**, including to the scientific community, civil society, affected communities, including people who use drugs, excluding sensitive non-classified and classified data in accordance with Article 49 of this Regulation**;	(b) ensuring wide dissemination of its analysis, conclusions and reports, ***including to the scientific community, civil society organisations, affected communities, including people who use drugs, with the exception of sensitive non-classified and classified data in accordance with Article 49 of this Regulation***; Text Origin: Council Mandate	G

	Article 6(5), point (c)					
Y	114	(c) ensuring wide dissemination of reliable data, excluding sensitive non-classified and classified data, through publishing, on the basis of data which it gathers, a regular report on the state of the drugs phenomenon, including data on emerging trends;	(c) ensuring wide dissemination of reliable data, excluding sensitive non-classified and classified data, through publishing, on the basis of data which it gathers, a regular report on the state of the drugs phenomenon, including data on emerging trends;	*deleted*	(c) ~~*ensuring wide dissemination of reliable data, excluding sensitive non-classified and classified data, through*~~ publishing, on the basis of data which it gathers, a regular report on the state of the drugs phenomenon~~*, including data on*~~ ***and*** emerging trends; Text Origin: Commission Proposal	Y
	Article 6(5), point (d)					
Y	115	(d) setting up and making available open scientific documentation resources and assisting in the promotion of information activities;	(d) setting up and making available open scientific documentation resources and assisting in the promotion of information activities;	(d) setting up and making available open scientific documentation resources ~~and assisting in the promotion of information activities;~~**;**	(d) setting up and making available open scientific documentation resources ~~*and assisting in the promotion of information activities;*~~***;*** Text Origin: Council Mandate	Y
	Article 6(5), point (e)					
Y	116	(e) providing information on quality standards, innovative best practices and implementable research results in the Member States and facilitating the exchange and implementation of such standard and practices.	(e) providing information on quality standards, innovative best practices***, innovative*** and implementable research results in the Member States and facilitating the exchange and implementation of such	(e) providing information on quality standards, ~~innovative~~**evidence-based** best practices**, innovative approaches,** and implementable research results in the Member States and facilitating the exchange	(e) providing information on quality standards, ~~*innovative*~~***evidence-based*** best practices***, innovative approaches,*** and implementable research results in the Member States and facilitating the exchange	Y

			standard and practices.	and implementation of such ~~standard~~**standards** and practices.	and implementation of such ~~*standard*~~***standards*** and practices. Text Origin: Council Mandate	
Article 6(5), point (ea)						
	116a			**(5a) The Agency may also disseminate information and data disaggregated by Member State.**		Look into lines 116a, c and 117 further. COM informal suggestion: *(5a)* ***Where relevant, the*** *Agency may* ~~*also*~~ *disseminate* ***disaggregated*** *information and data****, in particular*** ~~*disaggregated*~~ *by Member State****, gender/sex, age, disability and socio-economic status, in accordance with the relevant Union law, in particular on data protection.***
Article 6(5), point (eb)						
	116b			**(5b) When disseminating information and data, the Agency shall make a reference to the sources thereof.**	***(5b) When disseminating information and data, the Agency shall make a reference to the sources thereof.*** Text Origin: Council Mandate	COM informal suggestion: *(5c) When disseminating information and data, the Agency shall make a reference to the sources thereof.*

Article 6(5a)						
Y	116c		***5a. Where relevant, the Agency may disseminate information and data disaggregated by Member State, gender, age, disability and socio-economic status, in accordance with the relevant national legal framework and Union data protection law.*** Article 6 - paragraph 5 - subparagraph 1 a (new)			(see line 116a)
Article 6(6)						
Y	117	6. The Agency shall not collect any data making it possible to identify individuals or small groups of individuals. It shall refrain from any transmission of information relating to specific individuals.	6. The Agency shall not ~~*collect*~~***disseminate or transmit*** any data making it possible to identify individuals or small groups of individuals.~~*It shall refrain from any transmission of information relating to specific individuals.*~~	6. The Agency shall **ensure, where possible, that the data collected is disaggregated by sex and that the collection and presentation of data considers the gender-sensitive aspects of drugs policy. It shall** not collect any data making it possible to identify individuals or small groups of individuals. It shall refrain from any transmission of information relating to specific individuals.		Informal COM suggestion: (5b) The Agency shall not ~~collect~~ ***disseminate or transmit*** any data making it possible to identify individuals or small groups of individuals. ~~It shall refrain from any transmission of information relating to specific individuals.~~
Article 7						

G	118	Article 7 Monitoring of the drug phenomenon	Article 7 Monitoring of the drug phenomenon ***and sharing of best practices***	Article 7 Monitoring of the drug phenomenon **and sharing of best practices**	Article 7 Monitoring of the drug phenomenon ***and sharing of best practices*** Text Origin: EP Mandate		G
	Article 7(1), introductory part						
G	119	1. The Agency shall monitor:	1. The Agency shall monitor:	1. The Agency shall monitor:	1. The Agency shall monitor: Text Origin: Commission Proposal		G
	Article 7(1), point (a)						
Y	120	(a) the drugs phenomenon in the Union holistically, through epidemiological and other indicators, covering the health, safety and security aspects, including the implementation of the applicable Union strategies on drugs;	(a) the drugs phenomenon in the Union holistically, through epidemiological and other indicators, covering the ***public*** health, ***social and human rights, social reintegration,*** safety and security aspects ***thereof***, including the implementation of the applicable Union strategies on drugs;	(a) the drugs phenomenon in the Union holistically, through epidemiological and other indicators, covering the health, **social,** safety and security aspects, including the implementation of the applicable Union ~~strategies on drugs~~**drug-related strategic documents**;	(a) the drugs phenomenon in the Union holistically, through epidemiological and other indicators, covering the health, ***human rights, social,*** safety and security aspects ***[thereof]***, including the implementation of the applicable Union ~~*strategies on drugs*~~***drug-related strategic documents***; Text Origin: Council Mandate	Explain in recitals: public health vs health; that social aspects cover social reintegration. Exact wording on "strategic documents" (similarly as in line 91) + the need for "thereof" to be checked by lawyer-linguists.	Y
	Article 7(1), point (aa)						
Y	120a			**(aa) evidence-based best practices and innovative**	***(aa) evidence-based best practices and innovative***		Y

				approaches, regarding health, social, safety or security responses;	***approaches, regarding health, human rights, social, safety or security responses;*** Text Origin: Council Mandate	
Article 7(1), point (aa)						
Y	120b		***(aa) evidence-based best practices and innovative approaches to respond to the public health, social and human rights, safety and security aspects of the drugs phenomenon in the participating countries;***			Covered in line 120a above. To have a discussion separately on "participating countries".
Article 7(1), point (ab)						
Y	120c		***(ab) emerging trends in the Union and internationally with respect to drug use, drug use disorders, drug addictions and related health risks and harm in so far as they impact the participating countries;***			Covered in line 120d To have a discussion separately on "participating countries".
Article 7(1), point (ab)						
Y	120d			**(ab) drug use, drug use disorders, drug addictions and related health risks and harms and risky**	***(ab) drug use, drug use disorders, drug addictions and related health risks and harms [and risky***	EP to check "risky behaviours" Council to see if alternative

				behaviours as well as emerging trends in these fields;	***behaviours] as well as emerging trends in these fields;*** Text Origin: Council Mandate	wording more appropriate COM informal suggestion: (ab) drug use, drug use disorders, drug addictions and related health risks and ***drug-related*** harms ~~and risky behaviours~~***, as well as risk behaviours associated with drug use*** as well as emerging trends in these fields;
Article 7(1), point (ac)						
Y	120e			**(ac) poly-substance use and its consequences, in particular the increased risks of health and social problems, the social determinants of drug use, drug use disorders and addictions, as well as the implications for policies and responses;**	***(ac) poly-substance use and its consequences, in particular the increased risks of health and social problems, the social determinants of drug use, drug use disorders and addictions, as well as the implications for policies and responses;*** Text Origin: Council Mandate	Y
Article 7(1), point (ac)						
Y	120f		***(ac) poly-substance use and its consequences, in particular the increased risks of health and social problems, the social***			Covered in line 120e

			determinants of drug use, drug use disorders and drug addictions, and the implications for policies and responses;			
Article 7(1), point (ad)						
Y	120g			**(ad) drug and poly-substance use and their consequences from a gender perspective, in particular their impact on gender-based violence;**	***(ad) drug and poly-substance use and its consequences from a gender perspective, in particular their impact on gender-based violence;*** Text Origin: Council Mandate	Y
Article 7(1), point (ad)						
Y	120h		***(ad) drug and poly-substance use and its consequences from an age and gender perspective, in particular its impact on gender-based violence;***			Covered in line 120g; "age" covered elsewhere (e.g. Art. 4) Y
Article 7(1), point (b)						
	121	(b) emerging trends in the drugs phenomenon in the Union and internationally as far as these impact on the Union; this shall include the monitoring of the use of new technologies for drug	(b) emerging trends in the drugs phenomenon in the Union and internationally as far as these impact on the Union; this shall include the monitoring of the use of new technologies for drug	(b) emerging trends in the drugs phenomenon in the Union and internationally as far as these impact on the Union; this shall include the monitoring of ~~the use of new technologies for drug~~		This provision to be further discussed.

	services or drug trafficking, and links to other crime areas, as relevant;	services or drug trafficking, and links to other crime areas, as relevant;	~~services or drug trafficking, and links to other crime areas, as relevant~~**drug supply, including illicit production and trafficking and other related crimes as well as the use of new technologies, in cooperation with Europol within their respective mandates**;		
Article 7(1), point (c)					
G 122	(c) poly-substance use and its consequences, in particular the implications for policies and responses arising from the interaction between the use of drugs with one or more psychoactive substance or type of substance, whether licit or illicit; including the increased risks of health and social problems, which may occur when drugs and other psychoactive substances are consumed at the same time or sequentially within a short period of time or when different substances are produced or sold together; the need to consider the common causes of drug use and addictions; and the implications for monitoring and exchange of best	*deleted*	*deleted*	*deleted*	G

	practices, which arise when policies and responses target multiple substances holistically;					
Article 7(1), point (d)						
123	*(d)* drug-related problems and the solutions applied, in particular the implementation of innovative best practices and research results;	*deleted*	*deleted*	*deleted*		
Article 7(1), point (e)						
124	*(e)* in cooperation with Europol and with the support of the national focal points and the Europol national units, all new psychoactive substances that have been reported by Member States;	(e) in cooperation with Europol and with the support of the national focal points and the Europol national units, all new psychoactive substances that have been reported by Member States;	(e) in cooperation with Europol and with the support of the national focal points and the Europol national units, all new psychoactive substances that have been reported by Member States;	(e) in cooperation with Europol and with the support of the national focal points and the Europol national units, all new psychoactive substances that have been reported by Member States; Text Origin: Commission Proposal		
Article 7(1), point (f)						
125	(f) drug precursors and their trafficking and diversion;	(f) drug precursors and their trafficking and diversion;	(f) drug precursors and their trafficking and diversion;	(f) drug precursors and their trafficking and diversion; Text Origin: Commission Proposal	*[Last line discussed on 26/1]*	
Article 7(1), point (g)						

G	126	(g) Union and national drugs policies, including in view of supporting their development and independent evaluation;	(g) Union and national drugs policies, including in view of supporting their development and independent evaluation;	(g) **the implementation of the** Union and national drugs policies, including in view of supporting their development and independent evaluation~~;~~**.**	(g) ***the implementation of the*** Union and national drugs policies, including in view of supporting their development and independent evaluation~~;~~***.*** Text Origin: Council Mandate		G
	Article 7(1), point (h)						
G	127	(h) Technology-enabled drug markets, in cooperation with Europol within their respective mandates.	*deleted*	*deleted*	*deleted*	[linked to line 121]	G
	Article 7(2)						
Y	128	2. Based on its monitoring activities, the Agency shall identify innovative best practices and develop them further. The Agency shall provide and share information on innovative best practices in the Member States and facilitate the exchange of such practices among the Member States.	2. Based on its monitoring activities, the Agency shall ~~*identify innovative best practices and*~~ develop ~~*them further. The Agency shall provide and share information on innovative*~~***and identify innovative and evidence-based*** best practices***, share them with*** ~~*in*~~ the Member States and facilitate the exchange of such practices among ~~*the Member States*~~***them***.	2. Based on its monitoring activities, the Agency shall identify ~~innovative~~**and support evidence-based** best practices and ~~develop them further. The Agency shall provide~~**innovative approaches,** and share ~~information on innovative best practices in~~**them with** the Member States and facilitate the exchange ~~of such practices~~**thereof** among ~~the Member States~~**them**.	2. Based on its monitoring activities, the Agency shall identify ~~*innovative best practices and develop them further. The Agency shall provide and share information on innovative best practices in*~~***and support [and, where appropriate, co-develop] evidence-based best practices and innovative approaches, and share them with*** the Member States and facilitate the exchange ~~*of such practices*~~***thereof*** among ~~*the Member States*~~***them***.		Y

					Text Origin: Council Mandate	
Article 7(2a)						
Y	128a			**2a. The Agency shall, in cooperation with the national focal points, develop tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate Union policies.**	***2a. The Agency shall develop tools and instruments to help Member States to monitor and evaluate their national policies, in cooperation with the national focal points, and the Commission to monitor and evaluate Union policies.*** Text Origin: Council Mandate	NB: This provision does not prejudge the provisions on certification / assessment.
Article 7(3)						
G	129	3. The Agency shall undertake regular foresight exercises, taking into account the information available. It shall develop, on that basis, relevant predictions for the development of future drugs policy.	3. The Agency shall ~~*undertake regular foresight exercises, taking into account the information available. It*~~***provide data, analysis and best practices to, and share the latest evidence-based policy recommendations with, the Commission and the Member States, provided that such data, analysis, best practices and policy recommendations concern Union and national policies which address the phenomenon of drug***	3. The Agency shall undertake regular foresight exercises, taking into account the information available. It shall develop, on that basis, relevant ~~predictions~~**scenarios** for the development of future drugs policy.	3. The Agency shall undertake regular foresight exercises, taking into account the information available. It shall develop, on that basis, relevant ~~*predictions*~~***scenarios*** for the development of future drugs policy. Text Origin: Council Mandate	Elements from EP amendment covered in lines 113 and 128

			addictions. The Agency shall develop, on that basis, relevant ~~*predictions*~~***scenarios*** for the development of future drugs policy. ***The Agency shall undertake regular foresight exercises, taking into account the information available.***				
CHAPTER III							
G	130	CHAPTER III PREPAREDNESS	CHAPTER III PREPAREDNESS	CHAPTER III PREPAREDNESS	CHAPTER III PREPAREDNESS Text Origin: Commission Proposal		G
Article 8							
G	131	Article 8 Information exchange on, and early warning system for, new psychoactive substances	Article 8 Information exchange on, and early warning system for, new psychoactive substances	Article 8 Information exchange on, and early warning system for, new psychoactive substances	Article 8 Information exchange on, and early warning system for, new psychoactive substances Text Origin: Commission Proposal		G
Article 8(1), first subparagraph							
G	132	1. Each Member State shall ensure that its national focal point and its Europol national unit provide the Agency and Europol, taking	1. Each Member State shall ensure that its national focal point and its Europol national unit provide the Agency and Europol, taking	1. Each Member State shall ensure that its national focal point and its Europol national unit provide the Agency and Europol, taking	1. Each Member State shall ensure that its national focal point and its Europol national unit provide the Agency and Europol, taking		G

		into account their respective mandates, with the available information on new psychoactive substances in a timely manner and without undue delay.	into account their respective mandates, with the available information on new psychoactive substances in a timely manner and without undue delay.	into account their respective mandates, with the available information on new psychoactive substances in a timely manner and without undue delay.	into account their respective mandates, with the available information on new psychoactive substances in a timely manner and without undue delay. Text Origin: Commission Proposal	
Article 8(1), second subparagraph						
G	133	The information shall be related to the detection and identification, use and patterns of use, manufacture, extraction, distribution and distribution methods, trafficking, and commercial, medical and scientific use of, and potential and identified risks posed by, those substances.	The information shall be related to the detection and identification, use and patterns of use, manufacture, extraction, distribution and distribution methods, trafficking, and commercial, medical and scientific use of, and potential and identified risks posed by, those substances.	The information shall be related to the detection and identification, use and patterns of use, manufacture, extraction, distribution and distribution methods, trafficking, and commercial, medical and scientific use of, and potential and identified risks posed by, those substances.	The information shall be related to the detection and identification, use and patterns of use, manufacture, extraction, distribution and distribution methods, trafficking, and commercial, medical and scientific use of, and potential and identified risks posed by, those substances. Text Origin: Commission Proposal	G
Article 8(2), first subparagraph						
G	134	2. The Agency, in cooperation with Europol, shall collect, collate, analyse and assess information on new psychoactive substances. It shall communicate this information in a timely manner to the national focal	2. The Agency, in cooperation with Europol, shall collect, collate, analyse and assess information on new psychoactive substances. It shall communicate this information in a timely manner to the national focal	2. The Agency, in cooperation with Europol, shall collect, collate, analyse and assess information on new psychoactive substances. It shall communicate this information in a timely manner to the national focal	2. The Agency, in cooperation with Europol, shall collect, collate, analyse and assess information on new psychoactive substances. It shall communicate this information in a timely manner to the national focal	G

		points, the Europol national units, and the Commission with a view to providing them with any information required for the purposes of early warning.	points, the Europol national units, and the Commission with a view to providing them with any information required for the purposes of early warning.	points, the Europol national units, and the Commission with a view to providing them with any information required for the purposes of early warning.	points, the Europol national units, and the Commission with a view to providing them with any information required for the purposes of early warning. Text Origin: Commission Proposal	
	Article 8(2), second subparagraph					
G	135	The Agency shall draw up the initial report or the combined initial report pursuant to Article 9 based on the information collected pursuant to the first subparagraph.	The Agency shall draw up the initial report or the combined initial report pursuant to Article 9 based on the information collected pursuant to the first subparagraph.	The Agency shall draw up the initial report or the combined initial report pursuant to Article 9 based on the information collected pursuant to the first subparagraph.	The Agency shall draw up the initial report or the combined initial report pursuant to Article 9 based on the information collected pursuant to the first subparagraph. Text Origin: Commission Proposal	G
	Article 9					
G	136	Article 9 Initial report	Article 9 Initial report	Article 9 Initial report	Article 9 Initial report Text Origin: Commission Proposal	G
	Article 9(1), first subparagraph					
G	137	1. Where the Agency, the Commission or the majority of Member States considers that information shared on a new psychoactive substance	1. Where the Agency, the Commission or the majority of Member States considers that information shared on a new psychoactive substance	1. Where the Agency, the Commission or the majority of Member States considers that information shared on a new psychoactive substance	1. Where the Agency, the Commission or the majority of Member States considers that information shared on a new psychoactive substance	G

		collected in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks at Union level, the Agency shall draw up an initial report on the new psychoactive substance.	collected in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks at Union level, the Agency shall draw up an initial report on the new psychoactive substance.	collected in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks at Union level, the Agency shall draw up an initial report on the new psychoactive substance. Text Origin: Commission Proposal		
	Article 9(1), second subparagraph					
G	138	For the purpose of the first subparagraph, Member States shall inform the Commission and other Member States of their wish that an initial report be drawn up. Where the majority of Member States is reached, the Commission shall instruct the Agency accordingly and shall inform the Member States thereof.	For the purpose of the first subparagraph, Member States shall inform the Commission and other Member States of their wish that an initial report be drawn up. Where the majority of Member States is reached, the Commission shall instruct the Agency accordingly and shall inform the Member States thereof.	For the purpose of the first subparagraph, Member States shall inform the Commission and other Member States of their wish that an initial report be drawn up. Where the majority of Member States is reached, the Commission shall instruct the Agency accordingly and shall inform the Member States thereof.	For the purpose of the first subparagraph, Member States shall inform the Commission and other Member States of their wish that an initial report be drawn up. Where the majority of Member States is reached, the Commission shall instruct the Agency accordingly and shall inform the Member States thereof. Text Origin: Commission Proposal	G
	Article 9(2), introductory part					
G	139	2. The initial report shall contain:	2. The initial report shall contain:	2. The initial report shall contain:	2. The initial report shall contain: Text Origin: Commission Proposal	G

	Article 9(2), point (a)					
G	140	(a) a preliminary indication of the nature, number and scale of incidents showing health and social problems in which the new psychoactive substance may potentially be involved, and the patterns of use of the new psychoactive substance;	(a) a preliminary indication of the nature, number and scale of incidents showing health and social problems in which the new psychoactive substance may potentially be involved, and the patterns of use of the new psychoactive substance;	(a) a preliminary indication of the nature, number and scale of incidents showing health and social problems in which the new psychoactive substance may potentially be involved, and the patterns of use of the new psychoactive substance;	(a) a preliminary indication of the nature, number and scale of incidents showing health and social problems in which the new psychoactive substance may potentially be involved, and the patterns of use of the new psychoactive substance; Text Origin: Commission Proposal		G
	Article 9(2), point (b)					
G	141	(b) a preliminary indication of the chemical and physical description of the new psychoactive substance and the methods and precursors used for its manufacture or extraction;	(b) a preliminary indication of the chemical and physical description of the new psychoactive substance and the methods and precursors used for its manufacture or extraction;	(b) a preliminary indication of the chemical and physical description of the new psychoactive substance and the methods and precursors used for its manufacture or extraction;	(b) a preliminary indication of the chemical and physical description of the new psychoactive substance and the methods and precursors used for its manufacture or extraction; Text Origin: Commission Proposal		G
	Article 9(2), point (c)					
G	142	(c) a preliminary indication of the pharmacological and toxicological description of the new psychoactive substance;	(c) a preliminary indication of the pharmacological and toxicological description of the new psychoactive substance;	(c) a preliminary indication of the pharmacological and toxicological description of the new psychoactive substance;	(c) a preliminary indication of the pharmacological and toxicological description of the new psychoactive substance; Text Origin: Commission Proposal		G

Article 9(2), point (d)						
G	143	(d) a preliminary indication of the involvement of criminal groups in the manufacture or distribution of the new psychoactive substance;	(d) a preliminary indication of the involvement of criminal groups in the manufacture or distribution of the new psychoactive substance;	(d) a preliminary indication of the involvement of criminal groups in the manufacture or distribution of the new psychoactive substance;	(d) a preliminary indication of the involvement of criminal groups in the manufacture or distribution of the new psychoactive substance; Text Origin: Commission Proposal	G
Article 9(2), point (e)						
G	144	(e) information on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or in a veterinary medicinal product;	(e) information on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or in a veterinary medicinal product;	(e) information on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or in a veterinary medicinal product;	(e) information on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or in a veterinary medicinal product; Text Origin: Commission Proposal	G
Article 9(2), point (f)						
G	145	(f) information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;	(f) information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;	(f) information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;	(f) information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;	G

					Text Origin: Commission Proposal	
Article 9(2), point (fa)						
145a		***(fa) information on the health-related risks associated with new psychoactive substances;***			Covered in line 140.	
Article 9(2), point (g)						
146	(g) information on whether the new psychoactive substance is subject to any restrictive measures in the Member States;	(g) information on whether the new psychoactive substance is subject to any restrictive measures in the Member States;	(g) information on whether the new psychoactive substance is subject to any restrictive measures in the Member States;	(g) information on whether the new psychoactive substance is subject to any restrictive measures in the Member States; Text Origin: Commission Proposal		
Article 9(2), point (h)						
147	(h) information on whether the new psychoactive substance is currently or has been under assessment within the United Nations system;	(h) information on whether the new psychoactive substance is currently or has been under assessment within the United Nations system;	(h) information on whether the new psychoactive substance is currently or has been under assessment within the United Nations system;	(h) information on whether the new psychoactive substance is currently or has been under assessment within the United Nations system; Text Origin: Commission Proposal		
Article 9(2), point (i)						
148	(i) other relevant	(i) other relevant	(i) other relevant	(i) other relevant		

		information, where available.	information, where available.	information, where available.	information, where available. Text Origin: Commission Proposal		
	Article 9(3)						
G	149	3. For the purpose of the initial report, the Agency shall use information, which is at its disposal.	3. For the purpose of the initial report, the Agency shall use information, which is at its disposal***, including information obtained pursuant to Article 8***.	3. For the purpose of the initial report, the Agency shall use information, which is at its disposal.	3. For the purpose of the initial report, the Agency shall use information, which is at its disposal. Text Origin: Commission Proposal		G
	Article 9(4)						
Y	150	4. Where the Agency considers it necessary, it shall request the national focal points to provide additional information on the new psychoactive substance. The national focal points shall provide that information within two weeks of receipt of the request.	4. Where the Agency considers it necessary, it shall request the national focal points ***and the relevant stakeholders, including the scientific community, healthcare professionals, civil society organisations and affected communities,*** to provide additional information on the new psychoactive substance. The national focal points ***and the relevant stakeholders, as applicable,*** shall provide that information within two weeks of receipt of the request.	4. Where the Agency considers it necessary, it shall request the national focal points to provide additional information on the new psychoactive substance. The national focal points shall provide that information within two weeks of receipt of the request.	4. Where the Agency considers it necessary, it shall request the national focal points to provide additional information on the new psychoactive substance. The national focal points shall provide that information within two weeks of receipt of the request. Text Origin: Commission Proposal	Cooperation with stakeholders covered in line 93c; with civil society in Art. 55.	Y
	Article 9(5), first subparagraph, introductory part						

G	151	5. The Agency shall, without undue delay after the start of drawing up of the initial report pursuant to the first paragraph, request the European Medicines Agency to provide information on whether, at Union or national level, the new psychoactive substance is an active substance in:	5. The Agency shall, without undue delay after the start of drawing up of the initial report pursuant to the first paragraph, request the European Medicines Agency to provide information on whether, at Union or national level, the new psychoactive substance is an active substance in:	5. The Agency shall, without undue delay after the start of drawing up of the initial report pursuant to the first paragraph, request the European Medicines Agency to provide information on whether, at Union or national level, the new psychoactive substance is an active substance in:	5. The Agency shall, without undue delay after the start of drawing up of the initial report pursuant to the first paragraph, request the European Medicines Agency to provide information on whether, at Union or national level, the new psychoactive substance is an active substance in: Text Origin: Commission Proposal		G
Article 9(5), first subparagraph, point (a)							
G	152	(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC of the European Parliament and of the Council[1], Directive 2001/82/EC of the European Parliament and of the Council[2] or Regulation (EC) No 726/2004 of the European Parliament and of the Council[3]; 1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). 2. Directive 2001/82/EC of the	(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC of the European Parliament and of the Council[1], Directive 2001/82/EC of the European Parliament and of the Council[2] or Regulation (EC) No 726/2004 of the European Parliament and of the Council[3]; 1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). 2. Directive 2001/82/EC of the	(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC of the European Parliament and of the Council[1], Directive 2001/82/EC of the European Parliament and of the Council[2] or Regulation (EC) No 726/2004 of the European Parliament and of the Council[3]; 1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). 2. Directive 2001/82/EC of the	(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC of the European Parliament and of the Council[1], Directive 2001/82/EC of the European Parliament and of the Council[2] or Regulation (EC) No 726/2004 of the European Parliament and of the Council[3]; 1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). 2. Directive 2001/82/EC of the		G

	European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1). 3. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).	European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1). 3. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).	European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1). 3. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).	European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1). 3. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Text Origin: Commission Proposal	
Article 9(5), first subparagraph, point (b)					
G 153	(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;	(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;	(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;	(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation; Text Origin: Commission Proposal	G
Article 9(5), first subparagraph, point (c)					
G 154	(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;	(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;	(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;	(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority; Text Origin: Commission Proposal	G

Article 9(5), first subparagraph, point (d)					
155	(d) an unauthorised medicinal product for human use as referred to in Article 5(1) and (2) of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national law in accordance with Article 10(1), point (c), of Directive 2001/82/EC;	(d) an unauthorised medicinal product for human use as referred to in Article 5(1) and (2) of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national law in accordance with Article 10(1), point (c), of Directive 2001/82/EC;	(d) an unauthorised medicinal product for human use as referred to in Article 5(1) and (2) of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national law in accordance with Article 10(1), point (c), of Directive 2001/82/EC;	(d) an unauthorised medicinal product for human use as referred to in Article 5(1) and (2) of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national law in accordance with Article 10(1), point (c), of Directive 2001/82/EC; Text Origin: Commission Proposal	
Article 9(5), first subparagraph, point (e)					
156	(e) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC of the European Parliament and of the Council[1]. 1. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).	(e) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC of the European Parliament and of the Council[1]. 1. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).	(e) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC of the European Parliament and of the Council[1]. 1. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).	(e) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC of the European Parliament and of the Council[1]. 1. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34). Text Origin: Commission Proposal	

	Article 9(5), second subparagraph						
G	157	Where the information relates to marketing authorisations granted by Member States, the Member States concerned shall provide the European Medicines Agency with such information upon its request.	Where the information relates to marketing authorisations granted by Member States, the Member States concerned shall provide the European Medicines Agency with such information upon its request.	Where the information relates to marketing authorisations granted by Member States, the Member States concerned shall provide the European Medicines Agency with such information upon its request.	Where the information relates to marketing authorisations granted by Member States, the Member States concerned shall provide the European Medicines Agency with such information upon its request. Text Origin: Commission Proposal		G
	Article 9(6)						
G	158	6. The Agency shall, without undue delay after the start of the drawing up of the initial report pursuant to the first paragraph, request Europol to provide information on the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance, and in any use of the new psychoactive substance.	6. The Agency shall, without undue delay after the start of the drawing up of the initial report pursuant to the first paragraph, request Europol to provide information on the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance, and in any use of the new psychoactive substance.	6. The Agency shall, without undue delay after the start of the drawing up of the initial report pursuant to the first paragraph, request Europol to provide information on the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance, and in any use of the new psychoactive substance.	6. The Agency shall, without undue delay after the start of the drawing up of the initial report pursuant to the first paragraph, request Europol to provide information on the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance, and in any use of the new psychoactive substance. Text Origin: Commission Proposal		G
	Article 9(7)						

G	159	7. The Agency shall, without undue delay after the start of the drawing up of the initial report pursuant to the first paragraph, request the European Chemicals Agency, the European Centre for Disease Prevention and Control and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance.	7. The Agency shall, without undue delay after the start of the drawing up of the initial report pursuant to the first paragraph, request the European Chemicals Agency, the European Centre for Disease Prevention and Control and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance.	7. The Agency shall, without undue delay after the start of the drawing up of the initial report pursuant to the first paragraph, request the European Chemicals Agency, the European Centre for Disease Prevention and Control and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance.	7. The Agency shall, without undue delay after the start of the drawing up of the initial report pursuant to the first paragraph, request the European Chemicals Agency, the European Centre for Disease Prevention and Control and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance. Text Origin: Commission Proposal		G
	Article 9(8)						
G	160	8. The details of the cooperation between the Agency and the Union decentralised agencies referred to in paragraphs 5, 6 and 7 shall be governed by working arrangements. Such working arrangements shall be concluded in accordance with Article 53(2).	8. The details of the cooperation between the Agency and the Union decentralised agencies referred to in paragraphs 5, 6 and 7 shall be governed by working arrangements. Such working arrangements shall be concluded in accordance with Article 53(2).	8. The details of the cooperation between the Agency and the Union decentralised agencies referred to in paragraphs 5, 6 and 7 shall be governed by working arrangements. Such working arrangements shall be concluded in accordance with Article 53(2).	8. The details of the cooperation between the Agency and the Union decentralised agencies referred to in paragraphs 5, 6 and 7 shall be governed by working arrangements. Such working arrangements shall be concluded in accordance with Article 53(2). Text Origin: Commission Proposal		G
	Article 9(9)						
G	161	9. The Agency shall respect	9. The Agency shall respect	9. The Agency shall respect	9. The Agency shall respect		G

		the conditions on use of the information, which are communicated to the Agency, including conditions on access to documents, information and data security and protection of confidential data, including sensitive data and confidential business information of third parties.	the conditions on use of the information, which are communicated to the Agency, including conditions on access to documents, information and data security and protection of confidential data, including sensitive data and confidential business information of third parties.	the conditions on use of the information, which are communicated to the Agency, including conditions on access to documents, information and data security and protection of confidential data, including sensitive data and confidential business information of third parties. Text Origin: Commission Proposal		
	Article 9(10)					
G	162	10. The Agency shall submit the initial report to the Commission and the Member States within five weeks of making the requests for information referred to in paragraphs 5, 6 and 7.	10. The Agency shall submit the initial report to the Commission and the Member States within five weeks of making the requests for information referred to in paragraphs 5, 6 and 7.	10. The Agency shall submit the initial report to the Commission and the Member States within five weeks of making the requests for information referred to in paragraphs 5, 6 and 7. Text Origin: Commission Proposal		G
	Article 9(10), point (a)					
G	162a		***(a) Where appropriate, the Agency shall disseminate the initial report to the relevant stakeholders, including the scientific community, civil society organisations and affected***		Covered in line 113. Possibly additionally address these elements in the recitals [COM to suggest a wording]	G

		communities, for the purpose of raising awareness.			
Article 9(11)					
163	11. Where the Agency collects information on several new psychoactive substances that it considers to be of similar chemical structure, it shall submit to the Commission and to the Member States individual initial reports, or combined initial reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks of making the requests for information referred to in paragraphs 5, 6 and 7.	11. Where the Agency collects information on several new psychoactive substances that it considers to be of similar chemical structure, it shall submit to the Commission and to the Member States individual initial reports, or combined initial reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks of making the requests for information referred to in paragraphs 5, 6 and 7.	11. Where the Agency collects information on several new psychoactive substances that it considers to be of similar chemical structure, it shall submit to the Commission and to the Member States individual initial reports, or combined initial reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks of making the requests for information referred to in paragraphs 5, 6 and 7.	11. Where the Agency collects information on several new psychoactive substances that it considers to be of similar chemical structure, it shall submit to the Commission and to the Member States individual initial reports, or combined initial reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks of making the requests for information referred to in paragraphs 5, 6 and 7. Text Origin: Commission Proposal	
Article 10					
164	Article 10 Risk assessment procedure and report	Article 10 Risk assessment procedure and report	Article 10 Risk assessment procedure and report	Article 10 Risk assessment procedure and report Text Origin: Commission Proposal	

Article 10(1)					
165	1. Within two weeks of receipt of an initial report as referred to in Article 9(10), the Commission may request the Agency to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report, where there are indications in the initial report to believe that the substance may pose severe public health risks and, where applicable, severe social risks. The risk assessment shall be carried out by the Scientific Committee.	1. Within two weeks of receipt of an initial report as referred to in Article 9(10), the Commission may request the Agency to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report, where there are indications in the initial report to believe that the substance may pose severe public health risks and, where applicable, severe social risks. The risk assessment shall be carried out by the Scientific Committee.	1. Within two weeks of receipt of an initial report as referred to in Article 9(10), the Commission may request the Agency to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report, where there are indications in the initial report to believe that the substance may pose severe public health risks and, where applicable, severe social risks. The risk assessment shall be carried out by the Scientific Committee.	1. Within two weeks of receipt of an initial report as referred to in Article 9(10), the Commission may request the Agency to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report, where there are indications in the initial report to believe that the substance may pose severe public health risks and, where applicable, severe social risks. The risk assessment shall be carried out by the Scientific Committee. Text Origin: Commission Proposal	

Article 10(2)					
166	2. Within two weeks of receipt of a combined initial report as referred to in Article 9(11), the Commission may request the Agency to assess the potential risks posed by several new psychoactive substances with a similar chemical structure and to draw up a combined risk assessment report, where	2. Within two weeks of receipt of a combined initial report as referred to in Article 9(11), the Commission may request the Agency to assess the potential risks posed by several new psychoactive substances with a similar chemical structure and to draw up a combined risk assessment report, where	2. Within two weeks of receipt of a combined initial report as referred to in Article 9(11), the Commission may request the Agency to assess the potential risks posed by several new psychoactive substances with a similar chemical structure and to draw up a combined risk assessment report, where	2. Within two weeks of receipt of a combined initial report as referred to in Article 9(11), the Commission may request the Agency to assess the potential risks posed by several new psychoactive substances with a similar chemical structure and to draw up a combined risk assessment report, where	

		there are indications in the combined initial report to believe that the substances may pose severe public health risks and, where applicable, severe social risks. The combined risk assessment shall be carried out by the Scientific Committee.	there are indications in the combined initial report to believe that the substances may pose severe public health risks and, where applicable, severe social risks. The combined risk assessment shall be carried out by the Scientific Committee.	there are indications in the combined initial report to believe that the substances may pose severe public health risks and, where applicable, severe social risks. The combined risk assessment shall be carried out by the Scientific Committee.	there are indications in the combined initial report to believe that the substances may pose severe public health risks and, where applicable, severe social risks. The combined risk assessment shall be carried out by the Scientific Committee. Text Origin: Commission Proposal	
Article 10(3), introductory part						
G	167	3. The risk assessment report or combined risk assessment report shall contain:	3. The risk assessment report or combined risk assessment report shall contain:	3. The risk assessment report or combined risk assessment report shall contain:	3. The risk assessment report or combined risk assessment report shall contain: Text Origin: Commission Proposal	G
Article 10(3), point (a)						
G	168	(a) available information on the chemical and physical properties of the new psychoactive substance and the methods and the precursors used for its manufacture or extraction;	(a) available information on the chemical and physical properties of the new psychoactive substance and the methods and the precursors used for its manufacture or extraction;	(a) available information on the chemical and physical properties of the new psychoactive substance and the methods and the precursors used for its manufacture or extraction;	(a) available information on the chemical and physical properties of the new psychoactive substance and the methods and the precursors used for its manufacture or extraction; Text Origin: Commission Proposal	G
Article 10(3), point (b)						

G	169	(b) available information on the pharmacological and toxicological properties of the new psychoactive substance;	(b) available information on the pharmacological and toxicological properties of the new psychoactive substance;	(b) available information on the pharmacological and toxicological properties of the new psychoactive substance;	(b) available information on the pharmacological and toxicological properties of the new psychoactive substance; Text Origin: Commission Proposal		G
Article 10(3), point (c)							
G	170	(c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and physical, mental and behavioural effects;	(c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and physical, mental and behavioural effects ***and in relation to drug-related deaths, including where they are a result of overdoses***;	(c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and physical, mental and behavioural effects;	(c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and physical, mental and behavioural effects; Text Origin: Commission Proposal	Covered under "health risks / acute toxicity	G
Article 10(3), point (d)							
G	171	(d) an analysis of the social risks associated with the new psychoactive substance – in particular its impact on social functioning, public order and criminal activities, and the involvement of criminal groups in the manufacture, distribution	(d) an analysis of the social risks associated with the new psychoactive substance – in particular its impact on social functioning ***and social marginalisation***, public order and criminal activities, and the involvement of criminal groups in the	(d) an analysis of the social risks associated with the new psychoactive substance – in particular its impact on social functioning, public order and criminal activities, and the involvement of criminal groups in the manufacture, distribution	(d) an analysis of the social risks associated with the new psychoactive substance – in particular its impact on social functioning, public order and criminal activities, and the involvement of criminal groups in the manufacture, distribution	"Social marginalisation" could be covered in a recital relating to social aspects [COM to suggest a wording]	G

		and distribution methods, and trafficking of the new psychoactive substance;	manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance;	and distribution methods, and trafficking of the new psychoactive substance;	and distribution methods, and trafficking of the new psychoactive substance; Text Origin: Commission Proposal	
	Article 10(3), point (e)					
G	172	(e) available information on the extent and patterns of use of the new psychoactive substance, its availability and potential for diffusion within the Union;	(e) available information on the extent and patterns of use of the new psychoactive substance, its availability and potential for diffusion within the Union;	(e) available information on the extent and patterns of use of the new psychoactive substance, its availability and potential for diffusion within the Union;	(e) available information on the extent and patterns of use of the new psychoactive substance, its availability and potential for diffusion within the Union; Text Origin: Commission Proposal	G
	Article 10(3), point (f)					
G	173	(f) available information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;	(f) available information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;	(f) available information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;	(f) available information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes; Text Origin: Commission Proposal	G
	Article 10(3), point (fa)					
G	173a		***(fa) available information on recommended evidence-based demand reduction, harm reduction and***			No evidence-based responses might be available as this concerns new substances G

			recovery responses to minimise the risks and harms associated with the new psychoactive substance;			
Article 10(3), point (g)						
G	174	(g) other relevant information, where available.	(g) other relevant information, where available.	(g) other relevant information, where available. Text Origin: Commission Proposal		G
Article 10(4), first subparagraph						
G	175	4. The Scientific Committee shall assess the risks posed by the new psychoactive substance or group of new psychoactive substances.	4. The Scientific Committee shall assess the risks posed by the new psychoactive substance or group of new psychoactive substances.	4. The Scientific Committee shall assess the risks posed by the new psychoactive substance or group of new psychoactive substances. Text Origin: Commission Proposal		G
Article 10(4), second subparagraph						
G	176	The Commission, the Agency, Europol and the European Medicines Agency shall each have the right to appoint two observers.	The Commission, the Agency, Europol and the European Medicines Agency shall each have the right to appoint two observers.	The Commission, the Agency, Europol and the European Medicines Agency shall each have the right to appoint two observers. Text Origin: Commission Proposal		G

	Article 10(5)					
G	177	5. The Scientific Committee shall carry out the risk assessment on the basis of the available information and of any other relevant scientific evidence. It shall take into account all opinions held by its members. The Agency shall organise the risk assessment procedure, including identifying future information needs and relevant studies.	5. The Scientific Committee shall carry out the risk assessment on the basis of the available information and of any other relevant scientific evidence. It shall take into account all opinions held by its members. The Agency shall organise the risk assessment procedure, including identifying future information needs and relevant studies.	5. The Scientific Committee shall carry out the risk assessment on the basis of the available information and of any other relevant scientific evidence. It shall take into account all opinions held by its members. The Agency shall organise the risk assessment procedure, including identifying future information needs and relevant studies.	5. The Scientific Committee shall carry out the risk assessment on the basis of the available information and of any other relevant scientific evidence. It shall take into account all opinions held by its members. The Agency shall organise the risk assessment procedure, including identifying future information needs and relevant studies. Text Origin: Commission Proposal		G
	Article 10(6)					
G	178	6. The Agency shall submit the risk assessment report or the combined risk assessment report to the Commission and the Member States within six weeks of receipt of the request from the Commission to draw up a risk assessment report.	6. The Agency shall submit the risk assessment report or the combined risk assessment report to the Commission and the Member States within six weeks of receipt of the request from the Commission to draw up a risk assessment report.	6. The Agency shall submit the risk assessment report or the combined risk assessment report to the Commission and the Member States within six weeks of receipt of the request from the Commission to draw up a risk assessment report.	6. The Agency shall submit the risk assessment report or the combined risk assessment report to the Commission and the Member States within six weeks of receipt of the request from the Commission to draw up a risk assessment report. Text Origin: Commission Proposal		G
	Article 10(6), point (a)					
G	178a						G

			(a) Where appropriate, the Agency shall disseminate the risk assessment report or the combined risk assessment report to the relevant stakeholders, including the scientific community, civil society organisations and affected communities, for awareness-raising purposes.			Covered in line 113. Possibly additionally address these elements in the recitals [COM to suggest a wording, as for line 162a]
Article 10(7)						
G	179	7. Upon receipt of a duly reasoned request of the Agency, the Commission may extend the period for completion of the risk assessment or combined risk assessment to allow for additional research and data collection to take place. That request shall contain information on the period of time needed to complete the risk assessment or combined risk assessment.	7. Upon receipt of a duly reasoned request of the Agency, the Commission may extend the period for completion of the risk assessment or combined risk assessment to allow for additional research and data collection to take place. That request shall contain information on the period of time needed to complete the risk assessment or combined risk assessment.	7. Upon receipt of a duly reasoned request of the Agency, the Commission may extend the period for completion of the risk assessment or combined risk assessment to allow for additional research and data collection to take place. That request shall contain information on the period of time needed to complete the risk assessment or combined risk assessment.	7. Upon receipt of a duly reasoned request of the Agency, the Commission may extend the period for completion of the risk assessment or combined risk assessment to allow for additional research and data collection to take place. That request shall contain information on the period of time needed to complete the risk assessment or combined risk assessment. Text Origin: Commission Proposal	G
Article 10(8)						
G	180	8. The Agency shall also provide timely rapid risk assessments, in accordance	8. The Agency shall also provide timely rapid risk assessments, in accordance	8. The Agency shall also provide timely rapid risk assessments, in accordance	8. The Agency shall also provide timely rapid risk assessments, in accordance	G

		with Article 20 of Regulation (EU) …/… on serious cross-border threats to health and repealing Decision No 1082/2013/EU, in the case of a threat referred to in points (b) of Article 2(1) of that Regulation, where the threat falls under the mandate of the Agency.	with Article 20 of Regulation (EU) …/… on serious cross-border threats to health and repealing Decision No 1082/2013/EU, in the case of a threat referred to in points (b) of Article 2(1) of that Regulation, where the threat falls under the mandate of the Agency.	with Article 20 of Regulation (EU) …/… on serious cross-border threats to health and repealing Decision No 1082/2013/EU, in the case of a threat referred to in ~~points~~**point** (b) of Article 2(1) of that Regulation, where the threat falls under the mandate of the Agency.	with Article 20 of Regulation (EU) …/… on serious cross-border threats to health and repealing Decision No 1082/2013/EU, in the case of a threat referred to in ~~*points*~~***point*** (b) of Article 2(1) of that Regulation, where the threat falls under the mandate of the Agency. Text Origin: Council Mandate		
Article 11							
G	181	Article 11 Exclusion from risk assessment	Article 11 Exclusion from risk assessment	Article 11 Exclusion from risk assessment	Article 11 Exclusion from risk assessment Text Origin: Commission Proposal		G
Article 11(1)							
G	182	1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation Expert Committee on Drug Dependence has published its critical review together with a written	1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation Expert Committee on Drug Dependence has published its critical review together with a written	1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation Expert Committee on Drug Dependence has published its critical review together with a written	1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation Expert Committee on Drug Dependence has published its critical review together with a written		G

		recommendation, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.	recommendation, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.	recommendation, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.	recommendation, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report. Text Origin: Commission Proposal	
Article 11(2)						
G	183	2. No risk assessment shall be carried out where, following an assessment within the United Nations system, it has been decided not to schedule the new psychoactive substance, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.	2. No risk assessment shall be carried out where, following an assessment within the United Nations system, it has been decided not to schedule the new psychoactive substance, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.	2. No risk assessment shall be carried out where, following an assessment within the United Nations system, it has been decided not to schedule the new psychoactive substance, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.	2. No risk assessment shall be carried out where, following an assessment within the United Nations system, it has been decided not to schedule the new psychoactive substance, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report. Text Origin: Commission Proposal	G
Article 11(3), introductory part						
G	184	3. No risk assessment shall be carried out where the new psychoactive substance is an	3. No risk assessment shall be carried out where the new psychoactive substance is an	3. No risk assessment shall be carried out where the new psychoactive substance is an	3. No risk assessment shall be carried out where the new psychoactive substance is an	G

		active substance in:	active substance in:	active substance in:	active substance in: Text Origin: Commission Proposal	
	Article 11(3), point (a)					
G	185	(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC, Directive 2001/82/EC or Regulation (EC) No 726/2004;	(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC, Directive 2001/82/EC or Regulation (EC) No 726/2004;	(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC, Directive 2001/82/EC or Regulation (EC) No 726/2004;	(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC, Directive 2001/82/EC or Regulation (EC) No 726/2004; Text Origin: Commission Proposal	G
	Article 11(3), point (b)					
G	186	(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;	(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;	(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;	(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation; Text Origin: Commission Proposal	G
	Article 11(3), point (c)					
G	187	(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the	(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the	(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the	(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the	G

		competent authority;	competent authority;	competent authority;	competent authority; Text Origin: Commission Proposal	
	Article 11(3), point (d)					
G	188	(d) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC.	(d) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC.	(d) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC.	(d) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC. Text Origin: Commission Proposal	G
	Article 12					
G	189	Article 12 Threat assessment and preparedness	Article 12 ***Health and security*** threat assessment and preparedness	Article 12 **Health and security** threat assessment and preparedness	Article 12 ***Health and security*** threat assessment and preparedness Text Origin: EP Mandate	G
	Article 12(1)					
G	190	1. The Agency shall develop a strategic general threat assessment capability to identify at an early stage new developments of the drugs phenomenon that have a potential to impact negatively on public health, safety and security and, through doing so, to help increase the preparedness of the relevant stakeholders to	1. The Agency shall develop a strategic ~~general~~***evidence-based health and security*** threat assessment capability to identify at an early stage new developments of the drugs phenomenon that have a potential to impact negatively on public health, ***social matters,*** safety and security ***in the Union*** and,	1. The Agency shall develop a strategic **evidence-based** general **health and security** threat assessment capability to identify at an early stage new developments of the drugs ~~phenomenon~~**situation** that have a potential to impact negatively on ~~public health~~**health, social aspects**, safety ~~and~~**or** security **in the**	1. The Agency shall develop a strategic ~~general~~***evidence-based health and security*** threat assessment capability to identify at an early stage new developments of the drugs phenomenon that have a potential to impact negatively on ~~*public health*~~***health, social matters***, safety ~~*and*~~***or*** security ***in the***	Social matters / aspects to be aligned with other provisions, in line with advice from lawyer-linguists	G

		respond to new threats in a timely and effective manner.	through doing so, to help increase the preparedness of the relevant stakeholders to respond to new threats in a timely and effective manner.	**Union** and, through doing so, to help increase the preparedness of the relevant stakeholders to respond to new threats in ~~a timely and effective~~**an efficient and timely** manner.	***Union*** and, through doing so, to help increase the preparedness of the relevant stakeholders to respond to new threats in ~~*a timely and effective*~~***an effective and timely*** manner. Text Origin: Council Mandate	
Article 12(2), first subparagraph						
G	191	2. The Agency shall set out a set of criteria to evaluate when to trigger a threat assessment.	2. The Agency shall set out a set of ***objective*** criteria to evaluate when to trigger a ***health and security*** threat assessment.	*deleted*	*deleted*	G
Article 12(2), second subparagraph						
G	*192*	A threat assessment may be launched by the Agency on its own initiative based on an internal appraisal of signals arising from routine monitoring, research or other appropriate information sources. A threat assessment may also be launched at the request of the Commission or of a Member State, if the defined criteria are met.	A ***health and security*** threat assessment may be launched by the Agency on its own initiative based on an internal appraisal of signals arising from routine monitoring, research or other appropriate information sources. A ***health and security*** threat assessment may also be launched at the request of the Commission or of a Member State, if the defined criteria are met.	A threat assessment may be launched by the Agency on its own initiative based on an internal appraisal of signals arising from routine monitoring, research or other appropriate information sources. A threat assessment may also be launched at the request of the Commission or of a Member State, if the ~~defined criteria~~**criteria set out in paragraph 1** are met.	A ***health and security*** threat assessment may be launched by the Agency on its own initiative based on an internal appraisal of signals arising from routine monitoring, research or other appropriate information sources. A ***health and security*** threat assessment may also be launched at the request of the Commission or of a Member State, if the ~~*defined criteria*~~***criteria set out in paragraph 1*** are met. Text Origin: EP Mandate	G

	Article 12(3)					
G	193	3. A threat assessment shall consist of a rapid evaluation of existing information and, where necessary, the collection of new information through the Agency's information networks. The Agency shall develop appropriate scientific rapid assessment methods.	3. A ***health and security*** threat assessment shall consist of a rapid evaluation of existing information and, where necessary, the collection of new information through the Agency's information networks. The Agency shall develop appropriate scientific rapid assessment methods.	3. A threat assessment shall consist of a rapid evaluation of existing information and, where necessary, the collection of new information through the Agency's information networks. The Agency shall develop appropriate scientific rapid assessment methods.	3. A ***health and security*** threat assessment shall consist of a rapid evaluation of existing information and, where necessary, the collection of new information through the Agency's information networks. The Agency shall develop appropriate scientific rapid assessment methods. Text Origin: EP Mandate	G
	Article 12(4)					
Y	194	4. The threat assessment report shall describe the identified threat, the current situation based on available evidence, the potential outcomes in the event of no action, and set out options for preparedness and response that may be adopted to mitigate the threat identified. It may also contain potential follow-up measures to be adopted. The threat assessment report shall be sent to the Commission and the Member States, as	4. The ***health and security*** threat assessment report shall describe the identified threat, the current situation based on available evidence, the potential outcomes in the event of no action, and set out options for preparedness and response that may be adopted to mitigate ***and to respond to*** the threat identified***, including evidence-based interventions on demand reduction, risk and harm reduction and recovery***. It may also contain potential	4. The threat assessment report shall describe the identified threat, the current situation based on available evidence, the potential outcomes in the event of no action, and set out options for preparedness and response that may be adopted to mitigate the threat identified. It may also contain potential follow-up measures ~~to be adopted~~. The threat assessment report shall be sent to the Commission and the Member States, as	4. The ***health and security*** threat assessment report shall describe the identified threat, the current situation based on available evidence, the potential outcomes in the event of no action, and set out options for preparedness and response that may be adopted to mitigate ***and to respond to*** the threat identified***, including, where possible, evidence-based interventions on demand reduction, risk and harm reduction and recovery***. It may also contain potential	Y

		appropriate.	follow-up measures to be adopted. The ***health and security*** threat assessment report shall be sent to the Commission and ***to*** the Member States***. Where appropriate, the Agency shall disseminate health and security threat assessment reports to relevant stakeholders, including the scientific community, healthcare professionals, civil society organisations and affected communities*** ~~*, as appropriate*~~***. The Agency shall make summaries of those reports publicly available on its website.***	appropriate.	follow-up measures***. The health and security*** ~~*to be adopted. The*~~ threat assessment report shall be sent to the Commission and ***to*** the Member States***. [The Agency shall make summaries of those reports publicly available on its website, where*** ~~*, as*~~ appropriate***, except where prevented to do so by the use of sensitive non-classified and classified data.]*** Text Origin: EP Mandate	
Article 12(5)						
G	195	5. The Agency shall cooperate closely with other Union decentralised agencies and bodies, Union and international organisations in carrying out a threat assessment by involving them in the assessment as appropriate. Where the potential threat is already subject to an analysis under another Union mechanism, the Agency shall not carry out a threat assessment.	5. The Agency shall cooperate closely with ***Member States,*** other Union ~~*decentralised agencies and bodies, Union*~~***bodies, offices and agencies*** and international organisations in carrying out a ***health and security*** threat assessment by involving them in the assessment as appropriate. Where the potential threat is already subject to an analysis under another Union mechanism, the	5. The Agency shall cooperate closely with **Member States,** other Union decentralised agencies and bodies, Union and international organisations in carrying out a threat assessment by involving them in the assessment as appropriate. Where the potential threat is already subject to an analysis under another Union mechanism, the Agency shall not carry out a threat assessment.	5. The Agency shall cooperate closely with ***Member States,*** other Union ~~*decentralised agencies and bodies, Union*~~***bodies, offices and agencies*** and international organisations in carrying out a ***health and security*** threat assessment by involving them in the assessment as appropriate. Where the potential threat is already subject to an analysis under another Union mechanism, the	G

			Agency shall not carry out a ***health and security*** threat assessment.		Agency shall not carry out a ***health and security*** threat assessment. Text Origin: EP Mandate	
Article 12(6)						
196	6. With the agreement of the Commission, the Agency shall conduct threat assessments on drug related threats emerging from outside the Union, which have the potential to impact public health, safety and security within the Union.	6. With the agreement of the Commission, the Agency shall conduct ***health and security*** threat assessments on drug related threats emerging from outside the Union, which have the potential to impact public health***, social matters***, safety and security within the Union.	6. With the agreement of the Commission, the Agency shall conduct threat assessments on drug related threats emerging from outside the Union, which have the potential to impact ~~public health~~**health, social aspects**, safety ~~and~~**or** security within the Union.	6. With the agreement of the Commission, the Agency shall conduct ***health and security*** threat assessments on drug related threats emerging from outside the Union, which have the potential to impact ~~*public health*~~***health, social matters***, safety ~~*and*~~***or*** security within the Union. Text Origin: EP Mandate	Social matters / socials aspects tbc
Article 12(6), point (a)						
196a		***(a) The Agency shall monitor the evolution of new developments of the drugs phenomenon as referred to in paragraph 1 and update the threat assessments accordingly.***			Covered in line 196b
Article 12(6a)						
196b			**6a. The Agency shall, when needed, update the threat assessments and to**	***6a. The Agency shall monitor the evolution of the situation and, when***		

				monitor the evolution of the situation.	***necessary, update the threat assessments accordingly.*** Text Origin: Council Mandate		
	Article 13						
G	197	Article 13 European drug alert system	Article 13 European drug alert system	Article 13 European drug alert system	Article 13 European drug alert system Text Origin: Commission Proposal		G
	Article 13(1)						
G	198	1. The Agency shall set up and manage a rapid European drug alert system.	1. The Agency shall set up and manage a rapid European drug alert system.	1. The Agency shall set up and manage a rapid European drug alert system**, complementing and without prejudice to the relevant national alert systems. The system is complementary to the Early Warning System on the new psychoactive substances, referred to in Articles 8-11**.	1. The Agency shall set up and manage a rapid European drug alert system***, complementing and without prejudice to the relevant national alert systems. The system is complementary to the Early Warning System on the new psychoactive substances, referred to in Articles 8-11***. Text Origin: Council Mandate		G
	Article 13(2), introductory part						
Y	199	2. Member States shall immediately notify the Agency of any information relating to the appearance of a serious direct or indirect	2. Member States shall immediately notify the Agency of any information relating to the appearance of a serious direct or indirect	2. ~~Member States~~**The national focal points, in cooperation with the relevant national competent authorities,** shall	2. ~~*Member States*~~***The national focal points[, in cooperation with the relevant national competent authorities,]*** shall		Y

		drug-related risk to human health, safety or security as well as any information that may be useful for coordinating a response whenever they become aware of such information, such as:	drug-related risk to human health, ***social aspects,*** safety or security as well as any information that may be useful for coordinating a response whenever they become aware of such information, such as:	immediately notify the Agency of any information relating to the appearance of a serious direct or indirect drug-related risk to ~~human~~ health**, social aspects**, safety or security as well as any information that may be useful for coordinating a response whenever they become aware of such information, such as:	immediately notify the Agency of any information relating to the appearance of a serious direct or indirect drug-related risk to ~~*human*~~ health***, social aspects***, safety or security as well as any information that may be useful for coordinating a response whenever they become aware of such information, such as: Text Origin: Council Mandate		
	Article 13(2), point (a)						
G	200	(a) the type and origin of the risk;	(a) the type and origin of the risk;	(a) the type and origin of the risk;	(a) the type and origin of the risk; Text Origin: Commission Proposal		G
	Article 13(2), point (b)						
G	201	(b) the date and place of the event involving the risk;	(b) the date and place of the event involving the risk;	(b) the date and place of the event involving the risk;	(b) the date and place of the event involving the risk; Text Origin: Commission Proposal		G
	Article 13(2), point (c)						
G	202	(c) the means of exposure, transmission or dissemination;	(c) the means of exposure, transmission or dissemination;	(c) the means of exposure, transmission or dissemination;	(c) the means of exposure, transmission or dissemination;		G

					Text Origin: Commission Proposal	
Article 13(2), point (d)						
G	203	(d) analytical and toxicological data;	(d) analytical and toxicological data;	(d) analytical and toxicological data;	(d) analytical and toxicological data; Text Origin: Commission Proposal	G
Article 13(2), point (e)						
G	204	(e) identification methods;	(e) identification methods;	(e) identification methods;	(e) identification methods; Text Origin: Commission Proposal	G
Article 13(2), point (f)						
G	205	(f) public health risks;	(f) public health risks;	(f) ~~public~~ health risks;	(f) ~~*public*~~ health risks; Text Origin: Council Mandate	*[Last line discussed on 1/2/2023]* G

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Financial provisions

	Article 36					
G	427	Article 36 Budget	Article 36 Budget	Article 36 Budget	Article 36 Budget Text Origin: Commission Proposal	G
	Article 36(1)					
G	428	1. Estimates of all revenue and expenditure for the Agency shall be prepared each financial year, corresponding to the calendar year, and shall be shown in the Agency's budget.	1. Estimates of all revenue and expenditure for the Agency shall be prepared each financial year, corresponding to the calendar year, and shall be shown in the Agency's budget.	1. Estimates of all revenue and expenditure for the Agency shall be prepared each financial year, corresponding to the calendar year, and shall be shown in the Agency's budget.	1. Estimates of all revenue and expenditure for the Agency shall be prepared each financial year, corresponding to the calendar year, and shall be shown in the Agency's budget. Text Origin: Commission Proposal	G
	Article 36(2)					
Y	429	2. The Agency's budget shall be balanced in terms of revenue and of expenditure.	2. The Agency's budget shall be balanced in terms of revenue and of expenditure. ***The Agency shall be awarded an adequate budget to ensure sufficient staff and equipment in order to allow it to achieve the objectives and tasks set out in this Regulation.***	2. The Agency's budget shall be balanced in terms of revenue and of expenditure.	2. The Agency's budget shall be balanced in terms of revenue and of expenditure. Text Origin: Commission Proposal	Possible link to COM declaration in relation to recital 29 and other budget-related elements	Y

	Article 36(3), introductory part					
G	430	3. Without prejudice to other resources, the Agency's revenue shall comprise:	3. Without prejudice to other resources, the Agency's revenue shall comprise:	3. Without prejudice to other resources, the Agency's revenue shall comprise: Text Origin: Commission Proposal		G
	Article 36(3), point (a)					
G	431	(a) a contribution from the Union entered in the general budget of the European Union;	(a) a contribution from the Union entered in the general budget of the European Union;	(a) a contribution from the Union entered in the general budget of the European Union; Text Origin: Commission Proposal		G
	Article 36(3), point (b)					
G	432	(b) any voluntary financial contribution from the Member States;	(b) any voluntary financial contribution from the Member States;	(b) any voluntary financial contribution from the Member States; Text Origin: Commission Proposal		G
	Article 36(3), point (c)					
G	433	(c) the fees paid for services rendered in accordance with Article 37; and	(c) the fees paid for services rendered in accordance with Article 37; ~~*and*~~	(c) the fees paid for services rendered in accordance with Article 37; ~~*and*~~ Text Origin: EP Mandate		G
	Article 36(3), point (d)					

G	434	(d) any financial contributions from the organisations and bodies and third countries referred to in Articles 53 and 54, respectively.	(d) any financial contributions from the organisations and bodies and third countries referred to in Articles 53 and 54, respectively~~.~~ ***; and***	(d) any financial contributions from the organisations and bodies and third countries referred to in Articles 53 and 54, respectively~~.~~ ***; and*** Text Origin: EP Mandate			G
	Article 36(3), point (da)						
Y	434a		***(da) Union funding under indirect management or in the form of ad hoc grants in accordance with the financial rules applicable to the Agency and with the provisions of the relevant instruments supporting the policies of the Union.***		***(da) Union funding under indirect management or in the form of ad hoc grants in accordance with the financial rules applicable to the Agency and with the provisions of the relevant instruments supporting the policies of the Union.*** Text Origin: EP Mandate	To align this wording with texts of other Regulations.	Y
	Article 36(3a)						
Y	434b		***3a. The amount and origin of any revenue as referred to in points (b), (c) (d) and (da) of the first subparagraph of this paragraph shall be included in the annual accounts of the Agency and clearly detailed in the annual report on the Agency's budgetary and financial management referred to in***		***3a. The amount and origin of any revenue as referred to in points (b), (c) (d) and (da) of the first subparagraph of this paragraph shall be included in the annual accounts of the Agency and clearly detailed in the annual report on the Agency's budgetary and financial management referred to in***		Y

			Article 40(2). Article 36 - paragraph 3 - subparagraph 1 a (new)		***Article 40(2).*** Text Origin: EP Mandate		
Article 36(4)							
G	435	4. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure expenses, and operating costs. The operating costs may include expenditure in support of the national focal points, as referred to in Article 32(7).	4. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure expenses, and operating costs. The operating costs may include expenditure in support of the national focal points, as referred to in Article 32(7).	4. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure expenses, and operating costs. The operating costs may include expenditure in support of the national focal points, as referred to in Article 32(7).	4. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure expenses, and operating costs. The operating costs may include expenditure in support of the national focal points, as referred to in Article 32(7). Text Origin: Commission Proposal		G
Article 37							
G	436	Article 37 Fees	Article 37 Fees	Article 37 Fees	Article 37 Fees Text Origin: Commission Proposal		G
Article 37(1), introductory part							
Y	437	1. The Agency may charge fees for the following:	1. The Agency may charge fees for the following ***services where they are clearly separated from the tasks of the Agency laid down in this Regulation***:	1. The Agency may charge fees for the following:		Informal COM suggestion (see together with recital 30): 1. The Agency may ***decide to deliver and*** charge fees for the following ***additional***	Y

						services other than those laid down in this Regulation: *** Alternative suggestions by the Presidency, following the consultation with the Legal Service: 1. The Agency may ***decide to deliver and*** charge fees for the following ***additional services delivered upon request, other than those laid down in this Regulation:***
Article 37(1), point (a)						
Y	438	(a) training programmes;	(a) training programmes ***other than those referred to in Article 19***;	(a) training ~~programmes~~**pursuant to Article 19**;		Informal COM suggestion: (a) ***customised*** training;
Article 37(1), point (b)						
Y	439	(b) certain support activities for Member States that have not been identified as a priority but could be beneficially conducted if supported by national resources;	(b) ~~certain~~***necessary and duly justified*** support activities for Member States ***other than those provided for in this Regulation*** that have not been identified as a priority but could be beneficially conducted if supported by national resources;	(b) certain support activities for Member States that have not been identified as a priority but could be beneficially conducted if supported by national resources;		Informal COM suggestion: (b) certain support activities for Member States that have not been identified as a priority but could be beneficially conducted if supported by national resources;

Article 37(1), point (c)						
	440	(c) capacity-building programmes for third countries, which are not covered by separate dedicated Union funding;	(c) capacity-building programmes for third countries, which are not covered by separate dedicated Union funding;	(c) capacity-building programmes for third countries, which are not covered by separate dedicated Union funding;	(c) capacity-building programmes ***and training*** for third countries, which are not covered by separate dedicated Union funding; Text Origin: Commission Proposal	Informal COM suggestion: (c) capacity-building programmes for third countries which are not covered by separate dedicated Union funding;
Article 37(1), point (d)						
	441	(d) certification of national bodies set up in third countries pursuant to Article 20(3);	(d) certification of national bodies set up in third countries***, in particular candidate countries,*** pursuant to Article 20(3);	(d) ~~certification~~**assessment** of national bodies set up in third countries pursuant to Article 20(3);	(d) ***[***certification ***/ assessment]*** of national bodies set up in third countries***, in particular candidate countries,*** pursuant to Article 20(3); Linked to other provisions Text Origin: EP Mandate	Term "certification / assessment" depends on other articles. Informal COM suggestion: (d) certification of national bodies set up in third countries, ***in particular candidate countries,*** pursuant to Article 20(3);
Article 37(1), point (e)						
	442	(e) other services falling within its mandate and rendered at the request of a participating country which require the investment of resources in the support of national activities.	(e) other ***customised*** services falling within its mandate and rendered at the request of a participating country which require the investment of ***additional*** resources in the support of national activities.	(e) other services falling within its mandate and rendered at the request of a participating country which require the investment of resources in the support of national activities.	(e) other ***customised*** services ***and training*** falling within its mandate and rendered at the request of a participating country which require the investment of ***additional*** resources in the support of national activities.	Informal COM suggestion: (e) other ***customised*** services ~~falling within its mandate~~ rendered at the request of a participating country which require the investment of ***additional*** resources in the

					Text Origin: EP Mandate	support of national activities.	
Article 37(2)							
Y	443	2. At the proposal of the Executive Director, the Management Board of the Agency shall set the amount of the fees and the way in which they are paid.	2. At the proposal of the Executive Director, the Management Board of the Agency shall set the amount of the fees and the way in which they are paid ***in a transparent manner and after having consulted the Commission. Those fees shall cover only the human and financial costs associated with the provision of the services set out in paragraph 1***.	2. At the proposal of the Executive Director, the Management Board of the Agency shall set the amount of the fees and the way in which they are paid **in a transparent manner**.	2. At the proposal of the Executive Director, the Management Board of the Agency shall set the amount of the fees and the way in which they are paid ***in a transparent manner and after having consulted the Commission. Those fees shall cover only the costs associated with the provision of the services set out in paragraph 1***. Text Origin: EP Mandate	Informal COM suggestion: 2. At the proposal of the Executive Director ***and after having consulted the Commission***, the Management Board of the Agency shall set the ~~amount of~~ ***method for calculating the*** fees and the way in which they are paid ***in a transparent manner.***	Y
Article 37(3)							
G	444	3. Fees shall be proportionate to the costs of the relevant services as provided in a cost-effective way and shall be sufficient to cover those costs. Fees shall be set at such a level as to ensure that they are non-discriminatory and that they avoid placing an undue financial or administrative burden on stakeholders.	3. Fees shall be proportionate to the costs of the relevant services as provided in a cost-effective way and shall be sufficient to cover those costs. Fees shall be set at such a level as to ensure that they are non-discriminatory and that they avoid placing an undue financial or administrative burden on stakeholders.	3. Fees shall be proportionate to the costs of the relevant services as provided in a cost-effective way and shall be sufficient to cover those costs. Fees shall be set at such a level as to ensure that they are non-discriminatory and that they avoid placing an undue financial or administrative burden on stakeholders.	3. Fees shall be proportionate to the costs of the relevant services as provided in a cost-effective way and shall be sufficient to cover those costs. Fees shall be set at such a level as to ensure that they are non-discriminatory and that they avoid placing an undue financial or administrative burden on stakeholders. Text Origin: Commission Proposal	Informal COM suggestion: 3. Fees shall be proportionate to the costs of the relevant services as provided in a cost-effective way and shall be sufficient to cover those costs. Fees shall be set at such a level as to ensure that they are non-discriminatory and that they avoid placing an undue financial or administrative burden on stakeholders.	G

Article 37(4)						
	445	4. Fees should be set at a level such as to avoid a deficit or a significant accumulation of surplus in the budget. Should a significant positive balance in the budget, resulting from the provision of the services covered by fees, become recurrent, a revision of the level of the fees, or of the Union contribution, shall become mandatory. In case a significant negative balance results from the provision of the services covered by fees, a revision of the level of the fees shall become mandatory.	4. Fees should be set at a level such as to avoid a deficit or a significant accumulation of surplus in the budget. Should a significant positive balance in the budget, resulting from the provision of the services covered by fees, become recurrent, a revision of the level of the fees, or of the Union contribution, shall become mandatory. In case a significant negative balance results from the provision of the services covered by fees, ~~*a revision of*~~ the level of the fees shall ~~*become mandatory*~~***be revised***.	4. Fees should be set at a level such as to avoid a deficit or a significant accumulation of surplus in the budget. Should a significant positive balance in the budget, resulting from the provision of the services covered by fees, become recurrent, a revision of the level of the fees, or of the Union contribution, shall become mandatory. In case a significant negative balance results from the provision of the services covered by fees, a revision of the level of the fees ~~shall become mandatory~~**may be applied**.	4. Fees should be set at a level such as to avoid a deficit or a significant accumulation of surplus in the budget. Should a significant positive balance in the budget, resulting from the provision of the services covered by fees, become recurrent, a revision of the level of the fees, or of the Union contribution, shall become mandatory. In case a significant negative balance results from the provision of the services covered by fees, ~~*a revision of*~~ the level of the fees shall ~~*become mandatory*~~***be revised***. Text Origin: EP Mandate	Informal COM suggestion: 4. Fees should be set at a level such as to avoid a deficit or a significant accumulation of surplus in the budget. Should a significant positive balance in the budget, resulting from the provision of the services covered by fees, become recurrent, a revision of the level of the fees, or of the Union contribution, shall become mandatory. In case a significant negative balance results from the provision of the services covered by fees, ~~a revision of~~ the ***method for calculating the fees shall be revised*** ~~level of the fees shall become mandatory.~~
Article 37(4), point (a)						
	445a		***(a) An annual external audit shall be undertaken with regard to the fees collected by the Agency. The Agency shall transmit the results of such audits to the European Parliament without delay.***			Informal COM suggestion: ***5. Where applicable, the Agency shall include a report on the fees levied and their impact on the Agency's budget as part of the procedure for the presentation of accounts laid down Article 41 of this Regulation.***

Article 38						
G	446	Article 38 Establishment of the budget	Article 38 Establishment of the budget	Article 38 Establishment of the budget	Article 38 Establishment of the budget Text Origin: Commission Proposal	G
Article 38(1)						
G	447	1. Each year, the Executive Director shall draw up a draft statement of estimates of the Agency's revenue and expenditure for the following financial year, including the establishment plan, and send it to the Management Board.	1. Each year, the Executive Director shall draw up a draft statement of estimates of the Agency's revenue and expenditure for the following financial year, including the establishment plan, and send it to the Management Board.	1. Each year, the Executive Director shall draw up a draft statement of estimates of the Agency's revenue and expenditure for the following financial year, including the establishment plan, and send it to the Management Board.	1. Each year, the Executive Director shall draw up a draft statement of estimates of the Agency's revenue and expenditure for the following financial year, including the establishment plan, and send it to the Management Board. Text Origin: Commission Proposal	G
Article 38(2)						
G	448	2. The Management Board shall, based on that draft, adopt a provisional draft estimate of the Agency's revenue and expenditure for the following financial year.	2. The Management Board shall, based on that draft, adopt a provisional draft estimate of the Agency's revenue and expenditure for the following financial year.	2. The Management Board shall, based on that draft, adopt a provisional draft estimate of the Agency's revenue and expenditure for the following financial year.	2. The Management Board shall, based on that draft, adopt a provisional draft estimate of the Agency's revenue and expenditure for the following financial year. Text Origin: Commission Proposal	G
Article 38(3)						
G	449					G

	3. The provisional draft estimate of the Agency's revenue and expenditure shall be sent to the Commission by 31 January each year. The Management Board shall send the final draft estimate to the Commission by 31 March.	3. The provisional draft estimate of the Agency's revenue and expenditure shall be sent to the Commission by 31 January each year. The Management Board shall send the final draft estimate to the Commission by 31 March.	3. The provisional draft estimate of the Agency's revenue and expenditure shall be sent to the Commission by 31 January each year. The Management Board shall send the final draft estimate to the Commission by 31 March.	3. The provisional draft estimate of the Agency's revenue and expenditure shall be sent to the Commission by 31 January each year. The Management Board shall send the final draft estimate to the Commission by 31 March. Text Origin: Commission Proposal	
Article 38(4)					
G 450	4. The Commission shall send the statement of estimates to the budgetary authority together with the draft general budget of the European Union.	4. The Commission shall send the statement of estimates to the budgetary authority together with the draft general budget of the European Union.	4. The Commission shall send the statement of estimates to the budgetary authority together with the draft general budget of the European Union.	4. The Commission shall send the statement of estimates to the budgetary authority together with the draft general budget of the European Union. Text Origin: Commission Proposal	G
Article 38(5)					
G 451	5. On the basis of the statement of estimates, the Commission shall enter in the draft general budget of the Union the estimates it considers necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary	5. On the basis of the statement of estimates, the Commission shall enter in the draft general budget of the Union the estimates it considers necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary	5. On the basis of the statement of estimates, the Commission shall enter in the draft general budget of the Union the estimates it considers necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary	5. On the basis of the statement of estimates, the Commission shall enter in the draft general budget of the Union the estimates it considers necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary	G

		authority in accordance with Articles 313 and 314 TFEU.	authority in accordance with Articles 313 and 314 TFEU.	authority in accordance with Articles 313 and 314 TFEU.	authority in accordance with Articles 313 and 314 TFEU. Text Origin: Commission Proposal		
Article 38(6)							
G	452	6. The budgetary authority shall authorise the appropriations for the contribution to the Agency.	6. The budgetary authority shall authorise the appropriations for the contribution to the Agency.	6. The budgetary authority shall authorise the appropriations for the contribution to the Agency.	6. The budgetary authority shall authorise the appropriations for the contribution to the Agency. Text Origin: Commission Proposal		G
Article 38(7)							
G	453	7. The budgetary authority shall adopt the Agency's establishment plan.	7. The budgetary authority shall adopt the Agency's establishment plan.	7. The budgetary authority shall adopt the Agency's establishment plan.	7. The budgetary authority shall adopt the Agency's establishment plan. Text Origin: Commission Proposal		G
Article 38(8)							
G	454	8. The Agency's budget shall be adopted by the Management Board by a majority of two-thirds of members entitled to vote. It shall become final following final adoption of the general budget of the European Union. Where necessary, it shall be adjusted accordingly.	8. The Agency's budget shall be adopted by the Management Board by a majority of two-thirds of members entitled to vote. It shall become final following final adoption of the general budget of the European Union. Where necessary, it shall be adjusted accordingly.	8. The Agency's budget shall be adopted by the Management Board by a majority of two-thirds of members entitled to vote. It shall become final following final adoption of the general budget of the European Union. Where necessary, it shall be adjusted accordingly.	8. The Agency's budget shall be adopted by the Management Board by a majority of two-thirds of members entitled to vote. It shall become final following final adoption of the general budget of the European Union. Where necessary, it shall be adjusted accordingly.		G

					Text Origin: Commission Proposal	
Article 38(9)						
G	455	9. For any building project likely to have significant implications for the budget of the Agency, the provisions of Delegated Regulation (EU) 2019/715[1] apply. 1. OJ L 122, 10.5.2019, p. 1.	9. For any building project likely to have significant implications for the budget of the Agency, the provisions of ***Commission*** Delegated Regulation (EU) 2019/715[1] apply. 1. OJ L 122, 10.5.2019, p. 1.	9. For any building project likely to have significant implications for the budget of the Agency, the provisions of Delegated Regulation (EU) 2019/715[1] apply. 1. OJ L 122, 10.5.2019, p. 1.	9. For any building project likely to have significant implications for the budget of the Agency, the provisions of ***Commission*** Delegated Regulation (EU) 2019/715[1] apply. 1. OJ L 122, 10.5.2019, p. 1. Text Origin: EP Mandate	G
Article 39						
G	456	Article 39 Implementation of the budget	Article 39 Implementation of the budget	Article 39 Implementation of the budget	Article 39 Implementation of the budget Text Origin: Commission Proposal	G
Article 39(1)						
G	457	1. The Executive Director shall implement the Agency's budget.	1. The Executive Director shall implement the Agency's budget.	1. The Executive Director shall implement the Agency's budget.	1. The Executive Director shall implement the Agency's budget. Text Origin: Commission Proposal	G
Article 39(2)						

G	458	2. Each year the Executive Director shall send to the budgetary authority all information relevant for the evaluation procedures set out in Article 51.	2. Each year the Executive Director shall send to the budgetary authority all information relevant for the evaluation procedures set out in Article 51.	2. Each year the Executive Director shall send to the budgetary authority all information relevant for the evaluation procedures set out in Article 51.	2. Each year the Executive Director shall send to the budgetary authority all information relevant for the evaluation procedures set out in Article 51. Text Origin: Commission Proposal		G
	Article 40						
G	459	Article 40 Presentation of accounts and discharge	Article 40 Presentation of accounts and discharge	Article 40 Presentation of accounts and discharge	Article 40 Presentation of accounts and discharge Text Origin: Commission Proposal		G
	Article 40(1)						
G	460	1. By 1 March of the following financial year, the Agency's accounting officer shall send the provisional accounts to the Commission's accounting officer and to the Court of Auditors.	1. By 1 March of the following financial year, the Agency's accounting officer shall send the provisional accounts to the Commission's accounting officer and to the Court of Auditors.	1. By 1 March of the following financial year, the Agency's accounting officer shall send the provisional accounts to the Commission's accounting officer and to the Court of Auditors.	1. By 1 March of the following financial year, the Agency's accounting officer shall send the provisional accounts to the Commission's accounting officer and to the Court of Auditors. Text Origin: Commission Proposal		G
	Article 40(1a)						
G	460a			**1a. By 31 March of the following financial year,**	***1a. By 31 March of the following financial year, the***		G

				the Commission's accounting officer shall send the Agency's provisional accounts, consolidated with the Commission's accounts, to the Court of Auditors.	***Commission's accounting officer shall send the Agency's provisional accounts, consolidated with the Commission's accounts, to the Court of Auditors.*** Text Origin: Council Mandate	
Article 40(2)						
G	461	2. By 31 March of the following financial year, the Agency shall send the report on the budgetary and financial management to the European Parliament, the Council and the Court of Auditors.	2. By 31 March of the following financial year, the Agency shall send the report on the budgetary and financial management to the European Parliament, the Council and the Court of Auditors.	2. By 31 March of the following financial year, the Agency shall send the report on the budgetary and financial management to the European Parliament, the Council and the Court of Auditors.	2. By 31 March of the following financial year, the Agency shall send the report on the budgetary and financial management to the European Parliament, the Council and the Court of Auditors. Text Origin: Commission Proposal	G
Article 40(3)						
G	462	3. By 31 March of the following financial year, the Commission's accounting officer shall send the Agency's provisional accounts, consolidated with the Commission's accounts, to the Court of Auditors.	3. By 31 March of the following financial year, the Commission's accounting officer shall send the Agency's provisional accounts, consolidated with the Commission's accounts, to the Court of Auditors.	*deleted*	*deleted*	G
Article 40(4)						
G	*463*					G

	4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts pursuant to Article 246 of the Financial Regulation[1], the Executive Director shall draw up the Agency's final accounts under her/his own responsibility and submit them to the Management Board for an opinion. __________ 1. Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).	4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts pursuant to Article 246 of the Financial Regulation[1], the Executive Director shall draw up the Agency's final accounts under her/his own responsibility and submit them to the Management Board for an opinion. __________ 1. Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).	4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts pursuant to Article 246 of the Financial Regulation[1], the Executive Director shall draw up the Agency's final accounts under her/his own responsibility and submit them to the Management Board for an opinion. __________ 1. Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).	4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts pursuant to Article 246 of the Financial Regulation[1], the Executive Director shall draw up the Agency's final accounts under her/his own responsibility and submit them to the Management Board for an opinion. __________ 1. Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1). Text Origin: Commission Proposal	
Article 40(5)					
G 464	5. The Management Board shall deliver an opinion on the Agency's final accounts.	5. The Management Board shall deliver an opinion on the Agency's final accounts.	5. The Management Board shall deliver an opinion on the Agency's final accounts.	5. The Management Board shall deliver an opinion on the Agency's final accounts. Text Origin: Commission Proposal	G

	Article 40(6)					
G	465	6. The accounting officer shall, by 1 July following each financial year, send the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.	6. The accounting officer shall, by 1 July following each financial year, send the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.	6. The accounting officer shall, by 1 July following each financial year, send the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.	6. The accounting officer shall, by 1 July following each financial year, send the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion. Text Origin: Commission Proposal		G
	Article 40(7)					
G	466	7. The final accounts shall be published in the Official Journal of the European Union by 15 November of the following year.	7. The final accounts shall be published in the Official Journal of the European Union by 15 November of the following year.	7. The final accounts shall be published in the Official Journal of the European Union by 15 November of the following year.	7. The final accounts shall be published in the Official Journal of the European Union by 15 November of the following year. Text Origin: Commission Proposal		G
	Article 40(8)					
G	467	8. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September. The Executive Director shall also send this reply to the Management Board.	8. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September. The Executive Director shall also send this reply to the Management Board.	8. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September. The Executive Director shall also send this reply to the Management Board.	8. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September. The Executive Director shall also send this reply to the Management Board.		G

					Text Origin: Commission Proposal	
Article 40(9)						
G	468	9. The Executive Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year in question, in accordance with Article 261(3) of the Financial Regulation.	9. The Executive Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year in question, in accordance with Article 261(3) of the Financial Regulation.	9. The Executive Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year in question, in accordance with Article 261(3) of the Financial Regulation.	9. The Executive Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year in question, in accordance with Article 261(3) of the Financial Regulation. Text Origin: Commission Proposal	G
Article 40(10)						
G	469	10. On a recommendation from the Council acting by a qualified majority, the European Parliament shall, before 15 May of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.	10. On a recommendation from the Council acting by a qualified majority, the European Parliament shall, before 15 May of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.	10. On a recommendation from the Council acting by a qualified majority, the European Parliament shall, before 15 May of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.	10. On a recommendation from the Council acting by a qualified majority, the European Parliament shall, before 15 May of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N. Text Origin: Commission Proposal	G
Article 41						
G	470					G

		Article 41 Financial rules	Article 41 Financial rules	Article 41 Financial rules	Article 41 Financial rules Text Origin: Commission Proposal	
	Article 41, first paragraph					
G	471	The financial rules applicable to the Agency shall be adopted by the Management Board after consulting the Commission. They shall not depart from Delegated Regulation (EU) 2019/715 unless such a departure is specifically required for the Agency's operation and the Commission has given its prior consent.	The financial rules applicable to the Agency shall be adopted by the Management Board after consulting the Commission. They shall not depart from Delegated Regulation (EU) 2019/715 unless such a departure is specifically required for the Agency's operation and the Commission has given its prior consent.	The financial rules applicable to the Agency shall be adopted by the Management Board after consulting the Commission. They shall not depart from Delegated Regulation (EU) 2019/715 unless such a departure is specifically required for the Agency's operation and the Commission has given its prior consent.	The financial rules applicable to the Agency shall be adopted by the Management Board after consulting the Commission. They shall not depart from Delegated Regulation (EU) 2019/715 unless such a departure is specifically required for the Agency's operation and the Commission has given its prior consent. Text Origin: Commission Proposal	G