Nutritional and risk assessment of the consumption of pangasius

Opinion of the Scientific Advisory Committee on Food Safety .

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Abstract

Pangasius is a freshwater fish produced in fish farms in south-east Asia. The consumption of this fish is controversial as regards its nutritional value, the excessive content of contaminants and environmental sustainability. This document compiles opinions on controversial safety issues related to its consumption

Keywords

Pangasius, risk assessment, methylmercury, arsenic, semicarbazide.

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Introduction and nutritional composition

Pangasius – *Pangasianodon (Pangasius) hypophthalmus* – is a freshwater white fish produced with aquaculture techniques. Its production is concentrated in south-east Asia, with the fish marketed in our country coming mainly from Vietnam. Its consumption has raised a number of questions regarding its nutritional value, the excessive amount of contaminants and the environmental sustainability of its production. It is an economical product, which is usually presented in boneless fillets. It has a mild flavour due to a low fat content. As a result, it is commonly used in industrial food services.

From a nutritional point of view, its composition is similar to other freshwater and/or white fish. Its protein content, comparable to hake, is slightly lower than the level contained in other species. It has a low fat and cholesterol content. Like most freshwater white fish, it also contains a low proportion of Omega-3 fatty acids.

Table 1. Comparison of the nutritional composition of different fish per 100 grams

	ENERGY (kcal)	PROTEINS (g)	FAT (g)	Cholesterol (mg)	Omega-3 (g)
Pangasius	67	13.4	1.2	30	0.10[1]
River trout	91	19.4	3.8	80	1.23
Carp	116	17.8	5.0	66	0.77
Hake	65	11.9	1.8	67	0.33
Sole	79	16.5	1.3	60	0.74
Tilapia	96[2]	20.8[2]	1.4[2]	50[2]	0.1[2]

Sources: The Spanish food composition database (BEDCA)
[1]*Nutritional quality guidelines of fish products*
[2]*USDA Nutrient Database*

Risk assessment

As regards whether pangasius is safe to eat, first of all, it must be borne in mind that due to being an animal product from third-world countries, it cannot enter the European Union (EU) unless it complies with the requirements shown below:

- The production country has to be previously authorised by the EU, which bases its decision on whether the product guarantees a level of food safety equivalent to the one required in the EU.

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- Likewise, the establishment where the fish is produced must have previous authorisation from the EU.
- The product must be accompanied by a health certificate issued in the production country.
- The product has to enter the EU at a border inspection post (BIP), where all the documentation from the country of origin is checked and any pertinent inspections are carried out. In the event a batch that fails to comply with EU legislation is detected, it is either destroyed or returned.

Between 2015 and 2016, the Rapid Alert System for Food and Feed (RASFF) has issued 5890 notifications in Europe, of which 621 were related to fish products and 12 with pangasius. Of the 12 notifications that concerned pangasius – most of which were rejected at the border –, seven were due to the presence of nitrofuran metabolites. In all the cases the detected substance was semicarbazide (SEM), a nitrofuran metabolite. In most cases (six out of seven) the SEM values ranged between 1.1 and 1.9 µg/kg, and in the seventh case there was a concentration of 5.0 µg/kg.

Nitrofurans are antibiotics and in the EU it is forbidden to use them in food-producing animals, although there is evidence that they have been used in some countries in south-east Asia. For this reason, some specific monitoring mechanisms have been established for imports from this region. Nitrofurans metabolise quickly inside bodies and therefore analytical monitoring for detecting undue use is conducted on their main metabolites (furazolidone-AOZ, furaltadone-AMOZ, nitrofurantoin-AHD and nitrofurazone-SEM).

According to Commission Regulation (EU) No. 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, nitrofurans are forbidden substances and consequently no maximum residue limits (MRL) have been established. In the cases in which there is no MRL, in order to ensure suitable control, the official monitoring methods must comply with the specifications to detect the forbidden substance in a determined concentration, the minimum required performance limit (MRPL). In the case of nitrofuran metabolites in animal tissues, the analysis methods must be capable of detecting them at values that are higher or equal to 1 µg/kg.

In 2015 the European Food Safety Authority (EFSA) issued a scientific opinion on the risk to human health caused by the presence of nitrofurans in food and it assessed, as worst-case scenario, a situation in which all the food susceptible to containing residues of nitrofurans presented some of the metabolites at values of 1 µg/kg. In all the cases, the margins of exposure (MoE) were higher than $2x10^5$ for carcinogenic effects and 10^3 for toxicological considerations. For this reason, it was concluded that this scenario would hardly imply a risk to health if safety criteria were followed, which is to follow a $MoE>10^4$ for carcinogenic effects and a $MoE>10^2$ for toxicological considerations, basing the calculations on the $BMDL_{10}$ of each one of the substances. For nitrofurazone it was not possible to take any decision in regard to its carcinogenicity; in regard to semicarbazide (SEM), no reference point was established for possible carcinogenic effects.

Based on the information of RASFF, it can be concluded that the worst-case scenario would be created if all the marketed pangasius had a nitrofuran metabolite value of 5 µg/kg. If this scenario is incorporated into the situation considered in the study carried out by EFSA, MoE of $2x10^4$ would be calculated for carcinogenic effects and $2.5x10^2$ for toxicological considerations, something that would not imply any risk to health since they are values that have to be considered safe according to the established safety criteria.

In the specific case of SEM, the only analyte notified by RASFF, supposing that the three recommended portions are of pangasius with a content of 5 µg/kg, the MoE for toxicological considerations would be of $2.2x10^5$.

3 portions/week × 150 gr/portion × 5 µg /1000g = 0.0169 mg = 2.25 µg/week

This intake is equivalent to 0.0046 µg/kg bw/day and, due to the fact the $BMDL_{10}$ of the SEM for toxicological considerations is 1.0 mg/kg bw/day, it represents a MoE of $2.2x10^5$.

In addition to border controls, pangasius, like any other food product, is subjected to other official controls throughout the whole time it is being marketed in the EU. Therefore, within the framework of the Catalan Food Surveillance System (SIVAL), carried out in 2014-2016 by the Catalan Public Health Agency (ASPCAT) and the Food Health Quality (IQSA) Research Programme of the Public Health Agency of Barcelona (ASPB), a total of 84 samples of pangasius were analysed in order to research the parameters established by EC regulations.

As regards chemical contaminants, the previously mentioned monitoring programmes analysed the mercury content in 18 samples of pangasius. Practically all these tests - 17 out of 18 - gave values below the detection limit (0.050 mg/kg). In the positive sample, 0.05 mg/kg of mercury was found, a value 10 times lower than the legally established maximum levels for fish set by Commission Regulation (EC) No. 1881/2006, which are as follows:

- 1 mg/kg: the list of fish that excludes pangasius (monkfish, bonito, eel, halibut, pike, pink cusk-eel, goatfish, seabream, thornback skate, sailfish, sturgeon, swordfish, tuna...)

- 0.5 mg/kg: all other fish (among which pangasius is included) and fish products

Organic forms of mercury are the most harmful. Methyl mercury, the most common organic form, comes from the transformation of inorganic mercury in aquatic environments, which deposits in soil and water, either naturally or from emissions that come from different industrial activities. In water, the mercury is absorbed by microorganisms and plankton, which causes it to enter the trophic level, and because it has a high degree of bioaccumulation it undergoes a process of biomagnification, which means the highest concentrations are found in species that are at the top of the trophic level. Water filtering organisms, especially bivalves, can also accumulate significant amounts.

As safety levels have been set for methylmercury, it is necessary to establish the previously mentioned scenario for this organic form of mercury. Based upon the speciation data obtained from the report from ACSA, *Contaminats químics. Estudi de dieta total de Catalunya 2012*, methylmercury content represents an average of 74% of the total amount of mercury. Using the data gathered from official monitoring programmes, the worst-case scenario would be to consider that all pangasius were marketed with an equal level of mercury level as the detection limit (0.05 mg/kg) which according to the speciation data mentioned above would represent 0.0375 mg/kg of methyl mercury.

If the three recommended weekly portions of fish are pangasius with a content of methylmercury of 0.0375 mg/kg, the intake level would be calculated as follows:

3 portions /week x 150 g/portion x 0.0375 mg/1000 g = 0.0169 mg = 16.9 µg/week

EFSA has set the safety level at an intake of lower than 1.3 µg of MeHg/kg bw/week.

For an adult, this intake implies an exposure of 0.24 µg of MeHg/kg bw/week, a value that is way below the established safety level. In the case of children, (body weight of 24 kg), assuming an intake of the same portions, it would represent an exposure of 0.70 µg of MeHg/kg bw/week.

Consequently, the consumption of the portions described in this scenario, the worst one imaginable and highly unlikely with the available data, it would imply a weekly intake with no risk to health, as it is below the level of exposure considered safe by EFSA.

Continuing with chemical contaminants, different information that has appeared in the media has associated the consumption of pangasius with excessive exposure to arsenic, which is naturally present in soil, water and plants. The inorganic forms of arsenic are the most toxic, especially trivalents, which plants can absorb from the soil through their roots, or the air from contaminated particles that deposit onto leaves. The organic forms of arsenic, the least toxic, are mainly found in water animals.

In recent years there have been no notifications from RASFF about the presence of arsenic in pangasius; neither has it established legal limits of arsenic in fish. As a result, based on the risk analysis, no arsenic analyses have been scheduled in the official monitoring plans.

Bibliographic research has brought to light four recently published scientific studies on different fish produced in south-east Asia. Said papers report that pangasius contains the following total values of arsenic. In one of the studies on pangasius

(Daguer et al., 2016), with a detection limit of 0.0005 mg/kg, no arsenic was detected in any one of the analysed samples. In a study on different imported fish (Kulawik et al., 2016) pangasius was found to contain an average level of arsenic of 0.024 mg/kg. In a study on diet (Ahmed et al., 2015), it was detected that pangasius contained an average level of arsenic of 0.077 mg/kg; and in another study (López-Barrera & Barragán-Gonzalez, 2016), the average amount of arsenic in pangasius was found to be 0.038 mg/kg.

Considering these data, the worst-case scenario would be created if the marketed pangasius had a total level of arsenic of 0.077 mg/kg. When there were no data on chemical specification, it was estimated that 70% of the arsenic contained in fish was inorganic. The data included in the report published by ACSA *Contaminants químics. Estudi de dieta total de Catalunya 2012* indicate that the percentages of inorganic arsenic in fish would be very low (0.5%); however, it would widely vary between species. According to data on arsenic speciation in fish, we presume that 10% of the arsenic in pangasius is inorganic.

If the three weekly recommended portions of fish are pangasius with an arsenic content of 0.077 mg/kg (7.7 µg/kg inorganic arsenic), the intake level would be calculated as follows:

3 portions /week x 150 g/portion x 7.7 µg /1000 g = 3,5 µg/week

This calculated intake represents an exposure of 0.007 µg/kg bw/day.

For organic arsenic, EFSA suggests using a safety level of 0.3 µg/kg bw/day as a reference point. This is the benchmark dose lower confidence limit ($BMDL_{01}$) (0.3-8.0 µg/kg bw/day).

Therefore, the consumption described in the worst-case scenario would imply a level of exposure 43 times lower than the value considered safe by EFSA, and consequently there should be no health risk.

Conclusions

Pangasius is a freshwater white fish that has a similar nutritional profile to that of other white fish marketed in our surroundings. Taking into account the risk assessments carried out on the chemical profiles that have repeatedly been associated with the consumption of pangasius, it can be concluded that eating the fish does not imply a health risk. According to the opinion of the Scientific Advisory Committee on Food Safety, it is safe to consume pangasius as part of a varied and balanced diet.

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