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EMCDDA–Europol 2017 Annual Report on the implementation of Council Decision 2005/387/JHA

In accordance with Article 10 of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances

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Contents

About this report

This report presents the key activities performed by the EMCDDA and Europol in 2017, with details on all the relevant activities in support of the implementation of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances, including new psychoactive substances notified in 2017, Joint Reports produced, risk assessments conducted and public health alerts and advisories issued.

Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ L 127, 20.5.2005, p. 32. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0387:EN:HTML

Background to this report

As part of the response to new psychoactive substances (NPS) within the European Union (EU), the Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances (Council Decision) established a mechanism for rapid information exchange on substances that may pose public health and social threats, including the involvement of organised crime. This provides a legal basis for the institutions of the EU and the Member States to monitor all new narcotic and psychotropic substances that appear on the European drug market. Where necessary, the Council Decision also provides for an assessment of the risks associated with these new substances, so that control measures deriving from Member States' obligations to the United Nations (UN) drug control conventions ([1]) can also be applied to new psychoactive substances.

Under Article 4 of the Council Decision, the EMCDDA and Europol, in close collaboration with their respective expert networks, the Reitox National Focal Points and Europol National Units, are assigned a central role in detecting, notifying and monitoring new psychoactive substances. The information exchange element of the Council Decision has been implemented by the EMCDDA and Europol as the European Union Early Warning System on New Psychoactive Substances (EU Early Warning System) which is supported by the EU Early Warning System Network (Network).

In addition, where necessary, and in cooperation with the European Medicines Agency (EMA), the EMCDDA and Europol may collect, analyse and present information on a new psychoactive substance in the form of a *Joint Report* (Article 5). This report provides evidence to the Council of the European Union and the European Commission on the need to request a *risk assessment* on a new psychoactive substance. Such a risk assessment examines the health and social risks posed by a new substance including: the use of, manufacture of, and, traffic in, a new psychoactive substance; the involvement of organised crime; and the possible consequences of control measures. To conduct the risk assessment, the EMCDDA convenes a special meeting under the auspices of its Scientific Committee, extended with additional experts as necessary (Article 6).

To ensure transparency when implementing the Council Decision, Article 10 stipulates that:

'The EMCDDA and Europol shall report annually to the European Parliament, the Council and the Commission on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. The report shall, in particular, include experience relating to coordination between the system set out in this Decision and the Pharmacovigilance system.'

To comply with Article 10, the EMCDDA and Europol herewith present the 12th such annual report ([2]), which covers 1 January to 31 December 2017. In addition, some key activities from 2018 are included. The report outlines the results of the implementation, describes key issues arising from accumulated experiences, and also serves as a monitoring tool. To facilitate the reading of the report, the reader is referred to the text of the Council Decision ([3]).

([1]) The 1961 United Nations Single Convention on Narcotic Drugs and the 1971 United Nations Convention on Psychotropic Substances.
([2]) Implementation reports for 2005-2017 are available at: http://www.emcdda.europa.eu/publications-database?f[0]=field_series_type:551
([3]) Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ L 127, 20.5.2005, p. 32.

Annex 1 provides the list of new psychoactive substances notified for the first time in 2017. This includes the International Union of Pure and Applied Chemistry (IUPAC) chemical name, the reporting country, and date of notification for each substance. Further information on these substances is available from the EMCDDA and Europol.

Annex 2 provides a list of the risk communications issued to the EU Early Warning System Network in 2017.

1. Overview

In 2017, 51 new substances were formally notified in Europe for the first time (Section 3.1.1). This brings the total number of substances monitored by the EMCDDA to over 670 — more than twice the total number of substances controlled under the United Nations drug conventions. Importantly, the notifications for 2017 included an increase in the number of new opioids detected for the first time, with 10 fentanils ([4]) reported, up from the eight fentanils detected in 2016 and the three detected in 2015.

This year also saw an increase in reports of serious adverse events associated with the use of new substances such as fentanils and synthetic cannabinoids. These reports played a central role in the decisions to issue the Network with six risk communications (including public health-related alerts) (Section 3.2) and to launch 10 EMCDDA-Europol Joint Reports (Section 3.3). The detailed data collection and investigations undertaken during the preparation of the Joint Reports resulted in nine risk assessments conducted in 2017 and two conducted in 2018 (Section 3.4).

In keeping with the trend of the last few years, in 2016 the total number of NPS seizures, and the quantities seized, in Europe decreased slightly compared with the previous year (Section 3.1.2). In addition, of the some 670 substances monitored, around half (approximately 360) were detected across Europe during 2016, giving some insight into just how complex the market has become. Among other problems, this increases the risk of the substances being sold, either deliberately or accidentally, as other drugs. Sometimes, this can have fatal consequences, such as when new fentanils are sold as heroin or as fake medicines.

Headline activities in 2017 are presented in the box below. Headline seizure data for the 2016 reporting period are presented in the box in section 3.1.2 (page 17).

Headline early warning and risk assessment activities in 2017

- 51 new psychoactive substances were formally notified for the first time.
- Six risk communications were issued by the EMCDDA to the Network.
- 544 reporting forms were submitted by the Network to the EMCDDA.
- 10 Joint Reports were launched by the EMCDDA and Europol:
  - furanylfentanyl (launched 16 November 2016; submitted 23 January 2017);
  - AB-CHMINACA, ADB-CHMINACA, 5F-MDMB-PINACA, CUMYL-4CN-BINACA, 4-fluoroisobutyrylfentanyl (4F-iBF) and tetrahydrofuranylfentanyl (THF-F) (launched 25 April 2017; submitted 6 June 2017);
  - carfentanil (launched 18 May 2017; submitted 27 July 2017); and
  - cyclopropylfentanyl and methoxyacetylfentanyl (launched 12 October 2017; submitted 19 December 2017).
- Nine substances were risk assessed by the EMCDDA:
  - acryloylfentanyl (22 February 2017);
  - furanylfentanyl (23 May 2017); and
  - AB-CHMINACA, ADB-CHMINACA, 5F-MDMB-PINACA, CUMYL-4CN-BINACA, 4-fluoroisobutyrylfentanyl (4F-iBF), tetrahydrofuranylfentanyl (THF-F) and carfentanil (7 and 8 November 2017).
- In addition, two fentanils were risk assessed on 21 March 2018: cyclopropylfentanyl and methoxyacetylfentanyl.
- 670+ new psychoactive substances are now monitored by the EMCDDA.

([4]) The term 'fentanils' is used to refer to fentanyl and chemically related compounds.

2. Implementation arrangements and cooperation with the European Union Pharmacovigilance system

2.1 Specific implementation arrangements

2.1.1 Assistance to national early warning systems

Similar to previous years, the EMCDDA provided daily support to the 28 Member States, Turkey and Norway, as well as other members of the EU Early Warning System Network during 2017.

This assistance often related to the provision of timely information on the NPS situation in Europe, with a specific emphasis on emerging issues relevant to public health. The EMCDDA transmits essential and urgent technical information, as well as risk communications (such as public health alerts), to the Network by email. In addition, it also operates and maintains a web-based information system called the European Database on New Drugs (EDND). This system offers round-the-clock access to information on more than 670 new substances based on data reported by the Network, and identified by the EMCDDA through its additional monitoring systems, as well as that reported by other partners. Within the EDND, each substance has a profile that includes information on its chemistry and analysis, manufacture, pharmacology, toxicology, epidemiology, trafficking and distribution. The EDND remains the most comprehensive source of information on new substances in Europe, and is used on a daily basis by the Network to support national early warning and risk assessment activities (Section 3.1.1).

In addition, the EMCDDA responded to time-sensitive ad hoc technical requests from the Network, including from the national early warning systems and the national focal points. These included queries about developing appropriate chemical nomenclature for new substances and about chemical analytical data, as well as about EU legislation on new substances.

2.1.2 Annual meeting of the EU Early Warning System Network

The 17th annual meeting of the Reitox Early Warning System Network took place in Lisbon on 5 and 6 December 2017.

The main objectives of the meeting were to review and discuss:

- the implementation of Council Decision 2005/387/JHA during 2016-2017;
- the serious threat fentanils pose to health and security in Europe;
- key developments and challenges at national and EU levels during 2016-2017;
- preparing for the new legislation, Regulation (EU) 2017/2101;
- strengthening reporting of core data that is essential for early warning and preparedness at national and EU-level;
- the latest developments regarding synthetic cannabinoids in Europe; and
- the opportunities and challenges for 2018.

During the meeting, the national early warning correspondents provided information on recent developments in their national early warning system, including emerging concerns, national alert systems, research projects and challenges. The information from these updates was then discussed, allowing the participants to increase their understanding of the NPS situation across Europe. As part of this, data on and concerns about synthetic cannabinoids and new synthetic opioids were also presented and discussed.

The 18th annual meeting of the Reitox Early Warning System Network took place in Lisbon on 5 and 6 June 2018. The main objectives were to:

- review and discuss the implementation of Council Decision 2005/387/JHA during 2017-2018;
- review and discuss the key developments and challenges at national and EU levels during 2017-2018;
- discuss the implementation of Regulation (EU) 2017/2101;
- provide an introduction to and hands-on training on the pilot EDND II;
- discuss some of the different threats posed by globalised markets and how we can strengthen our preparedness for such threats; and
- discuss what we might see next with new psychoactive substances.

2.1.3 Strengthening early warning and response

The rapidly changing nature of the NPS market which is linked to the large number of substances being monitored presents challenges for early warning activities. In response to this development, the EMCDDA has undertaken a rolling programme of work to strengthen early warning and response activities to better protect public health. This includes developing a range of interconnected components as part of the EU Early Warning System — including a toxicovigilance component, a signal management system, open source information monitoring and a risk communication component — that allows it to better identify, understand, prioritise and respond to public health threats.

The toxicovigilance component of the EU Early Warning System allows the EMCDDA to identify, manage, understand and, through other components of the EU Early Warning System and risk assessment process, react to serious adverse events associated with new substances. Much of the initial work has focused on strengthening the detection, reporting and assessment of serious adverse events reported by the countries that are part of the EU Early Warning System, as well as those events the EMCDDA has identified from the scientific and medical literature and other open sources.

It is clear from recent developments that the early identification of and response to emerging threats requires proactive data collection systems. As a result, the EMCDDA is working to improve the ability of the Early Warning System to detect signals of public health relevance from open source information (OSI) by developing and implementing OSI monitoring and analysis systems that can provide new data on areas such as the online drug markets, epidemiology and reports of serious adverse events.

In 2017, the monitoring of OSI included monitoring for potential serious and urgent events of EU relevance. Relevant information identified through this system was cross-referenced with data reported by the Network to prioritise early warning activities and responses.

Internet snapshots were also conducted to determine the availability of certain substances under intensive monitoring.

The increase in data reported to the EMCDDA through the EU Early Warning System and identified from OSI includes an increase in health agencies' reports of acute poisonings and deaths, comprising outbreaks and chronic harms. As part of the EMCDDA's Signal Management System, these reports are collated, validated and assessed to prioritise and support early warning activities, such as public health alerts and Joint Reports, as well as risk assessment activities.

2.1.4 Links with forensic science and toxicology networks

Cooperation with the Customs Laboratories European Network (CLEN) project group, funded by the European Commission (EC) Customs 2020 programme, and the Institute for Health and Consumer Protection of the EC's Joint Research Centre (JRC), was further strengthened in 2017. The CLEN project group is composed of customs laboratories from the Member States and aims to promote cooperation among them by sharing analytical data, reference samples, expertise and best practice on the identification of chemicals, including new psychoactive substances. In 2017, the EMCDDA participated in two meetings of the CLEN project.

In addition, the EMCDDA continued to actively cooperate with the European Network of Forensic Science Institutes (ENFSI). This included participating in the ENFSI Drugs Working Group annual meeting, which took place in Sweden in May 2017.

During the year, the EMCDDA also further strengthened its links with other forensic science and toxicology networks, including the American Academy of Forensic Sciences (AAFS), the Federation of European Toxicologists & European Societies of Toxicology (Eurotox), the Brazilian Academy of Forensic Sciences and the Brazilian Society of Toxicology.

In order to support early warning and risk assessment activities within the EU, in third countries and at international level, the EMCDDA exchanged information with leading forensic and toxicology experts working in the field of new substances.

2.1.5 Supporting activities and cooperation with third countries

During 2017, the EMCDDA provided technical training on NPS in meetings, at conferences and at other events. These events served not only to increase understanding of the phenomenon and the visibility of the EU's actions in this area, but also to strengthen and provide technical assistance to the Network.

Headline events in 2017 included:

- the 5th International Conference on Novel Psychoactive Substances, organised by the United Nations Office on Drugs and Crime (UNODC), the EMCDDA, the World Anti-Doping Agency (WADA), the University of Hertfordshire and Sapienza University of Rome;
- Lisbon Addictions 2017, the second European Conference on Addictive Behaviours and Dependencies, organised by the Portuguese General-Directorate for Intervention on Addictive Behaviours and Dependencies (SICAD), the journal *Addiction*, the EMCDDA and the International Society of Addiction Journal Editors (ISAJE);

- the 8th Synthetic Drugs Enforcement Conference (SYNDEC 8);
- the 2nd COPOLAD (EU, Latin America and Caribbean countries Cooperation Programme on Drugs Policies) annual meeting of national drug observatories;
- presentations for EU and national decision-makers and policymakers who visited the EMCDDA.

Support was also provided to third countries, and particularly to EU candidate countries and potential candidate countries to help support the design and operation of national early warning systems. Four countries (Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia) attended the 17th Annual Meeting of the Reitox Early Warning System Network, and five countries (Albania, Bosnia and Herzegovina, Kosovo ([5]), Montenegro, and Serbia) attended the 18th meeting, where they discussed the status of development of their national early warning systems.

2.1.6 Cooperation with international organisations

During 2017, the EMCDDA also continued to be highly active in its cooperation with international organisations. These collaborations are based on the recognition of the world-leading role the EU Early Warning System and the EMCDDA play in the early identification of threats related to NPS.

In particular, to help support international activities in the responses to harms caused by new substances, the EMCDDA provided data and technical expertise to the United Nations Office on Drugs and Crime (UNODC), the International Narcotics Control Board (INCB) and the World Health Organization (WHO) Headquarters, Geneva. This cooperation included information exchange activities and support in prioritisation and scheduling discussions.

As part of this work, the EMCDDA and the UNODC strengthened their collaboration with respect to data on the identification and seizure of new substances in Europe.

On 12 May 2017, the EMCDDA hosted an EMCDDA-WHO expert meeting to discuss cooperation on new psychoactive substances in the context of the work of the WHO's Expert Committee on Drug Dependence (ECDD).

In addition, the EMCDDA assisted the WHO with data for prioritisation and preparation of the critical reviews of psychoactive substances, which were reviewed during the 39th meeting of the WHO's ECDD in November 2017.

2.1.7 Europol

The cooperation between the EMCDDA and Europol was maintained throughout 2017.

During 2017, Europol and the EMCDDA launched jointly 10 formal information requests and provided the replies from their Europol National Units to prepare 10 Joint Reports (Section 3.3). In addition, as a member of the extended Scientific Committee (Section 3.4), Europol participated in all risk assessments conducted by the EMCDDA.

([5]) This designation is without prejudice to positions on status, and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo declaration of independence. This applies to all mentions of Kosovo in this document.

Following the trend from the previous years, in 2017, Europol observed that law enforcement agencies across the EU were increasingly aware of, and more involved in investigations concerning, NPS, despite many legislative and administrative constraints. Many Member States have already used various advanced tactics and techniques, such as controlled deliveries and cyber-purchase operations, to respond to the increasing problem of NPS.

Strategically, new psychoactive substances are a priority as set by the EU Policy Cycle of Organised Crime. The Synthetic Drugs priority in the European Multidisciplinary Platform Against Criminal Threats (EMPACT) includes NPS, and, in 2017, several operational activities were conducted within the framework of the Operational Action Plan (OAP). For example, within the framework of the Large Scale Joint Action Day, Operation 'DRAGON' was planned in October 2017. Participating Member States carried out control activities based on intelligence information at the external and internal borders of the EU. Depending on the traffic and local risk criteria, each participating country decided which consignments, parcels or items should be checked. Europol specialists and analysts provided support from its headquarters and also on-the-spot support to the EU Member States. In total, 19 kg of amphetamines, 1.7 kg of MDMA and 327 MDMA tablets were seized during this operation.

Trafficking of synthetic drugs and NPS in small parcels by post remains one of the key issues for many European countries.

As noted in previous years, China has been reported by Member States as the main source of NPS delivered to Europe. To a lesser extent, India also plays a role as a source country.

In 2017, Europol observed an increased number of NPS investigations registered, as well as a growing number of requests for operational and on-the-spot support. Generally it has been noticed that Member States are showing a greater interest in, and focusing on, these types of investigations.

Some reports by Member States indicate that small-scale illicit synthesis of NPS takes place in Europe.

Another related issue of concern is the import of precursors, pre-precursors and essential chemicals that can be used in the production of synthetic drugs and NPS.

Law enforcement authorities are seizing increasingly large shipments of APAA (3-oxo-2-phenylbutanamide). APAA is the intermediate product produced during the reaction from APAAN (alpha-phenylacetoacetonitrile) to BMK (1-phenyl-2-propanone) by adding an acid, such as phosphoric, sulphuric or hydrochloric acid, or a strong base. APAA has very limited or no licit use, but it is used for the illicit manufacture of BMK, the main precursor used for the illicit production of amphetamine and methamphetamine. APAA is currently not included in the list of internationally or EU-controlled precursors, despite having no known licit use other than for research and analytical purposes.

The EU is a major producer of various synthetic drugs, including amphetamine, from where it is trafficked to different destinations across the world. Precursors and pre-precursors required for the production of these drugs are often trafficked to the EU from countries outside the EU such as China, India and, to a lesser degree, Russia. In 2016 and 2017, APAA was the most frequently seized precursor, after ephedrine and pseudoephedrine. In the first three months of 2018 alone, more than 10 tonnes of APAA were seized. The discovery of empty packaging at illicit laboratories, storage spaces and dump sites suggests that APAA is smuggled into Europe in significantly greater quantities (Figure 1).

FIGURE 1

Pictures of large seizures of APAA in the EU

260 kg seized in Poland in December 2014

4 000 kg seized in the Netherlands in February 2018

548 kg seized in Poland in February 2018

From the beginning of 2014, APAAN, previously the main pre-precursor for the production of BMK, was placed under international control. Before APAAN was scheduled, organised crime groups (OCGs) are believed to have stockpiled large amounts of it to sustain their amphetamine production. In response to the scheduling, OCGs involved in the production of amphetamine and methamphetamine in the EU appear to have increasingly shifted to using non-controlled APAA.

To address these concerns, a core group of forensic and law enforcement experts was created in the framework of the EMPACT Operational Action Plan 2017 to identify and understand the applications and practices used by OCGs in the production of synthetic drugs and NPS. Trends and developments in this area are continuously monitored by the Member States so that quick responses can be given by issuing Early Warning Notifications and alerts.

Based on a few indicators, such as the number of NPS reported for the first time, the number of seizures reported in the EU and the amount of NPS seized, as well as on intelligence, Europol believes that the number of operating illicit sites producing NPS is much greater than the number of those dismantled and reported to the agency.

With regard to trafficking, the modi operandi look similar to previous years. Bulk amounts of NPS are shipped from China to the EU and then further distributed across Europe. For small quantities, online orders are placed either with Chinese vendors directly or via internet smart shops located in some European countries. Orders are then shipped by post and courier (delivery companies).

Investigations conducted in Member States, and supported by Europol, have identified a few hubs (countries) that are currently used to receive, store and further distribute new substances imported from China (the Netherlands, Spain and the United Kingdom).

New substances are mainly imported in the form of bulk powder. Subsequently, they are further processed for sale to consumers. This can involve mixing them with other substances such as caffeine, or adding substances to the herbs or pressing them into tablets before packaging takes place.

Finally, there are increasing concerns about the availability and use of fentanyl, a highly potent synthetic opioid. Fentanyl, which can be produced illicitly or through the diversion of medicines, has been available on the European drug market since the early 1990s and many countries have reported deaths associated with its use.

The risk of overdose is even higher with carfentanil, a fentanil analogue that is also available within the EU.

In some US cities where a large number of fatal overdoses associated with fentanils have been reported, the use of these substances has reached epidemic proportions.

EMCDDA and Europol have issued an intelligence notification to the EU Early Warning System Network informing on the risks posed by accidental exposure to fentanils, and both agencies are monitoring the situation closely.

2.2 Cooperation with the European Medicines Agency and the Pharmacovigilance system

Cooperation between the EMCDDA and the European Medicines Agency (EMA) was maintained throughout 2017, as required by Regulation 1235/2010 and Council Decision 2005/387/JHA, and operationalised through the working arrangement between the two agencies ([6]).

During 2017, the EMA provided a response to the formal information requests made by the EMCDDA in order to prepare the Joint Reports (Section 3.3). As a member of the extended Scientific Committee (Section 3.4), the EMA also participated in all risk assessments conducted by the EMCDDA.

Alongside routine information exchange on NPS, including those substances also defined as medicinal products, the EMCDDA responded to ad hoc requests from the EMA. This included providing information on opioid use in Europe as part of a request related to novel treatments for reversing opioid intoxication.

2.3 New legislation

In November 2017, new EU legislation entered into force that will strengthen the Union's response to new psychoactive substances that may pose public health and social threats.

The legislation comprises:

- Regulation (EU) 2017/2101 amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances ([7]); and
- Directive (EU) 2017/2103 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA ([8]).

([6]) Working arrangement between the European Medicines Agency (EMA) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), signed on 7 September 2012. Available at: http://www.emcdda.europa.eu/attachements.cfm/att_185319_EN_EMA-EMCDDA-2012workingarrangement.pdf

([7]) Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances, OJ L 305, 21.11.2017, p. 1-7.

([8]) Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA, OJ L 305, 21.11.2017, p. 12-18.

The legislation retains the current three-step approach of early warning, risk assessment, and control measures of Council Decision 2005/387/JHA, while strengthening early warning and risk assessment procedures and introducing shorter deadlines throughout.

Although the legislation applies only from 23 November 2018, the EMCDDA has already begun a programme of work to prepare for its implementation in general, and, more specifically, in respect to the early warning and risk assessment tasks assigned to the EMCDDA under Regulation (EU) 2017/2101. Briefly:

- At the 17th Annual Meeting of the Reitox Early Warning System Network in December 2017, the EMCDDA discussed in detail the new legislation with the National Focal Points as well as holding some initial talks on its implementation.

- At the 18th Annual Meeting of the Reitox Early Warning System Network in May 2018, the EMCDDA followed up those discussions with thematic discussions on the key topic areas as well as providing training on using the EMCDDA's next generation information system — the European Database on New Drugs (EDND) — which has been designed from the ground up to support the new legislation. The EDND will be the major tool for managing data related to early warning and risk assessment activities, and will be deployed over the next few months.

- To meet the requirements of Article 5a, 'Information exchange on, and early warning system for, new psychoactive substances', and Article 5b, 'Initial report', the EMCDDA is drafting new Operating Guidelines for the Early Warning System, which will include components on toxicovigilance, signal management, open source information and risk communication.

- To meet the requirements of Article 5c, 'Risk assessment procedure and report', and Article 5d, 'Exclusion from risk assessment', the EMCDDA is drafting new Operating Guidelines for Risk Assessment and a new risk assessment procedure. In preparation for the implementation of the new legislation, the EMCDDA has held discussions with its Scientific Committee on the new legislation, and, specifically, on the requirements for a new risk assessment procedure. As part of this, in March 2018 the EMCDDA organised the initial expert meeting 'Strengthening the risk assessment of new psychoactive substances in the European Union' to feed into the development of the new guidelines. The meeting discussed: what data is essential to risk assessment; what are the core values required for risk assessment; what expertise will be needed; and the risk assessment process.

2.4 Cooperation with ECHA, EFSA and ECDC

The implementation of Regulation (EU) 2017/2101 will require new (or revised) working arrangements with relevant EU agencies. The EMCDDA has given high priority to developing and agreeing working arrangements with relevant EU Agencies as required by the new legislation. In most cases, the discussions and drafting are at an advanced stage.

In addition to strengthening the EMCDDA's well-established cooperation with Europol and the EMA, the new legislation requires collaboration to be established with the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC).

3. Core activities

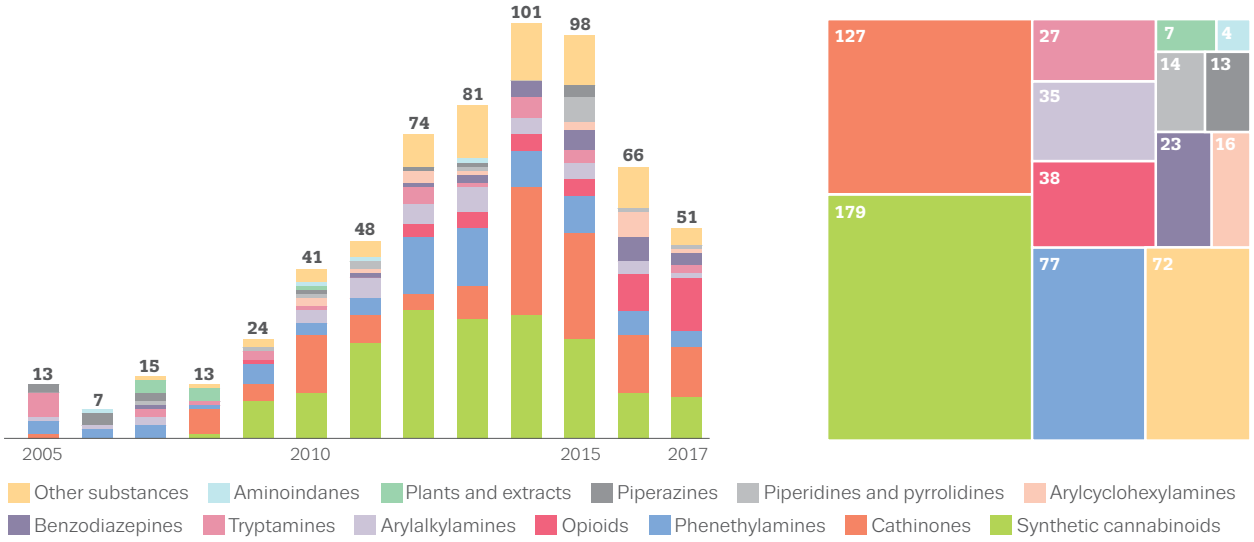
3.1 Early warning activities (Article 4)

3.1.1 New psychoactive substances detected and formally notified in 2017

Fifty-one new psychoactive substances were formally notified for the first time in Europe during 2017 (Figure 2 and Annex 1 ([9])).

FIGURE 2

Number and categories of new psychoactive substances formally notified for the first time in Europe, 2005-2017



Of the substances notified in 2017, there were: 13 opioids (including 10 fentanils), 12 cathinones, 10 synthetic cannabinoids, 4 phenethylamines, 3 benzodiazepines, 2 tryptamines, 1 arylcyclohexylamine, 1 arylalkylamine, 1 pyrrolidine and 4 substances that do not belong to these other groups (Figure 2).

This was the second year in a row when the number of new substances reported for the first time decreased, from a high of around 100 substances in 2014 and 2015 to around 50 to 60 substances per year (roughly one new substance every week). It also marked the first time when the new opioids were the single largest group of new substances to appear on the drug market in any one year — a position previously dominated by the cannabinoids and cathinones. With 38 substances overall, 2017 saw the opioids become the fourth largest group of substances monitored, after synthetic cannabinoids (179 substances) ([10]), cathinones (130) and phenethylamines (94), and not including the miscellaneous category 'other substances'.

([9]) Following the formal notification of 3'-Me-4F-iBF and 5F-MDMB-P4AICA, the EMCDDA was alerted to errors in the interpretation of analytical data related to the identification of these substances (Substances 23 and 39 in Annex 1). As a result, the formal notifications for 3'-Me-4F-iBF and 5F-MDMB-P4AICA were retracted on 30 August 2017 and 22 March 2018, respectively. While such retractions are rare, they are inherent in the very nature of early warning given the analytical challenges faced in this field, including those posed by the continuous appearance of large numbers of new substances and a lack of certified reference materials.

([10]) The figures provided here include substances reported in the period 1997–2017.

For each new substance that is reported by the Network for the first time, the EMCDDA analyses and reviews the information and performs a search to identify other important information that may have been previously published. If confirmed as a new substance, then the EMCDDA issues a formal notification on behalf of the reporting country of the identification of the substance for the first time in Europe. The notification includes the names and identifiers of the substance; its chemical and physical properties; analytical methodologies for its identification; pharmacology and toxicology; the circumstances of its detection; and any other relevant information. This is transmitted to the Network by email. At this point, the EMCDDA begins to formally monitor the substance as a new psychoactive substance as per the legal requirements of the Council Decision.

In 2017, 312 existing substance profiles were reviewed and updated with new information reported by the Network and from information identified by the EMCDDA from its monitoring of open source information as well as other sources.

The EMCDDA uses a structured reporting form to collect information on the identification of new substances in the countries that make up the Network. Such reports include the first time a new substance is identified in a country, large or unusual seizures, and trafficking and the involvement of criminal groups. This year, close to 550 of these forms reporting detections of new psychoactive substances in seizures, collected and/or biological samples were reported, reviewed and analysed by the EMCDDA; of these, 51 led to formal notifications. Importantly, this information is rapidly shared within the Network through email and the EDND, helping to ensure that those in the Network — such as the national early warning systems — are working with the latest information.

3.1.2 Reporting tools and 2016 seizure data

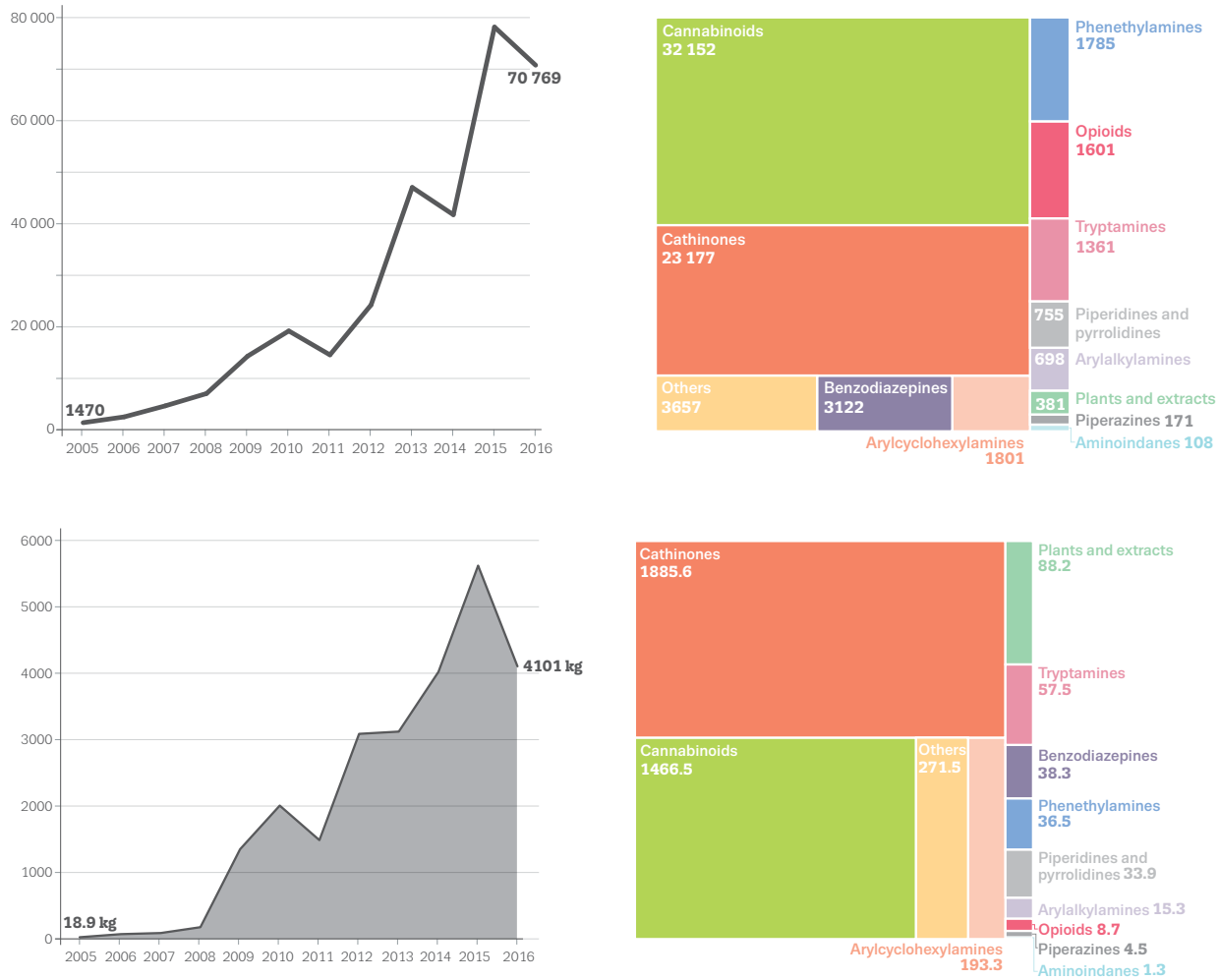
Formal notifications are an important indicator of the dynamism of the NPS market in Europe. Although they show that a large number of new psychoactive substances appear on the drug market each year, this does not reflect the foothold that each substance gains in the market.

One of the several ways that this information can be ascertained is through the routine reporting of seizures and biological detections of substances currently being monitored. National early warning systems provide this information to the EMCDDA every six months through Progress Reports and Final Reports. In 2017, 30 Final Reports from the 2016 reporting period and 25 Progress Reports from the 2017 reporting period were received, processed, analysed and published in the EDND. The resulting data and information were then incorporated into monitoring. Headline seizure data for the 2016 reporting period are presented in Box 2.

During 2016, more than 70 000 seizures of new substances, weighing 4.1 tonnes, were reported to the EMCDDA by law enforcement agencies from across Europe (Figure 3). While the number of seizures was similar to that reported in 2015, there was a drop of around 30 % in the quantities reported, mostly due to a dip in reports involving synthetic cannabinoids. Overall, seizures during 2016 were once again dominated by cannabinoids and cathinones, which, together, accounted for around 80 % of the total number and quantity of new substances reported.

FIGURE 3

Number and quantity of seizures of new psychoactive substance reported to the EU Early Warning System: trends and distribution by category in 2016



The reporting tool developed in 2015 to strengthen the reporting of serious adverse events — such as non-fatal and fatal poisonings — associated with new psychoactive substances was increasingly used in 2017. During the year, over 200 serious adverse events, including 133 deaths and 69 non-fatal intoxications, were spontaneously reported to the EMCDDA ([11]). These data were reviewed, validated and analysed, and the resulting information was used to prioritise and support early warning and risk assessment activities.

In addition, data collected using these and other tools developed by the EMCDDA have led to the launch of 10 Joint Reports in accordance with Article 5 of Council Decision 2005/387/JHA (Section 3.3).

In 2017, considerable progress was also made on developing a new information system to replace the European Database on New Drugs (EDND. During the 18th annual meeting of the Reitox Early Warning System Network, held in 2018 (Section 2.1.2), the new system was piloted with the national early warning systems. Among other features, the system allows the electronic submission and management of data related to seizures, collected samples, biological samples and serious adverse events.

([11]) This figure does not include all data formally reported as part of the information requests launched for the preparation of Joint Reports (Section 3.3) and Risk Assessments (Section 3.4), but may include some cases formally reported as part of these information requests.

Headline seizure data for 2016

- Approximately 360 different new psychoactive substances were detected across Europe.
- Both the number of seizures and the reported quantities of NPS seized decreased slightly compared with the previous year. In 2016, 70 769 seizures of new psychoactive substances were reported, amounting to over 4.1 tonnes. This represents a decrease of around 10 % on the previous year in terms of number of seizures and a decrease of over 25 % in terms of the total amount of NPS seized.
- Synthetic cannabinoids and cathinones continued to constitute the largest categories of NPS seized in Europe, amounting to 78 % of all cases and 82 % of the total amounts seized.
- Synthetic cannabinoids: 32 152 seizures, amounting to almost 1.5 tonnes.
- Synthetic cathinones: 23 177 seizures, amounting to almost 1.9 tonnes.
- Fentanils: 1 140 seizures, amounting to approximately 4.5 kg of powder. These figures represent a four-fold increase, as compared to 2015.

3.2 Public health-related alerts

One of the main functions of the EU Early Warning System is to detect signals of serious harms associated with new psychoactive substances and to respond to them as necessary. The challenge of fulfilling this important function implies monitoring signals related to a large number of substances of diverse chemical nature and pharmacological action.

The past few years have seen an increase in the reporting of serious adverse events, particularly in respect of severe and fatal poisonings, sometimes manifesting as outbreaks. Outbreaks of infections associated with new substances have also been reported.

The EMCDDA has responded to this challenge by strengthening the ability of the EU Early Warning System and its Network to detect, report, monitor, assess and respond to such harms.

During 2017, six risk communications, including public health-related alerts, were issued to the Network. Most were issued based on information received from the Network and supported by additional information from the EMCDDA's other data sources, including its open source information monitoring system.

The risk communications issued by the EMCDDA during 2017 addressed a range of public health concerns within the EU. Briefly, these include deaths associated with the synthetic cannabinoid CUMYL-4CN-BINACA, with 4-fluoroamphetamine, and with new opioids (such as U-47,700, as well as the fentanils carfentanil, cyclopropylfentanyl and methoxyacetylfentanyl). A full list of the risk communications issued in 2017 is provided in Annex 2.

In addition, following the recent increase in new opioids detected on the European drug market, and the concerns about risks to occupational exposure posed by these substances, the EMCDDA issued in 2017 the Joint Europol-EMCDDA Intelligence Notification '*Fentanils: Reducing the risk of occupational exposure in law enforcement personnel*' and a restricted briefing on fentanils produced for the EU institutions.

So far in 2018, the EMCDDA has issued risk communications dealing with falsified medicines containing fentanils in Europe, the risks of occupational exposure to fentanils, and outbreaks of serious adverse events in the United States related to synthetic cannabinoids containing brodifacoum and to kratom products.

3.3 EMCDDA-Europol Joint reports (Article 5)

As part of the day-to-day early warning activities, the EMCDDA intensively monitors substances that pose serious risks to health. During 2017, 10 of these substances — furanylfentanyl, AB-CHMINACA, ADB-CHMINACA, 5F-MDMB-PINACA, CUMYL-4CN-BINACA, 4-fluoroisobutyrylfentanyl (4F-iBF), tetrahydrofuranylfentanyl (THF-F), carfentanil, cyclopropylfentanyl and methoxyacetylfentanyl — met the criteria for the launch of a Joint Report in accordance with Article 5 of Council Decision 2005/387/JHA based on serious harms, including deaths, reported in Europe.

In the data collection processes for the preparation of the Joint Reports, data were collected from members of the Network — the 28 Member States, Turkey, Norway, and the EMA — as well as from the World Health Organization. In addition, the EMCDDA searched and reviewed open source information. These data were collated, reviewed, validated, and analysed to produce the Joint Reports within the 4-week deadline required by the Council Decision. The reports were submitted to the Council, the Commission and the EMA by the stipulated deadlines (Box 1).

3.4 Risk assessments (Article 6)

In accordance with Article 6 of the Council Decision, the Council of the European Union requested risk assessments be undertaken by the Scientific Committee of the EMCDDA on acryloylfentanyl, furanylfentanyl, AB-CHMINACA, ADB-CHMINACA, 5F-MDMB-PINACA, CUMYL-4CN-BINACA, 4-fluoroisobutyrylfentanyl (4F-iBF), tetrahydrofuranylfentanyl (THF-F) and carfentanil. In 2016-17, the five fentanils were involved in more than 250 deaths, with confirmed analytical exposure; the synthetic cannabinoids were involved in more than 100 deaths.

The Risk Assessment Reports were prepared and submitted to the Council and the Commission within the 12-week deadline required by the Council Decision.

Council Implementing Decisions were adopted on subjecting acryloylfentanyl ([12]) (25 September 2017), furanylfentanyl ([13]) (15 November 2017), and ADB-CHMINACA ([14]) and CUMYL-4CN-BINACA ([15]) (14 May 2018) to control measures across the EU.

As a result of the data sharing between the EMCDDA and the WHO Expert Committee on Drug Dependence (Section 2.1.6), and following the WHO recommendations, acryloylfentanyl, furanylfentanyl, 4-fluoroisobutyrylfentanyl and tetrahydrofuranylfentanyl were added to Schedule I of the Single Convention on Narcotic Drugs of 1961, while carfentanil was added to Schedule I and Schedule IV of the same Convention. AB-CHMINACA, and 5F-MDMB-PINACA were added to Schedule II of the Convention on Psychotropic Substances of 1971.

Key findings of the risk assessments conducted on the fentanils and on the synthetic cannabinoids are presented in Table 1 and Table 2, respectively.

In 2018, two risk assessments on cyclopropylfentanyl and methoxyacetylfentanyl were requested; these took place on 21 March 2018.

([12]) Council Implementing Decision (EU) 2017/1774 of 25 September 2017 on subjecting N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryloylfentanyl) to control measures. OJ L 251/21, 29.9.2017. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017D1774&qid=1506673462588&from=EN

([13]) Council Implementing Decision (EU) 2017/2170 of 15 November 2017 on subjecting N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl) to control measures. OJ L 306/19, 22.11.2017. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017D2170&from=EN

([14]) Council Implementing Decision (EU) 2018/747 of 14 May 2018 on subjecting the new psychoactive substance N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (ADB-CHMINACA) to control measures. OJ L 125/8, 22.5.2018. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32018D0747&from=EN

([15]) Council Implementing Decision (EU) 2018/748 of 14 May 2018 on subjecting the new psychoactive substance 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (CUMYL-4CN-BINACA) to control measures. OJ L 125/10, 22.5.2018. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32018D0748&from=EN

TABLE 1

Key findings of the risk assessments of acryloylfentanyl, furanylfentanyl, 4-fluoroisobutyrylfentanyl (4F-iBF), tetrahydrofuranylfentanyl (THF-F) and carfentanil

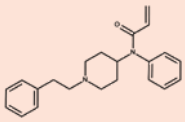
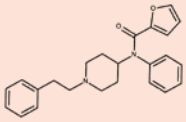
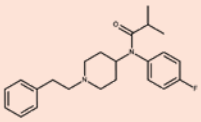
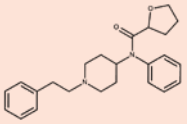
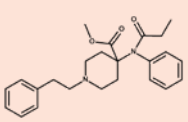
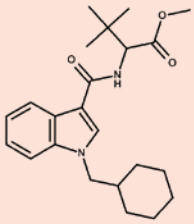
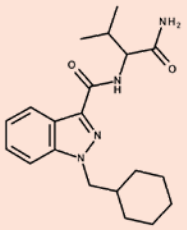
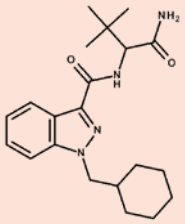
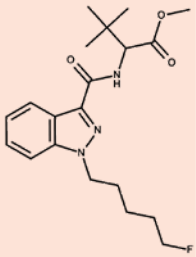
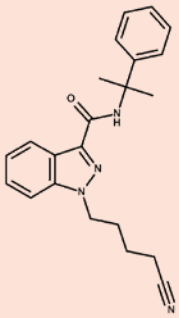
Common name	Acryloylfentanyl	Furanylfentanyl	4F-iBF	THF-F	Carfentanil
Chemical name	*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide	*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide	*N*-(4-Fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide	*N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide	Methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate
Chemical structure					
Category	Synthetic opioid	Synthetic opioid	Synthetic opioid	Synthetic opioid	Synthetic opioid
Pharmacology	μ- opioid receptor agonist	μ- opioid receptor agonist	μ- opioid receptor agonist	μ- opioid receptor agonist	μ- opioid receptor agonist
Formal notification to the EU Early Warning System	7 July 2016	3 November 2015	26 August 2016	23 December 2016	12 February 2013
Number of deaths	47	23	20	14	61
Number of countries where associated deaths occurred	3	6	2	1	8
Number of seizures by law enforcement	162	143	24	53	801
Number of countries where it has been seized	5	14	4	1	7
Total quantity seized	113 g of powder 1 495 ml liquid 896 tablets	1 036 g powder 6 g plant material 1 559 ml liquid 45 tablets	379 g powder 208 ml liquid 6 727 tablets	99 g powder 950 ml liquid	3.3 kg powder

TABLE 2

Key findings of the risk assessments of MDMB-CHMICA, AB-CHMINACA, ADB-CHMINACA, 5F-MDMB-PINACA and CUMYL-4CN-BINACA

Common name	MDMB-CHMICA	AB-CHMINACA	ADB-CHMINACA	5F-MDMB-PINACA	CUMYL-4CN-BINACA
Chemical name	Methyl 2-[[1-(cyclohexylmethyl)-1*H*-indole-3-carbonyl]amino]-3,3-dimethylbutanoate	*N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide	*N*-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide	Methyl 2-{[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino}-3,3-dimethylbutanoate	1-(4-Cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide
Chemical structure					
Category	Synthetic cannabinoid	Synthetic cannabinoid	Synthetic cannabinoid	Synthetic cannabinoid	Synthetic cannabinoid
Pharmacology	Full agonist at the CB_1 receptor; agonist at the CB_2 receptor	Full agonist at the CB_1 receptor; partial agonist at the CB_2 receptor	Full agonist at the CB_1 receptor; agonist at the CB_2 receptor	Full agonist at the CB_1 and CB_2 receptors	Full agonist at the CB_1 and CB_2 receptors
Formal notification to the EU Early Warning System	12 September 2014	10 April 2014	24 September 2014	8 January 2015	4 March 2016
Number of deaths	29	31	13	28	11
Number of countries where associated deaths occurred	6	6	3	2	2
Number of seizures by law enforcement	>3 600	6 422	3 794	1 986	2 461
Number of countries where it has been seized	25	26	19	27	12
Total quantity seized	67 kg plant material 46 kg powder	190 kg plant material 44 kg powder 293 ml liquid 194 g blotters	139 kg plant material 10 kg powder 25.5 g blotters	100 kg plant material 13 kg powder 309 g and 94 ml liquid blotters	261 kg plant material 52 kg powder blotters

4. Conclusions

Over the past decade, there has been a large increase in the number, type, and availability of new psychoactive substances in Europe. As a result, early warning and risk assessment activities, at both national and EU levels, have increased significantly.

Some of the developments over the past few years are encouraging. For example, the number of new substances reported for the first time each year during 2016 and 2017 fell by around 40 % compared with 2015. This is related to a decrease in the number of new synthetic cannabinoids and synthetic cathinones appearing each year. In part, the decrease may reflect the results of sustained efforts to control new substances in Europe, including their open sale as 'legal highs', and of law enforcement operations in China leading to the closure of illicit laboratories.

Other developments are less encouraging; in places, stronger links have developed with the established illicit drug market and it also appears that there is increasing interest among crime groups in making new substances, such as synthetic cathinones, in Europe. In addition, the availability of many new substances remains relatively high and a large number of highly potent new substances, such as the fentanils, have appeared on the market.

The fentanils pose a high risk of life-threatening poisoning to users and are capable of causing explosive outbreaks that can overwhelm local healthcare systems. They are also easier to conceal and smuggle, with a few grams sufficient to make many thousands of doses for the drug market. In some circumstances, personnel may also be at risk of poisoning from occupational exposure. Given the globalised nature of the market, these substances can pose serious cross-border threats to health.

While the growth of the market at the same pace as over the last decade is not inevitable, the continued availability of new psychoactive substances is driving greater complexity into the drug problem. As the range of substances and products has grown, consumer groups have also broadened out to wider groups of recreational users, people who self-medicate and people who want to improve how they look or their performance at work, as well as chronic and marginalised drug users. It has also led to growing interactions between the market in new substances and illicit drugs, as increasingly new substances are sold directly on the illicit drug market under their own name and passed off as illicit drugs to unsuspecting users — including feeding the illicit market when established drugs are in short supply.

In response to these developments, the EMCDDA and Europol have undertaken a rolling programme of work to strengthen early warning and response activities in order to better protect public health and public safety and security. This includes the development of a range of interconnected systems as part of the EU Early Warning System that allow to better detect, assess, prioritise and respond to public health threats. The foundation of these systems continues to be the chemical identification of new substances in law enforcement seizures and non-fatal and fatal poisonings.

In 2017, the increase in harms reported — such as severe and fatal poisonings, including outbreaks — resulted in 10 EMCDDA-Europol Joint Reports and nine EMCDDA risk assessments of substances causing concern.

This growing complexity highlights the importance of continued investment in strong early warning systems at both national and EU levels, as well as a more rapid risk assessment process at EU level in order to protect health and security within Europe. The proposed new legislative framework on new psychoactive substances will play a central role in helping achieve these objectives.

5. Publications

EMCDDA Risk assessments

- Report on the risk assessment of methyl 2-[[1-(cyclohexylmethyl)-1*H*-indole-3-carbonyl] amino]-3,3-dimethylbutanoate (MDMB-CHMICA) in the framework of the Council Decision on new psychoactive substances, March 2017. Available at: http://www.emcdda.europa.eu/publications/risk-assessments/mdmb-chmica_en
- Report on the risk assessment of *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl) in the framework of the Council Decision on new psychoactive substances, December 2017. Available at: http://www.emcdda.europa.eu/publications/risk-assessments/acryloylfentanyl_en
- Report on the risk assessment of *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl) in the framework of the Council Decision on new psychoactive substances, December 2017. Available at: http://www.emcdda.europa.eu/publications/risk-assessments/furanylfentanyl_en
- Report on the risk assessment of *N*-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (ADB-CHMINACA) in the framework of the Council Decision on new psychoactive substances, May 2018. Available at: http://www.emcdda.europa.eu/publications/risk-assessments/adb-chminaca_en
- Report on the risk assessment of 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (CUMYL-4CN-BINACA) in the framework of the Council Decision on new psychoactive substances, May 2018. Available at: http://www.emcdda.europa.eu/publications/risk-assessments/cumyl-4cn-binaca_en
- Risk assessment report on a new psychoactive substance: *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA), 2017. Available at: www.emcdda.europa.eu/attachements.cfm/att_259554_EN_AB-CHMINACA_RAR_with%20Annexes%20and%20cover.pdf
- Risk assessment report on a new psychoactive substance: methyl 2-{[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino}-3,3-dimethylbutanoate (5F-MDMB-PINACA; 5F-ADB), 2017. Available at: www.emcdda.europa.eu/attachements.cfm/att_259556_EN_5F-MDMB-PINACA_RAR_with%20Annexes%20and%20cover.pdf
- Risk assessment report on a new psychoactive substance: *N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide (4-fluoroisobutyrylfentanyl; 4F-iBF), 2017. Available at: www.emcdda.europa.eu/attachements.cfm/att_259558_EN_4F-iBF_RAR_with%20Annexes%20and%20cover.pdf
- Risk assessment report on a new psychoactive substance: *N*-phenyl-*N*-[1-(2-phenylethyl) piperidin-4-yl]oxolane-2-carboxamide (tetrahydrofuranylfentanyl; THF-F), 2017. Available at: www.emcdda.europa.eu/attachements.cfm/att_259559_EN_THF-F_RAR_with%20Annexes%20and%20cover.pdf
- Risk assessment report on a new psychoactive substance: methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate (carfentanil), 2017. Available at: www.emcdda.europa.eu/attachements.cfm/att_259560_EN_Carfentanil_RAR_with%20Annexes%20and%20cover.pdf
- Risk assessment report on a new psychoactive substance: *N*-phenyl-*N*-[1-(2-phenylethyl) piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl), 2018. Available at: www.emcdda.europa.eu/attachements.cfm/att_261520_EN_Cyclopropylfentanyl_RAR_with%20Annexes%20and%20cover.pdf

Risk assessment report on a new psychoactive substance: 2-methoxy-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl), 2018. Available at: www.emcdda.europa.eu/attachements.cfm/att_261521_EN_Methoxyacetylfentanyl_RAR_with%20Annexes%20and%20cover.pdf

EMCDDA-Europol Joint Reports

EMCDDA-Europol Joint Report on a new psychoactive substance: *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl), February 2017. Available at: www.emcdda.europa.eu/publications/joint-reports/acryloylfentanyl_en

EMCDDA-Europol Joint Report on a new psychoactive substance: *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]-furan-2-carboxamide (furanylfentanyl), July 2017. Available at: http://www.emcdda.europa.eu/publications/joint-reports/furanylfentanyl_en

EMCDDA-Europol Joint Report on a new psychoactive substance: *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA), September 2017. Available at: http://www.emcdda.europa.eu/publications/joint-reports/ab-chminaca_en

EMCDDA-Europol Joint Report on a new psychoactive substance: *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (ADB-CHMINACA), September 2017. Available at: http://www.emcdda.europa.eu/publications/joint-reports/adb-chminaca_en

EMCDDA-Europol Joint Report on a new psychoactive substance: methyl 2-{[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino}-3,3-dimethylbutanoate (5F-MDMB-PINACA; 5F-ADB), September 2017. Available at: http://www.emcdda.europa.eu/publications/joint-reports/5F-MDMB-PINACA_en

EMCDDA-Europol Joint Report on a new psychoactive substance: 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)indazole-3-carboxamide (CUMYL-4CN-BINACA), September 2017. Available at: http://www.emcdda.europa.eu/publications/joint-reports/cumyl-4cn-binaca_en

EMCDDA-Europol Joint Report on a new psychoactive substance: *N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide (4-fluoroisobutyrylfentanyl; 4F-iBF), September 2017. Available at: http://www.emcdda.europa.eu/publications/joint-reports/4F-iBF_en

EMCDDA-Europol Joint Report on a new psychoactive substance: *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]tetrahydrofuran-2-carboxamide (tetrahydrofuranylfentanyl; THF-F), September 2017. Available at: http://www.emcdda.europa.eu/publications/joint-reports/thf-f_en

EMCDDA-Europol Joint Report on a new psychoactive substance: methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate (carfentanil), November 2017. Available at: http://www.emcdda.europa.eu/publications/joint-reports/carfentanil_en

EMCDDA-Europol Joint Report on a new psychoactive substance: *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl), February 2018. Available at: http://www.emcdda.europa.eu/publications/joint-reports/cyclopropylfentanyl_en

EMCDDA-Europol Joint Report on a new psychoactive substance: 2-methoxy-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl), February 2018. Available at: http://www.emcdda.europa.eu/publications/joint-reports/methoxyacetylfentanyl_en

EMCDDA-Europol implementation reports

- EMCDDA-Europol Annual Reports on the implementation of Council Decision 2005/387/JHA. Available at: http://www.emcdda.europa.eu/publications/implementation-reports

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Article 168(5) of the Treaty of the Functioning of the European Union. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12008E168

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Further reading

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Annex 1

New psychoactive substances notified for the first time in 2017 under the terms of Council Decision 2005/387/JHA

1. **Cyclopentylfentanyl** (*N*-phenyl-*N*-[1-(2-phenylethyl)-4-piperidyl] cyclopentanecarboxamide), Sweden, 12 January 2017
2. **NiPH** (2-(isopropylamino)-1-phenyl-hexan-1-one), Sweden, 13 January 2017
3. **U-51,754** (2-(3,4-dichlorophenyl)-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methyl-acetamide), Slovenia, 20 January 2017
4. **Norfludiazepam** (7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one), Sweden, 30 January 2017
5. **25I-NB4OMe** (2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(4-methoxybenzyl)ethanamine), Italy, 2 February 2017
6. **CUMYL-PeGACLONE** (2-(1-methyl-1-phenyl-ethyl)-5-pentyl-pyrido[4,3-b]indol-1-one), Germany, 6 February 2017
7. **NDTDI** (*N,N*-diethyl-3-[methyl(1,3,4,5-tetrahydrobenzo[*cd*]indol-4-yl)amino] propanamide), Slovenia, 16 February 2017
8. **Ru-28306** (*N,N*-dimethyl-1,3,4,5-tetrahydrobenzo[*cd*]indol-4-amine), Slovenia, 7 March 2017
9. **Benzodioxole-fentanyl** (*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]-2*H*-1,3-benzodioxole-5-carboxamide), Slovenia, 9 March 2017
10. **5-Chloropentyl JWH 018 indazole analogue** ([1-(5-chloropentyl)-1H-indazol-3-yl] (naphthalen-1-yl)methanone), Belgium, 6 April 2017
11. **4-Chloropentedrone** (1-(4-chlorophenyl)-2-(methylamino)pentan-1-one), Sweden, 24 April 2017
12. **3-Methylflephedrone** (1-(4-chlorophenyl)-2-(methylamino)pentan-1-one), Sweden, 28 April 2017
13. **5Cl-AB-PINACA** (*N*-[(1*S*)-1-(aminocarbonyl)-2-methylpropyl]-1-(5-chloropentyl)1*H*-Indazole-3-carboxamide), Greece, 4 May 2017
14. **MDMB-PCZCA** (methyl 3,3-dimethyl-2-(9-pentyl-9*H*-carbazole-3-carboxamido) butanoate), Germany, 11 May 2017
15. **Octodrine** (6-methylheptan-2-amine), Belgium, 11 May 2017
16. **5F-NNEI-2** (1-(5-fluoropentyl)-*N*-(naphthalen-2-yl)-1*H*-indole-3-carboxamide), Latvia, 19 May 2017
17. **SDB-006 *N*-phenyl analogue** (1-pentyl-*N*-phenyl-1*H*-indole-3-carboxamide), Latvia, 22 May 2017

18. **Benzoylfentanyl** (*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]benzamide, Sweden, 23 May 2017

19. **4-fluoro-*N*-ethylpentedrone** (2-(ethylamino)-1-(4-fluorophenyl)pentan-1-one), Sweden, 24 May 2017

20. **3-phenylpropanoylfentanyl** (*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]-3-phenylpropanamide), Sweden, 24 May 2017

21. **4-chloro-*N*-butylcathinone (**2-(butylamino)-1-(4-chlorophenyl)propan-1-one), the Netherlands, 2 June 2017

22. **5F-3,5-AB-PFUPPYCA** (*N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-3-(4-fluorophenyl)-1*H*-pyrazole-5-carboxamide), Slovenia, 8 June 2017

23. **3'-Me-4F-iBF** (*N*-(4-fluorophenyl)-2-methyl-*N*-{1-[2-(3-methylphenyl)ethyl]piperidin-4-yl}propanamide), France, 14 June 2017
The formal notification was retracted on 30 August 2017

24. **2-methylamphetamine** (2-MA; 1-(2-methylphenyl)propan-2-amine), Sweden, 19 June 2017

25. **5Cl-MDMB-PINACA/5Cl-ADB** (methyl 2-{[1-(5-chloropentyl)-1*H*-indazole-3-carbonyl]amino}-3,3-dimethylbutanoate), Turkey, 29 June 2017

26. **Tetramethylcyclopropanefentanyl** (*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]-2,2,3,3-tetramethylcyclopropane-1-carboxamide), Sweden, 29 June 2017

27. **CUMYL-4CN-B7AICA** (1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b] pyridin-3-carboxamide), Sweden, 4 July 2017

28. **Ro 07-4065** (7-chloro-5-(2,6-difluorophenyl)-1-methyl-3*H*-1,4-benzodiazepin-2-one), Sweden, 5 July 2017

29. **Cyclopropylfentanyl** (*N*-phenyl-*N*-[1-(2-phenylethyl)-4-piperidyl] cyclopropanecarboxamide), Latvia, 4 August 2017

30. **U-48800** (2-(2,4-dichlorophenyl)-*N*-(2-(dimethylamino)cyclohexyl)-*N*-methylacetamide), Sweden, 15 September 2017

31. **1P-ETH-LAD** (*N,N,*7-triethyl-4-propionyl-4,6,6a,7,8,9-hexahydroindolo[4,3-fg] quinoline-9-carboxamide), Sweden, 22 September 2017

32. **Thionordazepam** (7-chloro-5-phenyl-1,3-dihydro-2*H*-1,4-benzodiazepin-2-thione), Sweden, 22 September 2017

33. **4-EAPB** (1-(1-benzofuran-4-yl)-*N*-ethylpropan-2-amine), Sweden, 29 September 2017

34. **4F-α-PHiP** (1-(4-fluorophenyl)-4-methyl-2-(pyrrolidin-1-yl)pentan-1-one), Sweden, 3 October 2017

35. **NEiH** (2-(ethylamino)-4-methyl-1-phenylpentan-1-one), Sweden, 4 October 2017

36. ***N*-propylnorpentedrone** (1-phenyl-2-(propylamino)-1-pentanone), Greece, 12 October 2017

37. **DOT** (1-[2,5-dimethoxy-4-(methylthio)phenyl]propan-2-amine), Sweden, 17 October 2017

38. **3-bromomethcathinone/3-BMC** (1-(3-bromophenyl)-2-(methylamino)propan-1-one), Sweden, 17 October 2017

39. **5F-MDMB-P4AICA** (methyl 2-(1-(5-fluoropentyl)-1*H*-pyrrolo[3,2-*b*]pyridine-3-carboxamido)-3,3-dimethylbutanoate), Germany, 19 October 2017
The formal notification was retracted on 22/03/2018

40. **5-MeO-pyr-T** (5-methoxy-3-(2-pyrrolidin-1-ylethyl)-1*H*-indole), United Kingdom, 23 October 2017

41. **Thiophenefentanyl** (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide), Poland, 15 November 2017

42. **3,4-dichloroethcathinone/3,4-DCEC** (1-(3,4-dichlorophenyl)-2-(ethylamino)propan-1-one), United Kingdom, 17 November 2017

43. **3-HO-PCE** (3-(1-(ethylamino)cyclohexyl)phenol), Sweden, 23 November 2017

44. **Benzylfentanyl** (*N*-phenyl-*N*-[1-(phenylmethyl)-4-piperidinyl]-propanamide), Slovenia, 27 November 2017

45. **Bromadoline** (U 4793e; 4-bromo-*N*-(2-(dimethylamino)cyclohexyl)benzamide), Slovenia, 13 December 2017

46. **Bk-IMP** (1-(2,3-dihydro-1*H*-inden-5-yl)-2-(methylamino)propan-1-one), Slovenia, 14 December 2017

47. **1-(1,3-diphenylpropan-2-yl)pyrrolidine**, Slovenia, 15 December 2017

48. **3,4-Dichloro-*N,N*-cyclohexylmethylmethcathinone** (2-[cyclohexyl(methyl)amino]-1-(3,4-dichlorophenyl)propan-1-one), Sweden, 18 December 2017

49. **3-Fluoroethamphetamine/3-FEA** (*N*-ethyl-1-(3-fluorophenyl)propan-2-amine), Sweden, 19 December 2017

50. **Zaleplon** (*N*-[3-(3-cyanopyrazolo[1,5-a]pyrimidin-7-yl)phenyl]-*N*-ethylacetamide), Ireland, 20 December 2017

51. **Benzoyloylbenzylfentanyl** (*N*-(1-benzyl-4-piperidyl)-*N*-phenyl-benzamide), Poland, 21 December 2017

52. **Acetylbenzylfentanyl** (*N*-(1-benzyl-4-piperidyl)-*N*-phenyl-acetamide), Poland, 21 December 2017

53. **5F-Cumyl-PeGaClone** (5-(5-fluoropentyl)-2-(1-methyl-1-phenylethyl)-pyrido[4,3-b] indol-1-one), Germany, 21 December 2017

Annex 2

List of risk communications issued to the EU Early Warning System Network in 2017 under the terms of Council Decision 2005/387/JHA

1. Deaths associated with CUMYL-4CN-BINACA — Hungary and Sweden, 2016, *Alert*, 23 April 2017.

2. Deaths associated with U-47,700 — multiple countries in Europe, January 2016 to May 2017, *Alert*, 6 July 2017.

3. Increase in carfentanil seizures and deaths — multiple countries in Europe, January to June 2017, *Alert*, 25 July 2017.

4. Deaths associated with cyclopropylfentanyl — Sweden, June to August 2017, *Alert*, 22 August 2017.

5. Deaths associated with methoxyacetylfentanyl — Sweden, December 2016 to June 2017, *Alert*, 24 September 2017.

6. Severe and fatal poisoning associated with 4-fluoroamphetamine — Netherlands, 2016, *Advisory*, 10 December 2017.

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The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is the central source and confirmed authority on drug-related issues in Europe. For over 20 years, it has been collecting, analysing and disseminating scientifically sound information on drugs and drug addiction and their consequences, providing its audiences with an evidence-based picture of the drug phenomenon at European level.

The EMCDDA's publications are a prime source of information for a wide range of audiences including: policymakers and their advisors; professionals and researchers working in the drugs field; and, more broadly, the media and general public. Based in Lisbon, the EMCDDA is one of the decentralised agencies of the European Union.

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For the full list of publications, please refer to Section 5.

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| EMCDDA Action on new drugs: www.emcdda.europa.eu/drug-situation/new-drugs

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