

Produktmeldungen in Frankreich Mixture notification in France

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French National Product Database (B.N.P.C.)



Product notification : Target & purpose 1/3

■ Risk assesment

- In case of exposure : acute, but also sub-acute & chronic

According to article D6141-37, French Health Regulation

- To exclude medical care :

- 84 % of assessed risk : null or low risk level !

- Only possible with full qualitative / quantitative known formulation

- Medical care = f (hazard, patient, route...)

- Medical discharge



Product notification : Target & purpose 2/3

■ Toxicovigilance

- Prevention
 - Occupationnal
 - General population
- Human exposures & poisoning description, epidemiology
- Track & watch
- Event detection : data mining --> "real time" alert
- [Fundamental improvement of human toxicology knowledge]

Product notification : Target & purpose 3/3

■ According to the CLP regulation...

Article 45

Appointment of bodies responsible for receiving information relating to emergency health response

1. Member States shall appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response, from importers and downstream users placing mixtures on the market. This information shall include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency, in accordance with Article 24.

2. The appointed bodies shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used:

(a) to meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency;

and

(b) where requested by the Member State, to undertake statistical analysis to identify where improved risk management measures may be needed.

Commercial mixtures involved in exposures (1/2)

Categories	A & V		Accidental (n=140 482)		Voluntary (n=22 680)		With Symptoms (n=66250)	
	Exposures	N	%	N	%	N	%	
COMMERCIAL MIXTURES	135987	115869	85,2	20118	14,8	51961	38,2	
CHEMICAL SUBSTANCES & MINERALS	11247	9832	7,0	1415	6,2	7234	64,3	
VEGETAL	7178	6937	4,9	241	1,1	1947	27,1	
MUSHROOM	2080	2017	1,4	63	0,3	1511	72,6	
ANIMAL	1888	1881	1,3	7	0,0	1612	85,4	
FOREIGN BODY	1453	1400	1,0	53	0,2	343	23,6	
WASTE	1147	1115	0,8	32	0,1	541	47,2	
SUBSTANCE OF ABUSE	769	131	0,1	638	2,8	623	81,0	
DOPING AGENT	749	642	0,5	107	0,5	336	44,9	
PHYSICAL	664	658	0,5	6	0,0	142	21,4	
Total	163162	140482	102,7	22680	26,1	66250	40,6	

French Poison & Toxicovigilance centres Information System. 2012.

Commercial mixtures involved in exposures (2/2)

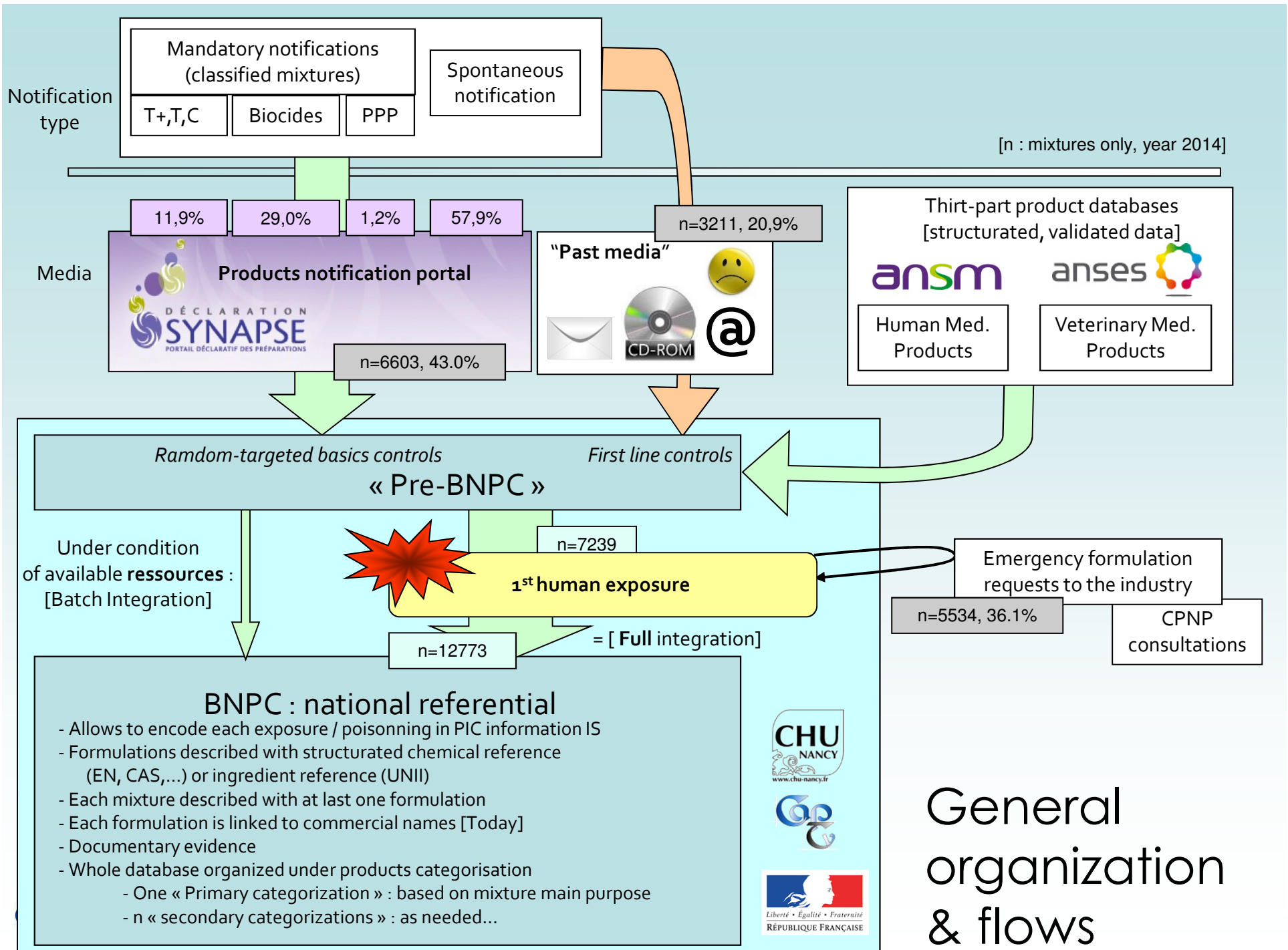
Categories	A & V	Accidental (n=140 482)		Voluntary (n=22 680)		With Symptoms (n=66250)	
	Exposures	N	%	N	%	N	%
COMMERCIAL MIXTURES	135987	115869	85,2	20118	14,8	51961	38,2
PHARMACEUTICALS	65906	49866	35,5	16040	70,7	231	0,4
GENERAL CLEANING AND DESCALING	33516	31869	22,7	1508	6,6	17010	50,8
COSMETIC PRODUCT	9797	9149	6,5	648	2,9	3266	33,3
FOOD AND DIETARY PRODUCT	7607	2864	2,0	4743	20,9	5537	72,8
PHYTOPHARMACEUTICAL	6501	5984	4,3	517	2,3	2662	40,9
FUEL / SOLVENT / LUBRICANT	3918	3651	2,6	236	1,0	2312	59,0
PARAPHARMACEUTICALS	3753	3641	2,6	112	0,5	1136	30,3
MATERIALS / BUILDING MATERIALS	3656	3579	2,5	61	0,3	2221	60,7
SPORTS / HOBBIES PRODUCTS	2296	2280	1,6	16	0,1	750	32,7
NON FOOD ADDITIVE	1724	1698	1,2	22	0,1	231	13,4
SCHOOL & OFFICE EQUIPMENT	1693	1633	1,2	60	0,3	389	23,0
AIR CONDITIONING / COOLING / HEATING MIXTURES	754	740	0,5	10	0,0	253	33,6
FOOD CONTACT MIXTURES	568	559	0,4	7	0,0	393	69,2
WEAPON / SELF-DEFENSE	420	247	0,2	173	0,8	370	88,1
MEDICAL PRODUCTS & ACCESORIES	384	361	0,3	23	0,1	203	52,9
MATERIALS / SURFACE TREATMENT	278	274	0,2	2	0,0	240	86,3
ELECTRIC / ELECTRONIC PURPOSE MIXTURES	170	160	0,1	9	0,0	99	58,2
FIRE-GUARD MIXTURE	168	137	0,1	30	0,1	131	78,0
WATER ADDITIVES & WATER TREATMENT	64	63	0,0	0	0,0	55	85,9
PRINTING & REPRODUCTION	53	53	0,0	0	0,0	27	50,9
LABORATORY REACTIVES & COLOURING	44	44	0,0	0	0,0	24	54,5
PHOTOGRAPHY	23	23	0,0	0	0,0	14	60,9
EMBALMING / TAXIDERMY	3	3	0,0	0	0,0	1	33,3



French health regulation pillars

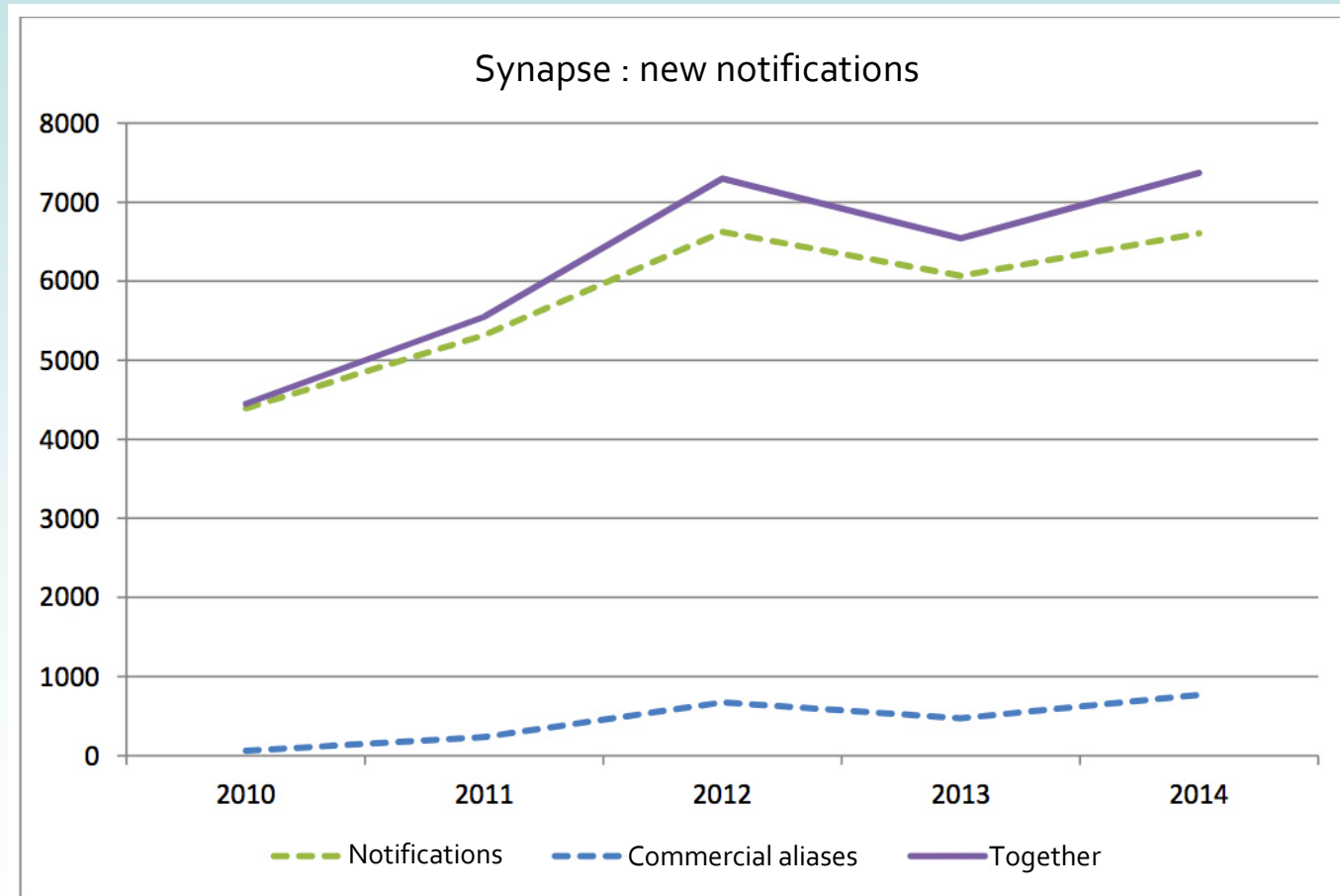
■ Article L 1341-1 << *Manufacturers, importers, downstream users of any substance or any mixture, notify, as soon as possible as they receive a request from the bodies in charge of toxicovigilance [Poison information centres] or from [National Institute of Research and Security for occupational exposures (INRS)] the usefull informations (...) for preventives and curative measures, in particular in medical emergency situation >>*

■ Article L1342-1 << *Importers or users downstream who place classified mixtures on the market notify all relevant informations on these mixtures, in particular their chemical composition. This notification is sent to the [Poison information centres and INRS] for preventive and curatives measures, in particular in medical emergency situation >>*



General organization & flows

Product notification : overview during 2014



Product notification : overview during 2014

Controlled BNPC reference	232932
Mixture	128243
Substances	93152
Categories	8961
Animals	218
Vegetals	1016
Mushrooms	220
Medical drugs category	1105
Articles	17

Controlled formulations 156937

Companies 8806

Aliases 75348

External references 213447

BNPC
General
situation
2014/12/31

Product notification : main actual issues

- Mixtures identification : label of the mixture [today]
 - Copy of the labels : obtaining, interpretation...
- Multiples products in one notification : “commercial aliases”
 - Poor temporal link between “main mixture” & its “commercial aliases”
- Mixture in Mixture (MIM)
 - Formulation not known by the compagny which place the final mixture on the market
 - Increase considerably the mixture notification management
- Notification content quality
 - Frequently occurring requests for further informations, precisions
 - First line correspondants : level of expertise
- Classical media still used to notify

Actual issues : « Mixture in mixture »

Notification including MIM (%), by year

Type	2010	2011	2012	2013	2014	Total
Other notification type					35,6%	35,6%
Biocide	43,8%	39,8%	46,8%	43,0%	37,9%	42,3%
Spontaneous notification	47,2%	46,2%	39,0%	44,9%	49,8%	44,3%
PPP				76,3%	54,4%	65,0%
T+, T, C	28,8%	24,0%	32,0%	24,3%	41,6%	29,1%
Total	41,2%	38,5%	39,9%	39,9%	40,2%	39,9%

MIM (n, total) in notification, by year

Type	2010	2011	2012	2013	2014	Total
Other notification type				1	3907	3908
Biocide	1337	1349	1598	1497	1232	7013
Spontaneous notification	1460	2610	3246	3094	3422	13832
PPP				61	50	111
T+, T, C	484	502	865	844	728	3423
Total	3281	4461	5709	5497	9339	28287

Average of MIM per notified mixture, by year

Type	2010	2011	2012	2013	2014	Total
Other notification type				1,0	4,5	4,5
Biocide	1,6	1,8	1,7	1,7	1,7	1,7
Spontaneous notification	2,1	2,7	2,5	2,8	4,9	2,9
PPP				1,0	1,2	1,1
T+, T, C	1,6	1,6	2,0	2,5	2,2	2,0
Total	1,8	2,2	2,2	2,3	3,5	2,4

Product notification : Perspectives & conclusion

- Risk assesment : depends not only on mandatory hazard classification
 - $f(\text{hazard, patient, route, circumstances...})$
 - Medical question
- Precises mixtures formulations are the first fondation level
 - For the patient : individual medical care
 - The best treatment (or no treatment !) to the right patient at the best time
 - For the population protection & public health :
 - Toxicovigilance, toxicosurveillance

Product notification : Perspectives & conclusion

- Huge notifications volume in the future :
 - Mixture identification questions strengthened
 - Should be resolved with the widest use of the UFI
 - Only random & targeted controls possible
 - Responsibility of the company which place the mixture on the market
 - To allow an acceptable risk assessment even for the first patient !

- European XML schema implementation !!
 - Signed / authenticated XML sent documents : built & sent by the right company
 - Guarantee of authenticity (medical decisions ++)
 - To allow to sent & receive notification between European PIC ?