



# 1

## 综合篇

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Comprehensive Chapter

## 1.1 综述

2011年,在国家食药监局、上海市委、市政府的坚强领导和具体指导下,上海市食品药品监督管理局始终以邓小平理论和“三个代表”重要思想为指导,深入贯彻落实科学发展观,大力践行科学监管理念,始终坚持公众利益高于一切的原则,紧紧围绕保障公众饮食用药安全这个中心,扎实有序推进各项工作。食品、药品专项整治取得预期效果,得到国家检查评估组的肯定,医疗器械、保健食品和化妆品监管工作进一步加强,圆满完成世游赛食品药品安全保障任务,新闻宣传工作取得成效,各项科技支撑体系建设和监管队伍建设有序推进,全市餐饮、药品安全事故发生率保持较低水平,市民饮食用药权益得到保障,消费信心逐步增强,实现了食品药品安全动态可控的监管目标。全市目前食品药品安全总体形势平稳,食品药品行业得到进一步规范,监管工作取得了丰硕成果——

### 一、保持高压,餐饮安全监管取得成效

2011年,按照市政府“五个最严”的工作要求,保持监管高压态势。对餐饮单位的监管主要表现为“三高一低”。一是保持高频次巡查,开展全覆盖巡回检查,对高风险企业如集体送餐配送单位、学校食堂等每月检查1-2次,大中型餐饮等每年检查不少于4次,小吃点、饮品店等小型单位不少于2次。年平均对餐饮单位的日常巡回检查频次保持在3.5次以上,大大高于国际上各大都市的水平;二是保持高力度执法,餐饮服务行政处罚5120件,罚没金额1708.66万元,有力促进了餐饮服务企业规范管理;三是保持高密度抽检,全年抽检食品和加工环节样品4万多件,评价性抽检显示食品总体合格率保持在高位。食物中毒事件继续控制在低水平,全年共发生集体性食物中毒事件8起,中毒201人,比2010年分别下降20%和32.55%,食物中毒发生率为0.87/10万,不到10年前的1/10。全市48415户各类餐饮服务单位实施了监督结果公示制度,实施率为78.65%,评定结果为“良好”(笑脸)、“一般”(平脸)、“较差”(哭脸)单位分别占22.32%、68.66%和9.02%。市民食品安全知晓率稳步提高,2011年市民食品安全知晓度总体得分80.7分,同比提高1.1分,比2006年提高4.5分,82.7%的市民认为2011年食品安全水平有所提高。2011年10月中旬,国务院食品安全委员会办公室检查评估组来沪检查后认为,上海市食品安全工作组织领导到位,任务责任明确,体制机制比较健全,监管措施周密,方法求实创新,工作成效明显,达到了预定的工作目标。

### 二、严控风险,药品专项整治工作扎实推进

根据国家六部局的部署和市委市政府的工作要求,坚持以维护好公众用药安全为出发点,

以科学监管、风险控制为监管工作的理念，以创新做法、推进机制转型为药品专项整治工作抓手，统一思想、落实责任、依法打击、快速处置，建立长效监管机制，严密组织药品研发、生产、流通、使用环节的监管工作，扎实推进开展药品专项整治工作，总体完成情况良好。2011年完成各类药品申请许可事项 3655 个，实现了对全市 203 家药品生产企业、近 800 家各类医疗机构、3300 余家零售药店、128 家药品批发企业、512 个互联网药品信息服务企业、7 家互联网药品交易服务企业的全覆盖监管。从主渠道共抽样药品 15549 件，不合格率 2.74%；抽检药包材 238 件，不合格率 10.08%。目前，全市已确立并落实了“地方政府负总责、监管部门各司其责、企业是第一责任人”的药品安全责任体系，进一步明晰了辖区政府责任、部门监管职责和企业守法义务，药品生产经营秩序持续好转，重大药品质量安全事故明显减少，人民群众的药品消费信心明显增强。2011 年 10 月中旬，工信部和国家食药监局等组成的药品专项整治检查评估组来沪检查，对本市药品专项整治工作总体成效表示肯定，认为上海市自评情况真实客观，总体情况良好。

### 三、有序运行，促进医疗器械行业规范管理

以“突出重点、扫除盲点、统筹协调”为原则，加强医疗器械安全监管工作。至 2011 年底，全市共有 940 家医疗器械生产企业、9154 家医疗器械经营企业；全年共受理涉及医疗器械注册、出口证明、各类报告申请 1534 项，完成 1171 项，退回 43 个；共抽样医疗器械 348 件，总体合格率 92.53%；查处医疗器械违法案件 151 个，有力规范了市场。全市未发生医疗器械相关的重大安全事故，医疗器械市场平稳可控。在做好注册审批、落实高风险医疗器械分类检查的基础上，对两类企业和两种产品重点加强监管，包括 2010 年产品（环境）抽检（监测）不合格的企业和未按要求填报基础信息的企业，以及定制式口腔义齿和体外诊断试剂两类产品。进一步推进医疗器械监管信息的集成信息数据库建设，加强医疗器械追溯体系建设，在上海率先推行的上市后监管方法（UDI）赢得国际认可。

### 四、完善机制，大力规范保健食品和化妆品市场

2011 年，本市保健食品和化妆品监管工作得到进一步加强，通过全面加强巡查抽检和曝光力度、建立挂牌督办机制、强化跨部门合作、创新监管技术手段等措施，大力督促企业规范生产经营。全年共检查保健食品生产经营单位 14614 户次，检查化妆品生产经营企业 14304 户次，监管密度和频次前所未有。启动保化违法产品挂牌督办制度，查处保健食品案件 157 件，罚没金额 312.94 万元，查处化妆品案件 187 件，罚没金额 147.22 万元，并先后 6 次对 81 个不合格保健食品进行公开曝光查处。通过整治，捣毁了一批窝点和地下产业链，全市保化市场得到一

定程度的净化。

### 五、全力以赴，圆满完成世游赛食品安全保障工作

2011年6月至7月期间，我局全力以赴承担第14届国际泳联世界锦标赛食品安全保障工作。一是提前充分准备，制定和修改完善了保障工作方案，进行了演练；二是加强沟通，积极与国际泳联和有关国家官员沟通，消除国外媒体对世游赛食品安全问题的顾虑；三是强化全程监管，赛事期间，会同相关监管部门共监督保障18家接待酒店参赛人员用餐880餐次、约400万人次；四是对指定的专供世游赛猪肉加强源头管控，重点防范兴奋剂误用事件。实现本届比赛食品安全零事故、食源性兴奋剂零事件、食品消费零投诉的工作目标，受到了国际泳联、国家体育总局的高度赞扬。

### 六、营造氛围，发挥新闻宣传工作舆论引导作用

新闻宣传工作保持稳步推进，在积极举办各类宣传活动、形成宣传声势的基础上，发挥大众媒体作用，扩大科普宣传覆盖面，取得了良好的社会效果。市民对食药监工作更加理解，对食品药品安全知识认识更加充分，饮食用药安全意识和防范能力进一步增强。与市教委合作，在全市开展“食品药品安全宣传进校园”活动和“让我们吃得更放心”宣教活动。与市科委合作在全市开展“合理使用抗生素”主题科普巡回宣传活动。与《家庭用药》合作开辟“药品安全百事通”等专栏，与纪实频道合作制作26集科普宣传短片。组织编印“谨防‘健康’陷阱”等宣传用品。通过东方明珠移动电视，每天在地铁、公交上播出细菌性食物中毒动态指数、合理使用抗生素等公益广告。在新浪、新民网等开设“药博士信箱”微博，通过与网民互动普及安全用药常识，新浪微博粉丝已达2万多。依靠食品安全监测体系和药品不良反应监测体系，定期开展风险分析，列出风险控制措施并及时发布，发挥食药安全预警和消费提示作用。

### 七、建章立制，科学制订规划和制修订食品药品安全法规标准

完成编制《上海市食品药品安全“十二五”规划》并上报。按照年度修订计划，配合市人大常委会、市食安委办公室完成《上海市实施〈中华人民共和国食品安全法〉办法》的地方立法工作；开展《关于加强本市食品生产经营企业食品安全工作的若干意见》等11项行政规范性文件制修订。开展食品安全地方标准制修订，确定《餐饮服务单位外卖膳食卫生规范》、《餐饮中心厨房卫生规范》等地方标准制修订项目共18项。研究收录现行有效国际、国内食品安全卫生标准和法规共1318项，涵盖了目前全部现行有效的国家强制性食品安全与卫生标准以及CAC、欧盟、澳大利亚和美国食品安全卫生通用标准、食品卫生操作指南和其他特殊用途食品等技术法规。参与国家食药监局药品GMP、医疗器械追溯管理等方面多个法规、技术标准

的制修订。此外，会同市食品安全委员会各成员单位，推出一系列贯彻落实《上海市实施〈中华人民共和国食品安全法〉办法》的规定。

#### 八、科技监管，完善食品药品安全技术支撑

采取政府出资购买服务的方式，打破各行业部门藩篱，有效整合社会资源，建立食品安全风险评价体系，在全市设置 16 家合同实验室和 105 个采样点，定期监测覆盖食品中化学污染物及有害因素、食源性致病菌等方面的 226 个检测项目。根据国家《药品不良反应报告和监测管理办法》，制订《上海市药品不良反应报告和监测工作实施细则》。本市不良反应监测网对药品生产、经营企业完成全覆盖，全市注册入网单位达 1217 家。2011 年共审核药品不良反应 / 事件报告 22893 份，其中严重报告 1564 份。以《上海市基本药物生产企业产品不良反应分析报告》等 9 个报告为载体，发布研究分析数据，提示上市药品使用的风险指向。与政府部门 43 家检验机构、20 多家社会检测和各企业自检中心多方力量合作研究，形成食品安全检测技术支撑体系。积极推广运用现场快速检测技术，筛选、集成、应用食品安全快速检测技术已达 80 多项，较 2010 年增加 20 项；开发并配备药品现场文号比对查询设备。全市各级食药监部门均配发快速检测装备，现场快速检测已经成为一线执法人员日常监管必需掌握的执法技能。积极推进食品药品安全监管和信息服务平台建设。运行并完善财政资金有效管理系统。

#### 九、严格管理，队伍建设得到进一步加强

不断提高监管队伍综合素质，促进各部门有效履职。开发“廉政风险防控”系统，对廉政风险点主要集中的行政许可受理环节、行政许可验收环节等 5 大环节制定切实可行的防范措施，进一步建立并完善包括“监督岗位责任制”等在内的 9 个制度。实施领导干部下基层督查暗访工作制度，每月定期进行领导带队督查暗访，将暗访发现的问题以及整改情况进行汇总通报，并开展抽查回访。局领导带队下基层暗访 45 人次，全系统处级领导干部暗访次数已达 2196 人次，督促各级监管责任的落实。精研业务，全面开展监管队伍培训，2011 年累计举办食品、药品、法规、信息化、电子监管、信息公开、保密等各类培训班和培训会议 40 余次，培训人数 5100 余人次，覆盖全系统各单位；在培训中实行培训考核机制，确保监管队伍的实际操作能力得到切实提高。开展效能监察，督促窗口服务水平和执法规范水平提升，全年政风测评反馈情况显示：公众对我局网上行政审批满意率为 99.12%（23/2599），对我局窗口办事满意率为 99.61%（28/7240），行政执法反馈满意率为 90.64%（628/6710）。

#### 十、建立机构，推进食品安全综合协调机制全面落实

根据国务院的工作部署，结合上海实际，全面贯彻落实《食品安全法》关于综合协调机制



的要求。市政府制定下发《上海市 2011 年食品安全工作要点》、《上海市人民政府关于进一步加强本市食品安全工作的若干意见》，颁布《上海市人民政府关于建立上海市食品安全委员会的决定》（沪府发〔2011〕21 号），明确要求完善市、区两级监管体制。市政府成立市食品安全委员会及其办公室，明确各部门工作职责以及对监管职责不清问题协调、裁决的办法。市编办专门核定充实了市、区两级食安办的编制。我局根据编制情况和市政府部署，进一步调整完善机关工作机制，配合安排工作人员，配置办公场所、工作资源，落实工作经费，完成了市食品安全委员会办公室的相关配置工作。市食安委办公室成立后，着重加强协调服务，从有关成员单位抽调人员，落实集中办公制度和联合执法制度，解决监管缝隙的问题，理顺体制机制。及时制定下发《上海市食品安全委员会会议事协调规则》和《关于区县成立食品安全委员会的指导意见》，明确了八项具体工作制度。目前，本市“两级政府、三级管理、四级网络”的食品安全监管体系已基本形成。市局机关各部门全力配合食安办开展食品安全综合协调工作，协助做好食品安全风险监测和评估分析、综合报告撰写、信息化支持、新闻宣传、信息公开和保密、举报投诉等方面工作，保障食安办正常运转稳定有序。

此外，全系统的精神文明建设、党建工作、政风建设、督查监察和队伍建设等也都取得了新的成绩和进步，对推进中心工作落实均发挥了重要作用。

## Overview

In 2011, under the strong leadership and specific guidance of State Food and Drug Administration (SFDA), CPC Shanghai committee and Shanghai municipal government, Shanghai Municipal Food and Drug Administration always stuck to the Deng Xiaoping Theory and important thought of “Three Represents”, implemented the scientific outlook on development intensively, vigorously practiced the concept of scientific supervision, always adhered to the principle of putting the public interest above everything else, closely centered on the safety of food and drug, and carried out all the work in a solid and orderly way. Special rectification on food and drug has gained expected result, which was affirmed by the national inspection and appraisal group. Supervision on medical devices, health care food and cosmetic has been further strengthened. The task of food and drug safety for 14<sup>th</sup> FINA World Championships –Shanghai 2011 was successfully completed. The press and publicity work has gained prominent achievement. Construction of all technical support systems and supervision team has been pushed forward successfully. Shanghai’s accident rate related to catering and drug safety was maintained at a relatively low level. Citizens’ rights to take drug and eat food were safeguarded and their consumption confidence was enhanced gradually. The goal of dynamic and controllable supervision on food and drug safety was achieved. Currently, the overall situation of Shanghai’s food and drug safety is steady. The food and drug industry is further regulated. Supervision work gains fruitful results——

### **I. Maintaining stringent supervision, achievement was made in supervision on catering**

In 2011, stringent supervision was maintained in accordance with the “Five Most Stringent Supervision” requirements of municipal government. The supervision on catering units can be summarized as “Three Highs and One Low”. First, Patrol inspections of high frequency were carried out in all sections. Units of high risks such as units providing dining services collectively, dining halls of schools were inspected once or twice every month; large- and medium-sized restaurants were inspected at least four times every year; such small units as snack bars and beverage stores were inspected at least two times. The annual average frequency of daily patrol inspection was maintained over 3.5 times, which is much higher than the level of other international metropolis. Second, law enforcement of high strength was maintained. Administrative penalties related to catering service amounted to 5120 cases; the amount of money equivalent fined and confiscated was RMB17,086,600, vigorously promoting the regulating management on catering service industry. Third, random inspection of high intensity was implemented. Over 40,000 samples of food and food processing links were randomly inspected all the year around. The result of evaluative random inspection shows that the overall percent of pass of food was maintained at a high level. Food poisoning was controlled at a low level. The collective food poisoning accidents of the whole year were 8 cases, involving 201 persons, reducing by 20% and 32.55% respectively compared with those of 2010. The food poisoning rate is 0.87/100,000, less than 1/10 of that of ten years before. Supervision result disclosure system was implemented in the 48415 catering service units in Shanghai. The implementation rate is 78.65%. 22.32% units were rated as “Adequate (smiling face)”, 68.66% units were rated as “Average (down face)”, 9.02% units were rated as “bad (crying face)”. Citizens’ awareness of food safety is increasing steadily. In 2011, the overall score of citizens’ awareness of food safety was 80.7 points, increasing by 1.1 points on year-on-year basis, increasing by 4.5 points compared with that of 2006.

82.7% citizens hold that the food safety level of 2011 has been improved to some extent. The inspection and appraisal group of the office of food safety commission under the State Council inspected Shanghai's food safety work in the middle of October, 2011. The inspection and appraisal group made the following evaluation upon the completion of inspection: Shanghai's food safety work was properly arranged and led; the expected work goal was achieved through its clear division of responsibility, well-established system and mechanism, sophisticated supervision measurements, innovative and practical methods.

## II. Tougher control on risks, special rectification on drug was pushed forward

In accordance with the state's "six arrangements" and work requirements of CPC Shanghai committee and Shanghai municipal government, we stuck to the starting point of doing a good job in maintaining the public's drug safety, regarded scientific supervision and risk control as the concept of supervision work, innovation and mechanism transformation as the grip of special rectification on drug. We seek a common understanding, implemented responsibility, fought illegal acts according to laws, dealt with problems quickly, and established a long-term supervision mechanism. The supervision on such links as drug research and development, production, circulation and use was tightly organized. Generally, the special rectification was pushed forward in a down-to-earth manner, gained adequate achievement. In 2011, 3655 license applications for various kinds of drugs were processed. Full supervision was implemented in Shanghai's 203 pharmaceutical production enterprises, near 800 medical institutions, over 3300 retail pharmaceutical stores, 128 wholesale pharmaceutical enterprises, 512 internet pharmaceutical information service enterprises and 7 internet pharmaceutical transaction service enterprises. 15549 drug samples were taken from main channels, percent defective was 2.74%. 238 pieces of drug packaging materials were randomly inspected, percent defective was 10.08%. Currently, Shanghai has established and implemented the drug safety responsibility system —local government assumes overall responsibility, supervision authorities assume their own specific responsibilities, enterprises act as the primary responsible parties; the government's responsibility, authorities' supervision duties and enterprises' obligations were further clarified and defined. The pharmaceutical operation order continued turning good; grave drug quality safety accidents were reduced significantly; the public confidence on drugs has been largely improved. The inspection and appraisal group for special rectification on drugs organized by Ministry of Industry and Information Technology and SFDA inspected Shanghai's work in the middle of October of 2011. The inspection and appraisal group affirmed Shanghai's overall achievement of special rectification on drug and held that Shanghai's self-evaluation was objective and overall situation was good.

## III. Maintaining a good order, medical devices industry was further regulated

The supervision on medical devices safety was strengthened on the principle of "highlighting priority, removing blind point, making overall plan and coordination". As of the end of 2011, Shanghai has 940 medical device manufacturers and 9154 medical device operation companies. 1534 applications related to medical device registration, export certification, and various kinds of reports were received, of which, 1171 applications were completed, 43 applications were rejected. 348 medical device samples were inspected, the percent of pass was 92.53%; 151 violation cases related to medical devices. The market was regulated vigorously. No grave safety accident related to medical devices took place in Shanghai and the medical device market is steady and controllable. Supervision on two kinds of enterprises and products have been strengthened on the basis of doing a good in registration approval and implementing classified inspection



on medical devices of high risks. The two kinds of enterprises are enterprises which didn't pass the 2010 random inspection (monitor) of product (environment) and enterprises which fail to provide basic information. The two kinds of products are custom denture and in-vitro diagnostic reagent. The construction of integral information database of medical device supervision and medical device tracing system were further pushed forward. Shanghai took the lead in implementing the Unique Device Identification (UDI) for post-market supervision, which was recognized internationally.

#### **IV. Improving mechanism, health care food and cosmetics market were vigorously regulated**

In 2011, the supervision on health care food and cosmetics was further strengthened through strengthening patrol inspection and disclosure, establishing the supervision mechanism of hanging out shingle, enhancing cooperation between different administrations, innovating supervision technologies and regulating enterprises' production and operation. 14614 health care food manufacturers and operation units, 14304 cosmetics production operation units were inspected around the year. The supervision intensity and frequency were unprecedented. The supervision system of hanging out shingle for illegal health care and cosmetic products were launched. 157 cases related to health care food were disposed; the amount of money equivalent fined and confiscated was RMB 3,129,400. 187 cases related to cosmetics were disposed; the amount of money equivalent fined and confiscated was RMB 1,472,200. 81 unqualified health care food were investigated during 6 times of public exposure. During the rectification, a batch of illegal dens and production chains were eliminated. Shanghai's health care food and cosmetics market were further purified.

#### **V. Making all effort, food safety for FINA World Championships was successfully completed**

During June and July of 2011, we spared in no effort in guaranteeing food safety of the 14<sup>th</sup> FINA World Championships. First, we make sufficient preparation in advance by working out and improving the work plan and carrying out drills; second, we strengthened communication with FINA and government officials from relevant countries, and eliminated foreign media's concern about the food and drug safety of FINA World Championships; third, we strengthened overall process supervision. During the champion, we worked together with relevant supervision administrations to safeguard the food safety of 4 million persons' 880 meals in 18 reception hotels; fourth, we strengthened supervision on the special pig meats for the champions. The priority was put on preventing misusing provocative. In this competition, no accidents related to food safety and food borne provocative took place. No compliant related food consumption received. We were spoken highly of by FINA and General Administration of Sport of China.

#### **VI. Making a good atmosphere, giving press and publicity work a full play in guiding public opinions**

The press and publicity work was pushed forward steadily. We gave mass media a full play, expanded the covering area of popular science propaganda and achieved good social effect on the basis of actively organizing various publicizing activities and forming a propaganda atmosphere. Citizens further understood the supervision on food and drug, more sufficiently recognized the knowledge of food and drug safety. They had higher awareness of food and drug safety and ability against food and drug safety problems. We carried out the "Food and Drug Safety Propaganda in Campus" activity and the activity of "Let Eat with more Reassurance" by cooperating with the Shanghai Municipal Education Commission. We carried out "Using Antibiotics Properly" popular science tour activity by cooperating with the Shanghai

Municipal Commission of Science and Technology. We opened “Know All of Drug Safety” column by cooperating with Family Medicines and made a 26 series popular science short film by cooperating with the Documentary Channel. We organized to edit and published brochures like Caution “Heath” Pitfall. We published the bacterial food poisoning dynamic index and public-interest ads related to proper use of antibiotics in subway and buses through Oriental Pearl Mobile TV every day. We opened the micro blog named “Drug Doctor’ Mailbox” in Sina’s and Xinmin’s websites, so as to popularize the common knowledge of drug safety through interaction with citizens. Our Sina micro blog’s fans have amounted to over 20,000 persons. Periodical risk analysis was carried out based on food safety monitoring system and adverse drug reaction monitoring system. In the analysis, risk control measurements were listed and published promptly to serve as an early-warning for food and drug safety and consumption tip.

#### **VII. Making scientific plan and working out or revising laws, regulations and standards related to food and drug safety**

We prepared and reported the Shanghai’s “The 12<sup>th</sup> Five-year Plan” for Food and Drug Safety. In accordance with annual revision plan, we assisted the legal work committee of Shanghai municipal people’s congress and the office of Shanghai municipal food safety commission in completing the local legislation work—Shanghai’s Implementation Methods for “Food Safety Law of the People’s Republic of China”; we prepared and revised 11 documents of administrative norms like Opinions on Strengthening on Food Safety of Food Production and Operation Enterprises of the City. We prepared and revised 18 local standards of food safety, including the Sanitary Regulations of Catering Units Providing Take-away Food, and Sanitary Regulations of Catering Central Kitchen etc. We studied and collected 1318 currently effective national standards, domestic food safety sanitary standards and regulations, which cover all the currently effective compulsory food safety and sanitary standards, and general standards, food sanitary operation guide and technical regulations related to other food for special use of CAC, EU, Australia and America. We also participated in the preparation and revision of several regulations and technical specifications in several aspects including SFDA GMP and medical device tracing management etc. In addition, we worked together with member units of Shanghai municipal food safety commission to promote a series of regulations related to implementation of Shanghai’s Implementation Methods for “Food Safety Law of the People’s Republic of China”.

#### **VIII. Supervising with technology, improving technical support for food and drug safety**

We adopted the method of buying service at the expense of government, broke the barrier between different industries and sections, effectively integrated social resources and established food safety risk evaluation system. We set up 16 contractual labs and 105 sampling places in the whole city so as to periodically inspect the 226 inspecting items including chemical contaminants and harmful agents in food, and food borne pathogenic bacteria etc. We prepared Implementing Rules for Shanghai’s Reporting and Monitoring of Adverse Drug Reaction in accordance with the Measures for the Reporting and Monitoring of Adverse Drug Reactions. Shanghai’s adverse drug reaction monitoring network has covered all the drug production and operation enterprise. 1217 units have registered into the network. In 2011, 22893 reports related to adverse drug reaction / accidents were reviewed, of which 1564 reports were serious reports. We published research and analysis data on the 9 media like ADR Analysis Report of Products of Shanghai’s Essential Drug Manufacturers. The data can serve as a risk indicator of drugs in the market.

We cooperated with 43 governmental inspection organs, over 20 non-governmental inspection and self-inspection centers to form a technical support system for food safety inspection. We also actively promoted, screened, integrated and applied over 80 express field inspection techniques, increasing by 20 techniques compared with that of 2010; we developed and equipped the field comparison and inquiry device of drug code. The city's food and drug administrations of all levels have been equipped with the express inspection equipment. The field express inspection has been an essential skill for the frontier law-enforcement officers in the daily supervision work. We actively enhanced the construction of food and drug safety supervision and information service platform. The effective management system of financial capital was launched and improved.

#### **IX.Strengthening administration, team construction was strengthened.**

We continued improving the comprehensive quality of supervision team, urging all administrations to perform their duties. "Honest Politic Risk Prevention" system was developed to make practical prevention measurements for 5 links including administrative license receiving and accepting links which are major risk points. 9 systems including "supervision post responsibility system" were further established and improved. We implemented the work system of secret investigation by leaders. Leaders would organize periodical secret investigation every month and report the problems found in the secret investigation and their solutions, at the same time, carry out random return investigation. The bureau leaders led 45 person-times. Leaders of division level of the whole system have carried out 2196 person-times in total, which supervised the implementation of supervision responsibility of all levels. We carefully analyzed our work and organized training to our supervision team. In 2011 we have held various 40 training classes and training meetings related to food, drug, regulations, information technology, electronic supervision, information disclosure, and conditionality etc. Participants of these training classes and meeting which cover all units of the whole system amounted to over 5100 person-times. In the training, assessment mechanism was adopted to make sure the practical operating ability of supervision team was really improved. We carried out efficiency supervision and promoted the improvement of service quality and standard law-enforcement level. The evaluation on work style of government bodies showed that: the public's satisfaction rate of our administration's administration license was 99.12% (23/2599), that of our administration's window work was 99.61% (28/7240) and that of administrative enforcement of law was 90.64% (628/6710).

#### **X.Establishing institution and promoting the overall implementation of comprehensive coordination mechanism for food safety**

We fully implemented the Food Safety Law's requirements concerning comprehensive coordination mechanism in accordance with State Council's work arrangement and Shanghai's specific circumstance. The Shanghai municipal government prepared and issued Shanghai's Food Safety Work Points of 2011, Opinions of the People's Government of Shanghai on Further Strengthening Food Safety Work of the City, and Decisions of the People's Government of Shanghai on Establishing Shanghai Food Safety Commission (Hu Fu Fa [2011] No. 21). It was clearly required to improve the municipal- and district-level supervision systems. The Shanghai municipal government established food safety commission and its office, and clarified work responsibility of all departments and the methods of coordinating and judging unclear division of supervision responsibility. The Shanghai Municipal Establishment Office verified and

enriched the establishment of municipal- and district -level food safety offices. Our administration further adjusted and improved the institutional work mechanism, arranged work staff, configured work space and work resources, fulfilled work fund, completed relevant configuration work of food safety commission office in accordance with the establishment and work arrangement of the Shanghai municipal government. After its foundation, the Shanghai Municipal Food Safety Commission Office put focus on coordination service, drew staff from relevant member units, implemented centralized office work system and combined law enforcement system, solved supervision interface problems and smoothed the system and mechanism. The office promptly prepared and issued the Procedure Rules of Shanghai Food Safety Commission and the Instructions of Establishing Food Safety Commission of District- and County-level, and clarified 8 specific work systems. Currently, the city has basically formed a food safety supervision system of “Two-level government, three-level administration, and four-level network”. All departments of the municipal administration spared no effort in assisting the Food Safety Commission Office in carrying out the work related to comprehensive coordination of food safety, monitoring and evaluation of food safety, preparation of comprehensive report, information technology support, press and publicity, information disclosure and confidentiality, report and complaint. The daily operation of Food Safety Commission Office was steady and in good order.

In addition, new achievements and progress have been made in such areas as spiritual civilization construction, party building work, construction of work style of government, supervision and team construction etc., which played an import role in promoting the implementation of the core work.

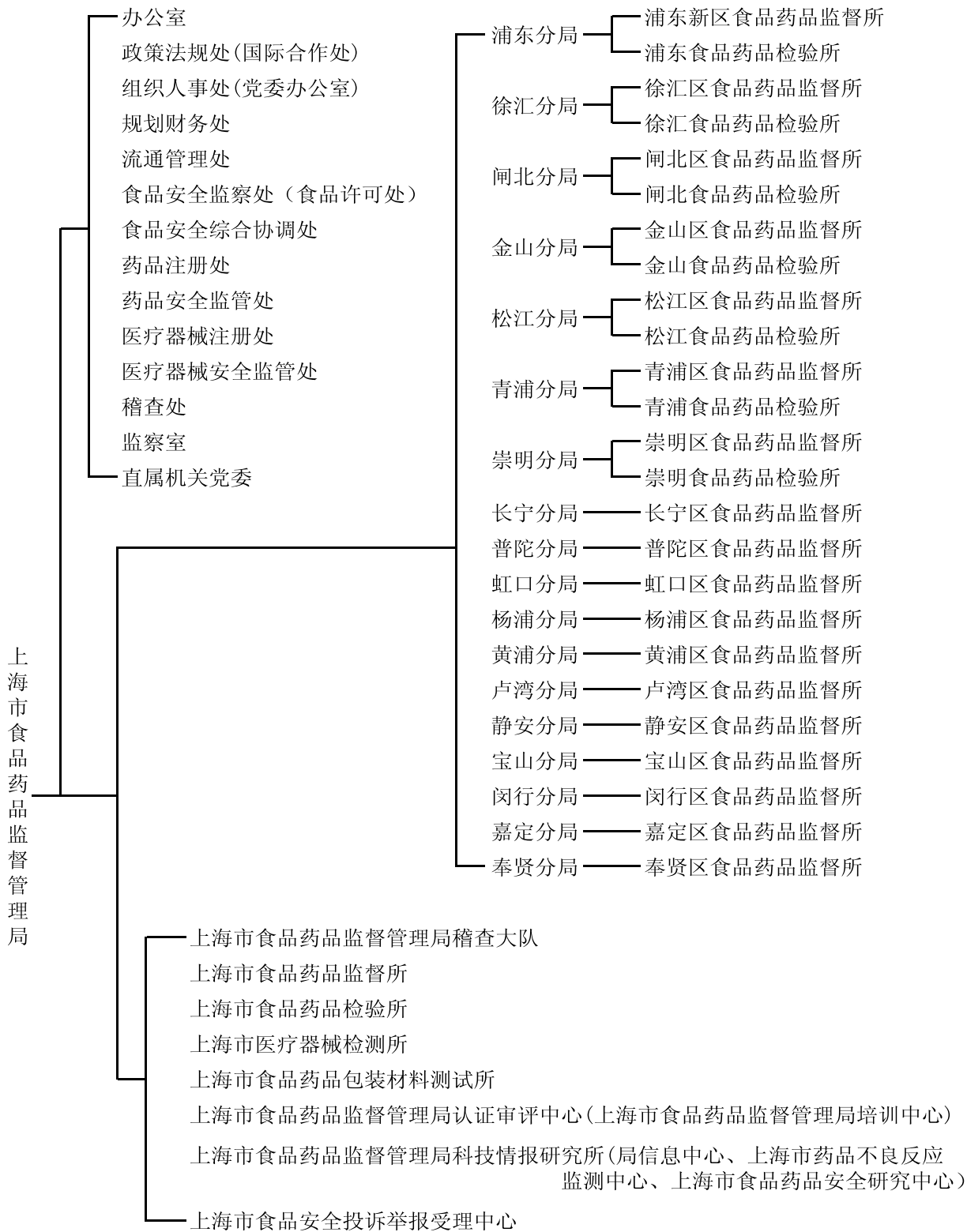
## 1.2 组织机构及职责、人员基本情况

### 1.2.1 组织机构及职责

#### 上海市食品药品监督管理局主要职责

上海市食品药品监督管理局负责对上海市辖区内药品（包括化学原料药及其制剂、生物制品、中成药、中药饮片、药用辅料、医用气体、放射性药品、麻醉药品、精神药品、毒性药品、医疗器械、卫生材料、医药包装材料等）的研究、生产、流通、使用环节行使行政监督和技术监督，并负责食品综合协调及食品餐饮服务环节（包括餐饮业、食堂等）的监管，负责保健食品和化妆品的生产加工、流通和消费环节的综合监管，依法组织开展对食品、保健食品、化妆品重大安全事故、案件的查处。

组织机构图：



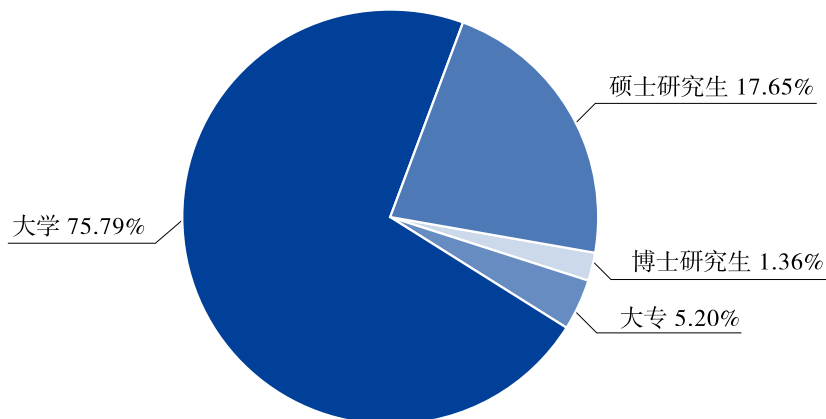
\* 2011年10月31日，黄浦分局与卢湾分局“撤二建一”成立新黄浦分局



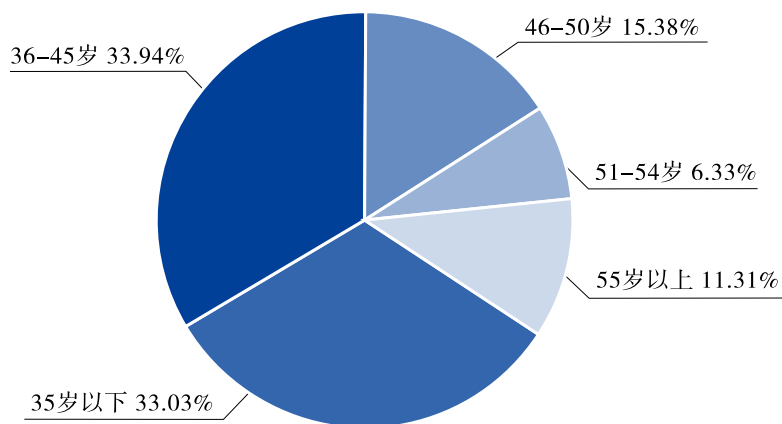
## 1.2.2 人员基本情况

### 1.2.2.1 行政机关（合计编制：499名，实有人数：442名）

学历分类：

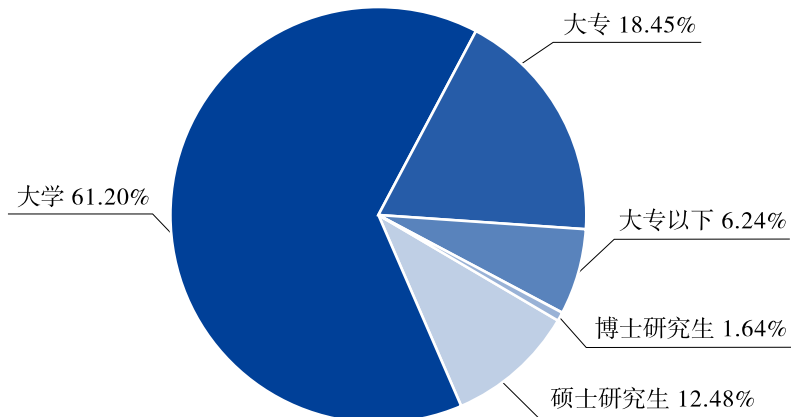


年龄分布：

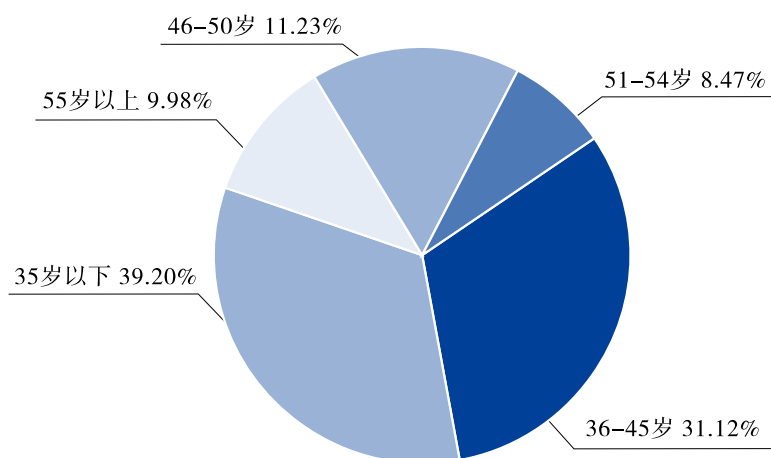


### 1.2.2.2 事业单位（合计编制：1770名，实有人数：1523名。其中执法类事业单位编制数1100人，实有人数970名。）

学历分类：



年龄分布：



### 1.3 监管基础设施建设

#### 1.3.1 技术支撑能力建设

##### 1.3.1.1 信息化建设

2011年，是我局信息化建设迈入重要发展的关键一年。在各方努力下，“局信息化十二五规划”编制完成，确定了“一个中心、一个门户、两个体系、五个平台”的具体目标，将应用建设推向深入。我局“食品安全综合信息平台”已列入上海市“智慧城市”的主要建设任务之中。在制度建设方面，广泛征求意见，完善并新修订了一系列相关的规章制度。

2011年，全系统网站群建设稳步推进，开展局党务信息公开专栏建设。局门户网站的第五次改版工作顺利完成，在全市2010年度政府网站测评中“监管信息公告”栏目作为优秀案例得到嘉奖。

##### 1.3.1.2 食品药品检验相关工作

一是获授权实施我国境内首个药品检测的国际能力验证项目。2011年我局上海市食品药品检验所获得亚太实验室认可组织(APLAC)的正式授权，与中国合格评定国家认可委员会(CNAS, 以下简称国家认可委)共同实施国际能力验证项目—“药物制剂有效成分含量测定”。这是我国境内药品检测实验室首次获得此项授权，此举不仅实现国内药检领域“零的突破”，还是我国药检系统走上国际舞台的重要里程碑，是我国国家认证认可制度十年发展的重要成就之一。

二是出色完成第14届国际泳联世界锦标赛食品兴奋剂检测工作。市食品药品检验所承担该项赛事的食品兴奋剂检测以及与餐饮相关的保障性检测任务，建立完善了四大类目标物质检

测的 SOP, 完成 157 批食品检验, 圆满地完成保障任务, 荣获组委会颁发的荣誉奖杯。

三是通过生物制品流感疫苗批签发检验资质机构专家组的现场检查。市食品药品检验所成为迄今为止唯一一家试点的省级药检所。同时该所还将在 2012 年向国际卫生组织 (WHO) 申请此项检测的国际资质认证。

四是市食品药品检验所顺利通过实验室认可以及资质认定的“二合一”复评审。中国合格评定国家认可委员会专家评审组及上海市质量技术监督局资质认定专家评审组对该所进行了五年一度的实验室认可以及资质认定复评审的现场考核, 确认药品、生物制品、医疗器械、食品和保健食品、化妆品等 5 大类共 696 个项目参数的检测能力, 同意通过实验室认可和资质认定复评审。这标志该所质量管理体系的日臻完善, 在药品、食品、化妆品等领域具备了更全面的检测能力, 为适应上海市食品药品监管需要, 依法履行药品、食品和化妆品技术监督职责发挥技术支撑和保障作用。

#### 1.3.1.3 医疗器械检测相关工作

一是我局上海市医疗器械检测所完成迁建项目。迁建后的上海市医疗器械检测所除拥有一流的实验、办公等场地, 先进的检测仪器和设施外, 在检测技术、业务能力上也得到进一步提升。新实验室顺利通过国家认可委 (CNAS) 和国家食药监局 (SFDA) 的复评审和扩项评审, 并新增检测能力 80 项, 2011 年该所还获得国家认监委的批准, 成为 X 射线设备“CCC”国家强制性产品认证检测的指定实验室。目前, 市医械所共获得国家认可委授权检测项目 512 项, 国家食药监局授权检测项目 666 项, 并得到德国 TUV、美国 UL 和英国 ITS 等世界著名认证机构的授权检测。

二是标准化工作。2011 年是该所成立近十年来制修订国家 / 行业标准项目最多、任务最繁重的一年, 该所归口的六个全国医疗器械标准化技术委员会共承担了国家 / 行业标准制修订任务 41 项, 均按时保质完成。标准宣贯培训方面, 在全国、全市等范围内举办 6 场共 33 项国家 / 行业标准宣贯培训活动, 参会人员达 400 人次。积极配合国家局开展 IEC 60601-1 第三版国际标准转化与实施研究工作, 此外, 还参与国家局组织的 YY0505 电磁兼容、YY0708 可编程医用电气系统、YY0709 报警系统等多项重要安全通用标准的实施研讨, 并承担重要工作任务。完成 ISO/IEC 国际标准草案对外投票和国际标准复审共 79 份。

#### 1.3.1.4 药包材相关国家标准制修订

我局上海市食品药品包装材料测试所完成 16 个药包材国家标准的制修订及试验验证工作。其中生胶标准是我国的药包材国家标准系列中首次制订的药包材用原料标准。

#### 1.3.2 局系统举报受理工作

2011 年, 局举报受理中心共接待各类举报、投诉、咨询 3.1 万余件次, 中心内部处理并回

复的为 84%。

具体受理 4975 件，涉及食品 3548 件（占总受理件的 71.31%）、药品 793 件（15.93%）、医疗器械 236 件（4.74%）、保健食品 204 件（4.1%）、化妆品 61 件（1.23%）、其他类 133 件（2.67%）。

市民对举报中心的来访接待工作满意率为 97%，对近 25% 的受理来电进行了电话回访，接受电话回访的市民对热线受理工作的满意率为 97.1%。

“3.15”期间，举报中心通过向市民派发《962727 市民举报指南》和赠送宣传品进行食品药品安全知识的宣传普及，收到良好的效果。

按照国家局建立全国统一的食品药品投诉举报受理热线和市委市政府设立上海市食品安全统一投诉举报电话的要求，经批准，原上海市食品药品监督管理局举报受理中心更名为上海市食品安全投诉举报受理中心，使用“12331”公益服务电话。目前上海市食品安全投诉举报受理中心正在紧张地筹建当中，“12331”于 2012 年元旦开始正式试运行。

### 1.3.3 法制工作

#### 1.3.3.1 推进食品安全地方性法规构建

在市人大教科文卫委、市人大常委会法工委、市食安委的指导下，我局牵头相关监管部门广泛听取意见，开展立法考察和实证研究，形成本市食品安全地方性法规草案。《上海市实施〈中华人民共和国食品安全法〉办法》（以下简称《办法》）经市府法制办报送市人大，经 2011 年市人大常委会三次审议和最终表决，以高票数通过。该《办法》自 2011 年 9 月 1 日起施行，是全国第一部全面实施《食品安全法》的地方性法规。

《办法》落实全国人大授权地方立法的迫切要求，明确食品生产加工小作坊和食品摊贩的基本管理制度。《办法》针对食品安全现状和本市主要问题，推行适应上海特大型消费城市特点的食品安全监管机制和有效做法，健全食品安全风险监测和评估、信息发布、应急处置、过期食品销毁、食物中毒查处等制度。《办法》充分发挥后世博效应，创新监管机制，建立了食品从业人员培训考核机制、委托生产食品的行为规范、食品安全控制措施、重大公共活动食品安全保障措施等机制，全面加大执法力度，切实维护本市人民群众的健康利益。

#### 1.3.3.2 推进行政审批标准化建设

2011 年，在市纪委、市审改办的统一部署和领导下，我局作为试点单位，就行政审批项目标准化建设工作进行试点，并将此项工作作为推进我局依法行政、完善行政审批的重要抓手，确定以局领导为组长，政策法规处为牵头部门，监察室、信息中心为会同部门，各业务处室为参与部门的行政审批标准化工作小组，同时明确各处室的职责分工。通过目录管理、业务手册、

办事指南、网上审批、数据共享、效能监察六大方面对食品药品监管部门行政审批的办事事项、流程、环节、时效等进行评估优化，通过设计新流程，提出新举措，逐步建立科学合理的审批管理机制、规范高效的审批运行机制、严密完善的审批监督制约机制，达到改善政府服务，提高行政效率，从权力运行中预防腐败，维护人民群众的饮食用药安全的目的。

### 1.3.3.3 执法规范性建设

组织开展系统行政执法检查。2011年我局的行政执法检查由行政处罚向行政许可推进，在全系统组织开展行政许可类的执法检查。通过行政许可类的执法检查，初步规范行政许可行为，为今后进一步提升行政许可执法水平奠定了基础。完成国家局组织开展的药品监管行政执法专项监督检查，查找过去执法中的薄弱环节，认真进行总结，为执法水平提升寻找制度上和做法上的突破。全年编写《案例评析与指导》12期，为食药监执法实践提供指导交流平台。2011年度共制定4项行政规范性文件。

生效时间	文件名称	文件编号	创制性规定
2011年4月28日	关于加强本市食品生产经营企业食品安全工作的若干意见	沪食药监食协〔2011〕320号	细化食品生产经营企业食品安全管理机制；增加了连锁超市进货管理的要求；增加了连锁超市对供货商进行实地查验的要求；明确了连锁超市过期食品的销毁义务；增加了对临近保质期食品的处理要求；增加了退（换）货和回收食品的管理要求。
2011年9月1日	关于印发《上海市餐饮服务许可管理办法》的通知	沪食药监法〔2011〕669号	进一步明确和细化本市餐饮服务许可管理规范和审查标准，加强餐饮服务监督管理，维护正常的餐饮服务秩序，保障公众身体健康和生命安全，实现制度可操作性和前瞻性的有机统一。
2012年2月1日	关于印发《上海市食品摊贩经营管理暂行办法》的通知	市政府发文	在本市食品安全地方性法规规定的方便群众、合理布局的原则基础上，确立了总量控制、疏堵结合、稳步推进、属地管理、有序监管的规划要求，明确了食品摊贩的信息登记管理和公示卡发放的操作流程，完善和细化了食品摊贩的经营要求，强化食品安全风险控制、完善预防体系，并规定了对食品摊贩加大联合执法力度，整治违法行为的管理机制。
2012年	上海市食品药品监督管理局举报有功人员奖励办法	上海市食品药品监督管理局与上海市财政局联合发文	与目前实施的举报奖励办法相比，此次办法一是进一步加大了奖励力度，将奖励分为一般奖励及双倍奖励，确立重奖机制，最高20万元；二是鼓励了解行业内幕的知情人士能够主动揭发，办法特别创设了隐名举报制度或委托他人代为申请、领取奖励制度来保护这些知情人士的合法利益不遭侵害。三是简化奖励申请流程，缩短奖励时限。



### 1.3.4 研究工作

2011年，全局系统软课题和技术攻关课题管理工作协调发展。经统计，2011年全局系统有各类研究项目共128项（不包括各单位自行立项课题），其中软课题67项、技术攻关课题41项、党建课题20项。

我局上海市食品药品包装材料测试所配合中检院承担的国家科技部十一五课题《药用新辅料临床前安全性评价及药品与包装材料的相容性安全研究》中子课题：《常用药包材的配方和工艺评价，建立合理的工艺、质量标准和标准通则》的研究工作，于2011年3月通过专家组验收。

我局上海市医疗器械检测所完成《骨科植入物失效分析的关键技术研究》（科委项目09441900300）课题的主要内容。新立项《支架质量安全性评价技术研究》（科委课题编号11441900600）；与交通大学附属第九人民医院合作，立项研究《宫内节育器用铜的技术规范》（科委课题编号11DZ0503300）。

通过2010年、2011年的努力，我局完成国家局课题《制度融合科技，提升制度执行力基础研究》，完善并有效运行《公共财政资金安全管理系统》，建成公共财政资金绩效评价的数学模型并着手在实际工作中使用。2011年底经国家局专家组审评，给予高度评价，认为课题将理论研究与实际使用有机结合，对管好、用好公共财政资金具有很强的现实意义，国家局将结合具体情况，将课题研究成果的推进运用作为2012年国家局财务系统的重点工作之一。

2011年上半年，我局系统有6个党建课题获得市教卫党委系统优秀奖项，其中一等奖1个，三等奖1个，鼓励奖4个，多数课题已经运用到我局的党建工作中。2011年底，我局系统又有20个党建课题向市教卫党委申报，成为提高我局党建科学化水平的重要手段和方法。

## 1.4 监管队伍建设

### 1.4.1 干部教育培训工作

2011年，我局加强领导班子建设，全年共组织中心组学习17次，415人次参加学习，及时开展十七届五中、六中全会和胡锦涛“七一”讲话精神的学习传达，并出台中心组学习考核制度。通过举办基层党政正职学习班、新提任处级干部学习班、食品药品监督所所长和分管局长学习班，进一步强化领导干部的宗旨意识和责任意识。

我局注重对专业监管队伍的学习培养，组织监管人员开展新版GMP学习研讨会、药品风险管理培训班、GSP认证检查员培训班、餐饮服务食品安全监管人员高级研修班、骨干培训班等30期共2872人次参与的培训，并通过食物中毒突发事件演练比赛和以轮岗学习、现场操作

为形式的检测技术轮训班，提升基层监督人员和检验人员的实战能力。

我局加强中青年出国（境）培训（即“蓝鸟计划”），2011年选送10名“蓝鸟”到国外参加中短期学习培训，并通过打擂台的形式选拔第二批20名“蓝鸟”人选。

#### 1.4.2 党建工作

##### 1.4.2.1 创先争优

局党委围绕提高食品药品监管能力和水平，促进上海食品药品监管事业新一轮发展，提出以“强素质，创科学监管之先；促监管，争食药安全之优”的创先争优活动主题，并在全系统组织开展“以为民服务创先争优”为主题的窗口创先争优活动和创先争优主题案例评选活动。结合建党90周年，全系统共表彰先进基层党组织3个，优秀党务工作者3名，优秀共产党员30名，并开展“两优一先”事迹巡回展、“党旗在我心，红歌伴我行”歌咏比赛和广播操比赛等一系列纪念活动，深入推进食药监文化建设。

##### 1.4.2.2 党务公开

局系统党务公开工作在前期试点的基础上，按计划有步骤推进。局党委、直属机关党委和直属单位制定党务公开目录，局政务网和局办公网开通党务公开专栏，保证党员对党内事务的参与权、知情权、监督权等各项权利，增强党员的凝聚力和战斗力。

##### 1.4.2.3 党风廉政建设

一是认真抓好学习教育，进一步筑牢反腐倡廉思想基础。2011年以来，我局坚持教育为主，预防在先的原则，认真学习贯彻十七届中纪委六次全会精神，围绕预防腐败，深入开展以“反腐倡廉法律法规学习”为主题的廉政教育。截止2011年年底，累计已有1305人参加网上学习活动，已有126名副处级以上干部和804名科以下干部全部通过网上十部法律法规考核。通过学习、培训、讲座、竞赛、案例和警示教育等方式，进一步增强反腐倡廉教育的针对性和有效性。

二是以制度建设为根本，进一步落实食品药品监管责任。为进一步加强依法行政行为，我局加大制度建设，全面落实食品药品监管责任，强化对制度执行力的监督检查。在全系统全面启动廉政风险防控机制建设，制定《建立廉政风险防控机制工作方案》，开发“廉政风险防控”系统，邀请专家进行“风险管理”基本理论讲座，对《工作方案》进行讲解培训等。制定并下发《关于进一步加强队伍建设、落实监管责任、提高监管效能的通知》，进一步建立并完善包括“监督岗位责任制”等在内的9个制度。制定下发《领导干部下基层督查暗访工作制度》，截止2011年年底，局领导亲历亲为，带头下基层暗访45人次，全系统处级领导干部暗访次数已达2196人次。

三是以效能监察为抓手，进一步强化制度的执行力。2011年对食品餐饮环节监管制度落

实的效能监察，包括发证程序和文书制作、许可审查标准、政务公开和便民利民、工作规范等环节。对网上行政审批的效能监察，采取定期对全系统行政许可网上审批超期情况以及对行政相对人的满意度评价情况进行通报，及时发现问题、及时解决问题。

2011年建党90周年前夕，市局纪委监察室荣获“上海市教卫党委系统纪检监察先进集体”。

### 1.4.3 政风“重点评议”工作

2011年我局被市纠风办确定为政风行风重点评议的六个部门(行业)之一，局党委高度重视，认真组织做好各项迎评工作，多措并举，全力推进全系统政风建设。面对来自社会各方面的舆论压力，全系统干部职工将“重点评议”作为契机，励精图治，齐心协力，以更加积极的态度、更加务实的精神、更加有利的措施，扎实推进各项监管工作和政风建设工作的落实，一年来的艰苦努力赢得了市纠风办、市纠风监督员组和社会各界的广泛认可和好评。

一是统一思想认识、落实工作部署。制定并下发我局2011年《迎接政风建设重点评议的工作方案》，要求各单位结合各自的实际，制定相应的工作措施。专题召开2011年全系统政风建设动员大会，动员全系统的广大干部职工进一步认清形势、统一思想，明确要求、突出重点，扎实推进政风建设工作。

二是加强组织领导，形成工作合力。成立由我局领导为成员的“局政风建设领导小组”，下设局政风建设领导小组办公室，负责组织、协调、联系、督促、检查有关纠风工作的具体任务。加强与市纠风办和市监督员组的沟通联系，认真听取有关重点评议工作要求和指导意见，并加以贯彻落实。同时积极协助市监督员组开展重点评议工作，及时落实各被查单位的各项准备工作。

三是狠抓重点环节、完善工作措施。重新组织编辑《全力履行监管职责保障市民饮食用药安全》和《上海市餐饮和药品安全服务手册》两本食品药品宣传手册，并及时发放至各区县分局。研究制定《窗口服务标准化建设实施意见(试行)》和《窗口服务标准化建设日常检查实施规范》。组织开展窗口工作人员业务培训，邀请市纠风办和市监督员组领导进行授课。完善已有的《窗口服务满意度调查》、《网上行政审批满意度调查》、《行政监管和执法过程满意度调查》系统，2011年全年，窗口办事满意率：99.61%（28/7240）；网上行政审批满意率：99.12%（23/2599）；行政执法反馈满意率：90.64%（628/6710）。完善了《食品药品行政监督管理系统》、《行政执法监察系统》、《窗口受理管理系统》。

四是重视“纠风在线”网站、开展政风行风热线工作。我局认真做好对“纠风在线”网站30件测评实例和投诉实例的收集，落实相关部门研处并及时予以答复。同时认真做好2次上海人民广播电台“政风行风热线”直播节目，宣传食品药品安全监管工作情况，接听群众提问，当场解答有关食品药品监管问题的咨询。

#### 1.4.4 精神文明建设

我局系统各直属单位和分局积极开展精神文明创建活动，直属单位中，有 3 家单位获得第十五届（即 2008-2010 年）市级文明单位，1 家被评为教卫系统文明单位，全系统共有 26 家单位被评为区级以上文明单位。

2010 年起我局党委和浦东新区北蔡镇杨桥村联合党总支签订了为期三年的结对帮扶协议。2011 年我局不仅在资金上给予杨桥村大力支持，还组成了食品药品安全知识宣讲团，为村民进行食品药品安全知识的专题讲座。