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Research Article

Enforcement and Credibility of the Safety Certificate of Chinese Genetically-Modified (GM) Food Crop

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Abstract: The study analyzes the second round safety certificate review of GM maize and GM rice by the Ministry of Agriculture of China. The research found, in the safety evaluation of the GM food crop, it reveals some negligence, such as, the test site of the GM food crop is not up to the requirements, the concluded assessment conclusion cannot positively respond the question of the material, the second assessment time is too short and the like. Meanwhile, during the process of the safety assessment for the GM food crop, the government has no enough neutral standpoint, the publicity of the argumentation and application data is insufficient, there is interest relevance between the scientists participating in safety assessment and GM industry, the government attitude on the GM safety is inconsistent, which makes the media and the public doubting government's credibility and affects the commercialization promotion of the GM food crop.

Keywords: Assessment, credibility, genetically-modified, negligence, safety

INTRODUCTION

On August 17, 2014, the Ministry of Agriculture confirmed that the safety certificates for the "BVLA430101" phytase genetically-modified maize, "Hua Hui No. 1", "Bt Shan You 63" genetically-modified rice issued in 2009 have expired. According to Chinese law, the validity of the safety certificate for the agricultural GM organism is five years, after expiration, the applicant needs re-submitting material to apply for new safety certificate (Zhang *et al*., 2010). In January 2015, the Ministry of Agriculture announced that the above mentioned three GM food crops obtained the new safety certificates.

The pros think that GM food crop in China is getting closer and closer to the commercialization promotion (Paarlberg, 2002). Another advantageous news for the pros is that the Ministry of Agriculture has approved the import of the GM soybean of the Bayer company and the Dopunt Pioneer Corporation and the GM maize of the *Syngenta* (Jia and Peng, 2002). However, combining with various aspects, it can be seen that this estimation is too optimistic (Huang *et al*., 2006), the commercialization prospect of the GM food crop in China is in an extremely indefinite state (Chen *et al*., 2011).

Whether for or against GM food crip, it need evidence (Qiu, 2008). Thia research should investigate whether there had occurred enforcement negligence and credibility absence during the approval process of the GM food crop (Gruhn *et al*., 2000), found the key factors which would become the fatal obstacle hindering the GM food crop appearing on the dinner table (Cohen and Paarlberg, 2004).

MATERIALS AND METHODS

In the three kinds of GM food crops, the phytase GM maize is cultivated by the Chinese Academy of Agricultural Sciences, the gene for transforming phytase in the maize is from A. Niger, the method is to add promoter specifically expressed in embryo to the phytase gene and to transform the promoter together with the phytase gene into the maize embryo. The phytase contained in such maize can hydrolyze the phytic acid in the stomach of the swine, chicken, duck and other monogastric animal to release phosphoric acid which is directly absorbed and used by chicken and swine, so as to improve the utilization rate of phosphorus. "Hua Hui No. 1" and "Bt Shan You 63" are developed by Huazhong Agricultural University in China, belonging to the GM rice strain for high-anti-*Lepidoptera* pests. With "Ming Hui 63" rice as the receptor variety, the "Hua Hui No. 1" GM rice is the *Bacillus thuringiensis* (Bt for short) insecticidal protein fusion gene (Cry1Ac/Cry1Ab) generated via artificial transformation and the method of gene gun mediation co-transformation, the expression product can specifically and sufficiently control rice-stem borer, *Tryporyza incertulas*, rice leaf folder and other rice

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Lepidoptera pests. The female parent of the "Bt Shan You 63" GM rice is the "Zhen Shan 97A" hybrid rice and its male parent is "Hua Hui No. 1".

The evaluation index system of the GMO Biosafety made by the Ministry of Agriculture includes the GM biomolecule feature, environmental safety, edible safety and other contents (Jing, 2013). Firstly, the safety assessment includes:

- **(A1) acute toxicity test:** Feed the small/large mouse with different doses of GM protein, continuously observe 7 to 10 days, detect whether the result of the acute toxicity is "nontoxicity".
- **(A2) genetic toxicity test:** It includes Ames test (mutagenesis test), mouse bone marrow micronucleus test, mouse *Teratospermia* test and mouse teratogenesis test, detect whether the GM protein has mutagenicity, damage effect on the mouse bone marrow cell chromosome, aberration effect on the mice sperm and whether it has teratogenesis on mice.
- **(A3) subchronic toxicity test:** Through the 90 days of test for feeding GM protein to mice, monitor whether there is significant difference between initial weight, final weight, food utility rate and control group, detect whether there is abnormal change in the mid-term blood, check whether the final blood is in normal range and check whether there is obvious effect on the laboratory animal organs in the aspect of histopathology.
- **(A4) subchronic toxicology test:** Through the 90 days of test for feeding GM food crop to mice, carry out weight and food-intake detection, hematology detection, blood biochemistry detection, viscera weighing and histopathology observation to the laboratory animal, contrast the laboratory animal fed GM crop with the one fed parent crop.
- **(A5) allergenic evaluation:** Evaluate the potential allergenicity risk of the GM protein contained in the GM crop from the following four aspects of transgene source, the homology between the newly-expressed protein and the given sensitinogen amino acid sequence, the digestion stability of the newly-expressed GM protein and the heat stability of the newly-expressed GM protein.
- **(A6) antinutritional factors evaluation:** Compare and detect the content of the trypsin inhibitor of the common food crop and GM food crop.
- **(A7) nutrient content evaluation:** Compare and detect albumen, fat, starch, cellulose, iron, zinc, calcium, magnesium and other element content of the GM food crop and common food crop.
- **(A8) antibiotic resistance evaluation:** Survey whether the resistance selection marker gene is used in the GM food crop in the GM process to know whether the expression kit fragment for transformation contains GM protein and its promoter and terminator.
- **(A9) bioavailability evaluation:** Feed chicken with the feedstuff made from common crop and the feedstuff added with exogenous GM protein, record the daily feed intake of the laboratory animal, the weight of the age in 1, 21 and 42 days, respectively daily gain, number of death during test duration, measure the serum, excreta, calcium, phosphorus and nitrogen content in tibia and test the influences of the GM food crop on the growth performance and calcium-phosphorus metabolism of the broiler chicken.

At the same time, the Ministry of Agriculture carried out the test and evaluation on environmental safety of GM food crop. It includes the following 11 aspects:

- (B1) difference evaluation between the reproductive way and reproductive rate of the parent plant and the GM one
- (B2) difference evaluation between the pollen spread mode and transmission capacity of the parent plant and the GM one
- (B3) evaluation on period of dormancy
- (B4) adaptability test
- **(B5) competitive capacity for existence:** Survey whether there is obvious difference between the germination rate, planting percent, growth vigor, plant height, flowering duration, fringe location, loose powder duration, setting percentage and the reaction to the common diseases and insect pests of the GM food crop and other biological characteristics and the common crop
- **(B6) evaluation possibility of transforming from GM genetic material to the wild sibling species:** Survey whether the GM food crop transfers into the wild sibling species or *Zea diploperennis*
- **(B7) evaluation possibility of transforming from GM genetic material to common cultivated variety:** Survey whether the exogenous gene of the GM food crop drifts towards the surrounding seed farm and germplasm resources breeding area
- (B8) evaluation possibility of transforming from GM material to other species
- (B9) evaluation possibility of transforming into weed
- **(B10) impact evaluation on beneficial and harmful organisms in environment:** It mainly detects whether there is significant difference between the insect and pest important natural enemy feeding GM food crop and the one feeding cross parent food crop on the aspects of survival rate, weight, relative ingestion rate, relative

metabolic rate, approximate digestibility, food utility rate, food conversion rate and the like and whether the situation of the GM food crop suffering insects and diseases and other situation is consistent with common crops

- **(B11) impact evaluation on soil fertilizer rate and structure:** It mainly surveys whether the phosphorus utilization rate of the soil used for sowing GM food crop is improved and surveys what is the influence on soil

RESULTS AND DISCUSSION

Negligence existing in safety assessment process of the GM food crop: After evaluation, the Ministry of Agriculture considered that the food safety of the above mentioned three GM food crops is equivalent to common crop and there is no harmful influence on environmental safety. But, from the view point of the Laws and Regulations on the Management of the Chinese GM Farm Products, there is some legal negligence during the test and assessment process of the GM food crop cultivation.

Test site of the GM food crop does not meet the requirements: It is stipulated in the article 11 of the Regulations on Administration of Agricultural Genetically Modified Organisms Safety that the unit engaging in the research and test of the agricultural GM organism shall possess the safety facilities and measures suitable for safety level to ensure the security of the research and test of the agricultural GM organism. It is stipulated in the article 20 of the Regulations on the Safety Assessment of the Agricultural Genetically Modified Organisms that the research unit shall report laboratory safety facility, safety management and precautionary measures to the agricultural GM organism safety management office. In the aspect of test condition, the optimum site for some key test links of the GM food crop shall be "negative pressure greenhouse and negative pressure lab" to ensure that the most of the air flows in the lab, all externally-discharged air shall be filtered to precipitate the filtering matters to a large box, so as to prevent the pollen, spore and other genetically modified microorganism not diffusing into the atmosphere outside the lab. At present, the research and development units of the GM rice and maize in China do not match such test condition. The scientist of Zhejiang University, China researched that the paddy pollen drifted down folium mori in the interbreed region of the mulberry and paddy, showing that the paddy pollen can completely floats on the 10 m height of folium mori and also showing that there is no difference between the drifting capacity of the pollens of the Bt GM rice and non-GM rice plants (Wang, 2011). Phytase GM maize also carries out the planting test in open area. According to study, it was reported that the diameter of the maize pollen was about 0.1 mm and the maximum pollen in anemophily pollen. Usually, the wind-spreading drift distance is not more than 150 m, the scattering scope of the pollen is about 1m during breeze and it is within 500 to 1000 m during larger wind power. Under field condition, when the temperature is 28.6 to 30°C, the relative air humidity is 65 to 81%, the *in-vitro* vitality of the maize pollen can maintain 5 to 6 h. These verify that the seed pollen of the GM food crop exposes and freely diffuses in the open air, which certainly causes risk. The Ministry of Agriculture did not neither point out the non-compliance problem of the test site in the assessment, nor further considered the risk caused by the diffusion of the GM matters.

Official assessment is challenged by recently scientific research: In the safety assessment of the GM organism, (A1) to (A4) toxicity evaluation, (B6) Evaluation possibility of transforming from GM genetic material to the wild sibling species and Evaluation possibility of transforming from GM genetic material to other species are concerned most (Kuiper *et al*., 2001). Recently, some researches revealed the problems of the GM food crop existing in the above several aspects. And in the aspect of the toxicity of the GM food crop, a research paper from the Hunan Normal University in China revealed that carry out the mouse feeding experiment with "Bt Shan You 63" GM rice, after 90 days, it was found that lesion hyperplasia appeared on the mouse intestinal gland cell, this study also pointed out that the GM rice has potential allergen, whether the above phenomenon was caused by GM protein, close tracking study is further needed (Huang *et al*., 2002). A research from the Jiangsu University in China showed that significant difference of the haematological index and organ coefficient index appeared in small part of animals in the experimental animal group feeding GM rice, additionally, there was difference between the testis cell cycle and reproductive organ coefficient. Although more study is further needed to verify these conclusions, it at least indicates that the risk of the GM food crop is approaching in any time. And in the aspect that the GM food crop has influences on the biotic environment in a certain region (König *et al*., 2004), with the GM Bt rice and its homologous rice (Bt rice) as materials, the scientists at Jiangsu University in China have studied the influences of the bacteria, fungi, *Actinomyces*, denitrifying bacteria and phosphate-solubilizing microorganisms in degradation process and found that the Bt protein in the GM rice has negative effects on bacteria and denitrifying bacteria. According to Regulations on Administration of Agricultural Genetically Modified Organisms Safety and based on the hazard level of the human, flora and fauna, microorganism and ecotope, the Genetically-Modified

(GM) organism in agriculture is divided into 4 levels, safety level I represents the inexistence danger, safety level II represents low degree of hazard, safety level III represents medium danger, safety level IV represents high danger (Wang, 2011). The Ministry of Agriculture did not make positive response to some questions of the scientific community while evaluating GM maize and GM rice, but only made the evaluation of safety level I.

Time of the second safety assessment is too short: The Ministry of Agriculture specifies that the applying the safety certificate of the GM organism should firstly carry out pilot experiment, environmental release and production test to obtain relevant evaluation data, the pilot experiment refers to the small-scale test carried out in the control system or under control condition. The environmental release refers to the medium-size test carried out under field conditions with corresponding safety measures. The production test refers to the larger-scale test carried out before production and application. Test results should be checked by provincial government and then submitted to the Safety Committee of the Genetically-Modified (GM) Organism in Agriculture. The Committee should organize a third party, testing organization to check and verify the environmental safety, edible safety, molecular characteristic and other indexes of the GM organism and should make suggestions whether safety certificate is issued. And then, the Ministry of Agriculture holds the safety management Inter-ministerial joint conference on the GM organism in agriculture composed of 11 departments of the State Council to vote the safety certificate issuance. The time spending on the first round of GM food crop is longer, in which, it took 11 years to evaluate GM rice and took 6 years to evaluate GM maize. But it only took less than 4 months for the second round of evaluation. The omission therein lies in that according to the provisions of the Chinese law, the data which should be submitted to the evaluation process of the re-applying safety certificate of the genetically modified crops includes the research progress of the last safety period and other data of the GM safety. However, regardless of the applicant of the GM maize and the GM rice, there is no substantive difference between the re-submitted application material in 2014 and the previous review and during the period of 5 years from 2009 to 2014, the scientific community got great progress of the GM researches, aiming at the GM health risk, GM genetic material transferring, privately planting GM seeds and other aspects appearing in China, there are so many problems, obviously, the Ministry of Agriculture has not taken enough time to evaluate it but issued new safety certificate rapidly.

CREDIBILITY ABSENCE IN THE SAFETY CERTIFICATE OF GM FOOD CROP

Although the Ministry of Agriculture stated China hold "positive research and cautious utilization" position to the GM and emphasized that the GM food with safety certificate is safe. But some behaviors of government could not be trusted by scientific community and the public.

Safety certificated information is not to the public for a long time, the public raises doubts to the certification process: The safety certificate process of the GM maize and rice from the Ministry of Agriculture is not transparent. Most of the information capable of being obtained to the external is provided by the GM inventors, such as, the inventor of the phytase GM maize stated that firstly, the gene source is safe, the transcriptional gene came from a kind of *Aspergillus niger* which has been approved for use by food industry; secondly, it is safe from the point of molecular biology, the phytase widely exists in nature and can be produced and secreted by a lot of microorganism, higher plant also contains phytase gene by itself, the gene sequence transcribed by the phytase maize and its transcriptional protein sequence are highly similar with the wheat phytase sequence; thirdly, the phytase fermented via same gene has been used for many years, there is no safety problem (Qaim and Zilberman, 2003). But, the inventors did not introduce their test environment, main test parameter, test results and other critical information. The Ministry of Agriculture has not notified the application materials submitted by the inventors during the safety demonstration of the first round GM food crop in 2009. It aroused some scientists' query, some media reported the news that the Monsanto Corporate Research Laboratories initiatively opened the GM crops data to criticize that the Chinese inventors of the GM food crop dare not open the application materials. In 2011, some lawyers wrote to the Ministry of Agriculture asking for publicity. Until August 2014, the applications for the safety certificate of the GM maize and rice were published. According to legal provisions, although the inventor is entitled to take confidentiality measures to the content in the application involving in inventor's business secret, such as the preparation of the study route, DNA sequences of various expression controlling elements, genetic manipulation strategies and various safety evaluation data, these are not enough to be the reasons why the Ministry of Agriculture and inventor did not open the application data.

Seeds with GM ingredients are illegally spread and still can be planted without safety certificate due to slack supervision of government: In accordance with the provisions of the Regulations on Administration of

Agricultural Genetically Modified Organisms Safety, Seed Law of the People's Republic of China, Certification Method of Major Crop Varieties and other laws and regulations, after obtaining the safety certificate, the GM maize and rice should be carried out strict regional testing and production testing firstly according to the provisions of the state Certification Method of Major Crop Varieties, only the one up to standard can obtain the variety certification certificate and afterwards, the relevant seed enterprise could not obtain the production licence and business certificate for the GM crops seeds and carry out the seeds production and management until pass the strict check. But the fact is that during the safety evaluation process of the GM maize and rice by the Ministry of Agriculture, the commercialization planting phenomenon of the GM maize and rice has been found in China. On the aspect of rice, in 2005, the Environal NGOs "Greenpeace" conducted an investigation in the international chain supermarket of Hunan Province and Hubei Province in China and found that the GM test results in some varieties of rice sold in the supermarket presented positive. Since 2006, the EU has detected the GM ingredients in the 184 testing of the rice products exported by China. According to the investigation, in April 2005, the Ministry of Agriculture found that Wuhan Coney Plant Gene Co., Ltd., Wuhan He Sheng Seed Coating Co., Ltd. and Huada New R and D Company arbitrarily expanded the seed production behavior during the process of assuming the productive experiment of the GM rice, resulting that the GM seeds flowed into market, the Ministry of Agriculture also ordered rooting out the GM rice planting in 10000 acres of farmland in Hubei Province. But Ministry of Agriculture cannot make a thorough investigation of how many GM seeds have flowed into market on earth. The above mentioned four companies have provided seed production business for the "Hua Hui No. 1", "Bt Shan You 63" GM rice. According to the provisions of the Seed Law, to sell seeds must make sure the obtaining of the variety certification certificate, seed production license and business certificate issued by the Ministry of Agriculture. In terms of maize, according to the agricultural breeding experts in China, it is estimated that the seeded area of the suspicious maize containing GM ingredients possibly has been up to 60 million acres in China. But the Ministry of Agriculture has repeatedly claimed to the external that so far, it has never approved the production and commercialization planting of any kind of GM staple food grain seed developed in China. The series of events makes the reputation of the Ministry of Agriculture being heavily damaged, many people doubt that the Ministry of Agriculture does not take the GM heath risk seriously and hold mistrustful attitude to the safety assessment of the GM food crop implemented by the Ministry of Agriculture.

The scientists supporting GM are found existing commercial interests and the public doubt that their standpoints are non-neutrality: According to the Regulations on Administration of Agricultural Genetically Modified Organisms Safety, the Ministry of Agriculture set up the GMOs safety committee, the committee members are the experts in GMOs research, production, processing, inspection and quarantine, health, environmental protection and other aspects, each term of office is 3 years. The committee is responsible for the safety evaluation works of the agricultural genetically modified organisms and providing technical advices for the safety management of the GMOs. And it has powerful voice on the granting of the GM food crops safety certificate. The agricultural GM safety certificates for the phytase GM maize, "Hua Hui No. 1", "Bt Shan You 63" GM rice were approved in the third term committee. There are 74 committee members in the third term committee, including 10 members from the inventor of GM maize (the Academy of Agricultural Sciences in China) and one member from the inventor of the GM rice (Huazhong Agricultural University). The fourth committee will make the second round of safety demonstration of the GM maize and rice in 2015, there are 64 members in the fourth committee, including 12 members from Chinese Academy of Agricultural Sciences and 1 member from the Huazhong Agricultural University. Based on the Working Rules of the Agricultural Genetically Modified Organism Safety Committee, if the committee member and its relatives in the safety committee involve in interest during the approval process, it should be actively avoided while discussing this item. Although these scientists are avoided in the process of examination and approval, the influences still exist and it is very difficult to make clear whether other scientists participating in the vote keep neutral standpoints. In recent years, many scientists have not only developed biotechnology research, but also formed company for marketing excellent seeds invented by own, some indications show that part of Chinese scientists have been involved in commercial interests vortex brought by GM farm products, they even overlook the phenomenon that the GM crops flow into market. The Ministry of Agriculture issued the No. 1504 Announcement in 2010 to judge the production stop of 27 maize varieties and to stop sales and promotion within one year from the date of announcement release and thoroughly withdraw the Chinese seed market. In the 27 maize varieties, the "Deng Hai 3686", "ZND No. 4" and "ZND 236" and "Te Yan 124" four varieties are specifically concerned. Li Denghai, the breeder of the "Deng Hai 3686" is the committee member of the Standing Committee of the National People's Congress and was called "father of the Chinese hybrid maize". The breeder of the "ZND No. 4" is the Jing-Rui Dai, the Chinese Academy of engineering and the professor of

the China Agricultural University, he participated in the study of the phytase gene maize and also held group leader of the "major special agro-ecological GM projects" corm project implementation expert group of the ministry of Science and Technology of China. Wang Shoucai, the breeder of the "ZND 236" is the director of the maize breeding engineering centre of the Chinese Education Department, the deputy director of the maize specialized committee of the State Crop Variety Certification Committee and the professor of the China Agricultural University. Initially, these four maize varieties were used to apply the national variety test, examination and approval, registration and finally approved in the name of non-GMO and afterwards, they were forbidden caused by containing GM ingredients. The Ministry of Agriculture explained the reason why these seeds were forbidden and said that "the breeder mistakenly introduced the foreign GM seed resources due to be lack of experience, resulting that actually, the cultivated varieties contained GM ingredients", "from breeder itself to breeding units, to production and management enterprises, belonging to unconsciously mistake made". Through this event, the public think that some famous scientists in China have been "kidnapped" by the GM profit chain and they could not be neutral in the GM safety assessment (Kuiper *et al*., 2001).

Uncertain official standpoint increases the doubts of the public: There is difference between the policies of the Chinese official on the GM staple food grain. In the aspect of promoting GM, the State Council issued the Regulations on Administration of Agricultural Genetically Modified Organisms Safety in 2001 and regulated the agricultural GMOs research, test, production, processing, management and import and export activities engaging within the territory of China. The Ministry of Agriculture and General Administration of Quality Supervision successively made five matching rules, issued the GMOs identification catalog, set up research, test, production, processing, management, import licensing approval and identity management system. In 2008, the Ministry of Science and Technology announced the investment of 20 billion Yuan funds to start up the "GMOs new variety breeding" science and technology major special project. In 2010, the ruling party, Chinese Communist Party put forward the annual political program to stress "accelerating the implementation of GMOs staple food grain industrialization". But the strength against GM is also very strong, the main opposition strength comes from deputy to the National People's Congress (Member of Parliament), during the National People's Congress held once a year, some NPC members jointly submit proposal to oppose the commercial popularizing of the GMOs staple food grain. And there are some cons voices in the economic management department. Officers think that the key point of the GMOs staple food grain promotion is the seed, at present there is less GM technology patent for the Chinese enterprises, the GM seeds commercialization cannot be opened untimely and it is also not allowed to set up the enterprise for managing and selling seeds by the foreign merchant freely.

The management practices of the Chinese government departments on the GM food crop are inconsistent. On one hand, the technical officials of the Ministry of Agriculture claimed that the GM food crops with safety certificates are safe and there is no essential difference with the non-GMO crops in various occasions. The Ministry of Agriculture also sponsored the writing of the A Rational Perspective on GM white paper. On the other hand, the Ministry of Agriculture required that agricultural product enterprises could not specially state that its product is "non-GMO" while advertising and could not slander other competitors with GM. After the GMOs staple food grain was exposed by media in many places in China, the Ministry of Agriculture carried out more strict controlling measures to the GMO crops. Such as, for the seed variety certification, GMO varieties are not permitted to appear on the certification list and it is not allowed that the GMO crop seeds are marketed in parallel with the non-GMO seeds. These behaviors broken the public trust in government, there are more and more people who do not receive the safety guarantee of the government and enterprises.

CONCLUSION

The route map of the GM farm products made by the Ministry of Agriculture is as follows: the first step is to develop unedible industrial crop, second step is to develop the feed crop and to process the raw material crop, third step is to develop common edible crop and the final one is to develop staple food grain. So far, the GM crops capable of being planted in large scale approved by China are only cotton and pawpaw and in food crop, it is only approved that the imported GM soybean, GM maize are served as feed processing and oil expression, the commercialized production of the GM food grain is not approved. The safety certificate granting of the GM food grain and the behavior of importing the foreign GM food grain seeds are the favorable signs to the GM food grain appearing on dinner table, but the non-precise evaluation procedure, weak supervision capacity of GM seeds expansion and poor credibility problems exposing in the Chinese government, indirectly facilitate the momentum and strength of the cons of the GM farm products. The Ministry of Agriculture needs to strictly crack down the violations in GM breeding and carry out comprehensive and dynamic supervision to the safety evaluation test and keep neutral position, the public confidence can be

restored and it is possible to go further on the commercialization promotion road of the GM staple food grain only in this way.

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