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The coenzyme Q10 "saga"

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In the fast-evolving world of food and health-food regulation, two recent court decisions deserve our attention as they rule in opposite direction a very interesting food regulatory case.
In both cases, a Chinese importer sold USA-imported CoQ10 capsules to Chinese consumers. The products had been imported as normal food after regular custom-clearance and CIQ inspection at entry port, and then put into the Chinese internal market.
However, coenzyme Q10 is a substance currently not clearly regulated in PRC law, and this triggered complaints launched by "professional consumers", claiming that CoQ10 capsules cannot be sold as normal food in China.

1.- CoQ10: A "special" substance

The products at stake are pills of coenzyme Q10 – also known as *ubiquinone, ubidecarenone*, *or CoQ10*. It is a substance naturally present also in the human cells, with important antioxidant functions, which can enhance anti-aging, cognitive and heart health functions. CoQ10 is sold as nutrition supplement in various countries, such as USA where it is certified as GRAS (*Generally Recognized As Safe*)[1].
CoQ10 is a substance listed as "*coenzyme drug*" ("辅酶类药") in the official 2015 *Chinese Pharmacopoeia*[2]. The *Chinese Pharmacopoeia* is the official code providing standard for production and composition of drugs[3].
A China Food and Drug Administration (*CFDA*) notice of September 2, 2009[4] applies to registration of health food products containing CoQ10 (*CoQ10 Health Food*). Such notice provides – amongst others – that:

- application documents for registration of CoQ10 Health Food shall also include
  raw material CoQ10 detailed production process, quality reports and quality standards,

CFDA quality inspection report of raw material;

- when CoQ10 is combined together with food, or other ingredients which are traditionally treated as both food and medicine, sufficient evidence shall be provided that CoQ10 will not react chemically with other raw materials. CoQ10 shall not be combined together with any other raw materials except food and ingredients which are traditionally treated as both food and medicine;
- raw material CoQ10 should comply with the standards of *Chinese Pharmacopoeia*;
- recommended intake of CoQ10 should not exceed 50mg/day;
- allowed claims for products containing coenzyme CoQ10 are: alleviate physical fatigue, anti-oxidation, helps reduce blood fat and enhance immunity;
- CoQ10 Health Food shall be labeled in compliance with health-food labeling regulation, and also include as not-suitable groups: "*children, pregnant women, nursing mothers, persons with allergies". In the "Precautions" space, it should be marked that "persons under medical treatment should consult a doctor before eating this food*".

2.- Legal background

Food products in China must comply with the *Food Safety Law*, which is the paramount piece of legislation applying to food safety, as well as to all of its (thousands of) implementing regulations.
These include mainly food safety standards: both

(1) *GRAS* is a qualification provided under US law allowing additives or other ingredients to be used in food without a prior risk assessment by FDA.
(2) *中华人民共和国药典,2015年版,二 部 (PRC Pharmacopoeia, 2015, Part 2).*
(3) *Pharmaceutical Administration Law*, article 32.
(4) 国食药监许[2009]566号, *关于含辅酶COQ10保健食品产品注册申报与审评有关规定的通知 (CFDA Notice n. 566/2009 on the regulations concerning registration and review of health food containing CoQ10).*

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vertical (related to the specific product: olive oil, sugar, chocolate, etc…) and horizontal (applicable to several products: labeling, additives, fortifiers, etc..).
Standards usually include items such as maximum or minimum allowed amounts of specific substances in the food, mandatory or forbidden content on the labels, etc…
Food products not complying with those standards are to be considered as illegal and therefore cannot be traded until rectification has been done (when possible – such as in case of mislabeling).
In the Chinese system we can refer to two main categories of food products: normal food and health-food. Health-food - defined in the paragraph below –shall obtain the Health-Food Certificate after registration with China Food and Drug Administration; without such certificate, it shall be treated as normal food.

Health-food

Health-food has (at least) two main definitions in PRC legal system:

- *The PRC Health-Food Registration Provisions*[5] define it as "*those foods which claim to have certain health functions or aim at supplementing vitamins and minerals, namely, those foods which are used for certain groups of people with the aim to adjust organic function instead of curing diseases and will not cause any acute, sub-acute or chronic damages to human body*";
- *GB 16740 (National Food Safety Standard Health-Food)*[6] defines it as "*Foods which claim to have certain specific health functions or can supplement certain vitamins and/or minerals, and have been legitimately licensed for the same*".

Despite differences in the two definitions, key elements appear to be (i) the claim of certain functions (which distinguish health-food from normal food), (ii) the legitimate license for such claims, (iii) the lack of medical treatment properties (which distinguish health-food from drugs).
It shall be noted that – according to PRC laws and regulations[7] – all health-food (which includes nutrition supplements) must undergo registration with CFDA, which will assess – through application documents provided by the applicant[8] as well as further analyses/tests by CFDA laboratories – their safety and the effectiveness for the claim applied for.
Allowed claims are today only 28 (including claim of "mineral/vitamin supplement"), with a fixed wording that cannot be modified. If such registration is rejected, the product cannot be sold as health-food. If registration succeeds, the product can be labeled with the approved claims as well as with the official "blue-cap logo" for health-food.
The last amendment of the *Food Safety Law* relaxes requirements for health-food registration,[9] which remains necessary only for health-food using ingredients not included in the specific *Health-Food Ingredient Catalogue* (currently in the process of being drafted) as well as for first-time-imported health-food[10].
Besides, a *Catalogue of Allowed Claims*[11] is also being drafted, which will likely expand the current list of allowed claims.
Due to the length and cost of such registration procedure, companies often opt to give-up the health-food status, and rather prefer to market those products as normal food (which basically results in waiving any claim as well as the blue cap).

(5) Art. 2.
(6) Art. 2.
(7) *Food Safety Law*, article 76.
(8) Art. 77 of the *Food Safety Law* lists as application document "*R&D report, formula, production techniques, assessment of safety and health functions, label, and instructions, product sample and relevant supporting documents*". More detailed lists are provided by the *PRC Health-Food Registration Provisions*.
(9) Art. 76.
(10) Definition of "first time import health-food" is provided by art. 195 of the current draft of *Implementing Regulation of the Food Safety Law* and refers to imported health-food "*not from the same country, same company, or the same formula*" as health-food already imported.
(11) Art. 75 of the *Food Safety Law*.

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Authorities

While until a few years ago a plethora of authorities shared powers and functions in the food-safety issue – often resulting in positive and negative conflicts between authorities – since 2013 CFDA has the leading role for food-safety regulation. For instance, it issues food licenses for food operators (producers, traders, catering companies), it approves health-foods and its ingredients, it plays an important role in the drafting of food safety standards, it leads and gives input to other authorities for inspection and risk assessments.
Under CFDA's lead, several other authorities maintain powers and functions. The most important are:
- NHFPC (*National Health and Family Planning Commission*) – which replaced the former Ministry of Health – is the leading authority for risk assessment, approving novel food and new additives, and it plays a leading role in the draft (jointly with CFDA) of food safety standards;
- AQSIQ (*Administration for Quality Supervision, Inspection and Quarantine*) is in charge of inspection and approval for imported food products. It registers foreign food exporters and approves those in the required categories (meat products, aquaculture products, dairy products, fresh produce). Inspection is conducted at the entry port by its local branches (CIQ), and it usually involves chemical analysis of the content of the product (ingredients, contaminants residues, other substances residues, etc..) and label inspection;
- AIC (*Administration for Industry and Commerce*) is in charge of market protection enforcement (consumer protection, anti-unfair competition, anti-counterfeiting);
- *Ministry of Agriculture* provides general overview for safety of agriculture products and contributes to draft of safety standards for pesticides/vet drug residue and testing.

Harmonization and full coordination among these authorities is far from being reached, but significant progresses are being made.

Imported food

Technically speaking, imported food is not a subcategory of food products, and food products can be imported into China either as normal food or as health-food. Imported health-food shall be also registered as such with CFDA and obtain Health-Food Certificate.
Any imported food products, in order to be legitimately traded in China, shall be firstly inspected by CIQ. After the inspection, if no non-compliance (ingredients, additives, contaminants, label, etc.) with Chinese laws is found, CIQ will issue a Sanitary Certificate stating that such imported food products meets the requirements of food safety.

Professional consumers

To curb the (countless) food safety frauds plaguing Chinese market, PRC legislator has introduced – at least since 2009 – strict provisions allowing consumers to be rewarded when food safety infringements occur.
This aims at motivating consumers to put pressure on food companies, pushing them eventually to improve food-safety compliance.
Article 148 of the *Food Safety Law* (article 96 prior to the 2015 modification) expressly provides that, in case of food not-compliant with PRC safety standards, consumers can ask – to either the retailer or the producer – refund of the harm suffered (i.e. the price paid plus any costs related to health treatment due to the non-compliant food consumption) as well as a compensation of 10 times the product price – or three time the loss[12]. Flaws of food labels and product descriptions, which do not affect the food safety or mislead customers, do not give the right to ask for such compensation.
Moreover, the Measures for Reward for food and drug whistle-blowing issued by CFDA in 2013[13] grant rewards (up to 300,000 RMB, depending on

([12]) According to article 148 of the Food Safety Law, such compensation can never be less than 1000 RMB.
([13]) 食品药品违法行为举报奖励办法 - 国食药监办[2013]13号 (Measures for Reward for food and drug whistle-blowing, CFDA n. 12/2013).

the level of the consumer's contribution and the size of the accident) to consumers that report or help CFDA with investigations over food-safety accidents.

In a few years, these provisions – as well as a few others similar – have generated the phenomenon of so-called *professional consumers*, i.e. consumers that intentionally target non-compliant food products with the only purpose of making a profit out of them. This phenomenon has grown significantly[14], with some professional consumers scaling their business and eventually turning into consultants for mass-market companies.

Retailers and producers involved in litigations against professional consumers have often tried to defend themselves claiming that those individuals cannot be considered as ordinary consumers, because they act in bad faith, do not intend to use the products they purchase and actually the non-compliance is the only/decisive reason for their purchase.

However, these arguments rarely helped; moreover in 2014 the People's Supreme Court expressly stated that "*where litigations are launched for disputes arising from the quality of foods or medicines, manufacturers' and sellers' defense cannot rely on grounds that purchasers buy food/medicines being aware of the defect*"[15].

Moreover, the Supreme Court's also added that[16] Court shall uphold consumer's petition against non-compliant food product and grant the 10-fold penalty if the infringement is confirmed: this provision is interpreted by several courts and commentators as not requiring that consumer have actually suffered any physical/health harm as condition to claim such penalty.

3.- Guangzhou case[17]

Guangzhou Intermediate Court was requested to decide on a second-instance case brought by a consumer – Mr. Zhang Bao Hui – against a health-food trader – Wuhan Boluo Trading Co., Ltd ("*Boluo*").

Mr. Zhang had purchased several CoQ10 health food capsules from Boluo for a total price of RMB 740. Claiming that such products were not compliant with PRC law, Mr. Zhang asked for refund of the price plus a ten-fold penalty of RMB 7400.

Mr. Zhang had lost the first instance case, during which the court had rejected his requests mainly based on grounds that Mr. Zhang had not proven any health damages as a result of intake of such products.

In the second instance case, Mr. Zhang argued that:

- Chinese law[18] does not require the plaintiff to prove any physical damages in order to claim the ten-fold punitive damages for non-compliance of food and drugs;
- The first instance Court had focused only on whether Mr. Zhang's health had been damaged, but had not taken into account the main issue: whether adding coenzyme CoQ10 to food products is compliant or not with PRC regulation.

Boluo defense was mainly based on the fact that (i) it had legally imported all such health-food products, which (ii) were successfully inspected by CIQ at import port, (iii) had duly obtained the sanitary certificate required for input into commerce in China and (iv) had regularly cleared customs.

The second instance court upheld the requests from Mr. Zhang, deeming that:

- under article 62.1 of the PRC *Food Safety Law*[19]

(14) For instance, according to an article by the Chinese newspaper Morning Post (新闻晨报), professional consumers generated around 90% of the consumer protection litigations filed with People's Court of Shanghai – Jing'An district in 2012 (http://www.jfdaily.com/a/2029229.html). According to the Jurisprudence Daily 法制日报, the People's Court of Haidian district in Beijing, 60% of the 3270 consumer protection cases filed in 2010 involved professional consumer (http://www.mzyfz.com/cms/lvshijulebu/falvdongtai/jinritoutiao/html/804/2011-03-15/content-42449.html)

(15) Art. 3 of the *Judicial Interpretation on Issues concerning the Application of Laws relating to Food and Drug Disputes* of 9 January, 2014.

(16) Art. 15 of the *Judicial Interpretation on Issues concerning the Application of Laws relating to Food and Drug Disputes* of 9 January, 2014.

(17) Decision n. 4080/2015 - (2015)穗中法民一终字第4080号.

(18) See footnotes 15 and 16.

(19) Such article has become article 92 in the revised 2015 *Food Safety Law*.

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all imported food, food additives and food-related products shall conform to the national food safety standards of China;
- under article 28.1 of the PRC Food Safety Law[20], production and commerce of food produced with non-edible raw materials, or food containing non-food-additive chemical substances and other substances potentially hazardous to human health is forbidden;
- CoQ10 cannot be considered ordinary food/food ingredient because: (i) it belongs to coenzyme drugs according to Chinese Pharmacopoeia, (ii) it cannot be obtained through natural methods, and (iii) it is not a traditionally-eaten food in China;
- although the products were regularly imported and inspected by CIQ, this does not imply complete compliance clearance with PRC food safety laws and regulations;
- CoQ10 is tightly regulated under CFDA Notice n. 566/2009, which sets specific limits to the recommended daily intake, mark of not suitable groups, and requires prior CFDA approval when it is added into health-food. This confirms that products containing CoQ10 – such as those purchased by Mr. Zhang – have potential risks for health and must be sold under health-food regime;
- In this scenario, as the products had been imported as normal food, they should be considered illegally sold in China.

4.- Shanghai case[21]

In a similar case, Shanghai Intermediate court issued a completely opposite decision. The health-food trader Niuhai Technology (Shanghai) Co., Ltd. ("*Niuhai*") appealed against a non-favorable first instance decision.
Mr. Sun Haitao – the appellee – had purchased 20 bottles of CoQ10 soft capsules on Niuhai's online shop on October, 2014 for an amount of RMB 1,980. The label showed that each capsule contained 100mg CoQ10.
The first instance court had ruled in favor of Mr. Sun (i.e. punitive damages of 19,800 RMB) considering that:
- The imported food must comply with national food safety standards of China;
- Successful CIQ inspection does not imply complete clearance of food compliance;
- CoQ10 is included in the Chinese Pharmacopoeia and considered as "drug". Moreover, under notice 566/2009, the recommended daily intake should not exceed 50 mg/day;
- In the specific case, not only the products were sold without health-food registration, but also the product does not comply with the CFDA recommended daily intake of 50 mg.

Niuhai appealed, and obtained a favorable decision by the Intermediate Court which completely overturned the first instance's one.
The appeal court held, this time, that:
- The involved goods can be sold legally after obtain the CIQ clearance. The involved products are imported from USA, have been positively inspected by CIQ, obtained the sanitation certificate, comply with PRC food safety requirements and are legally allowed to be sold;
- The products are not food products with CoQ10 added; the products are rather just pure CoQ10 capsules, as its core ingredient is CoQ10;
- CFDA Notice n. 566/2009 merely applies to the registration procedure of domestically-produced health-food, and cannot be considered as food safety standard;
- Despite complain by Mr. Sun that the products violate PRC food safety standard, he was not able to prove any risk for the health.

5.- Two different interpretation approaches

First of all we shall clarify that this kind of cases are rather frequent and decisions like Guangzhou Intermediate Court's are the norm, while the one issued by the Shanghai's Intermediate court is

([20]) Such article has become article 34 in the revised 2015 *Food Safety Law*.
([21]) Decision n. 1878/2015 - (2015) 沪一中民一（民）终字第1878号.

rather an exception. Moreover, based on the current draft of the *Implementing Regulation of the Food Safety Law* – not into force yet, though – it appears that cases similar to these will be decided in future in consistency with Guangzhou Intermediate Court's decision.

Yet, several interesting issues arise from the Shanghai Intermediate Court's decision.

Shanghai's decision basically implies that food that could have health-food status can be imported and sold as normal food.

Even more significantly in our opinion, Shanghai decision also implies that the plaintiff should take the burden of proving that such food bears risks for health. In this case, a first assessment had already been done by CIQ, which tested the product and deemed that it posed no risk for health and it complied with PRC's regulations. Briefly, it seems to us that the court has approached the law's interpretation from a substantial - rather than formalistic – perspective, and considered that:

- from regulation compliance perspective, PRC law does not clearly forbid adding CoQ10 into normal food;
- from food safety perspective, Mr. Sun did not prove the existence of a risk[22] (important: the Court does not mention the need to prove harm to the health, but at least the existence of a risk). Which prove would have been sufficient, the Court does not say. We imagine that research papers, or official opinion by medical institutions might have been of help to Mr. Sun. Shanghai court deemed that an official safety assessment carried out by CIQ could not be overturned without a substantial element (the prove of risk).

Even from a formal perspective, Shanghai's court decision can have its stand: despite generally accepted interpretation, art. 15 of the Supreme Court's *Judicial Interpretation on Issues concerning the Application of Laws relating to Food and Drug Disputes* of 2014 does not expressly say that the claim by consumer against non-compliant food product must be upheld in the absence of physical damages or of risk. Shanghai's court therefore has added one layer (to prove of potential risk, which is per se a mere potential element) to the application of article 148 of Food Safety Law, which in our opinion better adheres to the *rationale* of such provision.

Guangzhou's Intermediate court, on the other hand, had a more formal approach to the law. As we have seen, it deems and implies that only health-food can contain "non-natural" ingredients, and that any other food containing those is non-compliant with PRC safety standards. Its decision implies that CIQ should have rejected the import of such food. Based on such assumption, the producer and/or distributor are liable for the 10-fold penalty without any need for the consumer to prove any real risk for health.

6.- Some further considerations

In our view, the courts involved might not be too familiar with the scientific technicality of these products. This can be seen as the decisions (all of them) appear to be extremely short, and do not give detailed explanations of the legal grounds considered by the Court to decide the various issues at stake.

There is indeed a stark contrast between these two final decisions – which rule in completely opposite way on identical cases. This gives space to some comments and considerations.

Normal food or special food?

The Guangzhou second instance decision, as well the Shanghai first instance decision, stated some criteria whereby an ingredient cannot be considered as normal food.

The first criterion is when such ingredient/substance is included on the *Chinese Pharmacopoeia*.

The second element is when an ingredient/substance cannot be obtained (the court uses the term "取得", which literally means "*obtain, acquire*") through natural methods. The likely interpretation is that the ingredient (CoQ10) added into this product

(22) In the decision, the term used is 危害.

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had been synthetically produced, and not extracted by natural elements that contain it.
The third criterion is when an ingredient/substance is not a traditionally-eaten food in China.
In our view, the court shall implicitly mean that at least the first and second criterion stated by the court must be jointly present and co-exist:

- the first criterion alone would mean that any food containing vitamins or minerals (which are substances included in the Chinese Pharmacopoeia) cannot be considered as "normal". An argument against such thesis would be that the first criterion would not apply to food naturally containing such substances. Such argument - though – conflicts with the legal recognition of the so-called fortified food (i.e. food with nutrition fortification substances – such as vitamins or minerals – added[23]);
- the second criterion alone would lead to the assumption that any food containing additives, or ingredients artificially produced/processed (such as wine, cheese, oil, etc..) cannot be considered as "normal".

It would have been interesting having the court's definition of the concept of "*natural methods to obtain ingredients*": does this exclude chemical/synthetic methods? or also mechanical methods?
Moreover, it will be interesting to see how this 3-criterion approach will be considered in future by the jurisprudence.

What can be added to normal food?

Guanghzou's Intermediate Court referred to art. 28 of the 2009 *Food Safety Law* to rule that CoQ10 cannot be added to food. Such provision forbids "*non-food raw materials*[24]" from food. Does CoQ10 belong to this category? In the absence of a clear legal definition, we observe that CoQ10 is naturally present in the human body and that the law expressly allows it as ingredient of health-food. In our opinion, applicability of art.28 of the 2009 *Food Safety Law* in the current legal framework is at least uncertain.
Article 38 of the *Food Safety Law* forbids adding medicine to food, except for substances which are considered as both food and Chinese traditional medicine (which are listed on a specific catalogue). Which are exactly the medicines that cannot be added to food? Guangzhou's court – as we have seen – clearly referred to substances included in the *Chinese Pharmacopoeia*.
In our opinion, however, this approach might be not correct. Purely referring to any substances included in the *Chinese Pharmacopoeia* would mean banning substances like vitamins, minerals and – why not – CoQ10, which – even if artificially produced – are present/existing in nature. Moreover, as we have mentioned in the previous paragraph, this would mean banning or questioning the legality of so called fortified food[25].
As we have seen, *Notice 566/2009* expressly confirms that CoQ10 can be combined to normal food ingredients; however, such Notice applies only to the registration of health-food, and it simply confirms that CoQ10 can be combined to normal food ingredients in order to produce health-food. Therefore it does not help to solve the doubt whether normal food can include CoQ10.
We believe then that it would be appropriate referring then to the criterion of article 150 of the *Food Safety Law*, which defines food/normal as "*any substance that has been processed or not processed that is suitable for eating and/or drinking, including substances traditionally used as food and Chinese herb medicine*" and which excludes "substances *only used for disease treatment*[26]". Based on this, if CoQ10 is a substance only used for disease treatment, then it cannot be added to normal food.

([23]) GB 14880, article 2.4.
([24]) In the Chinese text: 非食品原料.
([25]) Regulated by GB 14880.
([26]) The Chinese text*但是不包括以治疗为目的的物品* literally translates "excluding substances used for disease treatment", without the word "only". However, such clause shall – in our opinion – be interpreted as excluding substances only used for disease treatment, as disease treatment might need/involve also other kinds of substances, including ordinary food and nutrients, etc.

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However, this appears not to be the case: Notice 566/2009 confirms that CoQ10 can be used for preparation of health-food, which – by law – cannot have any disease treatment function[27].
This – in our opinion – appears to us a good argument to support that – under the current legal framework as of the date of writing of this article – normal food can contain CoQ10.

Legal force of CIQ sanitation certificate

According to PRC law[28], CIQ inspection is carried out on imported products. The aim of such inspection is to assess "*whether the commodities conform to the requirements on safety, sanitation, health, environmental protection, fraud prevention, etc., and to the relevant items of quality, quantity, weight, etc.*"[29]. Inspection shall be conducted by CIQ in compliance with specific requirements of National Health and Family Planning Commission[30]. Only products which – according to the inspection – are compliant with PRC safety regulations can be imported and sold.
In our opinion, however, while an importer legitimately relies on such CIQ approval to legally sell food products, on the other hand the positive outcome of such CIQ inspection cannot be a valid argument per se to reject an objection on the legal compliance of an imported product. In the two cases considered by this article the consumers were not challenging the result of the product analysis; they were basically questioning the background legal grounds upon which the CIQ had assessed the product compliance – i.e. the fact that CoQ10 capsules were considered as normal food.
Upon such a request, a Court shall critically evaluate whether CIQ's decision was legally correct or not. Affirming the contrary would mean, for instance, that it would basically be impossible to challenge a non-compliant label after it has been wrongfully (or even simply questionably) approved by CIQ.
An implicit and indirect confirmation of this principle can be found in article 94 of the Food Safety Law, which considers the case of imported food (therefore, food that has already passed CIQ inspection and obtained sanitation certificate) which fails to meet PRC food safety standards or may cause harm to human health[31].

Legal value of Notice 566/2009

The legal force of Notice 566/2009 is also debated: does it provide binding food-safety standard? Or is rather just a document regulating certain aspects of an administrative procedure?
In our opinion the second interpretation seems more correct.
First of all, such notice is formally addressed to the CFDA department of province, municipality and autonomous province's level. As such, it dictates the rules to be followed by those departments when they receive applications for CoQ10 Health-Food registration.
The limit of a maximum daily intake of 50 mg/day in such notice is – in our opinion – only recommendation[32] to these departments when processing CoQ10 Health-Food applications. It might have de facto binding value – meaning that applications not compliant with such recommendation might fail or need to be amended – but it is not the express and official statement of a risk for health.
Moreover, the scope of such notice is exclusively referred to CoQ10 Health-Food, not normal food. Nowhere in such notice is stated that this limit is mandatory to avoid health risk. In theory, as far as we can assume, the reason why such amount is recommended as maximum amount in health-food might be related not to risk assessment, but rather to the quantity needed in order to obtain the best performance of health-food functions (i.e. above

(27) Amongst others, article 2 of *Provisions for Health Food Registration (Interim) of 2005; article 78 of 2015 Food Safety Law*; article 2 of GB 16740.
(28) *Food Safety Law*, article 92; *Law of the People's Republic of China on Import and Export Commodity Inspection* of 10 August, 2005.
(29) Article 9 of *Implementing Regulation of Law of the People's Republic of China on Import and Export Commodity Inspection* of 1 December, 2005.
(30) Article 93 of *Food Safety Law*.
(31) According to such provision, the importer shall immediately stop importing the food and shall recall the food already imported.

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this amount the intake could prove less effective). If this would be the case, a person could well assume higher dosage of such pills as long as they are sold as normal food without any risk for health, and – as long as those products are sold as normal food (which therefore bears no health/function claims) – labels could suggest a higher dosage.

Pursuant to the *Food Safety Law* in its previous 2009 version – which was into force when Notice 566/2009 was issued – food risk assessment shall be evaluated and carried out by specific commissions established under the former Ministry of Health[33], the final result of such risk assessment shall be communicated by the Ministry of Health to other Ministries[34] and such results shall provide the scientific grounds for formulation and revision of food-safety standards[35].

What we want to stress is that – if the limit of 50mg per day is considered the limit for health safety – such limit should have been stated as mandatory under relevant regulations and/or standards, and not simply recommended in a notice with regulating the way CoQ10 Health-food applications shall be handled.

Instead, neither in *Chinese Pharmacopoeia* nor in the GB 22252/2008[36] there is any mandatory provision limiting the maximum daily intake of CoQ10.

7.- Grey areas in PRC food regulatory system and future evolution

In the end, these cases highlight a lack of internal coordination within PRC legal and administrative system.

Several authorities were involved: CFDA, with paramount competence on food safety; CIQ, with competence to clear import food products; NHFPC, in charge of carrying out risk assessment and issuing food safety standards; the Pharmacopoeia Commission, which approves and issues the *Chinese Pharmacopoeia*.

Despite clear improvement to the consistency of the PRC administrative food safety environment, vagueness in the relevant regulations as well as some confusion on the involved authorities' powers and scope still exists:

- provisions[37] of the Food Safety Law forbidding use of non-edible raw material or chemical substances into food remains – in the end – very vague. There is no – today – a clear list of (or criteria to identify) ingredients/substances that can be used only for health food and cannot be added to normal food;
- food safety standards – issued by NHFPC – mention the role of CoQ10 in health-food but do not expressly forbid CoQ10 from being added into normal food;
- *Notice 566/2009* of CFDA merely "*recommends*" a maximum daily intake of CoQ10 when it is added into health food (not mentioning whether this recommendation is for health-safety purpose or for enhancing function purpose). Moreover the circular does not mention use of CoQ10 in normal food;
- *Chinese Pharmacopoeia* defines CoQ10 as "*coenzyme drug*". However, it is unlikely that this means that CoQ10 is considered as a drug at full extent (as vitamins are also defined in the *Chinese Pharmacopoeia* as "*vitamin drugs*", but they can be legally sold as health-food and added into normal food as fortifiers).

On the other hand, as the implementation of the *Food Safety Law* is taking shape day by day[38], we

(32) Chinese text uses the word "推荐", recommendation. It is the same word used – for example – for non-binding GB standards (which are defined as GB/T).
(33) Art. 13 of the 2009 *Food Safety Law* (prior to modification in 2015).
(34) Art. 15 of the 2009 *Food Safety Law* (prior to modification in 2015).
(35) Art. 16 of the 2009 *Food Safety Law* (prior to modification in 2015).
(36) It is the safety standard applicable to CoQ12 in health-food.
(37) Article 28 of *Food Safety Law*.
(38) The draft Implementing Regulations of the *Food Safety Law* have been published on December 9, 2015 and are currently undergoing to the public-comments phase, following which the draft might be modified and finally entry into force. *Catalogue for Health-Food Ingredients* and for *Catalogue for Health-Food Claims* are being drafted.

can forecast that the correct categorization of products such as CoQ10 – as well as other similar regulatory issues – might be easier under the new regulatory framework.
In fact:

- a catalogue of health food ingredients will be published. Such ingredients can be used only for production of health food, and cannot be contained in normal food (article 75 *Food Safety Law*; article 81 of the current draft *Implementing Regulation of the Food Safety Law*);
- products containing ingredients only allowed for health-food might soon not be legally imported as ordinary food (art. 115 of the current draft *Implementing Regulation of the Food Safety Law*);
- definition of health food provided by the current draft of the *Implementing Regulation of the PRC Food Safety Law*[39] seems more complete and rich that the current ones, as it refers to "*food with health function claims, or for supplementing nutrients (such as vitamins/minerals), for regulating body functions, not intending to cure diseases, containing specific functional ingredients, suit for special groups of persons, and with fixed amount consumption*."

Therefore, should the CoQ10 be inserted in the health-food ingredients catalogue as a "sole health-food ingredient", it will be crystal clear that current importation of such product as normal food will not be allowed anymore. At the same time, it will be clear that any different conduct by CIQ – allowing import of such product as normal food – will lack legal grounds.

ABSTRACT

The legal qualification of Co-enzyme Q-10 appears uncertain in Chinese system: because of its properties as well as its inclusion into Chinese pharmacopoeia it is often considered as a drug-substance, which as such should be banned from ordinary food. Many consumers –supported by PRC la provisions that grant them punitive damages calculated based on the amount of non-compliant products purchased – have filed cases against food distributors claiming non-compliance of Co-Q10 products. This article (i) compares some interesting decisions issued by Chinese Courts in different cities which – while ruling in opposite sense – highlight some loopholes of the current PRC regulation of health-food and ordinary food, and (ii) goes through the legal grounds relied upon by courts in those cases – which have not been easy for them to decide.

□

([39]) Art. 195.