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Investigate, evaluate, protect

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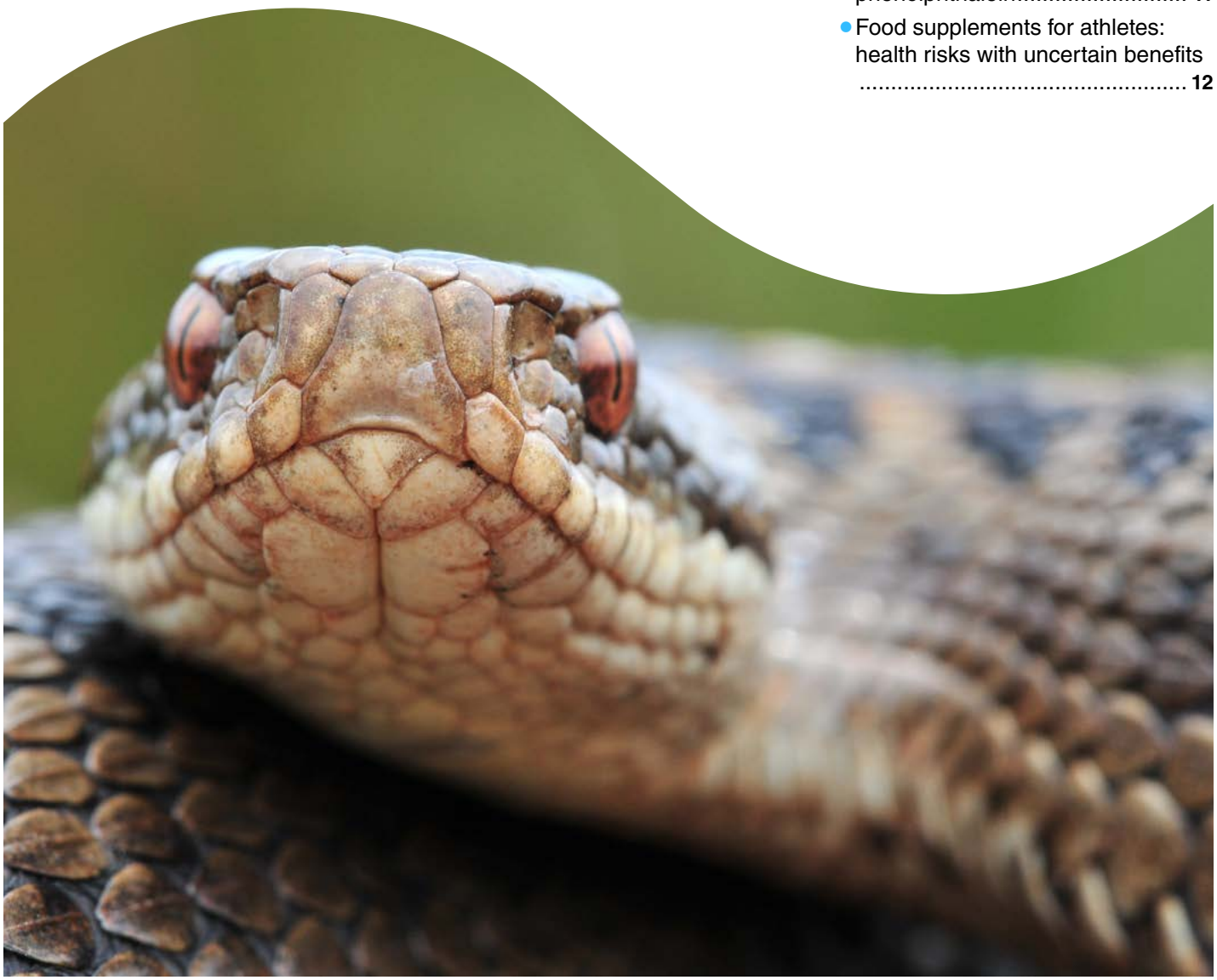


In recent years, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has been given responsibility for managing several vigilance schemes.
Four schemes are defined by law. Pharmacovigilance of veterinary medicinal products has been in place since 2002 and was entrusted to the French Agency for Veterinary Medicinal Products, itself a part of ANSES. The nutrivigilance scheme (What is nutrivigilance?) was created in 2009, under the French Act on Regional Health Governance (HPST), to identify risks associated with the consumption of food supplements, novel foods, fortified foods and beverages, or foods intended for specific populations. Phytopharmacovigilance, created by the Act on the future of agriculture, food and forestry of 13 October 2014 and entrusted to ANSES in July 2015 (Phytopharmacovigilance), works to detect as early as possible any signals that may require measures to be taken to prevent or limit the risks of plant protection products to living organisms and ecosystems, as well as the emergence of resistance. Toxicovigilance, which was previously the responsibility of the French Institute for Public Health Surveillance (InVS), was entrusted to ANSES in January 2016 by the Act on the modernisation of our health system. Essentially based on data from Poison Control Centres, it concerns the adverse effects of all agents that are not covered by other vigilance schemes, such as everyday products, agents found in the environment, and pollution phenomena. Lastly, ANSES also runs the National Network for the Monitoring and Prevention of Occupational Diseases (RNV3P), which groups together the occupational disease consultation centres and nine occupational health services. It is an invaluable tool for detecting emerging signals in occupational health.

While these vigilance schemes differ greatly in terms of their subject matter and the networks of experts they can call on, they also have many points in common. They are based on the routine collection of data or events, requiring specific analysis to identify a signal which, if confirmed, will trigger an alert and the necessary measures for early action, and ultimately prevention. Sometimes, a single event already constitutes an alert; in other cases, it is an abnormal repetition of events that constitutes the signal, which must then be demonstrated with evidence. All these vigilance schemes could not exist without the professionals in the areas concerned (doctors, veterinarians, researchers, etc.), who report and record the data, or the users. ANSES has a duty to ensure that nothing is overlooked.

Following on from the InVS's *Epitox* bulletin, ANSES was keen to raise the profile of its own vigilance activities, as most of the time these are low-key and therefore relatively unknown to public health stakeholders, healthcare professionals, companies placing products on the market and users in general. It also wanted to highlight the importance of the reports submitted by professionals and users.

This quarterly newsletter will present the main results of the activities carried out by the Agency with its partners, professional networks (occupational disease consultation centres and Poison Control Centres in particular) and expert groups, as well as the actions taken. Short summaries will include links to more comprehensive texts available on the Agency's website (www.anses.fr). By subscribing, professionals can receive a list of each issue's contents as soon as it is published.

We hope this new publication will be of interest to you.

Juliette Bloch, Editor-in-Chief of Vigil'Anses

Alert concerning snake bites during summer 2016

In late July 2016, a pharmacist at the La Roche-Sur-Yon hospital in the Vendée *département* was concerned that three people in that month alone had been brought to the emergency department after being bitten by land snakes. To confirm this signal, ANSES and the network of Poison Control Centres (PCCs) studied cases of land snake bites for which a PCC[1] had been called since 2012.

The monthly distribution of bite cases showed a strong seasonal pattern, from April to September each year, corresponding to the emergence of land snake species from hibernation: about 90% of the cases observed in any year occur during this period. The number of cases observed in July 2016, the month when the alert was raised, was similar to the number observed in July 2013, and higher than that observed in July of the previous two years (Figure 1).

These results therefore confirmed the signal and the alert issued in July 2016.

The precise species of land snakes responsible for these bites are often difficult to determine, as the walkers who are bitten do not get a clear view of the animal, and/or cannot recall the information necessary to describe it. As an example, of the 369 cases of land snake bites reported to PCCs in 2016, 61% and 8% respectively were due to a viper or colubrid, with the remaining cases being due to an unspecified snake.

A regional analysis showed that the Pays de la Loire region, which encompasses the Vendée, was indeed the most affected region in 2016, with 20.5% of all land snake bites observed by PCCs between January and July, whereas this region accounted for only 6.3% of poisoning cases all agents combined during the same period.

For the cumulative period 2012 to 2016, the Pays de la Loire region had the highest incidence of land snake bites observed by PCCs (6.8 cases/105 inhabitants), followed by Centre Val-de-Loire (5.2 cases/105 inhabitants), Aquitaine Limousin Poitou-Charentes (4.6 cases/105 inhabitants) and Languedoc-Roussillon - Midi-Pyrénées (4.4 cases/105 inhabitants). While not exhaustive, this regional distribution of land snake bites observed by the PCCs seems representative, at least for the most serious bites, given that PCC toxicology experts are the first to be contacted to assess whether or not an antidote needs to be administered (see below). The geographical gradient of the regions most at risk, increasing from the north to the south of France and becoming more pronounced south of the Loire, raises the question of the changing geographical range of these indigenous species, linked to meteorological factors at least.

Following the analysis of this signal, ANSES alerted the Ministry of Health on 3 August 2016, due to the issue of venom antiserum availability in hospital departments and a possible shortage of antidote.

This is because some viper bites (but not colibrid bites) cause envenomation. Besides the mark of the fangs, which by itself does not necessarily mean an injection of venom, this results in sharp pain and local oedema (swelling, redness, heat, etc.). In the most severe cases (grades II and III), the oedema may extend beyond the bitten area and the patient may develop general complications requiring hospital care and antivenom immunotherapy. Viperfav® is an antidote to the venom of the European asp (*Vipera aspis*), European adder (*Vipera berus*) and horned viper (*Vipera ammodytes*), which has been on the market since 1999 and is well tolerated by patients. Follow-up of the medical care of bite victims, carried out by the PCCs, showed that antivenom therapy had been administered in more than a third of the 369 cases of land snake bites reported from January to December 2016.

Pressure on stocks of the Viperfav® antidote had been reported by the French Health Products Safety Agency (ANSM). During the summer 2016 alert, distribution of residual stock was subject to quotas and was reserved by the manufacturer Sanofi for emergencies, with inter-hospital exchanges prioritised.

An antidote location and management tool called Slogan® was made available in late 2015 by the Toulouse PCC and the Midi-Pyrénées regional emergency observatory (ORU-MiP). Slogan® is a secure computer application designed mainly for professionals in PCCs and hospital in-house pharmacies.

1. Each of the nine PCCs records in their shared information system (SICAP) the details of the calls it receives from individuals or healthcare professionals. This system comprises the National Database of Poisoning Cases (BNCI) and the National Database on Products and Compositions (BPNC), which reference the names and, if applicable, the composition of all agents (plants, animals, fungi, chemicals, medicinal products, etc.) associated with these cases.

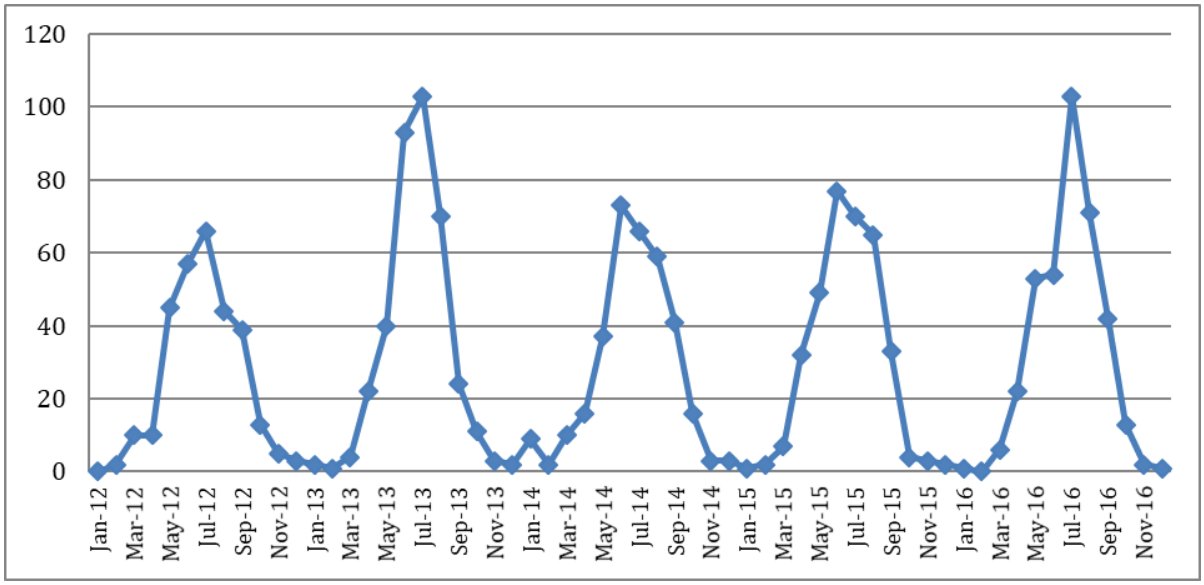


Figure 1. Monthly distribution of land snake bites observed by PCCs in metropolitan France between 01/01/2012 and 30/10/2016 (Source: SICAP)

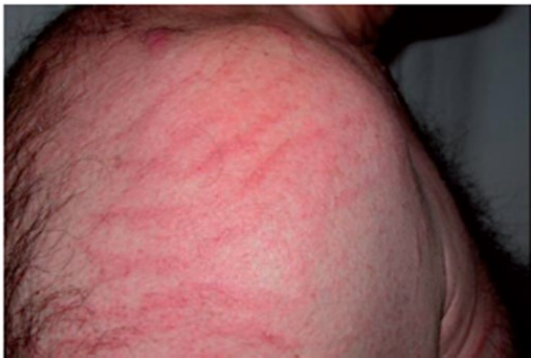
It enables the tracking and tracing of some 15 antidotes, including Viperfav®, providing for each one the number, location and expiry dates of vials in health establishments within a particular region. The PCC doctor can therefore refer the viper poisoning victim to the nearest facility with the appropriate antidote, or send the antidote to the hospital where the victim has been admitted. In mid-2016, this scheme included some 50 establishments in several different regions. Following this summer's alert, the possibility of extending the scheme to the entire country is being studied by the Ministry of Health.

The signal of an increase in land snake bites and its prompt analysis by the members of the toxicovigilance network ensured that health authorities were alerted at the time of the summer peak, and guaranteed the efficient distribution of venom antiserum in line with health needs. Bites, especially from vipers, can be serious and lead to complications. While antivenoms exist, their cost and availability are such that good regional management is vital.

Sandra SINNO-TELLIER (Anses)

Shiitake mushrooms: be sure to cook them if you want to avoid itching!

The shiitake mushroom or oak mushroom (*Lentinula edodes*) is the world's most widely consumed fungus after the common cultivated mushroom. Native to Asia where it was first grown in China and Japan, it is used in these countries both as a culinary ingredient and in traditional medicine. It has been on the European market for several years and is today grown and produced in France. While it was traditionally an ingredient to be eaten cooked, the growing trend towards the **consumption of raw foods can lead to a highly specific form of poisoning called toxic "flagellate" dermatitis, which is extremely itchy** (photo).



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This appears within hours or days of eating raw or undercooked shiitake, and covers the entire body, including the face and scalp. First described in Japan in 1977, its pathophysiological mechanism is not yet fully understood. The agent involved is lentinan, a thermolabile substance (i.e. destroyed by cooking) found in the mushroom, and its mechanism of action seems to be toxic and not allergenic. Treatment is purely symptomatic, with the toxic dermatitis eventually regressing in two to three weeks. Only a fraction of the population is likely to be affected (about 2% according to a study conducted in Japan [1]). The amount of product ingested may play a role and the dermatitis can recur in the event of re-ingestion. Note that this dermatitis can be confused with photodermatosis (a skin reaction following exposure to sunlight) even though the clinical picture is different. **In addition, this dermatitis is probably underdiagnosed, as the link with mushroom consumption is not always made by the consumer or his/her doctor, since this disorder is still only poorly understood.**

For several years now, the nine French poison control centres (CAPs) have been dealing with calls from consumers with this condition, and have published a series of 15 cases reported between January 2000 and December 2013 [2]. All the cases described in this paper occurred after ingestion of uncooked shiitake mushrooms, regardless of the mode of consumption: fresh, dried and rehydrated in water, powder or infusion.

References

[1] Mowad CM, Nguyen TV, Elenitsas R, Leyden JJ. Bleomycin-induced flagellate dermatitis: a clinical and histopathological review. *Br J Dermatol* 1994; 131: 700-702

[2] Boels D, Landreau A, Bruneau C, Garnier R, Pulce C, Labadie M, de Haro L, Harry P. Shiitake dermatitis recorded by French Poison Control Centers - new case series with clinical observations. *Clin Toxicol* (Phila) 2014; 52(6):625

Having reported this problem to the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), the CAPs updated the data they had published and sent them to the Ministry of Health in July 2015.

A total of 63 cases were recorded between 2010 and 2016, but they only represent a very small fraction of the actual cases, as they only concern people who actually telephoned a poison control centre, having made the link between the dermatitis and consumption. **On 21 August 2015, a press release from the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) informed the general public of the need to cook this food thoroughly**. On the basis of ANSES's recommendation and in order to inform consumers at the time of purchase of the possible effects of consuming raw shiitake, a Ministerial Order of 5 August 2016 suspended "for a period of one year, the placing on the market intended for the final consumer, whether or not in return for payment, of mushrooms of the species (...) *Lentinula edodes*, when presented fresh, in bulk or prepackaged, if they are not accompanied by clear information informing the consumer of the need for thorough cooking before consumption".

Juliette BLOCH (Anses)

To find out more, visit:

http://www.economie.gouv.fr/files/files/directions_services/dgccrf/presse/communique/2015/cp-champignon-shiitake.pdf

https://www.legifrance.gouv.fr/eli/arrete/2016/8/5/EINC1622686A/jo/texte

Exposure to heat transfer fluid leakage in drinking water systems

Drinking water circuits are sometimes connected to heat transfer circuits by means of a non-return valve. This heat transfer circuit can then potentially contaminate the drinking water system if the non-return valve malfunctions (leaving it partially open). Depending on the instantaneous pressure conditions at the connection point, the heat transfer fluid may leak into the drinking water circuit either occasionally or continuously. This device malfunction may go unnoticed for a period of time.

The regulations on the marketing of heat transfer fluids needed to be updated to clarify for manufacturers the minimum health requirements these products must meet before being placed on the market, to ensure the safety of drinking water. In this context, the Directorate General for Health (DGS) called on the French toxicovigilance network and poison control centres (PCCs) to analyse cases of accidental exposure due to leakage of heat transfer fluids into drinking water systems. The PCCs studied the cases collected from 01/01/2008 to 30/09/2015. They compiled an inventory of the products and substances involved in these accidents, analysed the levels of exposure, and examined the dossiers of the patients concerned.

One hundred and ninety-one cases were identified, a quarter of which involved children under 15 years of age. In three of these 191 cases, information on symptoms was missing. In total, of the remaining 188 cases, only 48 cases (26%) were symptomatic, with all of them having mild initial symptoms (mainly digestive signs such as abdominal pain, diarrhoea, nausea, or neurological/sensory disorders such as headaches). The outcome was favourable in all cases where progression was known.

The products involved varied according to the system. Specific heat transfer fluids may be combined with one or more additives such as biocides, corrosion inhibitors, stop-leak agents, surfactants and pH adjusters. Alternatively, the water may be untreated but kept in a closed circuit. In this case, it can potentially be contaminated by degradation products from the circuit and possibly by micro-organisms. A total of 373 mixtures were identified in these dossiers, belonging to two classes in the PCCs' National Database on Products and Compositions (BNPC): specific heat transfer fluids and heat transfer system additives.

As expected, the origin of the contamination was essentially due to a return of water containing heat transfer fluid at the point where it was connected to the drinking water system. When mentioned in the dossiers, the exposure was of short duration when the contamination was evident (change in colour or taste of the water, appearance of foam). More subtle pollution (lasting from one day to three weeks) was only discovered when the interconnection between the two systems was examined. The highest number of cases was observed in October and December, corresponding to the period when the heating systems were back in use again.

In view of the observations analysed over the study period, contamination of a drinking water system by a heat transfer fluid does not therefore appear to have any significant consequences for the health of anyone briefly exposed. Given the composition of the fluids, the benign nature of these cases is probably due to the extent of dilution or the low dose ingested when the contamination was detected visually or by taste.

Cécilia SOLAL (Anses)

TO FIND OUT MORE, VISIT:

http://www.centres-antipoison.net/CCTV/CCTV_Rapport_Contamination_fluide_caloporteur_2008_2015_VMISE_A_JOUR.pdf

Methylisothiazolinone: still too much of this allergen around

Methylisothiazolinone (MIT) is a chemical mainly used for its preservative properties in many commercial mixtures or products such as paints, coatings, detergents and cosmetics, as well as in mixtures for professional use.

Over the last few years, in France and elsewhere in Europe, there has been an increase in the number of cases of skin allergies to MIT.

This led ANSES to issue an internal request to identify the product categories involving the most exposure to MIT and make recommendations for limiting the exposure of people, whether or not they are already sensitised.

In the context of this internal request, ANSES asked French Poison Control Centres (PCCs) to extract data from their National Database on Products and Compositions (BNPC) in order to identify mixtures containing MIT, the product classes and categories and the associated MIT concentrations. The objective was to describe how this chemical is used by consumers and professionals and identify the products or product categories with the highest concentrations of MIT.

More than 1,500 mixtures have been recorded in the BNPC since 1994, corresponding to 40 product classes and 165 product categories: cosmetics (37%), textile care products (22%), cleaning products (20%), paints (2%), and waxing products/polishes (1.6%). Among the products for professional use, eight classes were identified corresponding to 133 mixtures. Over time, there has been an increase in the number of mixtures containing MIT registered in the BNPC from 2006 (72 mixtures), with a peak in 2009 (282 mixtures) and then a decline until 2014 (92 mixtures).

According to the data extracted from the BNPC, the concentration of MIT in the mixtures was predominantly below 0.5%. More than 40% of the products contained less than 0.1% MIT, which was the average concentration in products registered in the BNPC in 2014 (concentrations ranging from 0.000009% to 1.2%). For the most commonly identified product classes according to the BNPC, MIT concentrations ranged from 0.17% to 8.5% for cleaning products, 0.08% to 9.9% for paints and 0.31% to 5% for fabric softeners. It is important to emphasise that these preparations containing MIT are often incorporated into commercial products, ultimately increasing the overall concentration of MIT in the mixture.

These data revealed the presence of MIT in a vast range of product uses/categories, for both the public and professionals. **With some products, the concentrations recorded in the BNPC were very high and above the threshold associated with a risk of skin allergies (100 ppm).** This work confirmed the need for action to limit people's exposure to MIT, whether or not they are already allergic. ANSES therefore recommended introducing systematic information on packaging of products containing MIT, regardless of the concentration, to make it easier for sensitised individuals to avoid this allergen. With this in mind, ANSES published comments for harmonising the classification of MIT at European level and limiting its presence in mixtures. **In March 2016, the European Chemicals Agency (ECHA) adopted a harmonised classification for MIT: "Category 1A skin sensitiser" with a specific concentration limit in mixtures of 15 ppm.**

Lastly, a work on the analysis of occupational allergic contact dermatitis is currently being conducted through the National Network for the Monitoring and Prevention of Occupational Diseases (RNV3P). The results will help better characterise the occupational sectors at risk and the types of diseases induced.

Cécilia SOLAL (Anses)

TO FIND OUT MORE, VISIT:

https://www.anses.fr/en/content/exposure-mit-anses-recommends-consumers-and-workers-be-better-informed-and-protected

Exposure to alphachloralose in France and its overseas territories

Alphachloralose is an active substance approved as a PT 14 (rodenticide) biocide on 01/07/2011. However, this substance is no longer authorised in Europe as a plant protection active substance.

Alphachloralose is used in commercial preparations, but was also available over the counter in pharmacies in the French Caribbean as officinal preparations of 20-40% in lard, dispensed in 60-100g tubs for use as a rodenticide. A study carried out at the Pointe-à-Pitre University Hospital over the period 2000-2006 found many serious poisonings.

The clinical symptoms of acute alphachloralosis poisoning are well documented in humans. The time to onset of the first signs may vary from a few minutes (for massive doses) to a few hours after ingestion. The clinical signs are mainly neurological, combining consciousness disorders and motor hyperexcitability (focal and generalised myoclonus), often accompanied by salivary and bronchial hypercrinia, which can lead to respiratory distress.

As part of the regulatory assessment of commercial rodenticide products containing alphachloralose, ANSES required a detailed description of the human poisoning cases involving this substance that occurred in France.

The Agency therefore asked the network of poison control centres (PCCs) to study the cases of human exposure to alphachloralose recorded in their information system, in metropolitan France and the overseas territories. The aim was to describe exposure in terms of incidence, circumstances, products, severity and geographical distribution, and then to compare this information with the situation in the overseas territories, in order to confirm whether or not the latter were more affected due to local practices.

A retrospective study was conducted to analyse exposure to alphachloralose preparations, collected by French PCCs in the National Database of Poisoning Cases (BNCI) from 1 July 1999 to 31 December 2012 inclusive.

One thousand and seventy-one dossiers were collected over this period, with the number of annual exposures varying from 63 to 108 cases per year.

The poisonings were symptomatic and with a causality between the exposure agent(s) and the observed adverse effects non-null in more than half of the cases (n=537). A third of cases were serious (n=348), with deaths being observed in 2% of cases (n=21). The majority of people exposed were adults (61%), in contrast to other studies where children can account for 80% of accidental poisoning cases.

Accidental exposures, which represented 48% of cases, were symptomatic in 17% of cases (n=87) and serious in about 2% of cases (n=12), while no deaths were reported.

Exposure was intentional in more than 52% of cases (n=539), symptomatic in more than 81% of these cases (n=437), serious in almost 61% and 19 deaths were recorded. Note that the percentage of exposure with suicidal intent was much higher with this agent than with all the other exposure cases recorded in the BNCI, with 52% versus 15% of cases, respectively.

Single-agent suicidal poisonings (360 cases) were serious even when the presumed ingested dose was low, since 41% of patients in whom this dose was less than 3 grams had serious symptoms. This is consistent with the low toxic dose of the substance.

Two chronic intentional exposures resulting in multiple seizure episodes were noted.

1.Biocidal products are governed by Regulation (EU) No 528/2012. They are preparations of active substances for domestic or industrial use. These products include household disinfectants, insecticides and other products designed to eliminate, destroy or repel pests (fungi, bacteria, viruses, rodents, insects) by chemical or biological action.
2. Plant protection substances and products are governed by Regulation (EC) No 1107/2009. They are preparations intended to protect plants and crop products, preserve plant products and destroy undesirable plants. They are pesticides, a category that also includes biocides

The focus on the French overseas territories showed an incidence of 53.4 cases/10^7 person-years [45.1-62.8], while the incidence for France as a whole was 16.3 per 10^7 person-years. These exposures were symptomatic slightly less often (41.8% versus 50.1%) but the proportion of severe cases (32%) remained similar to that in the national study (whole France) (33%). There were an equivalent number of accidental and intentional exposure cases (n=72 versus n=72). The idea of preparation on a carrier food (bread, flour, tomato, cheese, biscuit, lard) featured in almost 40% of accidental exposure cases (n=28/72). In 7% of cases (n=5) the preparation was officinal.

Cases of exposure to alphachloralose were characterised by the frequency, products involved and severity of suicide attempts, even when small amounts were ingested. Accidental poisonings, although less often serious, sometimes involved small quantities, reflecting the high toxicity of this substance.

The marketing of alphachloralose products is currently subject to "biocide" regulations. Following this study and in order to prevent such accidents, the Ministry of Health referred the matter to the National Council of the Order of Pharmacists, to remind them that since alphachloralose is no longer listed in the Pharmacopoeia, pharmacists are no longer authorised to prepare or sell alphachloralose products unless they comply with the biocide regulations, which ensure safe use: concentration < 40 g/kg in tamper-proof bait boxes.

Marie-Odile RAMBOURG (Anses)

TO FIND OUT MORE, VISIT:

https://centres-antipoison.net/wp-content/uploads/2017/08/CCTV_Alphachloralose.pdf

"Slimming" food supplements adulterated with sibutramine and phenolphthalein

In August last year, the Montpellier regional pharmacovigilance centre reported two cases of poisoning to ANSES's Nutrivigilance Unit, following consumption of the food supplement Chewell® manufactured by Irem Naturel®. Claimed by the manufacturer to be a slimming and appetite-suppressant product, according to the label it contains guarana, tragacanth gum, green tea, red pepper, ginseng and starch extracts.

The two women concerned obtained the product on the internet after being "recruited" through social media via a Facebook group.

The first presented with polydipsia (severe thirst), followed by insomnia and significant weight loss (5 kg in one month). The second woman experienced episodes of discomfort from the first few days of taking the food supplement, as well as chest pains, palpitations and huge weight loss, of around 300 to 500 g/d.

The excessive weight loss, the adverse effects experienced by these two patients and the manufacturer's previous judicial offences raised suspicions that these food supplements had been adulterated with an anorectic substance. In 2015, a similar alert had revealed the presence of sibutramine and fluoxetine in Irem Naturel® from the same manufacturer, following reports from two people who had experienced cardiovascular adverse effects related to consumption of the product. A health enforcement decision was taken at the time by the French Health Products Safety Agency (ANSM).

Analysis of the remaining Chewell® capsules by the ANSM's Control Department revealed the presence of sibutramine and phenolphthalein. The estimated content in the analysed samples corresponded to pharmacologically active levels i.e. likely to have an effect on health.

As a reminder, sibutramine is an anorectic that was banned in Europe in 2010 due to the cardiovascular risk previously revealed by several cases of serious adverse effects. Phenolphthalein has been prohibited in France since 1988 because of its potential carcinogenicity.

As a result of these reports, a health enforcement decision against the manufacturer is under way at the ANSM. Information was also sent to the Rapid Alert System for Food and Feed (RASFF), the European network.

Such cases of adulteration of food supplements with unauthorised active substances have been on the increase for several years [1-5].

The substances usually encountered include benzodiazepines (estazolam, clonazepam) in food supplements promoting sleep, anorectic substances such as sibutramine or fenfluramine in food supplements for weight loss, sildenafil or equivalent substances (tadalafil, vardenafil) in food supplements for erectile dysfunction, and steroids in products for muscle development.

These adulterated food supplements represent a real threat to consumer health. Indeed, consumers think the products they are using are safe because of their seemingly harmless composition, but are in fact exposed to hazardous substances.

Healthcare professionals are invited to report to ANSES's Nutrivigilance Unit any adverse effects of food supplements observed in their patients (https://pro.anses.fr/nutrivigilance/) and to keep the suspect tablets or capsules for possible analysis. Consumers can contact a poison control centre or report the adverse event on the Ministry of Health's adverse effect reporting portal (opened in January 2017). Websites selling fraudulent products can be reported on the Ministry of the Interior's portal (https://www.internet-signalement.gouv.fr/PortailWeb/).

In view of the increase in these reports in France and Europe, it seems important to improve communication to consumers about these products.

Chloé GREILLET (Anses)

References

[1] Petroczi A. *et al.*, *Food and Chem. Toxicol.*, 2011; 49, 393-402
[2] Venhuis BJ *et al.* Trends in drug substances detected in illegal weight-loss medicines and food supplements: a 2002-2007 survey and health risk analysis.
[3] Evaluation des risques liés à l'utilisation de produits de santé à des fins d'amaigrissement [Assessment of the risks of using health products for weight loss]. ANSM, Expert appraisal report – July 2012, 33p
[4] Ozdemir B, Sahin I, Kapucu H, Celbis O, Karakoc Y, Erdogan S, Onal Y. How safe is the use of herbal weight-loss products sold over the internet? *Hum Exp Toxicol*. 2013; 32(1):101-6
[5] Müller D, Weinmann W, Hermanns-Clausen M. Chinese slimming capsules containing sibutramine sold over the Internet: a case series. *Dtsch Arztebl Int* 2009;106(13):218-2

Food supplements for athletes: health risks with uncertain benefits

Between 2009 and February 2016, ANSES's national nutrivigilance scheme collected 49 reports of adverse effects potentially related to the consumption of food supplements aiming to develop muscle mass or reduce body fat in athletes.

The adverse effects reported were primarily cardiovascular (tachycardia, arrhythmia and stroke) and psychological (anxiety and nervousness).

These reports of adverse effects led ANSES to assess the risks associated with the consumption of these supplements and to draw the attention of the athletes concerned to the health risks induced by these practices.

In order to reduce these risks, ANSES recommends that consumers take care to ensure that these food supplements are compatible with their nutritional status, state of health and the objectives sought. It is therefore essential to obtain personalised advice from a healthcare professional, where applicable in cooperation with the trainer or the fitness coach, and with reference to the training periods and loads. To ensure an effective interdisciplinary dialogue, it is important that the healthcare professionals have obtained solid initial and continuing training in the field of nutrition, and sport nutrition in particular.

In addition, and more specifically when seeking to reduce body fat and/or increase muscle mass, people practising sport should be informed of the risks associated with the consumption of pharmacologically-active products, and the health risks associated with following weight-loss diets without medical assistance.

ANSES emphasises that any claimed effects of these food supplements on performance do not in any way rule out the health risk. In general, the absence of scientifically demonstrated data on effectiveness makes the expected benefits of these food supplements extremely hypothetical, meaning that the merits of products containing them are highly questionable in view of the risks incurred. In addition, purchases on the Internet de facto increase the athlete's exposure to the consumption of fraudulent or adulterated food supplements, liable to lead to positive anti-doping tests and cause effects on health.

The Agency's recommendations

In light of the results of its expert appraisal, ANSES strongly advises against the consumption of food supplements aiming to develop muscle or reduce body fat:

- for people with cardiovascular risk factors or suffering from heart disease, impaired kidney or liver function, or neuropsychiatric disorders;
- for children and adolescents;
- for pregnant or breastfeeding women.

ANSES is issuing the following recommendations:

For consumers:

- The consumption of food supplements containing caffeine should be avoided before and during any sporting activity, as well as by any individuals susceptible to the effects of this substance.
- The concomitant consumption of several food supplements or their combined consumption with medicinal products should be avoided.
- The consumption objectives of the food supplements should be discussed with a healthcare professional.
- The individual's doctor and pharmacist should be informed that he/she is taking food supplements.
- Athletes should pay attention to the composition of the products consumed, and favour products complying with AFNOR standard NF V 94-001 (July 2012) as well as supply channels with the best oversight by the public authorities (compliance with French regulations, traceability and identification of the manufacturer).

For sports managers:

- The use of food supplements should only be considered as part of a multidisciplinary approach involving both sports managers and healthcare professionals;
- Effective information for sports practitioners, especially targeting young athletes, should be provided.

In addition, considering the widespread consumption of these food supplements, the Agency recommends that the public authorities conduct a debate on whether it is appropriate to distribute these products at sites where sports are practised.

Lastly, ANSES reminds **healthcare professionals** of the importance of reporting to its nutrivigilance scheme any adverse effects potentially related to the consumption of food supplements for athletes about which they become aware.

Charlotte LEGER (Anses)

TO FIND OUT MORE, VISIT:

https://www.anses.fr/en/content/food-supplements-athletes-risks-health-and-uncertain-benefits

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ANSES is in charge of several health vigilance systems: pharmacovigilance for veterinary medicinal products, nutrivigilance, phytopharmacovigilance, toxicovigilance and vigilance for occupational diseases. Our vigilance activities make little noise and are therefore poorly known to public health actors, health professionals, marketers and users in general. And so, in order to make our work more visible we have decided to create a dedicated newsletter entitled Vigil'Anses.

As news on each of our vigilance topics crops up, this quarterly newsletter presents the main results of the work carried out by ANSES within the framework of its vigilance missions, in conjunction with its partners, professional networks and expert groups, as well as the actions we have undertaken.
The articles are deliberately short, and are intended for all those involved in the occupational and environmental health and safety field: public authorities, health agencies, institutes and expert bodies that are partners of ANSES, prevention policy managers, the scientific community, professionals, associations and users. Vigil'Anses also invites the interested reader to delve deeper and discover publications, opinions and reports available online that will further their knowledge.

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