European Monitoring Centre
for Drugs and Drug Addiction

EMCDDA and the EU actions on new drugs

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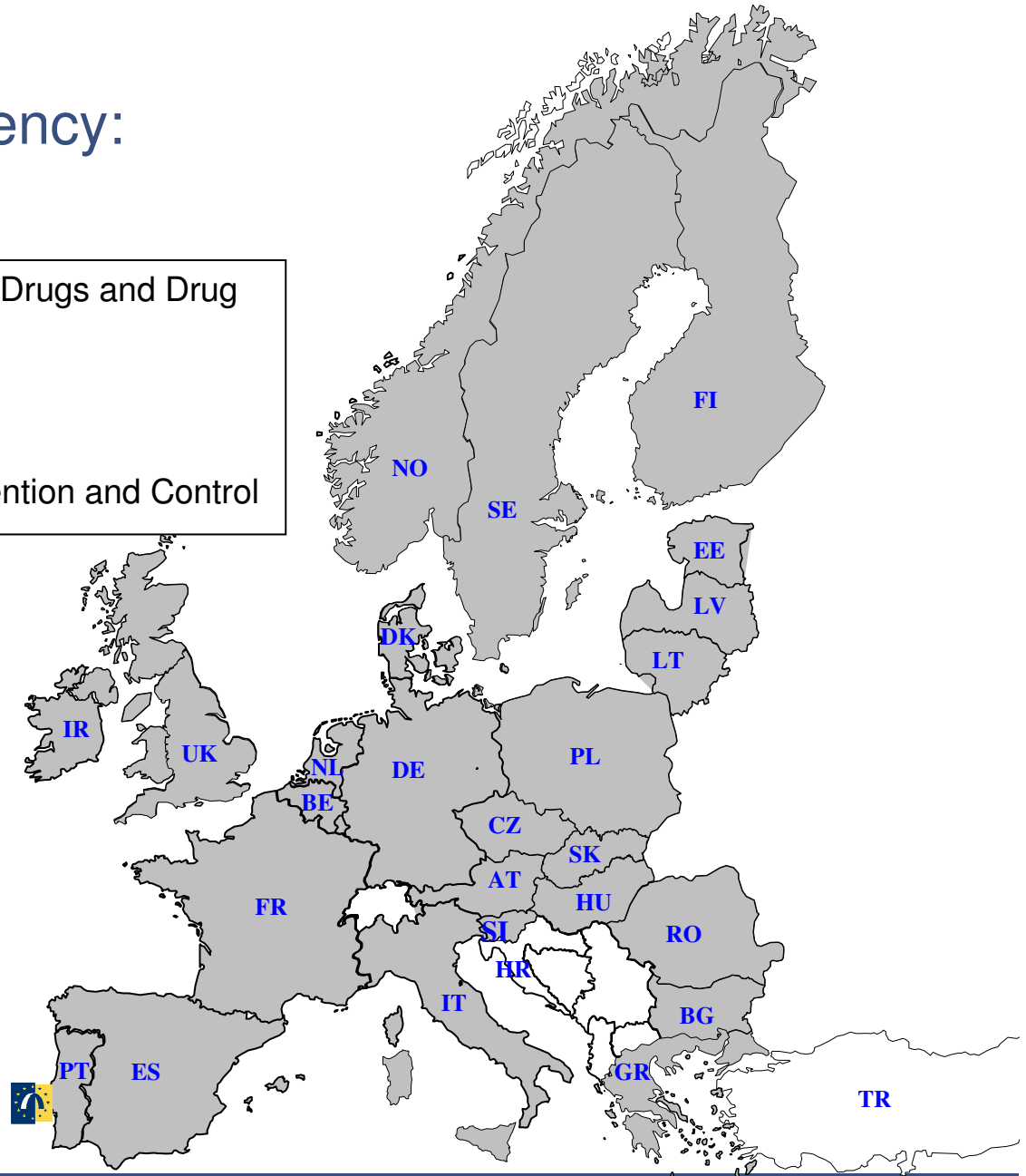
EMCDDA the EU drugs agency: data (EWS) coverage

EMCDDA – European Monitoring Center for Drugs and Drug Addiction, Lisbon

Two sister agencies
EMEA – European Medicines Agency
ECDC – European Centre for Disease Prevention and Control



EMCDDA monitoring fields

- 5 key epidemiological indicators
  - Prevalence & patterns of drug use in the general population
  - Prevalence & patterns of problem drug use
  - Drug-related infectious diseases (HIV, HCV, HBV)
  - Drug-related deaths and mortality of drug users
  - Demand for drug treatment

- Core data situation
  - Crime and market/supply/availability
  - Youth and school surveys (incl. ESPAD)

- Action on new drugs
  - Early-warning system on new psychoactive substances
  - Risk assessment of new psychoactive substances
  - Emerging trends: European-perspectives on drugs (E-POD)

- Core data responses
  - Prevention (EDDRA), treatment, rehabilitation, harm reduction
  - National and Community strategies
  - National and Community legislation (ELDD)

EU actions on new drugs: legal base

- June 1997 – May 2005

Joint Action of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs (NSD).

- May 2005 – present

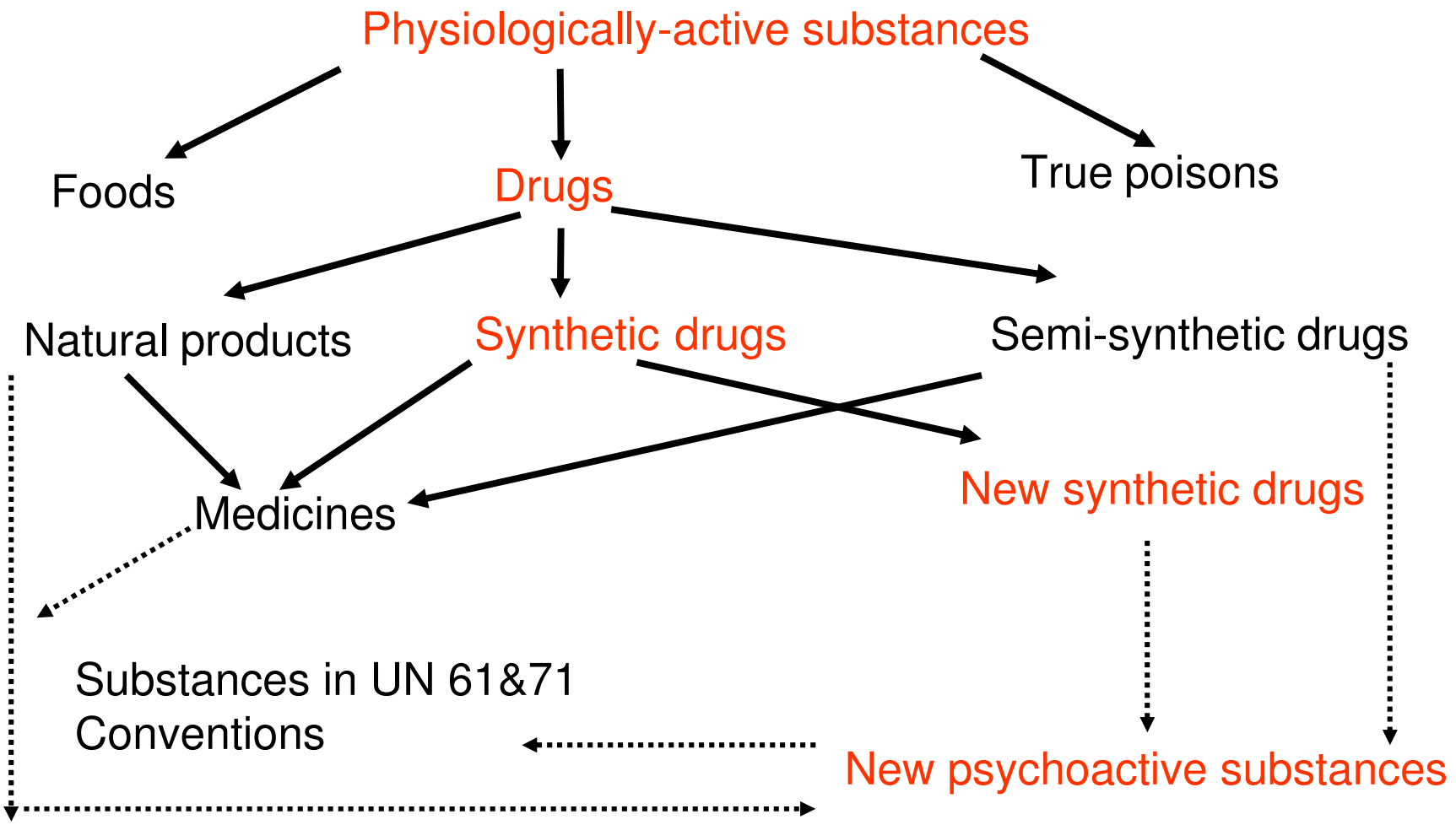
Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk assessment and control of new psychoactive substances (NPSA).

Council Decision 2005/387/JHA: scope and provisions

Council Decision 2005/387/JHA concerns NPAS:

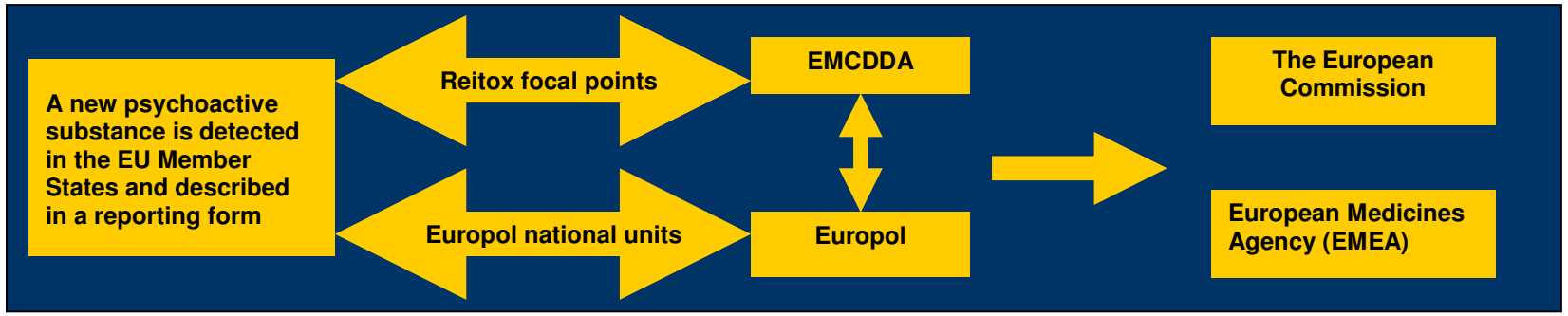
- new psychotropic and new narcotic drugs (synthetic and natural alike) similar to those listed 1961 & 1971 UN Conventions, i.e. natural and synthetic alike;
- may include preparations containing NPAS;
- end products (excluding precursors);
- may include medicinal products as defined in Directive 2001/82/EC and in Directive 2001/83/EC but substances of established and acknowledged medical value are excluded from control measures based on the Decision, i.e. medicinal products and API are in the scope of the info exchange only;
- stimulates exchange of information on misused psychoactive medicines and on emerging trends in new uses of existing substances;
- maintains the three steps - EWS, risk assessment, decision-making.

Scope of the substances covered



Council Decision 2005/387/JHA: a three-step process

Information exchange/Early-warning



Risk assessment

Decision-making

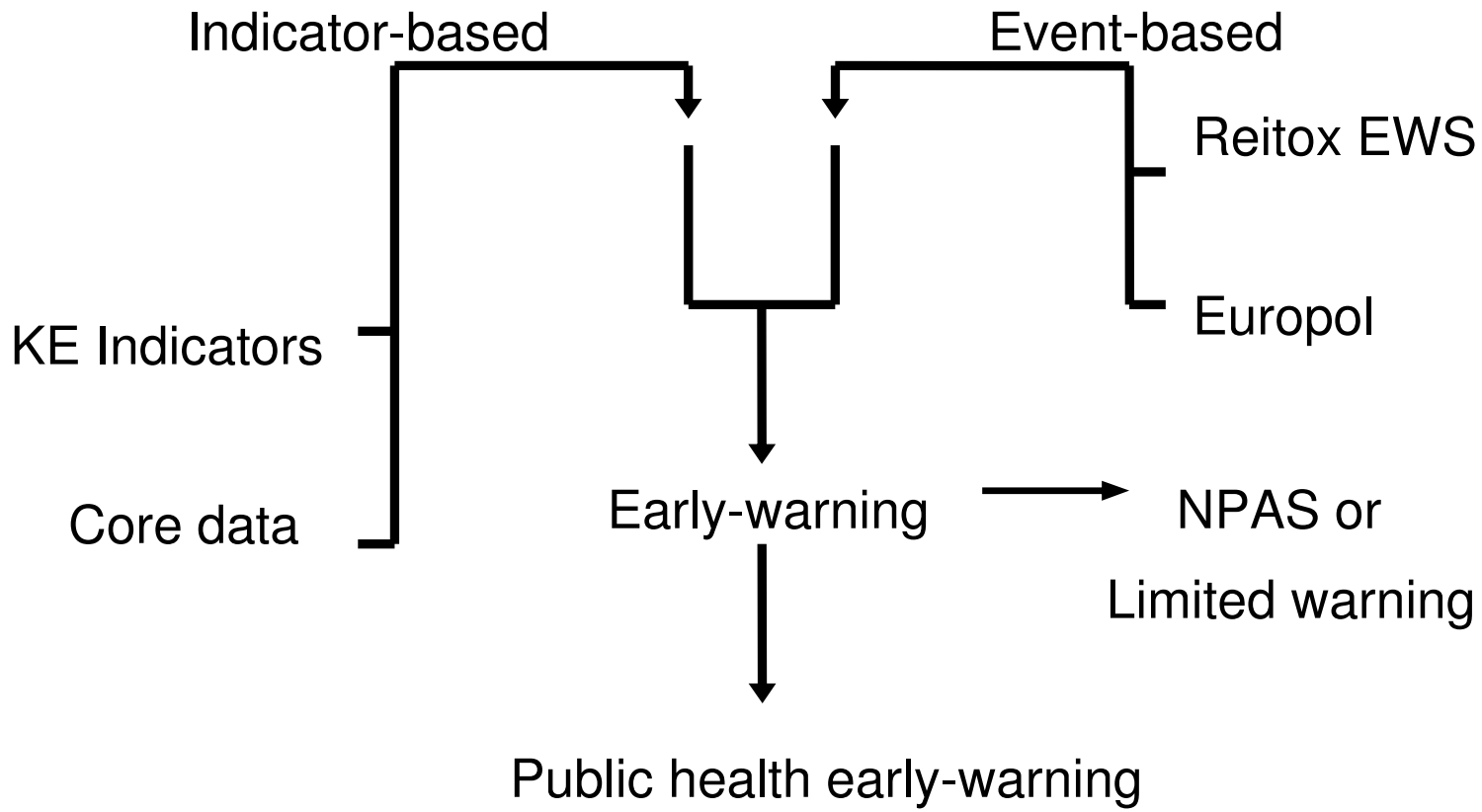
EWS as a public health notion

- EWS aims to detect a significant risk to public health and to inform relevant authorities as quickly as possible

  For example, the second pillar of the communicable disease network is an early warning and response system to alert public health authorities in MS and the Commission on outbreaks with greater than national dimensions, so that coordinated EU action may be taken (now ECDC).

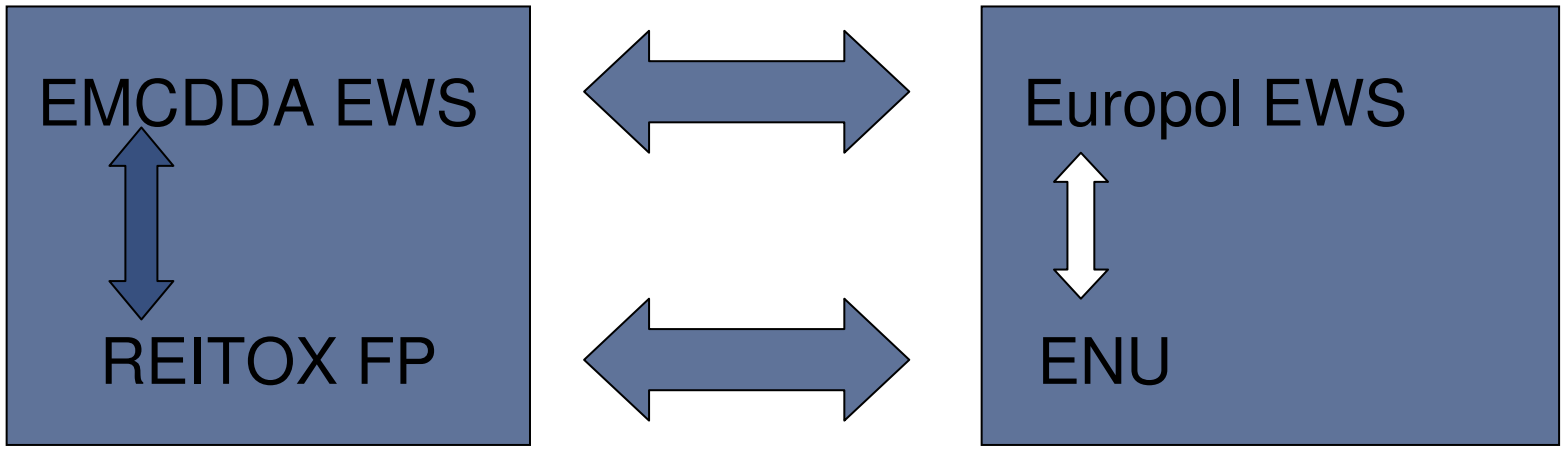
- Existing EWSs cover specific areas, according to the type of threat – this approach may lead to a situation where some very relevant threats to public health are not fully covered

Early-warning system: sources and response



Adapted from R. Kaiser at al., 2005

EWS: a truly multidisciplinary effort



- EWS is a combination of rapid exchange, collection and appraisal (input - analysis/validation - output) of information over a short period of time

- The EWS allows for longer-term monitoring of substances and trends in (new) synthetic drugs

EWS information

Primary data on new psychoactive substances

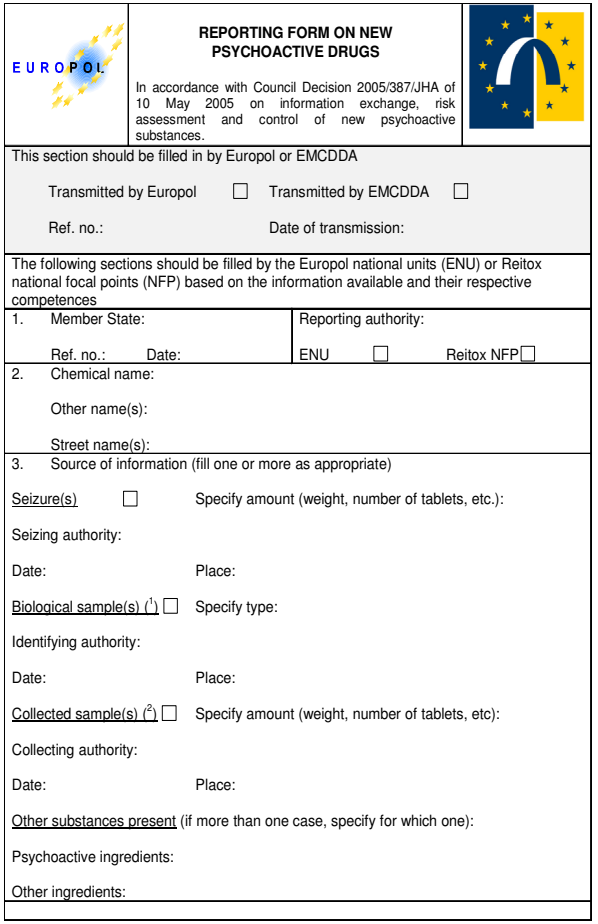
- use, traffic and manufacture: chemical and physical description, names, frequency and circumstances, means and methods, organised crime, first indications of health and social risks
- technical information (analytical data and spectra)
- scientific literature

Tools

- reporting form
- progress reports (longer-term monitoring)
- joint report
- active monitoring

Public-health related information/health alerts

- unusual adulterants
- seizures or detections of uncommon scheduled drugs
- Problems with established drugs, e.g. dosage units (tablets, etc.) containing unusually large amounts of active substance, etc



EUROPOL

REPORTING FORM ON NEW PSYCHOACTIVE DRUGS

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

This section should be filled in by Europol or EMCDDA

Transmitted by Europol ☐ Transmitted by EMCDDA ☐

Ref. no.: Date of transmission:

The following sections should be filled by the Europol national units (ENU) or Reitox national focal points (NFP) based on the information available and their respective competences

1. Member State: | Reporting authority:

Ref. no.: Date: | ENU ☐ Reitox NFP ☐

2. Chemical name:

Other name(s):

Street name(s):

3. Source of information (fill one or more as appropriate)

Seizure(s) ☐ Specify amount (weight, number of tablets, etc.):

Seizing authority:

Date: Place:

Biological sample(s) (1) ☐ Specify type:

Identifying authority:

Date: Place:

Collected sample(s) (2) ☐ Specify amount (weight, number of tablets, etc):

Collecting authority:

Date: Place:

Other substances present (if more than one case, specify for which one):

Psychoactive ingredients:

Other ingredients:

(1) Biological (human) samples e.g. body fluids (urine, blood), tissues, hair, etc.
(2) Actively collected by drug monitoring systems for monitoring or research purposes

Identification of NPAS

A substance seen before:

- If reported in another member state *or*
- Described in scientific literature *then*
- Analytical details can be circulated *and*
- Reference samples can be produced

A substance never seen before:

- For powders and tablets then the only efficient method of identification is Nuclear Magnetic Resonance Spectroscopy (NMR)

Characteristics of EWS (and related information)

At national level

- Clear objectives and case definition (i.e. balance between specificity and sensitivity)
- Coverage - national, regional, local, city, etc.
- Pro-activity vs. reactivity
- Integration of sources
- Validity – the data is true and certain (backed by evidence)
- Reliability – consistent and replicable over time
- Comparability
- Usefulness of information
- Emergency and routine functions
- Ethically correct

Main sources of EWS-related information at national level

- **Heath and care system:** specialised and non-specialised treatment centres, hospitals' emergency rooms, psychiatric departments, low threshold, outreach and street-work agencies, drug prevention centres, drug help lines, GPs, etc.

- **Law enforcement agencies:** police, specialised drug units, customs, prosecution authority, border guards, etc.

- **National medicines agencies** and the national pharmacovigilance systems

- **Laboratory networks:** forensic analysis of seized drugs, toxicological analyses of specimens from deceased persons or analyses of blood and urine samples from living individuals

- **Universities and research** establishments, scientific publications and grey literature in national languages

- **Key informants:** users, organisers of youth venues (concerts, raves, etc.), owners and staff of night clubs, cafés, etc.

- **Media and internet** (discussion groups and forums) etc.

Risk assessment: headings

- Description
  - physical and chemical
  - mechanism of action
  - medical value
- Health risks
  - pharmacotoxicological evidence
  - psychological risk assessment
  - public health risks – epidemiological evidence
- Social risks
  - sociological evidence
  - criminological evidence
- Involvement of organised crime
- Options for control and possible consequences
- Chemical precursors

Risk assessment on new synthetic drugs 1998-2003

MBDB	N-methyl-1-(1,3-benzo-dioxol-5-yl)-2-butanamine (1998)
4-MTA	4-methylthioamphetamine (1999)
ketamine	2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone (2000)
GHB	gamma-hydroxybutyrate (2000/2001)
PMMA	para-methoxymethamphetamine (2001)
2C-I	2,5-dimethoxy-4-iodophenethylamine (2003)
2C-T-2	2,5-dimethoxy-4ethylthiophenethylamine (2003)
2C-T-7	2,5-dimethoxy-4-(n)-propylthiophenethylamine (2003)
TMA-2	2,4,5-trimethoxyamphetamine (2003)

New substances notified in 2007

1. **2C-B-FIy** (8-bromo-2,3,6,7-benzo-dihydro-difuran-ethylamine) – 15 February 2007 – Finland

2. **5-MeO-Dalt** (N,N-diallyl-5-methoxytryptamine) – 15 February 2007 – Finland

3. **N-ethyl-2C-B** (N-ethyl- 4-Bromo-2,5-dimethoxybenzeneethanamine) – 22 February 2007 – Finland

4. **Vanoxerine** (1-[2-[bis(4-fluorophenyl)methoxy]ethyl]-4-(3-phenylpropyl)piperazine) – 3 May 2007 – Belgium

5. **D2PM** ((S)-(-)-α,α-Diphenyl-2-pyrrolidinylmethanol) –11 May 2007 – United Kingdom

6. **N-Acetyl-DOB** (N-Acetyl-4-bromo-2,5-dimethoxyamphetamine) – 11 June 2007 – United Kingdom

7. **Glaucine** ((6aS)-1,2,9,10-tetramethoxyaporphine) – 2 July 2007 – United Kingdom

4-MTA (4-methylthioamphetamine) – 5 June 2007 – France

New substances notified in 2007 (cont.)

8. **Fenazepam** (7-brom-5/o-chlorphenyl/1,2-dihydro-3H-1,4-benzodiazepin-2-on) – 1st half 2007 – Finland

9. **Harmine** (7-Methoxy-1-methyl-9H-pyrido[3,4-b]indole) – 1st half 2007 – Finland

10. **Bufotenine** (3-(2-dimethylaminoethyl)-1H-indol-5-ol) – 1st half 2007 – United Kingdom

11. **Salvia Divinorum** – 1st half 2007 – United Kingdom

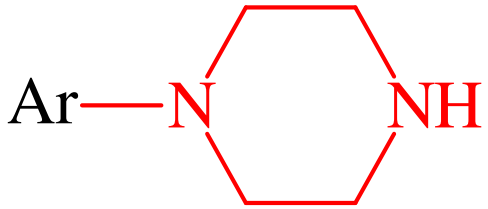
12. **1-PEA** (1-Phenylethylamine) – 1st half 2007 – United Kingdom

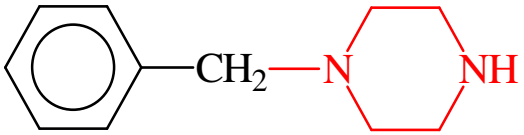
13. **Nimetazepam** (2-methyl-9-nitro-6-phenyl-2,5-diazabicyclo[5.4.0]undeca-5,8,10,12-tetraen-3-one) – 1st half 2007 – United Kingdom

14. **Gelbes** 1-(3-chlorophenyl)-4-(3-chloropropyl)piperazine – Austria

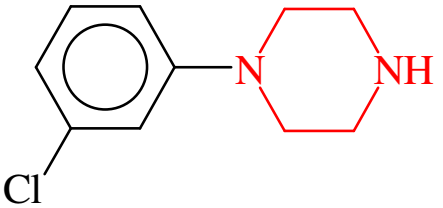
15. **NMPEA** (N methyl phenylethylamine) – 6 December 2007

N-Arylpiperazines: Structures

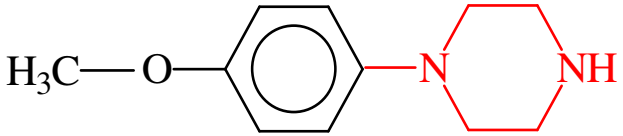




Benzylpiperazine (BZP)



m-Chlorophenylpiperazine (CPP)



p-Methoxyphenylpiperazine (MeOPP)

All reported in EU as NSD/NPAS

m-Chlorophenylpiperazine (mCPP): dosage units

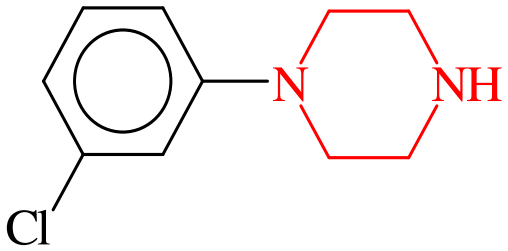






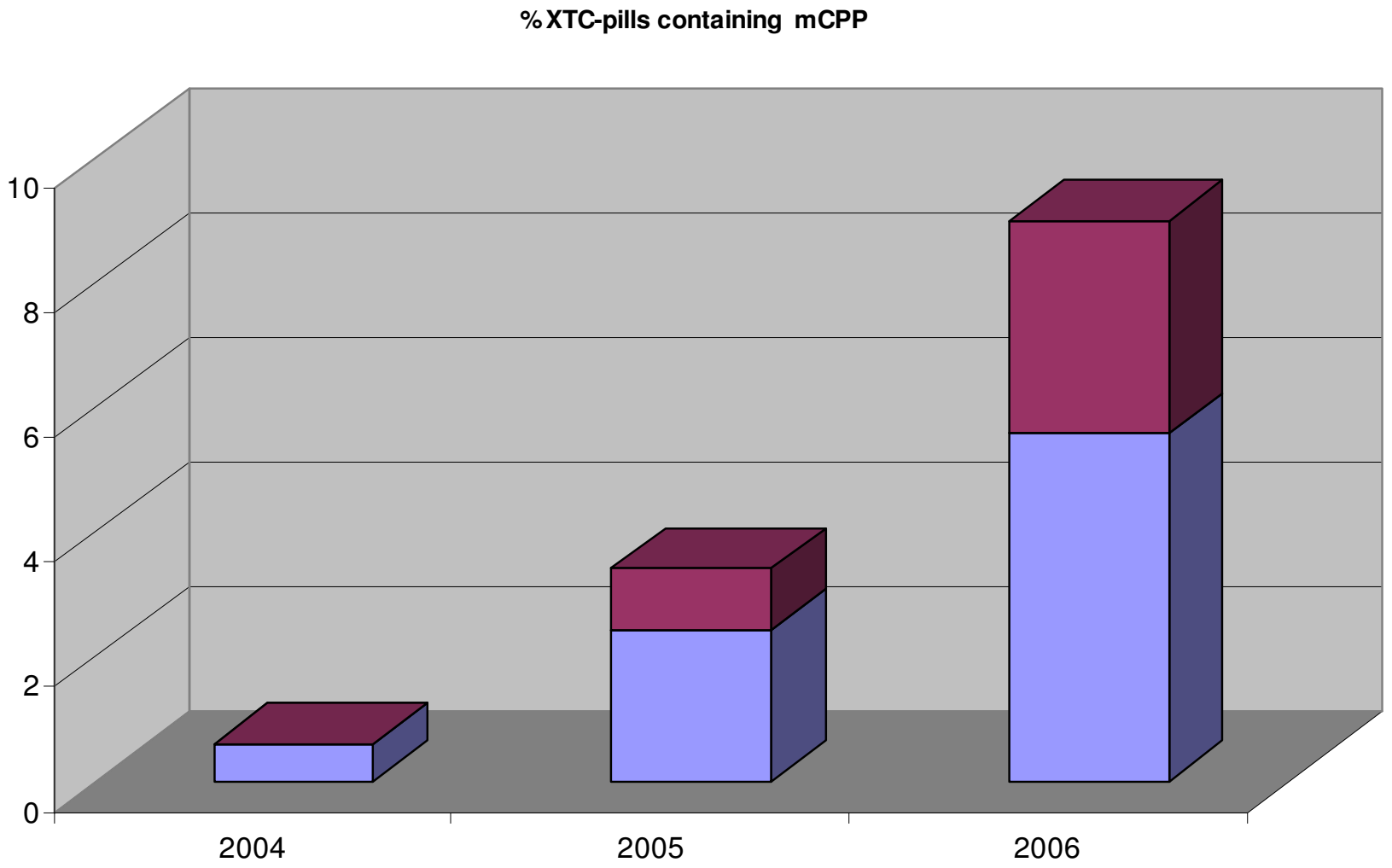
Tablets known in different European countries as: X4' (Netherlands, Sweden), 'duhovka' (Hungary, Czech Republic), 'regenboogies', 'arc-en-ciel' (Belgium), 'arlequin' (France), 'rainbow' (Slovenia), Rolls Royce', 'smarties' (Switzerland)

m-Chlorophenylpiperazine (mCPP)



- Reported in all Member States since 2004
- Usually as tablets (8 - 80mg mCPP), some powders
- Sometimes mixed with MDMA in dosage units
- A mixed agonist and antagonist at 5HT receptors
- Little reaction with dopaminergic system
- Widely used in experimental human pharmacology
- Intoxications resemble the ‘serotonin syndrome’
- Not neurotoxic
- No major impairment of cognitive functions
- Little potential for dependence
- No fatal poisonings reported
- Commercially available
- Ortho- and para-CPP isomers also occur

DIMS – Trimbos institute

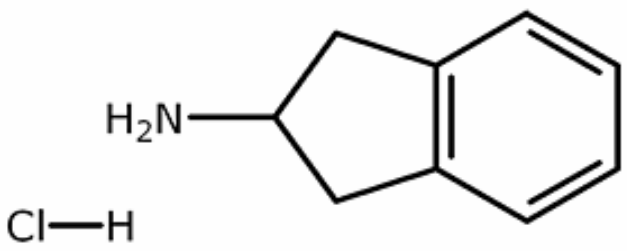


Risk assessed in 2007: 1- benzylpiperazine (BZP)

First notified via the EWS in 1999, but its emergence as a recreational drug with potential for spread in Europe lay relatively latent until the second half of 2004. In the last two years, BZP-containing products are aggressively marketed by various retailers as a legal alternative to ecstasy, but clearly specified as piperazine products, often erroneously or intentionally misrepresented as ‘natural’ or ‘herbal’. On the illegal drugs market, BZP may also be sold/bought as the popular drug ecstasy.

EWS monitors new groups (examples)

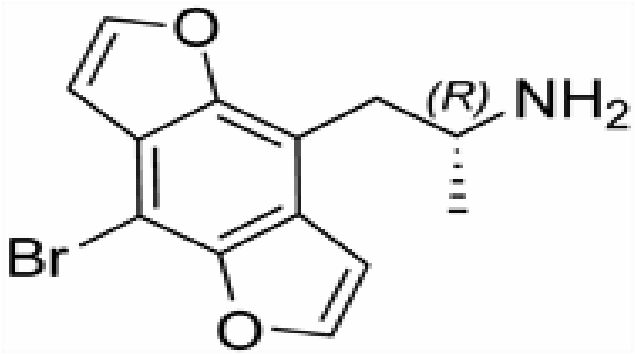
Aminoindans



2-aminoindan

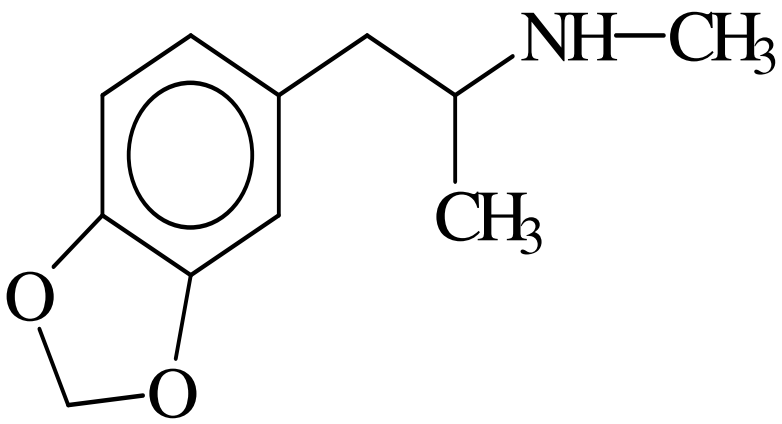
1H-Inden-2-amine, 2,3-dihydro

Benzodifuranyls



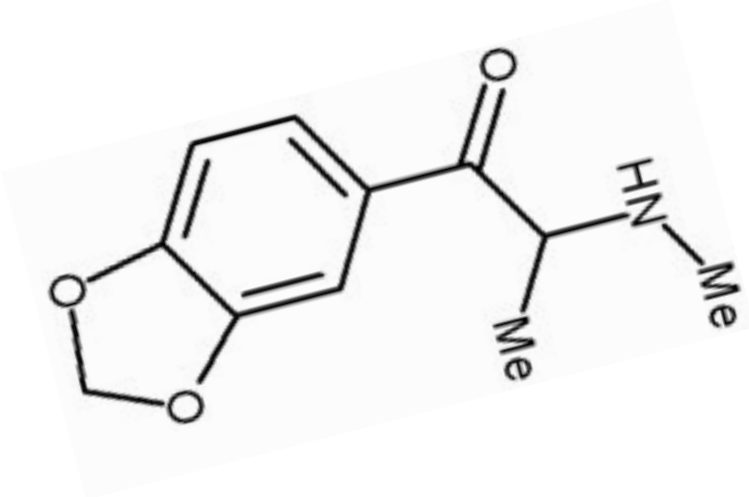
Bromo-dragonfly
Bromo-benzodifuranyl-isoprophylamine
1-(8-brombenso[1,2-b;4,5-b']difuran-4-yl)-2-aminopropane

EWS monitors new groups: methylone (MDMCAT)



3,4-methylenedioxymethylamphetamine

The benzylic ketone derivate of MDMA – can be described as ring-substituted cathinone



3,4-methylenedioxymethcathinone
2-methylamino-1-[3,4-methylenedioxyphenyl]propan-1-one

Challenges

- Internet sales
- New unanticipated chemicals, plants, medicinal products
- Reference materials (seized substances or reference substances)
- Risk assessment guidelines
- Beyond the legal scope of the Council Decision (cannabis, cocatropine, Fentanyl)
- New trends identification and monitoring (GHB, ketamine, MA,)

Contacts

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