



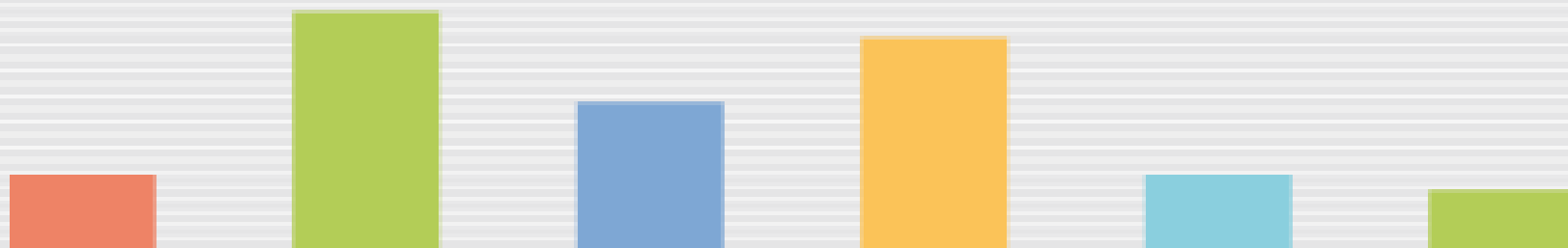
Observatorio Europeo de las
Drogas y las Toxicomanías

Lisbon, 15 November 2017

The EU Early Warning System on new psychoactive substances – the EU EWS model

Ana Gallegos, PhD

Head of sector • Action on new drugs • Supply reduction and new drugs unit



police
customs medicine regulators
public health treatment providers
chemists **30** pathologists

**national early warning
systems**

toxicologists policy makers
poison centres
researchers

police/customs seizures
serious adverse events
epidemiology

**El sistema europeo de alerta temprana
y de evaluación de riesgos de
nuevas sustancias psicoactivas**

Operativo desde 1997

open source
information

data management
analysis

EMCDDA

signal management
risk communication

**early warning
risk assessment**

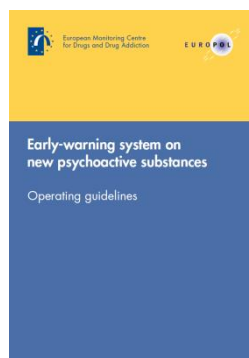


Council Decision 2005/387/JHA

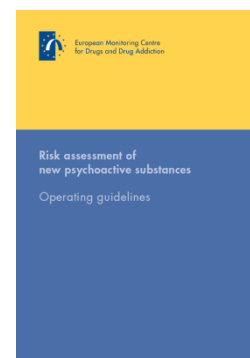
EMCDDA – Europol annual implementation reports



EWS guidelines



Risk assessments guidelines



I. Information exchange
Early warning system (EWS)

II. Risk assessment

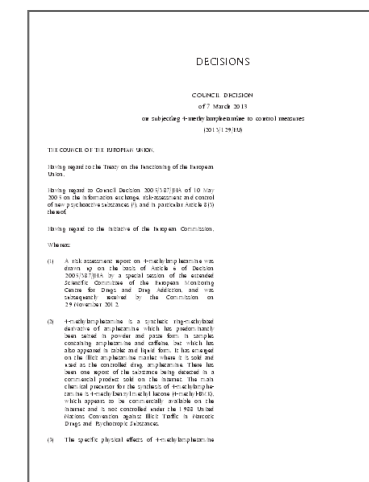
III. Decision-making

Joint Report
Biannual EWS reports
Reporting forms (ad hoc)

Risk assessment reports



Council Decisions on control



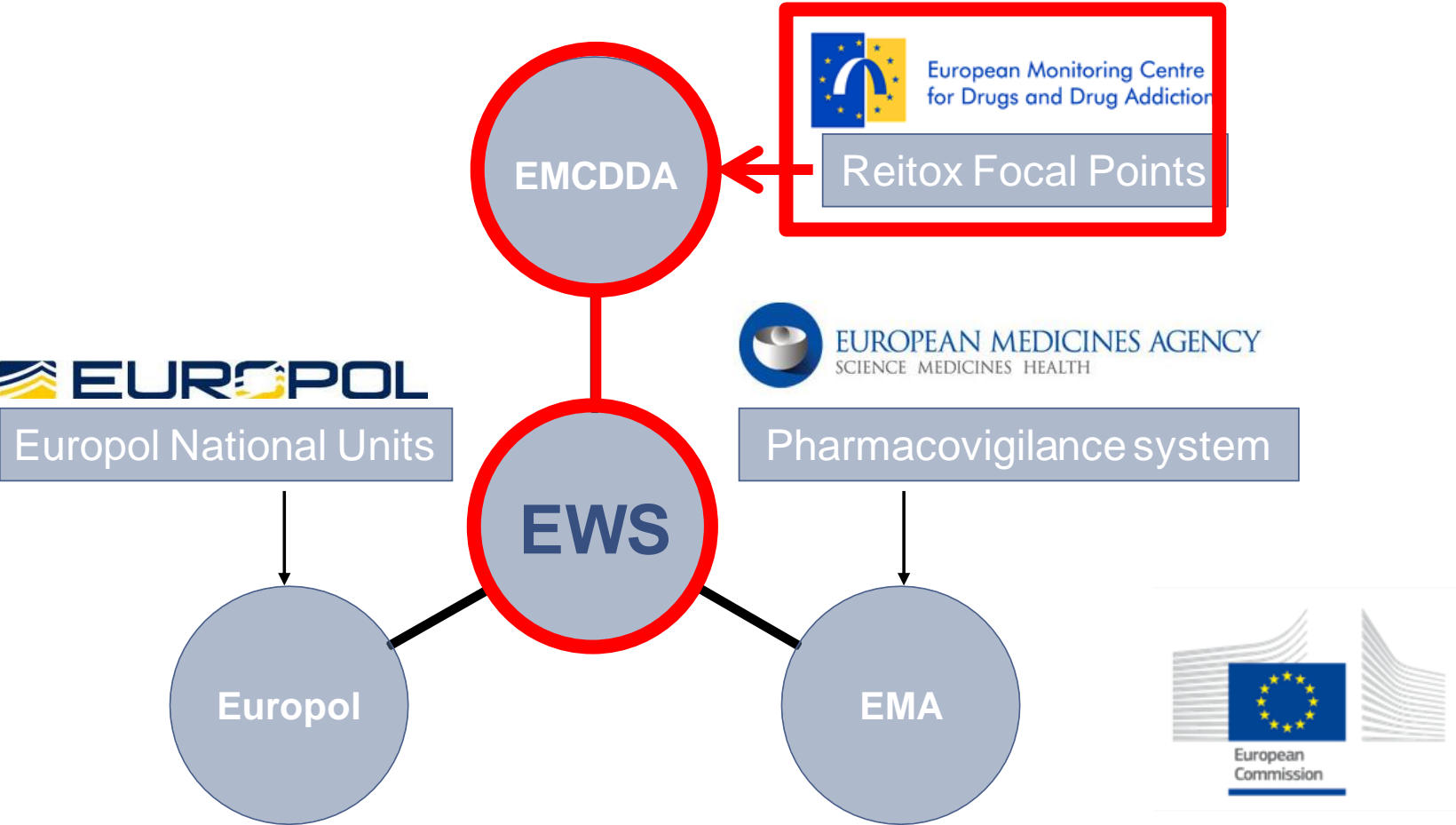
European Database on New Drugs (EDND)

<http://www.emcdda.europa.eu/drug-situation/new-drugs>

Distinction between controlled drugs and NPS

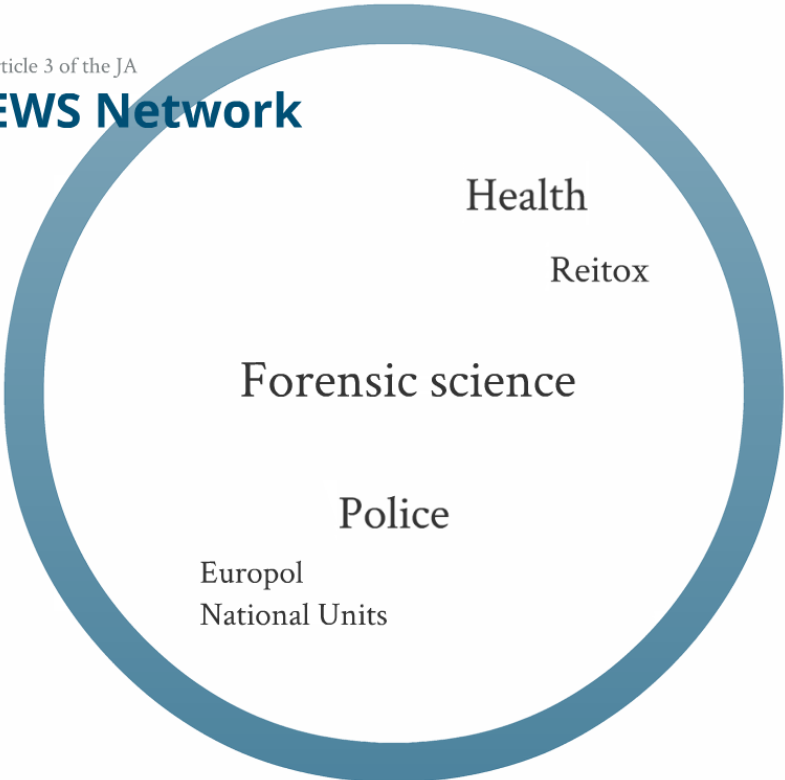


EWS institutional partners

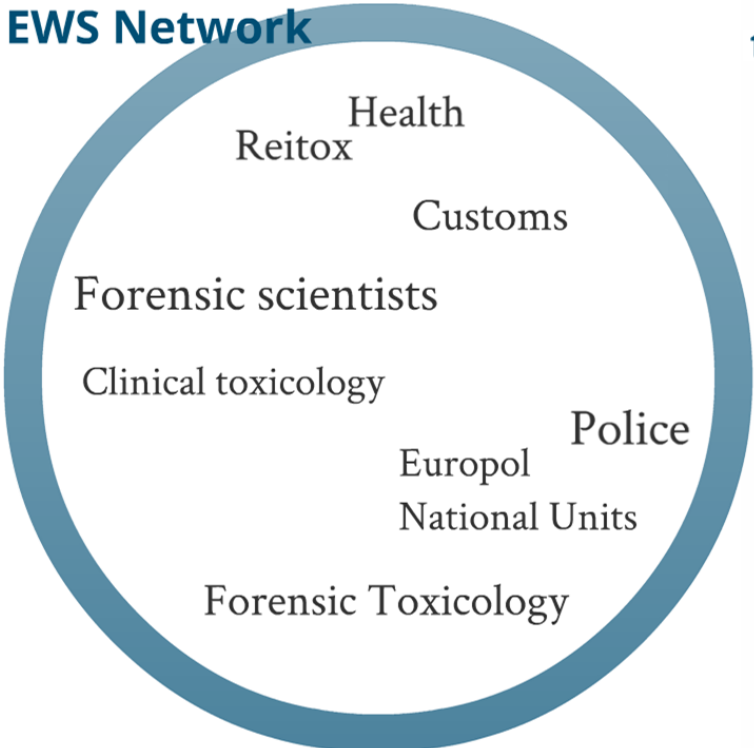


hed under Article 3 of the JA

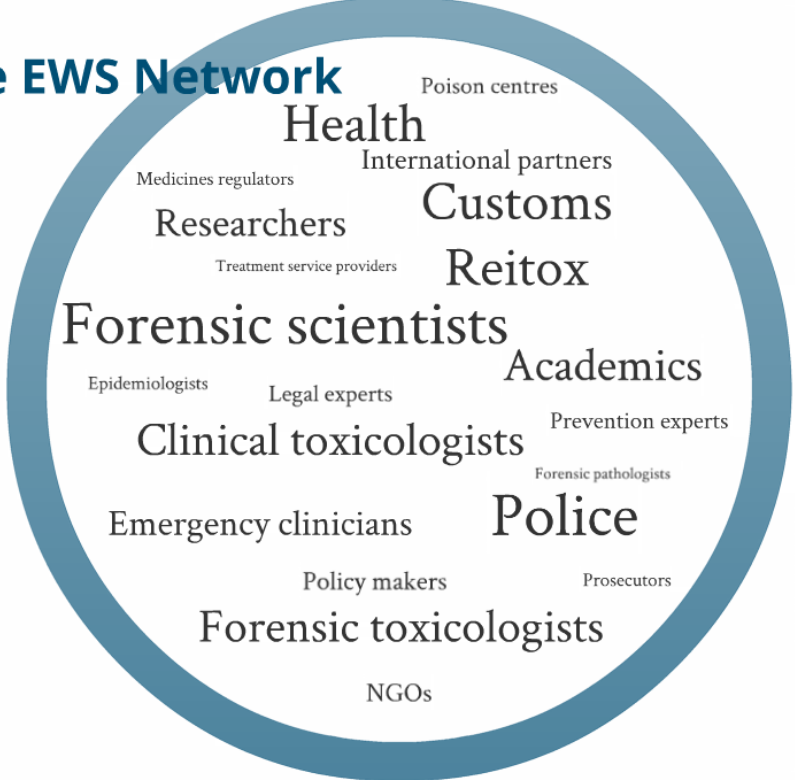
the EWS Network



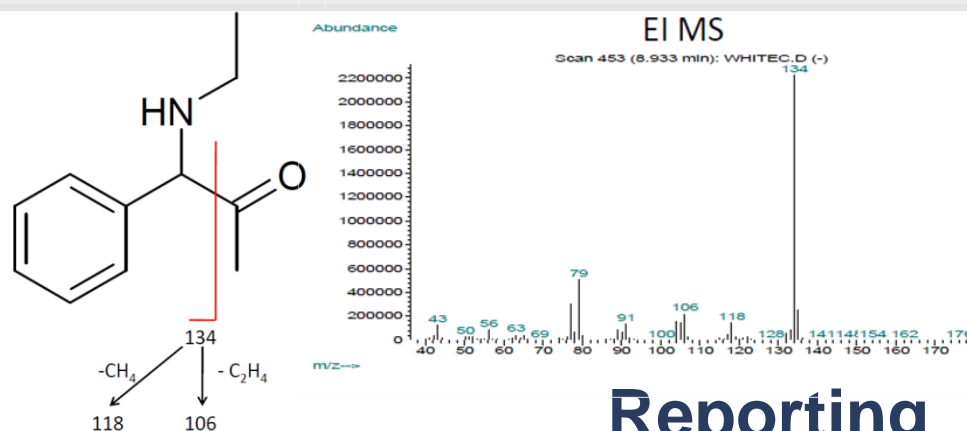
the EWS Network



the EWS Network



Multi-source information, data triangulation



Reporting
forensic analysis & toxicology
law enforcement
drug checking & surveys
health & care

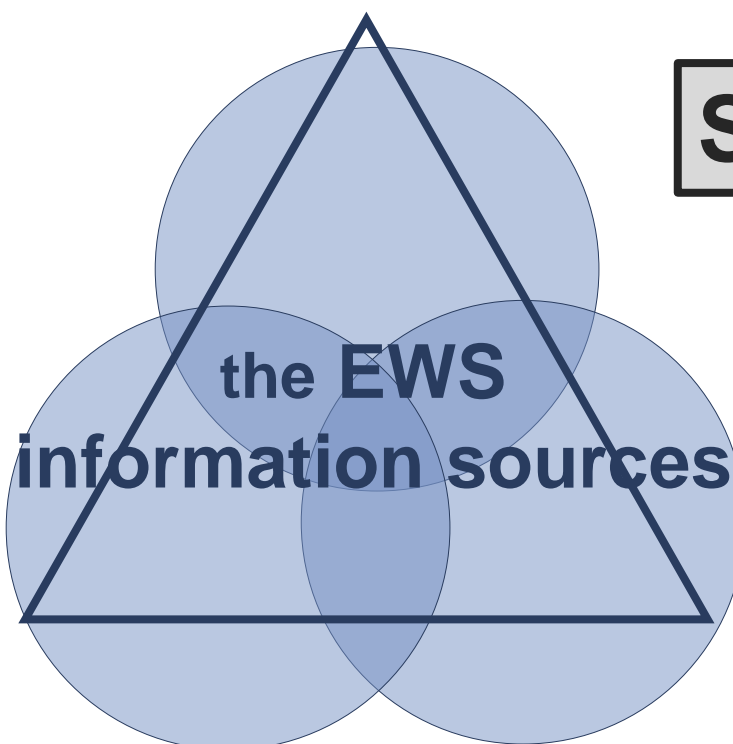
Event-based data

Aggregated data

Seizures

Collected samples
Biological samples

Serious adverse events



Targeted research

test purchase,
wastewater analysis,
computational modelling,
pharmacotoxicological profiling

Open source information

Internet, media, users,
scientific/grey literature



Essential considerations

1. Identify the challenges relevant for the region/country
2. Define the scope and framework
3. Define core functions
4. Define the information flow
5. Engage multidisciplinary stakeholders
6. Provide reporting tools, information exchange platforms and outputs

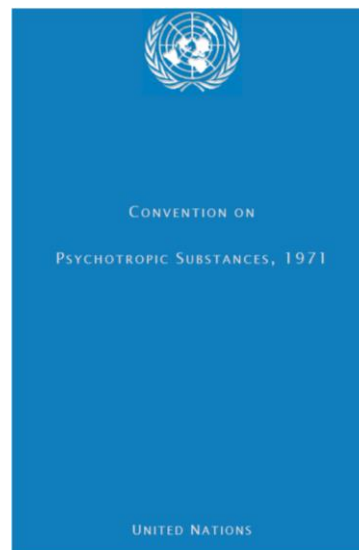
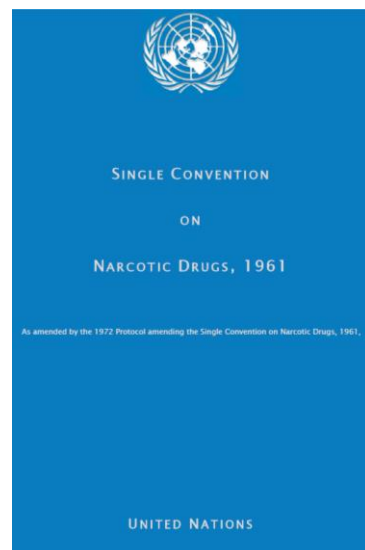
1. Identify the challenges relevant at national level

- Globalization and innovation have led to new drugs becoming widely available and new trends spread at an unprecedented pace
- At least initially, many new drugs/trends do not spread beyond small groups of experienced users
- To minimise harms, stakeholders, including policy makers, law enforcement, practitioners, and researchers need access to timely evidence-based and authoritative information on these substances and trends in their use
- Early warning systems play a critical role in detecting, identifying, and monitoring new drugs/trends, as well as helping to inform the responses required

2. Define the scope and framework

- What kind of phenomena can be reported?
 - Definition of a 'new psychoactive substance' under the Council Decision:

'New narcotic or psychotropic drug, in pure form or in preparation, that is not controlled by the 1961 or the 1971 UN Conventions, but which may pose a public health threat comparable to that posed by substances listed in Schedule I or II or IV of the former and in Schedule I or II or III or IV of the latter convention'.



2. Define the scope and framework

- What kind of phenomena can be reported?
 - New psychoactive substances
'New' to the drug market or newly misused
 - Changes in purity of established (controlled) drugs
 - Established (controlled) drugs adulterated with unusual and/or harmful cutting agents
Anthrax outbreak among heroin injecting drug users, cocaine adulterated with levamisole, etc.
 - Substances sold as others
Heroin sold as cocaine
 - New patterns (forms) of use
Recreational use of methamphetamine injected
 - Fatal and non-fatal intoxications
 - Large seizures, seizures that show evidence of international trafficking and/or involvement of organised crime



3. Define core functions and characteristics of the network

- Core functions
 - Early identification – drug monitoring system
 - Early intervention – rapid assessment & response capability
 - Emergency and routine functions
 - Answer key policy questions
 - Inform the general public
- Characteristics of the network
 - **Coverage** – national, regional, local, city, etc.
 - **Specificity vs sensitivity** – clear objectives and case definition
 - **Pro-active vs reactive** – anticipation capability
 - Ethically correct



4. Define the information flow

- Define information flow – institutions & stakeholders involved
- Integration of **multidisciplinary** information sources
- **Timeliness** of reporting, **rapidity**
- **Reliability** – consistent and replicable over time
Assess the reliability according to the information source
- **Validity** – the data is true and certain (backed by evidence)
Multi source validation of information
- **Comparability**
- **Usefulness** of information
- Handling **sensitive** information
- **Sustainability, adaptability, relevance**

5. Engage multidisciplinary stakeholders

- **Forensic science and toxicology networks:** forensic analysis of seized drugs, toxicological analyses of specimens from deceased persons or analyses of blood & urine samples from living individuals
- **Health and care system:** hospitals' emergency rooms, poisoning centres, psychiatric departments, specialised and non-specialised treatment centres, low threshold, outreach and street-work agencies, drug prevention centres, drug help lines, GPs, etc.
- **Law enforcement agencies:** prosecution authority, police, specialised drug units, customs, border guards, etc.
- **Relevant national agencies:** government departments responsible for enacting drug legislation, national drugs agencies, national medicines agencies and pharmacovigilance systems
- **'Street' level key informants:** users, organizers of youth venues (concerts, raves, etc.), owners and staff of night clubs, cafés, etc.
- **Other:** scientific publications, Internet, Internet discussion groups and forums, media sources, etc.

6. Provide reporting tools, information exchange platforms and outputs

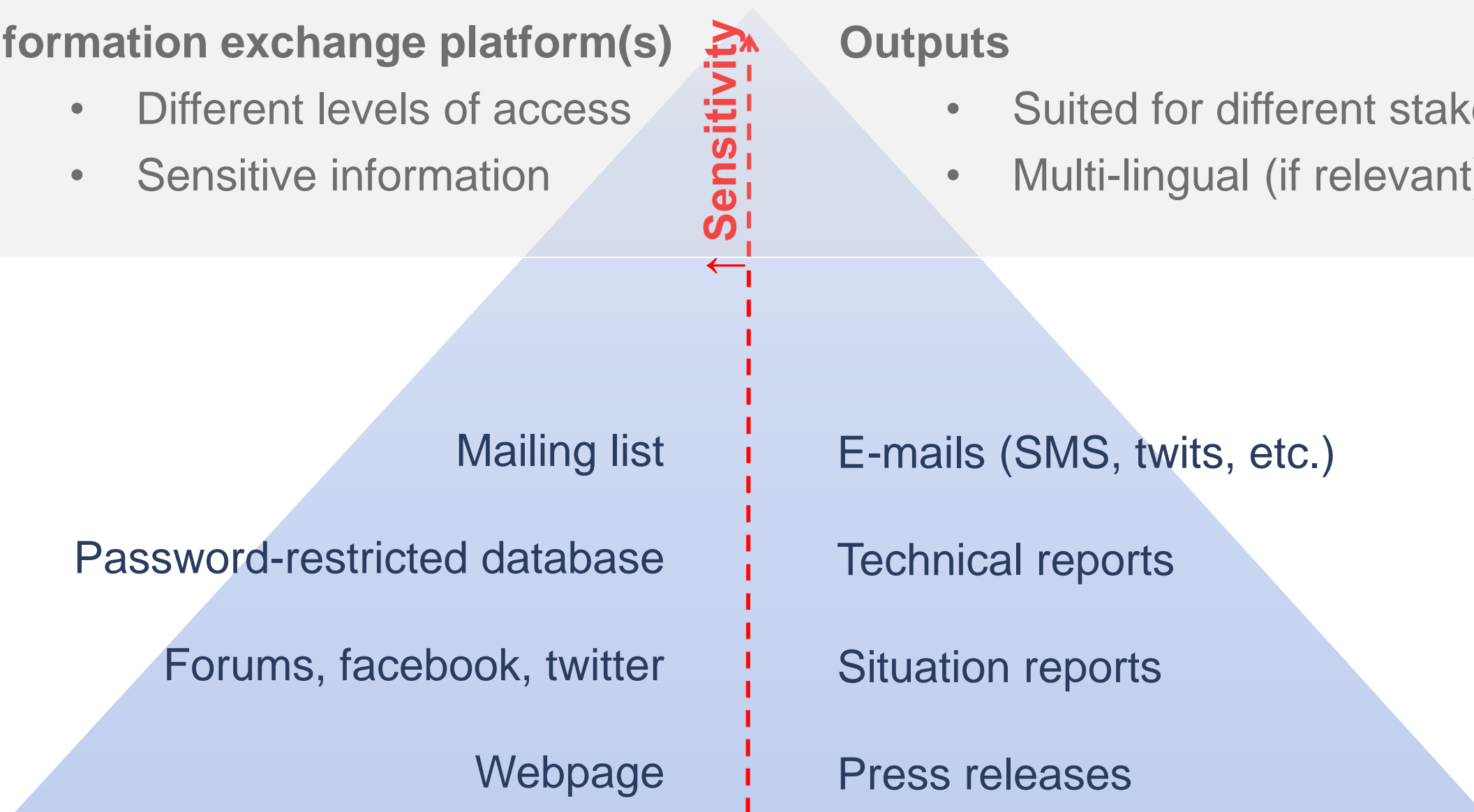
- How to collect, register, store and disseminate the information?
- Reporting tools for ad hoc events and for routine monitoring

Information exchange platform(s)

- Different levels of access
- Sensitive information

Outputs

- Suited for different stakeholders
- Multi-lingual (if relevant)



Lessons learnt from developing the European EWS

- Networks are people & need investment – active participation of stakeholders is key
 - Need nurturing, renew, consolidate and (ultimately) expand
 - Share best practices & compare experiences
 - Provide training & offer technical assistance
 - Provide feedback – added value
- Adapt networks to new technologies and trends
- Early identification & rapid response to emerging drug trends

Some reflections on the added value of the EWS

- Successful and sound mechanism to share information on new drugs and threats
 - Rapid (real time) information exchange system
 - It is based on existing resources and structures: cost-effective
 - Shared investment & shared benefits
- A greater capacity to identify, share information and assess the health implications of the wide variety of new substances now becoming available is needed

The NPS market

Designer drugs

Passed off as drugs such as MDMA and heroin. Produced in clandestine labs by organised crime. Sold on illicit drug market by drug dealers.

Research chemicals

Sold under the guise of being used for scientific research. Aimed at 'psychonauts' who explore the effects of psychoactive substances. Sold openly online.

Medicines

Medicines that are diverted from patients or illegally imported into Europe. Sold on illicit drug market by drug dealers.

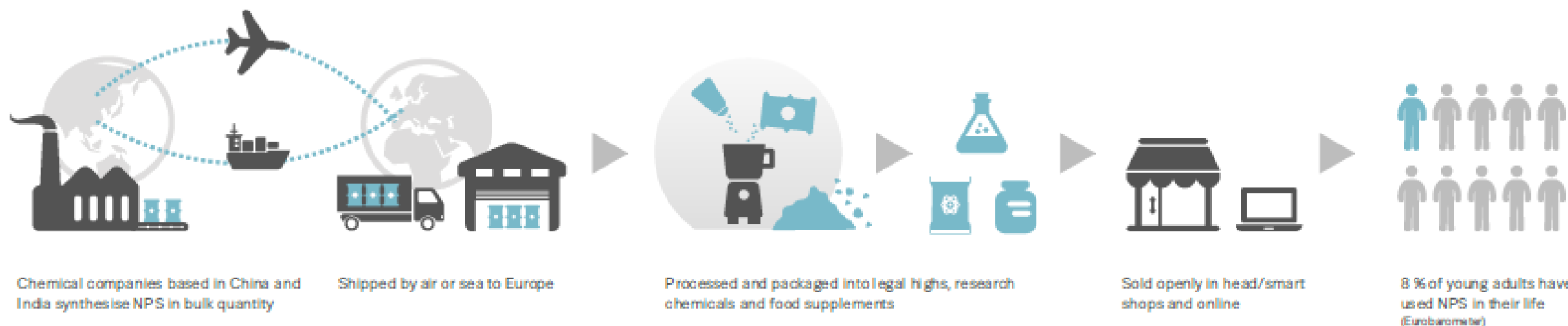
Legal highs

Marketed in bright and attractive packaging. Sold openly in head/smart shops and online. Aimed at recreational users.

Food supplements

Sold under the guise of being food or dietary supplements. Aimed at people wanting to enhance their body and mind. Sold openly in fitness shops and online.

From synthesis to consumer



The NPS market



police
customs medicine regulators
public health treatment providers
chemists **30** pathologists

**national early warning
systems**

toxicologists policy makers
poison centres
researchers

police/customs seizures
serious adverse events
epidemiology

2015 seizures

+ 78,000 seizures (+ 2-fold increase as compared to 2014)
~ 5 tonnes seized (+ 2-fold increase as compared to 2013)

20 years of monitoring NPS
+660 NPS monitored
~150 public health alerts
30 risk assessments

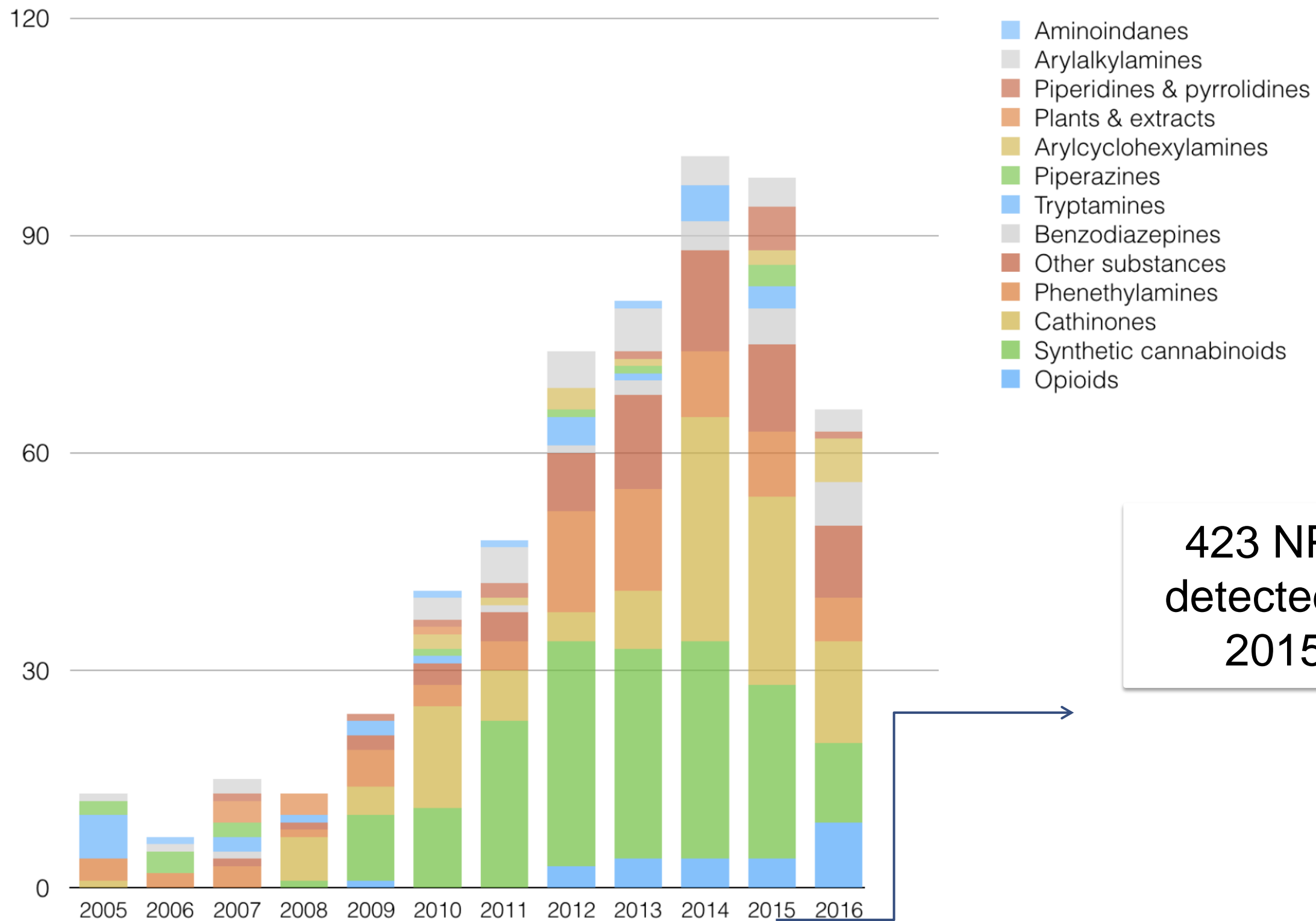
in the last 3 years

300 NPS detected
+50 public health alerts
17 risk assessments

EMCDDA

signal management
risk communication
early warning
risk assessment

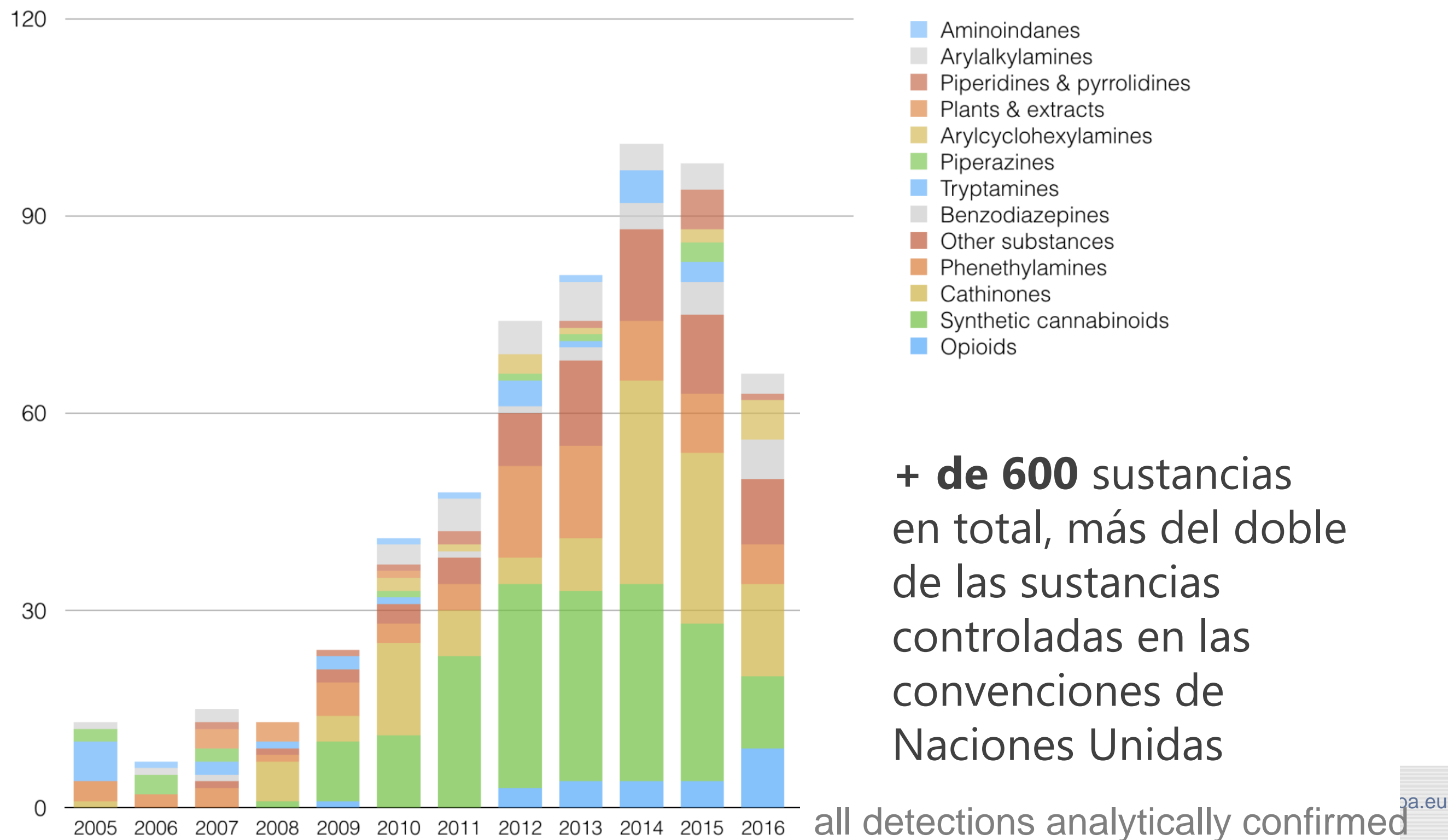
NPS in Europe



423 NPS
detected in
2015

Number of NPS reported to the EWS (2005-2016)

Nuevas drogas – gran diversidad y cantidad



What should be reported?

EMCDDA EWS guidelines

First detection in Europe → formal notification

- EMCDDA-Europol Reporting Form
- Complete analytical report

First detection in the country → event-based data

- EMCDDA-Europol Reporting Form



• Subsequent detections → aggregated data

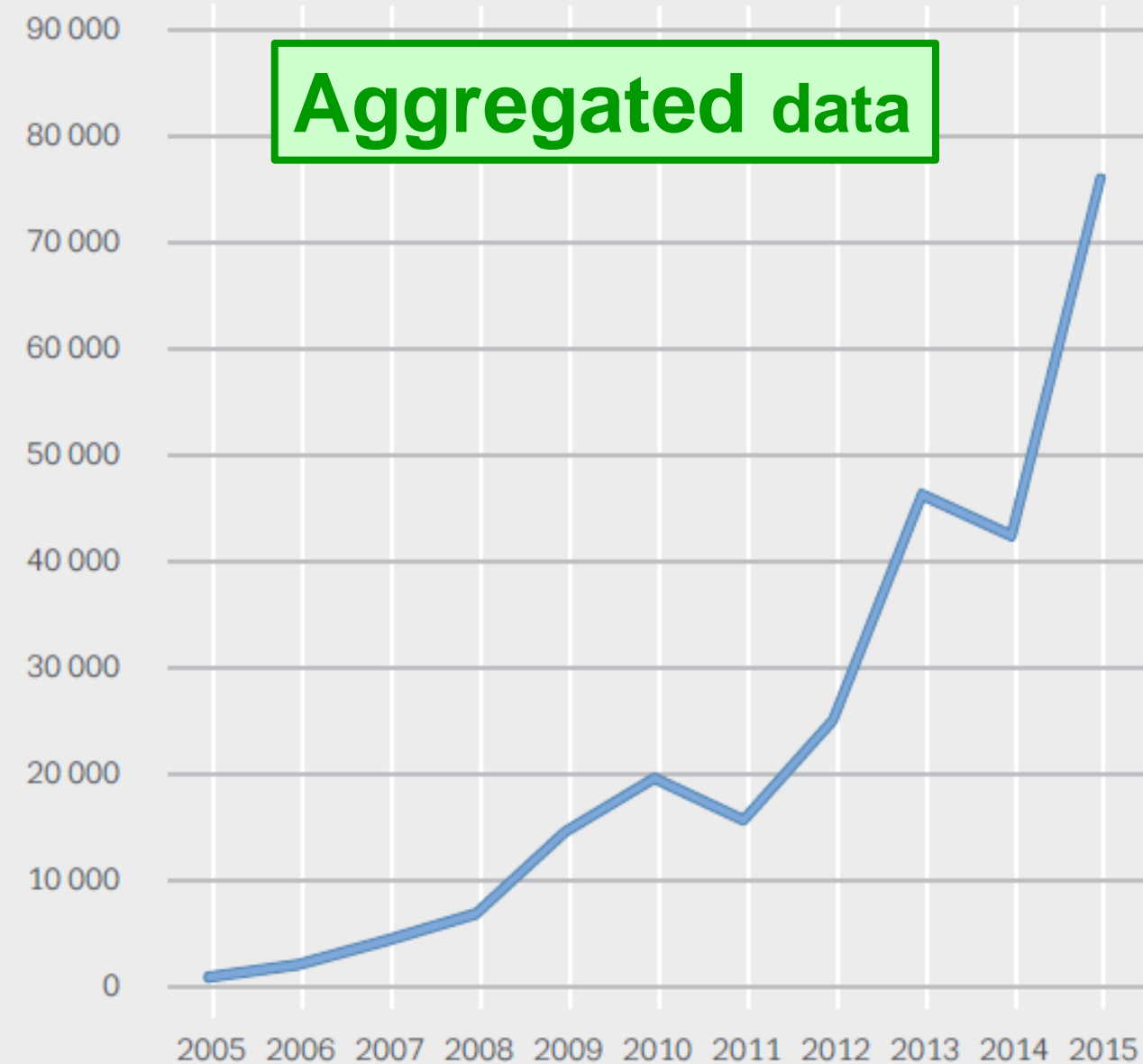
- EWS Progress Reports (January – June)
- EWS Final Reports (July – December)



Seizures of new psychoactive substances in Europe

Number of seizures of new psychoactive substances reported to the EU Early Warning System: trends and distribution by category in 2015

Number of seizure cases



Cathinones
33 %

Cannabinoids
29 %

Benzodiazepines
11 %

Phenethylamines
6 %

Piperazines
6 %

Others
5 %

Arylalkyl-
amines
4 %

Arylcyclohexyl-
amines
2 %

Tryptamines
1 %

Piperidines and
pyrrolidines
1 %

Opioids
1 %

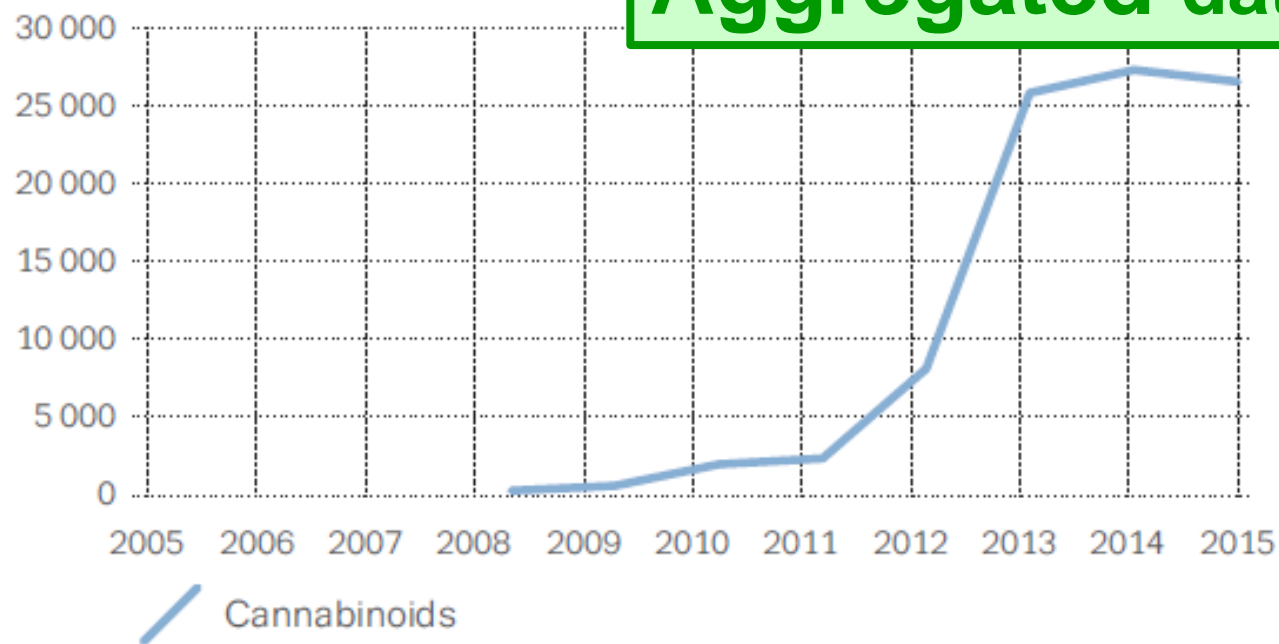
Increasing seizures of synthetic cannabinoids and cathinones



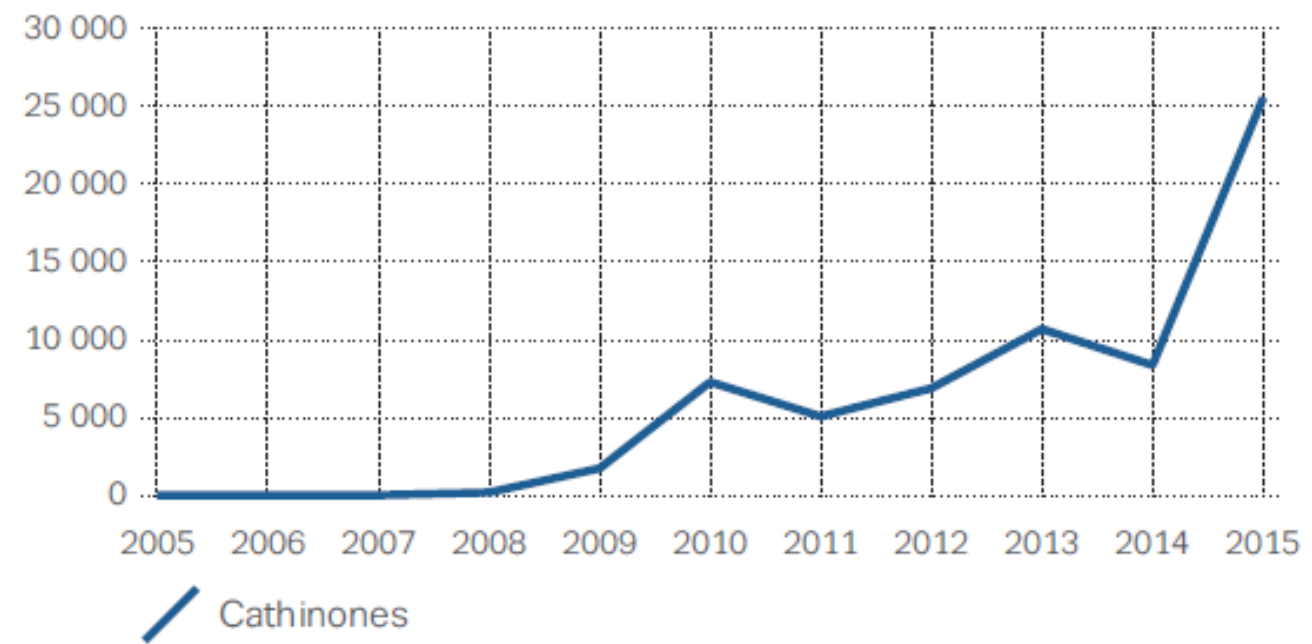
Seizures of synthetic cannabinoids and cathinones reported to the EU Early Warning System: trends in number of seizures and quantity seized

Aggregated data

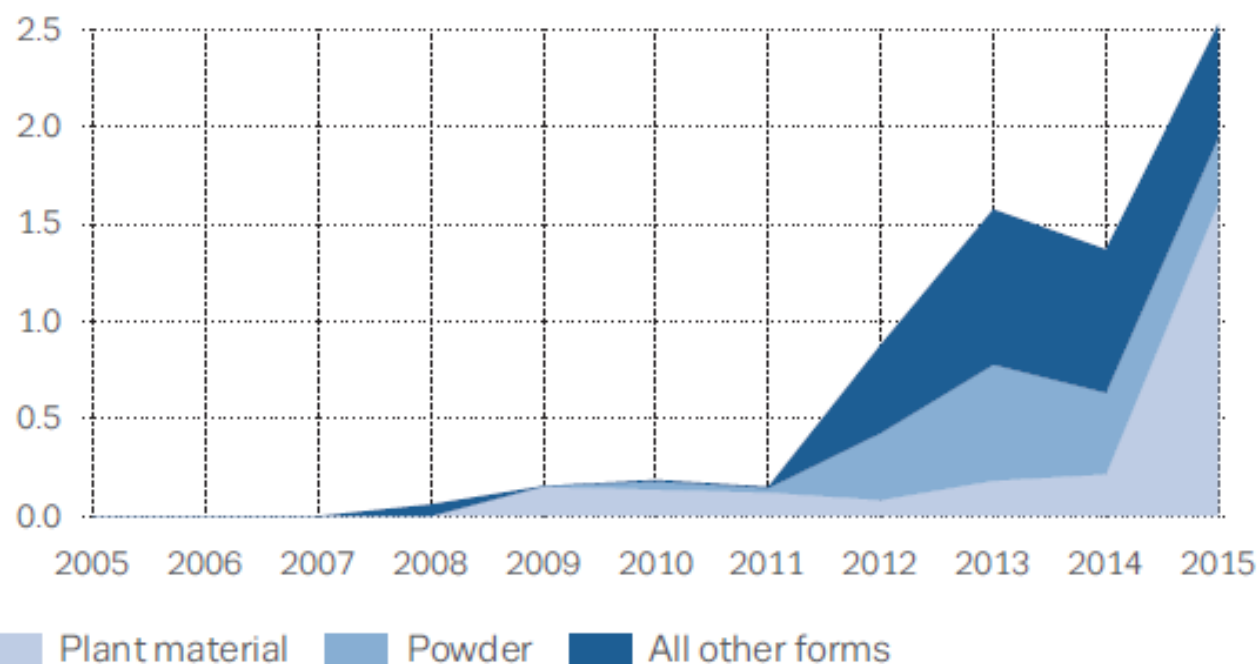
Number of seizure cases



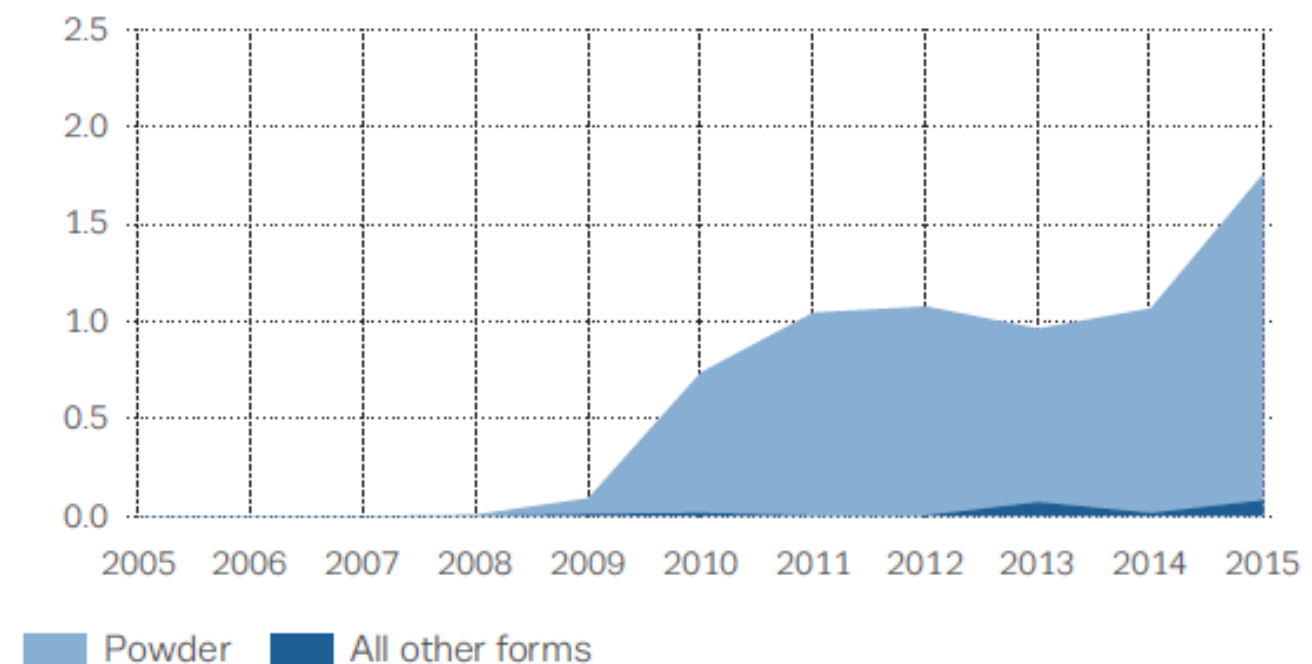
Number of seizure cases



Cannabinoids (tonnes)



Cathinones (tonnes)



Cannabinoides sintéticos

- Sustancias que actúan en el cerebro sobre los mismos receptores que el cannabis
- De origen sintético; con gran diversidad estructural; monitorizamos más de 170
- Habitualmente se fuman
- **Cómo se fabrican los productos que contienen cannabinoides sintéticos?**
La(s) sustancia(s) activa(s) se rocían sobre material vegetal (hierba) usando disolventes. Esto puede conllevar riesgo de distribución desigual de las sustancias y productos con altas concentraciones de sustancia activa.



Productos que contienen NPS – variabilidad e incertidumbre en la composición

Ejemplo: el producto 'Mocarz' (= atleta) en Polonia
En 2015, más de 350 personas fueron hospitalizadas en un corto plazo de tiempo después de haber fumado el producto llamado 'Mocarz'

Composición variable (fuente: punto focal polaco):

2010 - JWH-203, JWH-081, JWH-019,

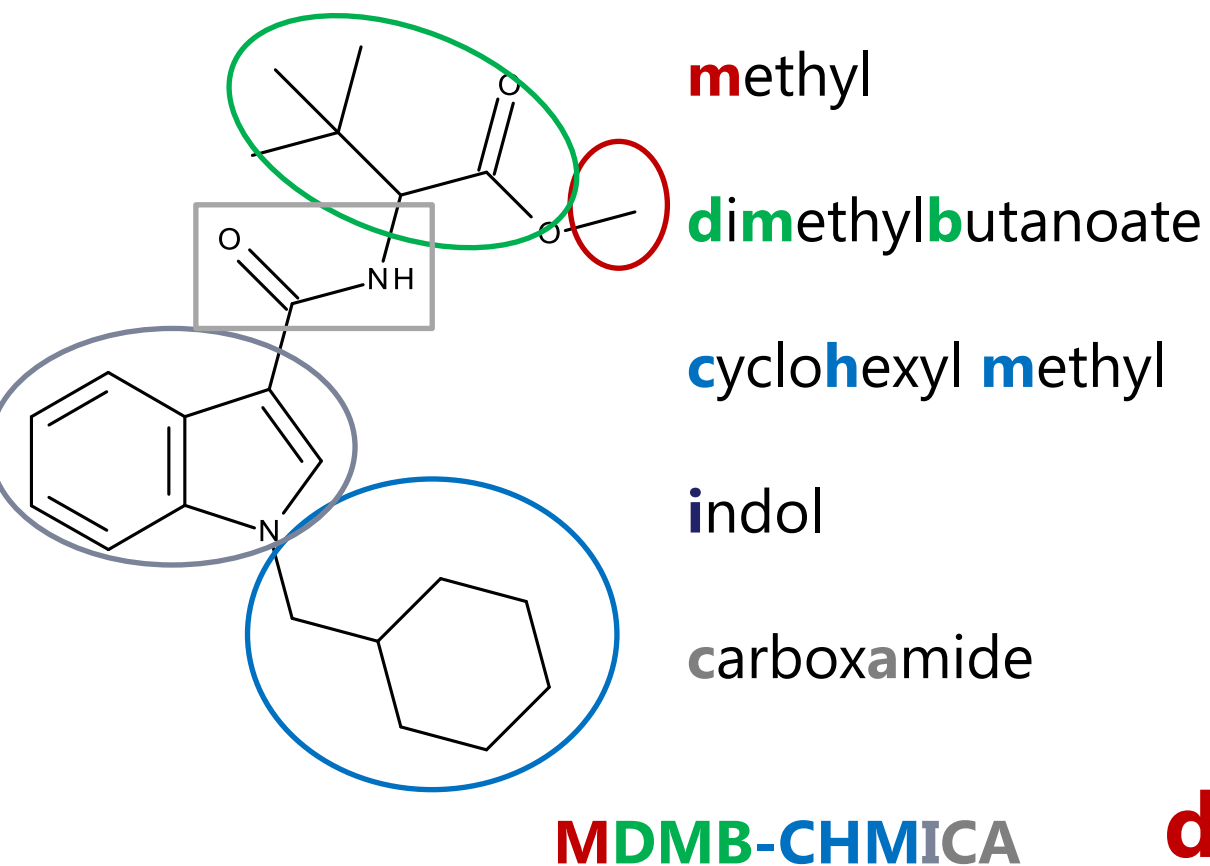
2014 - UR-144 and 5F-AKB-48

2015 – UR-144 and 5-FUR-144, BB-22, 5F-PB22,

MDMB-CHMICA



El cannabinoide sintético MDMB-CHMICA



Agosto 2014 – primera detección (HU)

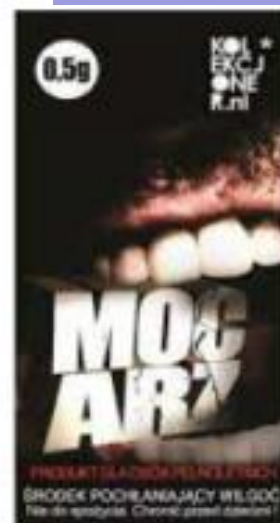
Diciembre 2014 – decomiso de 40 kg (LU)

Julio 2016 – evaluación de riesgos (28 muertes)

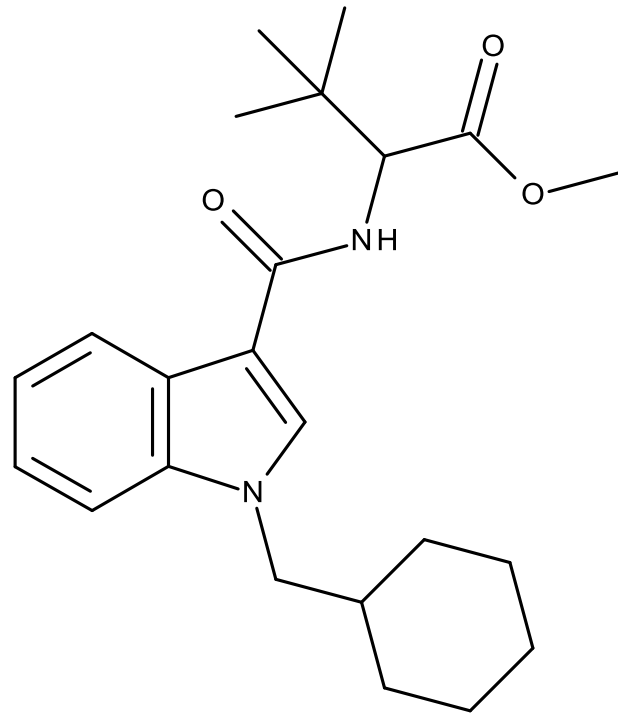
Agosto 2016 – propuesta de medidas de control

Febrero 2017 – adopción de medidas de control

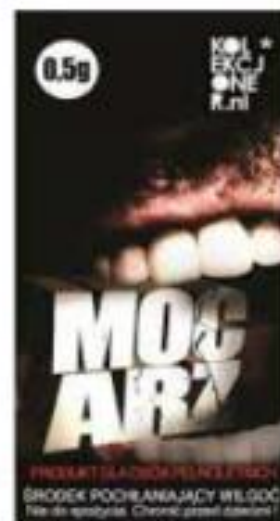
dosis de como máximo 1 miligramo
40 millones de dosis individuales!!!



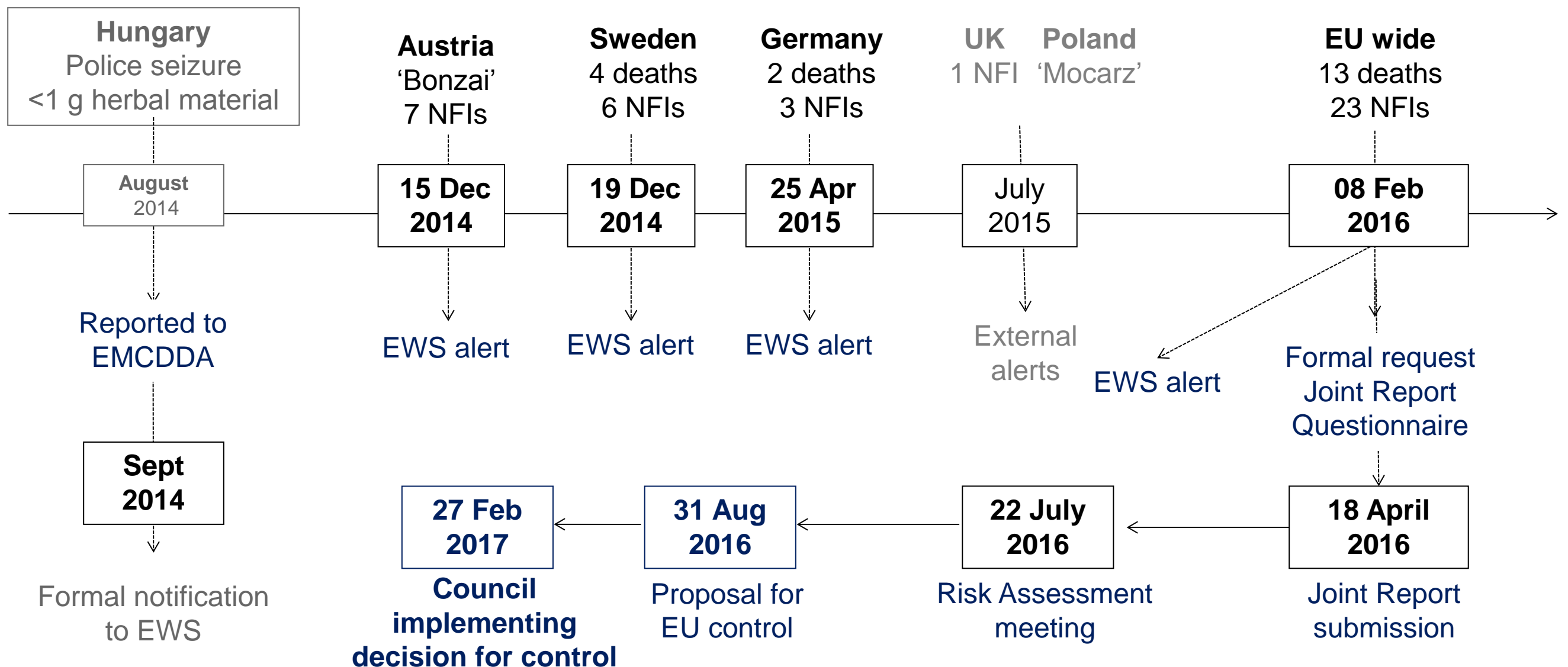
Sensibilización y mejora de la salud pública



- A través del **sistema de alerta temprana** se emitieron 4 alertas dirigidas a profesionales de los Estados Miembros (fuerzas del orden, personal sanitario, organizaciones no gubernamentales, usuarios, etc.)
- La **evaluación de riesgos** permite conocer la farmacología y toxicidad de la sustancia, así como los riesgos que entraña su consumo.
- Las **medidas de control** regulan el tráfico y uso de esta sustancia no sólo a nivel europeo sino también de los Estados Miembros.



MDMB-CHMICA timeline



The biggest single seizure on MDMB-CHMICA was reported in December 2014 by **Luxembourg: 40 kg of white powder packed in 1 kg packages** were seized in Dec 2014 by the Customs at Luxembourg Airport (Cargo). The product was on transit: the origin of the 2 barrels was China (Shanghai) and the destination was Spain (Madrid).

Responding to NPS causing concerns

- Toxicovigilance system
- Signal Management system
- Risk Communication system
- **Risk Assessments**

Toxicovigilance

The active process of detecting, reporting, evaluating, understanding, monitoring and responding to adverse events associated with new psychoactive substances

In the context of early warning it focuses on serious adverse events...

Prioritisation: which substances should we react to?

Signal management system

Signal management is a stepwise process covering six steps; it begins with the detection of a signal and ends with a recommendation for action that details how we should react to the signal.

1. detection
2. validation
3. analysis
4. prioritisation – which substances should we react to?
5. assessment
6. recommendation for action

Recommendations for action

- Awareness
- Intensive monitoring (solicited reporting)
- Risk communication (push and pull of information)
 - Formal notifications
 - **Alerts**
 - **Advisories**
 - Briefings
- **Joint Report**

Substances of Concern – monitoring and responding to harms

Public health alerts issued by the EMCDDA in 2015:

- Deaths associated with the use of potent opioids
- Clusters and outbreaks of intoxications associated with cannabinoids
- Seizures of ecstasy tablets containing 4-CMA
- Deaths associated with PMMA sold as ecstasy and heroin sold as cocaine

• **Public health alerts issued in 2016 included:**

- Serious adverse events associated with the use of cannabinoids
- Deaths associated with the use of potent opioids
- Superman logo ecstasy tablets containing PMMA

• **Public health-related advisories were also issued in 2016:**

- Fatty acid amide hydrolase (FAAH) inhibitors;
- Ocfentanil sold as heroin
- Cocaine containing scopolamine and associated intoxications

Joint Report — the next stage of early warning

1. Evidence of intoxication or fatalities = serious adverse events
2. **Toxicopharmacological properties** of the new psychoactive substance or analogy with better-studied compounds
3. Amount of seized material
4. Evidence of the **potential for further (rapid) spread**
5. Evidence of **international trafficking**
6. Evidence of **organised crime** involvement

Based on the Joint Report the Council may request a **risk assessment** of the health and social risks

Risk assessments

A) Physical, chemical, pharmaceutical and pharmacological information

B) Dependence and abuse potential

D) Health risks

E) Social risks

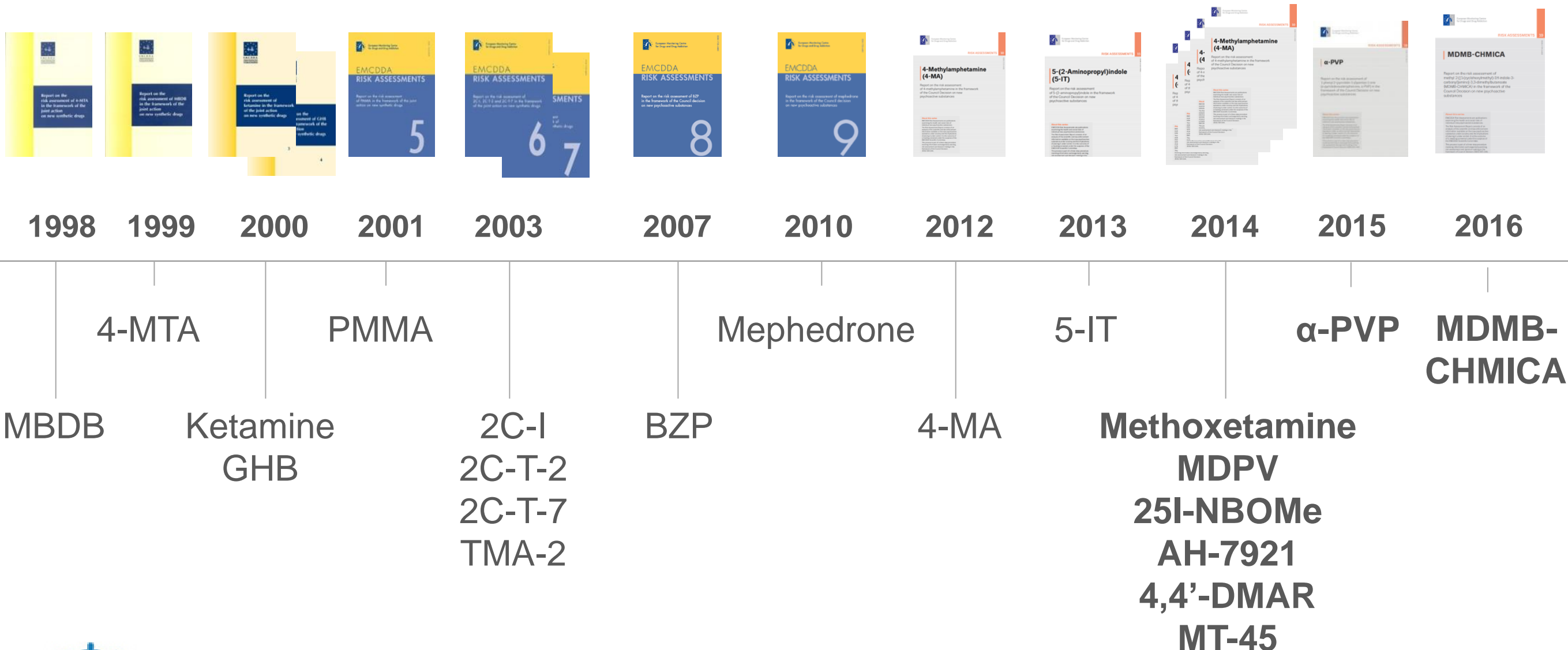
F) Involvement of organised crime

C) Prevalence level

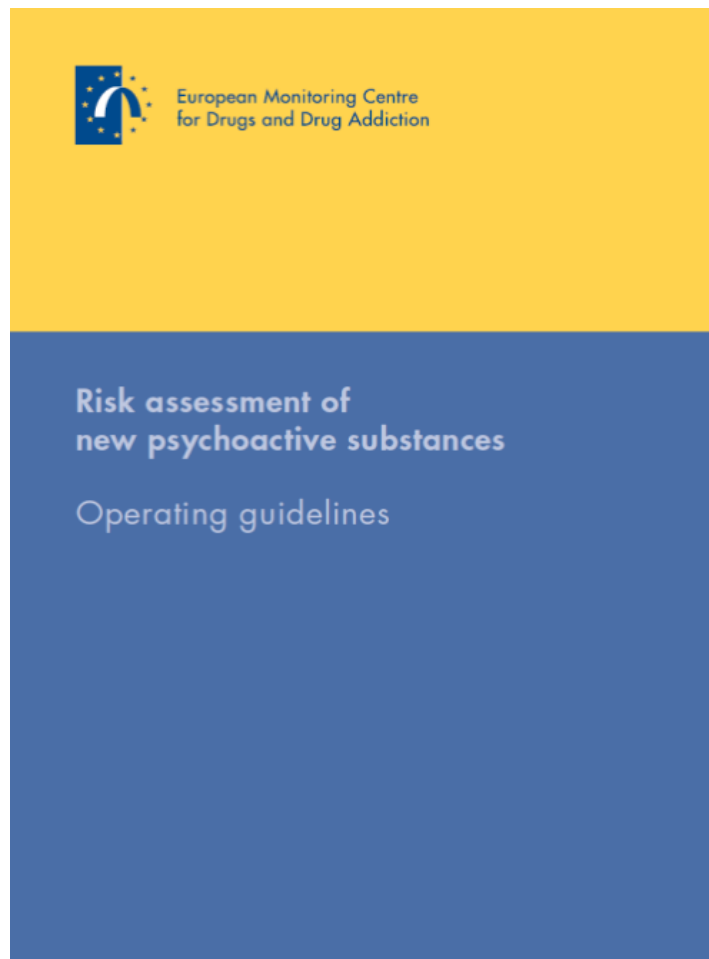
Little evidence available

Semi-quantitative assessment procedure – risks relative to other substances

Risk assessments

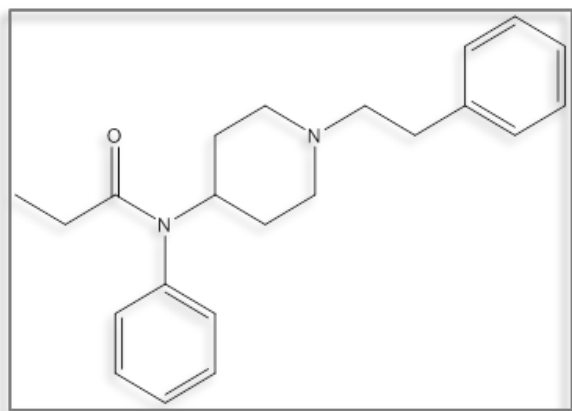


Risk assessments 2017



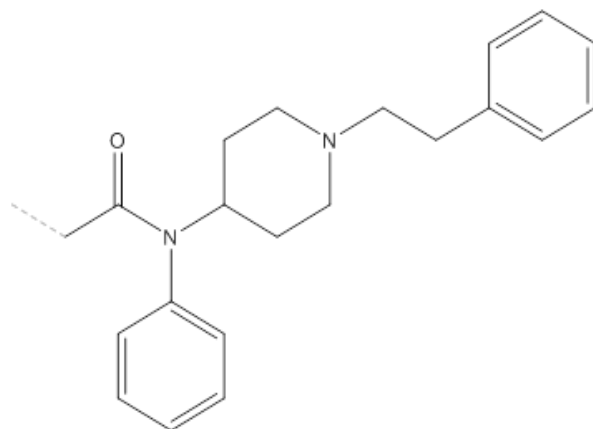
1. **Acryloylfentanyl** asociado con 42 muertes
2. **Furanylfentanyl** asociado con 19 muertes
3. **AB-CHMINACA**
4. **ADB-CHMINACA**
5. **5F-MDMB-PINACA**
6. **CUMYL-4CN-BINACA**
7. **4-Fluoroisobutyrylfentanyl (4F-IBF)**
8. **Tetrohydrofuranylfentanyl (THF-F)**
9. **Carfentanil**

Fentanyl derivatives



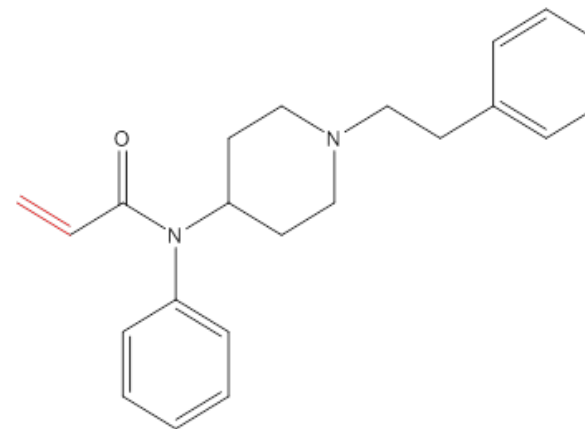
Fentanyl

- Internationally controlled Schedule I, of the Single Convention on Narcotic Drugs of 1961



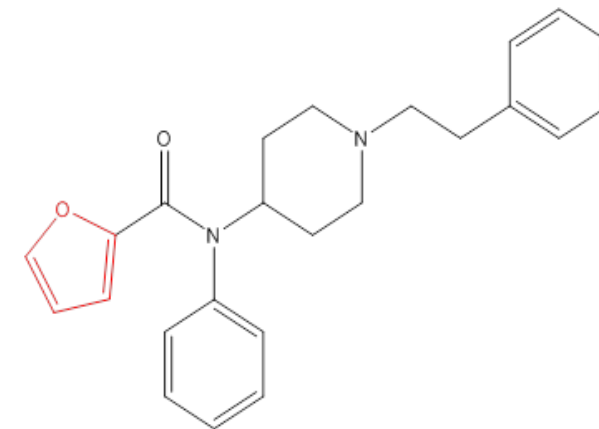
Acetylfentanyl ('AF')

- Joint Report (2015)
- Internationally Controlled (2016) Schedule I, of the Single Convention on Narcotic Drugs of 1961)



Acryloylfentanyl ('ACF')

- Joint Report (2016)
- Risk Assessment (2017)



Furanylfentanyl ('FU-F')

- Joint Report (2017)
- Risk Assessment will be completed in 2017

Bajo control internacional: Fentanyl and 14 fentanyl derivatives are controlled under the Single Convention on Narcotic Drugs of 1961 – acetyl- α -methylfentanyl, *acetylfentanyl*, alfentanil, *butyrfentanyl*, α -methylfentanyl, α -methylthiofentanyl, β -hydroxyfentanyl, β -hydroxy-3-methylfentanyl, 3-methylfentanyl, 3-methylthiofentanyl, para-fluorofentanyl, remifentanil, sufentanil and thiofentanil.

23 fentanyl derivatives have been reported to the EMCDDA EWS since 2012 that are not internationally controlled



Fentanils: why are they important?

- Sold as 'legal' replacements to illicit opioids, but also...
- Sold as heroin, cocaine, fake medicines
- Highly potent
- Disposable (appear, controlled, replaced)
- ↑↑ availability — ↑↑ open manufacture, open sale
- ↑↑ sales on surface web, ↑↑ sales on darknets
- ↑↑ sales of ready-to-use nasal sprays and e-liquids
- Life-threatening respiratory depression
 - ↑↑ outbreaks of poisonings, including deaths
 - Outbreaks have potential to overwhelm emergency responders/ERs and deplete naloxone supplies
- Users have no experience with using new opioids and their effects



© Georgia Bureau of Investigation





Naloxone works with fentanils, but...

- Clinical and community experience in treating poisonings suggests that larger than normal doses as well as repeated doses may be required
- In the past two years a number of outbreaks of poisoning caused by fentanils have been reported in the United States and Canada
- Outbreaks can overwhelm emergency departments and deplete stocks of naloxone
- Stocks and availability of the naloxone, as well as adequacy of training in how to resuscitate poisoned patients both in clinical and community settings may need to be assessed
- Availability of naloxone to users through community and take-home naloxone programmes?



Accidental exposure in others...

- Fentanils pose a risk of poisoning to those who may come into contact with them
- Family and friends of users, law enforcement, emergency personnel, as well as medical and forensic laboratory personnel
- Extreme caution when handling materials suspected to contain fentanils
- Working environments and personnel should be equipped with appropriate protective equipment
- Antidote naloxone should be readily available to personnel in sufficient quantities; training in naloxone administration and resuscitation should also be available
- Responses should allow delivery of appropriate treatment without delay to patients with suspected ODs

FENTANYL EXPOSURE PREVENTION FOR EMERGENCY RESPONDERS

To manage the low risk of occupational fentanyl and fentanyl analog exposure, take these precautions. You cannot get sick just from being in the same room as the drug. Fentanyl and its analogs are unlikely to be in the air and are not absorbed well through skin.

PREVENTION



Gloves

Always wear nitrile gloves to prevent skin exposure to fentanyl or its analogs.



Goggles and/or Mask

In the unlikely event that there is opioid in the air, wear a N95 mask. If you are worried about splash, wear goggles.

TREATMENT



Wash

If suspected fentanyl or analog gets on your skin, wash it off with water.



Naloxone


Give naloxone (Narcan[®]) only if someone has objective signs of poisoning - decreased or absent breathing.



Communicating risk to users and public


- **Evidence base for risk communications to users and general public is poor**
 - Beware of boomerang effects
 - Avoid unintended promotion of the substances
 - Terms such as 'potent', 'strong', 'deadly', and 'toxic' can lead to users actively seeking fentanils (or any opioid)
 - Concerns over promotion to former users and new user groups

1041

 European Monitoring Centre
for Drugs and Drug Addiction

**Risk assessment of
new psychoactive substances**

Operating guidelines



European Monitoring Centre
for Drugs and Drug Addiction

RISK ASSESSMENTS

α-PVP

Report on the risk assessment of
1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one
(α-pyrrolidinovalerophenone, α-PVP) in the
framework of the Council Decision on new
psychoactive substances

About this series

EMCDDA Risk Assessments are publications examining the health and social risks of individual new psychoactive substances.

The Risk Assessment Report consists of an analysis of the scientific and law enforcement information available on the new psychoactive substance under scrutiny and the implications of placing it under control. It is the outcome of a meeting convened under the auspices of the EMCDDA Scientific Committee.

This process is part of a three-step procedure involving information exchange/early warning, risk assessment and decision-making in the framework of Council Decision 2005/387/JHA.

The cover features the European Monitoring Centre for Drugs and Drug Addiction logo at the top left, which includes a stylized 'e' and 'm' inside a blue square. Below the logo, the title 'New psychoactive substances in Europe' is prominently displayed in a large, bold, black sans-serif font. Underneath the title, a subtitle reads 'An update from the EU Early Warning System' followed by the date 'March 2015'. The bottom of the cover is decorated with four small, square images: a row of glass bottles, a collection of various pills and capsules, a close-up of a white pill, and a pile of colorful, patterned pills.

emcdda.europa.eu