IADSA Newsflash

December 2016

Celebrating Global Diversity

There are two eternal truths about regulation in the food supplement area: it takes a great deal of time and it is hard to make it perfect.

However, there is another truth that is, in some ways, surprising: That each country tries to create their regulation in their own specific way. Considering the similarities in food supplement markets, the common basis of science that underpins most products, and the simple fact that so many established systems of regulation exist, you would expect that governments would broadly copy regulation from each other. But experience is showing that this is not the case.

For example, as the details emerge of the new notification system for health food in China, it is clear that it will be unique. Despite its goal to create a simpler route to market that is in place in a range of countries, there are many aspects of the approach that have not been seen before and some elements that will be extremely challenging to implement. This is not for a lack of information. The officials in charge have had more access to information than just about any other officials on the planet. There are just so many approaches that could have been used in China with international experience behind them. But the result is simply different. It comes from the officials making the laws fit the specific regulatory and political environment in China and it is about them wanting to do things their way.

In India, after many years of discussion and revision of drafts, the new food supplements and nutraceuticals regulation is also uniquely Indian.

It is certainly a big leap forward for the sector, even if it is not perfect at this point. However, you could not imagine seeing the same text or even a similar text in any other major market.

Early on in IADSA's evolution we realised our job was not to provide to governments a one-size fits all approach. We recognised instead that we had to be flexible enough to provide information to support a direction, help correct a course that was going wrong, and broadly sustain dialogue and engagement for the long-term. Our task was to offer an a carte menu of options, while appreciating that some of the time governments would actually like to order something which was not even on the menu.

As we see a world that appears to increasingly want to reflect national identities and differences rather than any globalised homogeneity, this approach is one that is even more relevant today than ever before.

While it can be frustrating to see so much reinvention and diversity of approaches, we also need to celebrate the cultural, historical and political differences that create this process. And we need to continue to get better at playing our part in this evolution.

IADSA

International Alliance of Dietary/
Food Supplement Associations

International Alliance of Dietary/Food Supplement Associations
Gridiron Building
One Pancras Square
London N1C 4AG, UK
www.iadsa.org

Regulatory news

ASEAN

ASEAN implementation deadline pushed back

The date for signing has been pushed back to March 2018 from September 2017. This also means that the deadline for implementation will now be March 2023. The reason for this shift is that Singapore could not agree at the meeting to the proposed changes to the terminology for the Agreement, following previous objections from Indonesia to the previous wording. The proposed revised title that Singapore will now consider is: ASEAN Agreement on Regulatory Framework for Health Supplements. To prepare for implementation a number of training programmes for government have been agreed.

China

China - Cross Border E-Commerce

The Ministry of Commerce (MOFCOM) , formerly Ministry of Foreign Trade and Economic Co-operation, has issued an announcement to extend the grace period from May 11th to the end of 2017 for implementation of new regulations. It means that it will not be required to register some special products, including health foods sold through the channel of cross border e-commerce, until the end of 2017 at least.
Trial cites have been changed from 12 to 10, with 5 cities (Chengdu, Hefei, Dalian, Suzhou, and Qingdao) not included on the list on the list, but three (Hangzhou, Fuzhou, and Pingtan) added.

Further information can be found at: http://www.mofcom.gov.cn/article/ae/ag/201611/20161101760012.shtml

Rules for Evaluation and Approval of Health Food released

The new regulation on Detailed Rules for Evaluation and Approval of Health Food Registration has been published on the CFDA website. In addition to the requirements for the evaluation and approval of health foods, four templates - Certificate for Registration of Health Food, Certificate for Registration of Imported Health Food, Product Labelling, and Technical Requirements of Health Food Product (product standard) - are included.

http://www.cfda.gov.cn/WS01/CL0847/166399.html
Indonesia

India

Indonesia consults on its draft Regulation on health supplements

Indonesia has recently consulted the sector on its draft Regulation on health food. Major challenges for companies operating in Indonesia are foreseen if the text, proposing a pharmaceutical-style approach, is not amended.

India

FSSAI publishes its Standards for health supplements

The Food Safety and Standards Authority of India (FSSAI) has issued its first standards for health supplements, nutraceuticals, foods for special dietary care, foods for medicinal purpose, functional foods and novel foods.

While the industry would have welcome a different approach on maximum limits for vitamins & minerals still limited to 1xRDA for supplements, the long awaited Standards have the merit of bringing clarity for companies operating in India. They specifically allow the use of an exhaustive list of ingredients with nutritional or physiological effects used alone or in combination. The new Rules also clarify the possibility to use structure/function/wellbeing claims for both supplements and nutraceuticals. A period of one year is given to companies to comply with the new provisions.

India publishes its draft Regulation on new product approval procedures

Food products covered under this Regulation are:

- Novel foods or foods containing novel ingredients which do not have a history of human consumption in India;
- Food ingredients that have a history of human consumption in India, but are not specified under and existing Regulations under the Food Safety Act, 2006;
- New additives and processing aids; and
- Foods manufactured or processed using novel technology.

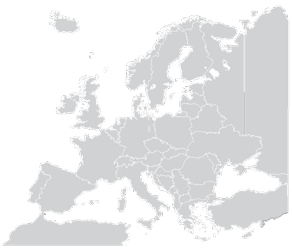
The proposed Regulation includes the application formats along with details on the supporting documentation required when applying for product approval.

South Korea

Korea notifies WTO of proposed Amendments for "Standards and Specifications of Health Functional Foods"

Korea has notified WTO of its revised draft Standards and Specifications of Health Functional Foods. The draft provisions aim to:

- Amend the requirement of adding functional ingredients in "Standards and Specifications of Health Functional Foods": The functional ingredients recognized under the Regulation on Approval of Functional Ingredients for Health Functional Food can be added to the Code when six years have passed from the date of recognition as a functional ingredient
- Add health claims of some functional ingredients: Red ginseng, Chlorella, Edible oil containing EPA & DHA, Edible oil containing gamma-linoleic acid, Probiotics
- Clarify some part of the standards and specifications for some functional ingredients: Edible oil containing EPA & DHA, Hyaluronic acid.



European Union

Changes to the list of foodstuffs exempt from veterinary checks

Commission Decision 2007/275 sets out the products that are subject to veterinary checks. The principle is that all products of animal origin are subject to veterinary checks, unless they are specifically exempted because they meet all of the requirements of Article 6. Composite products listed in Annex II, which have any dairy content must meet the requirements of Article 6(2).

Annex II has recently been replaced by Commission Implementing Decision 2016/1196. These changes apply to consignments arriving from the 1 January 2017. They impact in particular the import of empty capsules and food supplements in retail packs containing more than 20% of ingredients of animal origin.

Extension of the conditions of use for Dimethyl Ether

The European Commission publishes an amendment to the conditions of use of Dimethyl Ether (DME) as an extraction solvent (Dir. 2016/1855).

This decision follows the re-evaluation of the solvent by EFSA for the preparation of defatted animal protein products: collagen and gelatine. It was noted that under the intended conditions of use and with the proposed MRLs of 3 mg/kg in collagen and collagen derivatives and 0,009 mg/kg in gelatine, the use of DME should not be of safety concern.

http://www.efsa.europa.eu/en/press/news/161110

EFSA guidance on Novel food finalized

EFSA has published two guidance documents on novel food and traditional food from third countries to help evaluate the safety of new food before they can be marketed in the EU.
EFSA developed the guidance following the adoption of the new European regulation on novel food in November 2015. The regulation, which replaces the previous one from 1997 and comes into effect in January 2018, introduces a centralised assessment and authorisation procedure involving EFSA when a scientific risk assessment will need to be conducted.

EFSA establishes vitamin D recommendations

EFSA has published its long-awaited DRV values for Vitamin D, following the public consultation earlier this year. For all healthy children and adults over a year old including pregnant and lactating women, an adequate intake (AI) of vitamin D is set at 15 mcg/day, based on a meta-regression analysis. EFSA highlights that the meta-regression was done on data collected under conditions of assumed minimal cutaneous vitamin D synthesis. In the presence of cutaneous vitamin D synthesis, the authority highlighted that the requirement for dietary vitamin D could be lower or may even be zero.

EFSA opinion on trimagnesium dicitrate anhydrous (TMDC) as food additive in FS

EFSA has published its opinion on the Safety of trimagnesium dicitrate anhydrous (TMDC) to be used as a food additive in food supplements in solid and chewable forms (EFSA-Q-2015-00460) - applicant: RDA Scientific Consultants GmbH

This application relates to a request for the use of the additive as a stabilizer and/or anti-caking agent in food supplements in solid and chewable forms (food categories 17.1 and 17.3 of part E of Annex II to EC Regulation 1333/2008).

Safety of beta-cyclodextin E 459 addressed

The European Food Safety Authority maintained the acceptable Daily intake (ADI) of 5mg/kg bodyweight indicated that many all population groups except for infants were exceeding this amount.
The presence of the residual solvent trichloroethylene classified as carcinogenic to humans (Group 1) was also highlighted.

EFSA advise on Potassium

EFSA has set dietary reference values for potassium as part of its review of scientific advice on nutrient intakes. The Panel on Dietetic Products, Nutrition and Allergies (NDA) defines specifically daily adequate intakes (AIs) for potassium as follows:

- 800mg for children aged 1-3 years.
- 1,100mg for children aged 4-6.
- 1,800mg for children aged 7-10.
- 2,700mg for children aged 11-14.
- 3,500mg for adolescents aged 15-17.
- 3,500mg for adults including pregnant women.
- 4,000mg for lactating women.

Low potassium intakes are associated with raised blood pressure and increased risk of stroke. Data on these relationships were taken into account by the Authority when setting DRVs.

EFSA opens public consultation on a draft opinion setting a DRV for Thiamine

EFSA has opened a public consultation on a draft opinion setting a DRV for Thiamine. The Panel in charge of the assessment endorses the Average Requirement (AR) of 0.072 mg/MJ (0.3 mg/1,000 kcal) for all adults as proposed by the Scientific Committee for Food (SCF) in 1993 on the basis of one depletion-repletion study, in which both αETK and urinary thiamine excretion were measured. Results from other depletion-repletion studies are in agreement with this value. The same AR and PRI as for adults, expressed in mg/MJ, are proposed for infants aged 7 to 11 months, children aged 1 to < 18 years, and during pregnancy and lactation, under the assumption that the relationship between thiamine requirement and energy requirement is the same in all population groups.

EU Commission Revises specifications for steviol glycosides (E 960)

The European Commission has published an amendment to the specifications of the food additive steviol glycosides (E 960).
The specifications now include: The rebaudioside M as a permitted sterol glycoside and the chemical names and molecular weights and CAS numbers for all permitted Steviol glycosides.

EFSA to assess Pyrroloquinoline Quinone Disodium Salt (PQQ) for supplement use

EFSA has recently received a request for a scientific option on Pyrroloquinoline Quinone Disodium Salt (PQQ) as a novel food ingredient proposed for use in food supplements. The application was originally

submitted to the Irish authorities who raised concerns regarding the genotoxicity of the substance.
PQQ is a fermentation product of Hyphomicrobium denitrifican. The applicant is proposing that the ingredient PQQ, in the form of 99% pure red brown powder, is added to food supplements at the level of up to 50mg/day. The applicant has agreed that the supplement containing PQQ would not be recommended for use by children or pregnant women given the uncertainty addressed by Ireland regarding the product's safety.

Re-evaluation of Iron oxide

The European Commission has launched the call for data on food additive, Iron oxides, (E 172). This call is a follow-up on the EFSA opinion of last year 2015 where it says that there is data missing in order for EFSA to complete its assessment

requested data includes:

- Toxicological data: for red iron oxides in vivo genotoxicity and subtonic toxicity, for yellow iron oxides: a complete set of genotoxicity studies and subtonic toxicity, for black iron oxides: ADME, in vivo genotoxicity and subtonic toxicity.
- as required by EFSA on red, yellow and black iron oxides
- Data on particle size and particle size distribution
- Data on the lowest achievable limits for the impurities of toxic elements (cadmium, arsenic, lead, mercury and nickel)
- Data on actual use levels of yellow iron oxide, red iron oxide and black iron oxide

Companies have until 19 January 2017 to inform the European Commission of their interest in submitting information

https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

Belgium

Belgium notifies Royal Decree on Food Supplements

Belgium has notified its new Royal decree specifying maximum levels for vitamins and minerals in foods and food supplements.
These levels are based on the opinion of the Superior Health Council of 7 September 2016, the advisory body of the authorities and had been subject to a consultation with the stakeholders.

The main highlights:

- No changes to the maximum levels as compared to the current levels allowed for vitamin A, niacin, vitamin B6, calcium, chromium, phosphorus, iodine, potassium, magnesium, molybdenum, selenium, silicon, zinc;
- Removal of the existing maximum levels for thiamin, riboflavin, pantothenic acid, vitamin B12, biotin, chloride, sodium, silicon;
- maximum levels for vitamin C, vitamin D, vitamin E, vitamin K, folic acid, boron, fluoride, iron increased
- maximum level for manganese reduce
- Warning statements for products containing levels above a certain threshold or Vitamin K, Potassium and Zinc
- Nicotinic acid and inositol hexaniacinate not permitted as sources of niacin, whereas these sources are allowed under Directive 46/2002.

The notification can be found at the following link:
http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2016&num=615

The standstill period runs until 27 February 2017

France

France publishes its Order regarding the use of other substances in supplements

French Order related to the use of other substances in supplements has been published.
The Order confirms that the use of substances other than those listed in Annex I, which lays down specific conditions of use for four ingredients, may be used in supplements provided they are not novel.
www.legifrance.gouv.fr/eli/arrete/2016/9/26/ECFC1518714A/jo/texte

Norway

Norway notifies labelling restrictions for food supplements to the European Union

Norway has notified to the European Commission a new draft regulation on the use of vitamins and minerals in food supplements, amending their food supplements law.

This amendment foresees warning statements for food supplements intended for children and adolescents containing Folic acid, Vitamin C, Vitamin D and Calcium. Food supplements that contain more than the recommended daily portion of consumption for adolescents from 11 years and up to 18 years old in one measured small unit quantity must be labelled: «Can be injurious to health for children and adolescents less than 18 years». The same applies for supplements intended for children from 3 years and up to 11 years old (for Folic acid, Vitamin C and Vitamin D), and for children from1 and up to 3 years old (For Folic acid and Vitamin C). The law specifies maximum levels for Vitamin D, Folic acid, Vitamin C, Calcium and Magnesium for these age categories and for adults. The maximum level of Folic acid for adults is maintained at 960 mcg/daily quantity. For Magnesium it is reduced to 350 mg and for Calcium to 705 mg.

Iran

Iran sets limits for supplements

The Food And Drug Administration of The Islamic Republic of Iran has recently published a notice number 665/131908 setting limits for vitamins and minerals and some other substances

Glucosamine.Chondroitin,MSM,Coenzyme Q10,PABA,Lecitin,Taurin and Resveratrol

Argentina

Proposal to review and update the Argentinean Food Code

The National Commission of Foods (CONAL) held its 112° and 113° Meeting in October and November. Some of the main highlights that could be of impact for the food supplements' industry: Revision of food additives regulation: During the meeting the authorities from the National Institute of Foods (INAL) proposed to modify Chapter XVIII of the Argentinean Food Code on Food Additives as a way to update it. CONAL created an Ad-Hoc working group that will be coordinated by INAL, to develop a proposal to update Chapter XVIII on Food Additives. The main objectives will be:
- To update identity and purity specifications
- To review the use of certain additives that are being questioned at global level
- To re-order inside the CAA (under another Chapter) those substances under Chapter XVIII that are not additives, such as caffeine, taurine, methionine and iron
- To update identity and purity specifications for flavourings and colourants foreseen in Chapter XVI
- To review Article 1398 of the CAA since some of the additives listed there are not foreseen in Resolution GMC N°11/06 "Harmonized List of foods Additives and its Functional Classes".

Brazil

Draft Regulation for implementing the declaration of lactose

ANVISA opens to public consultation the regulation that will implement Law N° 13.305 that makes mandatory the declaration of lactose presence on food labels. The draft regulation proposes the minimum lactose content for which it becomes mandatory to declare "Contains lactose" and the specifications for using the claim "Lactose free" and "Low lactose". The consultation closed at the beginning of November and ANVISA seeks to publish the final regulation between the end of December and beginning of January 2017.

Modification to the permitted additives in fish oil

ANVISA opened for public consultation some modifications to the food additives regulation. From 16 November until 15 December the proposal to include tocopherol concentrate mixed (INS 307b) as antioxidant in the category of fish oil (max. 0,6g/100g) will be open for comments.

Chile

Bill proposes to restrict the commercialization of food supplements

Bill N° 9914-1 which proposes to modify the Medicines Law, has been proposed to be amended by Senator Guido Girardi who has requested the inclusion of food supplements under the classification of medicines (and not under the food law anymore). In early 2016 the Ministry of Health already proposed to ban the use of health claims in food supplements.

Ecuador

Public consultation of Ecuadorean Technical Standards for Labeling

The Ecuadorean Institute for Normalization (INEN) has opened for public consultation two of the major labeling standards covering the setting of Dietary Reference Values and rules governing the use of health claims. It is proposed to remove, in particular, the positive list of health claims and propose a case by case evaluation, making the use of claims more restrictive.

Mexico

Update of food additives regulation

During September 2016 COFEPRIS updated some specifications on the Agreement that Establishes the Additives and Processing Aids in foods, beverages and food supplements. The updates were carried out on the following annexes: Annex I "Additives with diverse functional classes and an Acceptable Daily Intake (ADI) defined", Annex III "Colorants with a ADI defined", and Annex VI "Enzymes".

Uruguay

Proposal to modify the GMO labelling regulation in Montevideo

Although the regulation for GMO labelling is in force, the Laboratory of Bromatology from the Government of Montevideo and the Laboratory of Molecular Food Traceability from the University of the Republic are in the process of analyzing the current regulation. This follows concerns raised by the Montevideo Director of Health who declared that the current symbol indicating GMO content could have a negative connotation, making consumers think that the food product could be toxic. A new proposal could be a white circle with the "T" inside and the legend "Contains genetically modified organisms" is considered. The proposal would include a period between 6 to 18 months to amend labels. However, this is still under discussion.

Gluten Free declaration becomes official

The Ministry of Health finally approved the regulation with the provisions for the declaration of gluten presence / absence. Products containing less than 20ppm of gluten could be labelled as gluten free. However, any food product, including food supplements, containing 20ppm of gluten or more, shall be labeled as "Contains gluten", or "Can contain gluten".

USA

Warning requirement for aloe and goldenseal

Companies selling products in California containing "Aloe vera, non-decolorized whole leaf extract" and "goldenseal root powder" must provide a "clear and reasonable warning" compliant with the requirements of Proposition 65 (Prop 65), unless otherwise exempted, beginning 4 December 2016. AHPA has issued guidance for companies regarding the listing of these substances under Prop

65

Science Review of Isolated and Synthetic Non-Digestible Carbohydrates

The Food and Drug Administration is requesting scientific data, information, and comments that would help evaluate the beneficial physiological effects to human health of isolated or synthetic non-digestible carbohydrates that are added to foods. The FDA is requesting such information to help determine whether a particular isolated or synthetic non-digestible carbohydrate should be added to the definition of "dietary fiber" for purposes of being declared as dietary fiber on a Nutrition Facts or Supplement Facts label.

FDA Begins Posting Adverse Event Report Data for Foods and Cosmetics

The U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) will now post on a quarterly basis data extracted from adverse event reports, including conventional foods and dietary supplements, and cosmetics, in order to increase transparency and improve access to government data for consumers, health care providers, researchers and academics.
The CFSAN Adverse Event Reporting System (CAERS) is one of the post-market surveillance tools that the FDA uses to monitor the safety of foods and cosmetic products. Adverse event reports related to conventional foods, dietary supplements, and cosmetics come primarily from consumers and health care providers: of these products, only dietary supplement manufacturers have a legal obligation to report adverse events to the agency.

From 1 January 2004 through 30 September 2016, the FDA received 56,574 adverse event reports. Of these, 26,840 adverse events were reported for conventional food; 25,412 were reported for dietary supplements; and 4,322 were reported for cosmetic products.

FDA releases final guidance for Voluntary Qualified Importer Program (FDA)

FDA issued its final Voluntary Qualified Importer Program industry guidance for a voluntary, fee-based program to allow the expedited review and importation of foods into the U.S. from importers with a proven track record of food safety and security. The final guidance is issued in a question-and-answer format to explain how this program will work.

Russia

Federal Antimonopoly Service to amend rules of circulation for dietary supplements

Federal Antimonopoly Service Russia's (FAS) is drafting a document clarifying the law on the fundamental principles of state regulation of commercial activity in Russia, namely Article 9 of the law which covers sales of dietary supplements both through retail network and through pharmacies. According to the head of the FAS directorate for social and commercial oversight, the need for the clarification is explained by the ambiguity that pharmacies are permitted to sell specialised foods and parapharmaceutical products, which are not covered by the law on the circulation of medicines. distribute dietary supplements via pharmacies, so that consumers believe these products have a therapeutic effect, while dietary supplements are classed by the regulation as food products rather than medicines or parapharmaceuticals.

The FAS is currently looking into the possibility of harmonising the two laws and is expected to publish further information on the issue soon. It is however highly likely that a decision will be made to the effect that Article 9, with all associated restrictions, will continue to apply to sales of dietary supplements both through retail networks and through pharmacies.

Azerbaijan

Azerbaijan restricts sales, advertising of dietary supplements

The Azeri law on medicines, which also regulates the circulation of dietary supplements, has been amended to include an article stating that doctors may recommend dietary supplements for health promotion and diet enrichment purposes, but not as substitutes for medicines prescribed for the prevention and treatment of diseases.

In addition, the Azeri Code of Administrative Violations was amended to introduce a fine of $600 to $1,200 for legal entities omitting to state in advertisements for dietary supplements that these products and not medicines.

CCNFSDU 38th session 5 - 9 December 2016 Highlights

Vitamin E

- 1 mg α-tocopherol (1mg RRR- α-tocopherol) as the dietary equivalent for vitamin E proposed for adoption at Step 5/8
- The NRV for vitamin E of 9 mg/day proposed for adoption at Step 8

Vitamin D

- The NRV for vitamin D for a range from 5 – 15 µg with the following footnote proposed for adoption at Step 5/8

The value of 15 µg is based on minimal sunlight exposure throughout the year. Competent national and/or regional authorities should determine an appropriate NRV-R that best accounts for population sunlight exposure and other relevant factors

NRV-NCD for EPA/DHA

- Agreement to defer discussion until next year.
- The eWG, led by Russia and Chile, re-established to take into account the final report of NUGAG and to make a recommendations for consideration by CCNFSDU at the next session.

IADSA

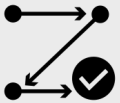
International Alliance of Dietary/ Food Supplement Associations

INTRODUCTION TO EPIDEMIOLOGICAL STUDIES

Systematic Review

A systematic review brings together all available evidence to find an answer to a research question.

Systematic reviews are characterised by being objective, systematic, transparent and replicable.



Key steps to conduct a systematic review

1. Framing questions. The question is commonly formulated according to the PICO method.
2. Identifying the studies
3. Assessing the quality of studies
4. Summarizing the evidence
5. Interpreting the findings

Cochrane Review

Cochrane Reviews are systematic reviews of research in healthcare and health policy that are published in the Cochrane Database of Systematic Reviews (CDSR), which is considered to be the leading resource for systematic reviews in healthcare.

There are five types of Cochrane Review, including intervention reviews aiming at assessing benefits and harms of interventions used in healthcare and health policy.

Meta-Analysis

Data from individual studies may be pooled quantitatively and reanalysed using established statistical methods. A meta-analysis may be part of a systematic review.

PICO Method

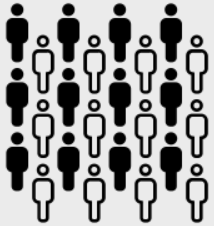
The PICO method is used to frame and answer a clinical or healthcare related question.

The acronym PICO stands for:

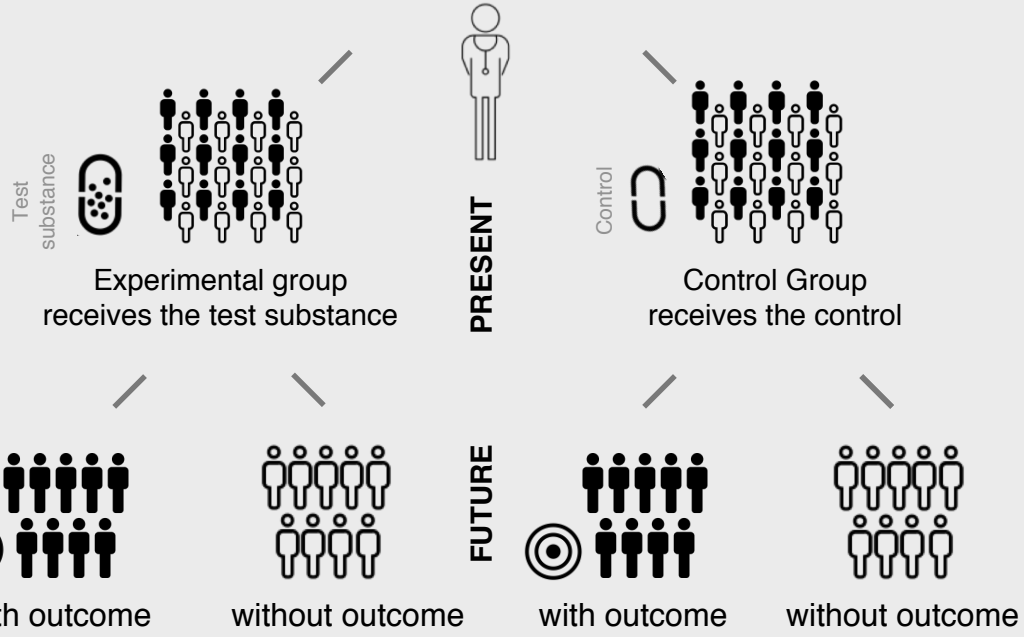
Population (Participants, Probem),
Intervention (or Exposure for observational studies)
Control (Comparison or Comparator), and
Outcomes of interest

Randomised Control Trial (RCT)

EXPERIMENTAL



Participants are randomly assigned to an experimental or a control group by the experimenter

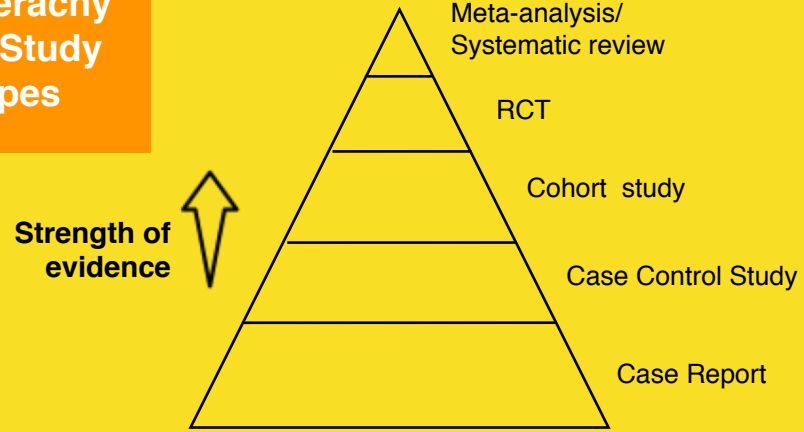


The outcome in each group (arm) is measured and compared so as to define whether a cause & effect relationship exists between the test substance and the outcome.

RCTs could be unblinded or single/double blinded.

RCTs are prospective.

Hierachy of Study Types



Case Report

DESCRIPTIVE

Exposed with outcome

A case report describes and interprets an individual case.

Blinding

Single blind

The participants do not know who have been given the test substance or the control

Double blind

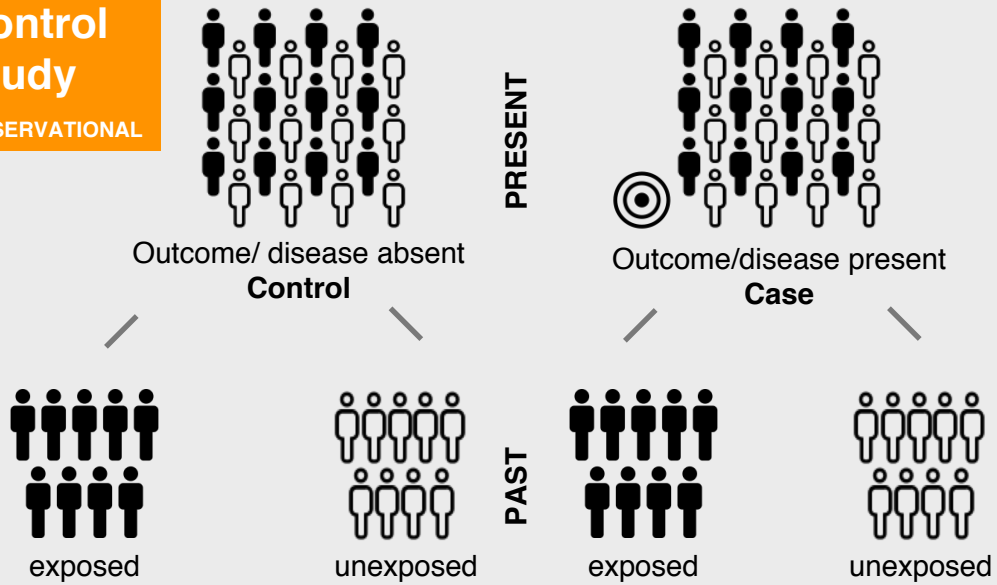
The participants and the experimenter do not know who have been given the test substance or the control

INTRODUCTION TO EPIDEMIOLOGICAL STUDIES

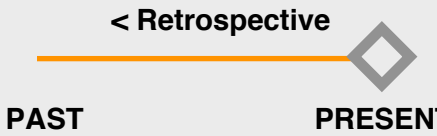
INTRODUCTION TO EPIDEMIOLOGICAL STUDIES

Case Control Study

OBSERVATIONAL



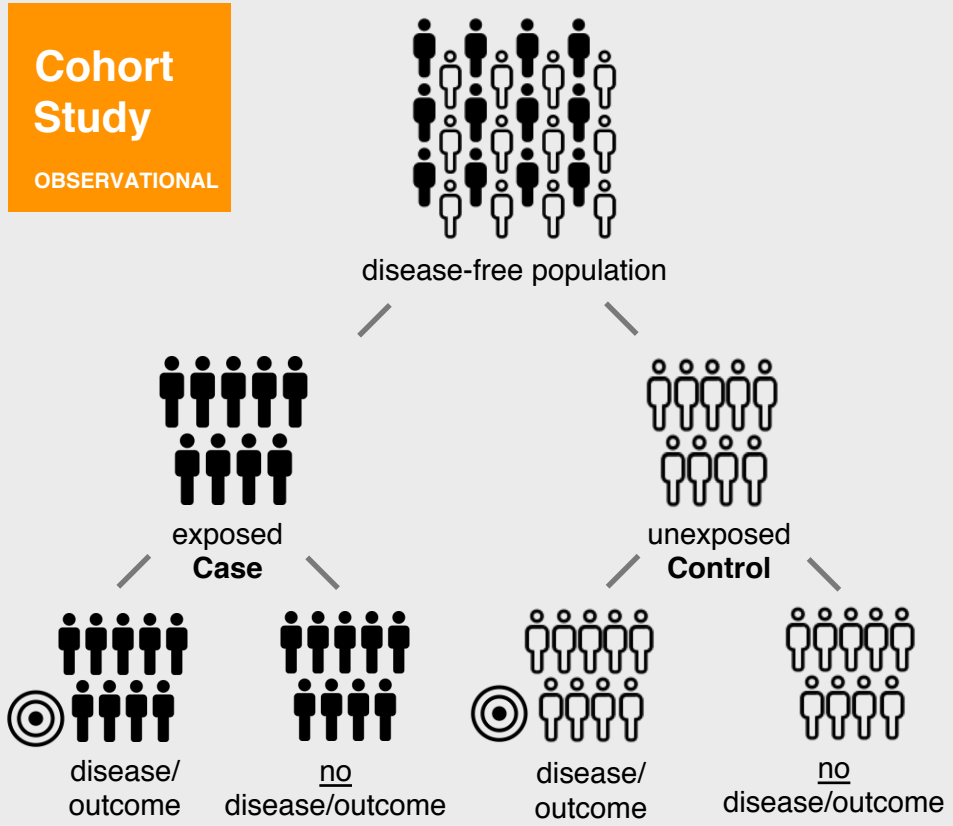
A case control study compares groups who have a disease or outcome of interest (cases) with groups who do not have the disease/outcome (controls). It looks back retrospectively to compare how frequently the exposure to a risk factor is present in each group so as determine the relationship between the risk factor and the disease/outcome.



Population split by outcome/disease status

Cohort Study

OBSERVATIONAL



In a cohort study, an outcome / disease-free study population is first identified by the exposure of interest and followed until the outcome of interest/disease occurs. The objective is to establish and measure the link between the exposure of interest and the outcome/disease.
Cohort studies can be prospective or retrospective.

Population split by the exposure status in retrospective cohort